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**U.S. EPA Water Technology Innovation Cluster Leaders Meeting—
“Successfully Supporting Early-Stage Companies:
The Role of Technology Testing”
March 24-26, 2014
Cincinnati, Ohio**

Meeting Summary Report

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EXECUTIVE SUMMARY

The U.S. Environmental Protection Agency (EPA) hosted a meeting of the Water Technology Innovation Cluster Leaders from March 24–26, 2014, at the Andrew W. Breidenbach Environmental Research Center in Cincinnati, Ohio. Approximately 60 individuals attended. The meeting was organized to bring together various stakeholders who have a dedicated interest in water technology innovation and implementation. Participants included members of each of the clusters in various stages of development, government officials, water technology developers and entrepreneurs, utility representatives, and testing facility representatives—all of whom expressed an interest in increasing collaboration and starting a productive conversation on the topic of technology testing. The focus of this meeting was to identify and discuss the difficult issues surrounding the testing of innovative technologies that must be addressed before a new water technology can go to market.

The goals of this workshop were to: (1) increase the cluster leaders' level of knowledge regarding past and current water technology testing programs, facilities and requirements; (2) learn from the experiences of technology vendors in getting innovative, commercial-ready products to the marketplace, including the use of testing, permitting and labeling programs; (3) discuss model approaches for technology testing that benefit early-stage companies and identify the role(s) of cluster organizations; and (4) encourage cluster leader networking and collaboration.

Many of the participants gave presentations outlining their own involvement and experiences in this field. The audience heard presentations from U.S. EPA and Ohio EPA personnel, cluster members, water innovation organization leaders and business owners. In addition to the primary presentations, three panel sessions gave additional participants the opportunity to talk about their experiences and foster group discussions.

The meeting culminated with a facilitated brainstorming session and group discussion regarding water technology testing. The goal of this discussion was to create a list of best management practices (BMPs) and challenges that would enable the clusters to determine where and how they can make an impact. Participants first identified the BMPs that they had employed or hoped to employ to successfully test new technologies and bring them to market. The list of BMPs that were acknowledged was extensive and primarily focused on:

- Good communication and engagement between stakeholders.
- Organization and collaboration in testing.
- High-level of knowledge of the goals, market, regulations and other stakeholders' positions.
- Thorough data collection and tracking.

Participants discussed the challenges that developers face when testing their new technologies and offered ideas for how to tackle the issues at hand:

- **Standards and reciprocity** concerns primarily focused on the lack of national standards and permitting reciprocity across states for regulatory acceptance, which leads to high costs and lengthy time frames for testing and approval. States often do not have a clear picture of their own needs (or the resources to determine what those needs are), and many of them are reluctant to embrace reciprocity for various reasons. It is very difficult for developers to understand the complex and continually changing regulatory landscape.
 - **Ideas for improvement:** Creation of a collection of technology testing data that states can share and use to make their own independent decisions. Development of jointly approved testing protocols (e.g., EPA is working with the states of Ohio, Kentucky and Indiana to

develop a joint protocol for ultraviolet testing). Establishment by EPA of global standards for method performance for as many analytical methods as possible. Creation of a comprehensive list of certification criteria that each state requires.

- **Financing** difficulties were the most frequently discussed challenges throughout the entire meeting. Participants brought up the fact that the amount of money entering the water market is decreasing, and venture capitalists tend to avoid environmental technologies because of the constantly changing regulatory environment. Technologies are expensive to test and come with high risks. The requirement that technologies be piloted in each state leads to prohibitively high costs for getting a technology into the national market. It is difficult to develop metrics to quantify the economic and social benefits of green technologies and green infrastructure, which makes it harder to obtain funding.
 - **Ideas for improvement:** Applying core competencies of successful industries to the water technology industry. Utilizing the water clusters for networking and funding opportunities. Educating the public of the benefits of water technology as a means to garner support. Utilizing local resources, capital and expertise. Moving away from pilot projects that are not scalable or sustainable.
- **Lack of knowledge and collaboration** tends to occur among businesses because they see each other as competitors—however, it is clear that cooperation would be useful given the difficult environment surrounding green technologies.
 - **Ideas for improvement:** Recognition that collaboration is beneficial because all of the clusters have the same overarching goals. Development of peer-to-peer groups and sharing of best practices among water clusters and utilities. Creation of a national database of testing programs and test beds.
 - **Please see Appendix B for the summaries of eight successful testing programs.**
- **End-user engagement** is lacking and leads to a lack of identification of the needs of the market.
 - **Ideas for improvement:** Develop methods for engaging and managing the end-user, as this will help developers to define system and product requirements. Create an accessible system in which users can easily share their experiences, product reviews and performance ratings for a technology.
- **Other challenges** included: utilities' reluctance to adopt new technologies because of the high risk and mandate to protect public health; reliance on pilot projects as a hindrance to success; lack of field-based accreditation options; how to enable and adopt a systems-holistic approach to water management; and how to address the EPA Environmental Technology Verification Program legacy.

The meeting ended with a session to brainstorm the agenda for the next meeting.

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ABBREVIATIONS AND ACRONYMS

ACE	(American Water Works Association) Annual Conference and Exposition
ANSI	American National Standards Institute
AWWA	American Water Works Association
BMP	best management practice
ECA	Environmental Compliance Approval
EPA	U.S. Environmental Protection Agency
ETV	Environmental Technology Verification (Program)
LIFT	Leaders Innovation Forum for Technology
NJCAT	New Jersey Corporation for Advanced Technology
NJDEP	New Jersey Department of Environmental Protection
ORD	Office of Research and Development
OW	Office of Water
PCR	polymerase chain reaction
SORA	State Onsite Regulators Association
SOWC	Southern Ontario Water Consortium
STEPP	Stormwater Testing and Evaluation of Products and Practices
SWAT	Smart Water Application Technologies
TAPE	(Washington State's) Technology Assessment Protocol—Ecology
UV	ultraviolet
WEF	Water Environment Federation
WEFTEC	Water Environment Federation's Annual Technical Exhibition and Conference
WERF	Water Environment Research Foundation

INTRODUCTION AND OVERVIEW

The U.S. Environmental Protection Agency (EPA) Water Technology Innovation Cluster Leaders Meeting was held March 24–26, 2014, in Cincinnati, Ohio. The purpose of this workshop was to: (1) increase cluster-leader level of knowledge regarding past and current water technology testing programs, facilities and requirements; (2) learn from the experiences of technology vendors in getting innovative, commercial-ready products to the marketplace, including the use of testing, permitting and labeling programs; (3) discuss model approaches for technology testing that benefit early-stage companies and identify the role(s) of cluster organizations; and (4) encourage cluster leader networking and collaboration. Nearly 60 individuals attended.

MARCH 24, 2014

Participants met for a networking hour and group dinner to commence the meeting.

MARCH 25, 2014

Welcome, Introductions and Meeting Objectives

Sally Gutierrez, Director, Environmental Technology Innovation Clusters Program, Office of Research and Development (ORD), EPA

Ms. Sally Gutierrez welcomed the participants to Cincinnati and the largest federal water research facility in the United States. The federal government has sponsored water research in Cincinnati for 101 years. Ms. Gutierrez next had the participants introduce themselves.

Keynote Speakers

Ellen Gilinsky, Senior Policy Advisor, Office of Water (OW), EPA, and Lek Kadeli, Acting Assistant Administrator, ORD, EPA

Dr. Ellen Gilinsky stated that communities and individuals are beginning to change how they think about water. Although the water supply had been thought to be limitless, communities now are dealing with water issues related to its finite supply. There is a strong desire to use the resource intelligently and ensure that the manner in which water is treated and used serves as an economic driver that promotes urban revitalization and sustainability. Aging water infrastructure is a challenge. Wastewater increases as the population increases, and because of the sheer volume, contaminants and nutrients also have increased despite advances in treatment quality. It is important to manage water resources, and technology innovation is fundamental to a sustainable future and progress toward clean and safe water. EPA desires to support technology innovation, which also acts as an economic driver. The United States would like to be a leader in innovative water technologies.

EPA released the *Blueprint for Integrating Technology Innovation into the National Water Program (Version 1.0)* to highlight the Agency's activities in this area and identify opportunities to increase innovation, including improving and greening the country's infrastructure. Technology innovation will increase the resiliency of water infrastructure and help rebuild infrastructure in the smartest manner following natural disasters such as hurricanes. Technology innovation is needed to decrease consumption of natural resources; water reuse is an important activity, which technology innovation can help. The term "wastewater" is evolving into "water resource recovery" because the water is not waste. States and localities are turning to EPA regarding the safety of water reuse. Helping communities provide safe drinking water is important. The blueprint, which is a living document, will provide a stronger business case for technology innovation, provide information about current technology development, and frame a broader range of Agency actions to move technology innovation forward.

Mr. Lek Kadeli discussed the importance of moving technology innovation and ideas into commerce while ensuring that the regulatory environment does not become an obstacle. The current challenges regarding water resources are different from those of the past. EPA faced obvious environmental problems when it was created and has made progress on those, but today's challenges are more subtle, difficult to define, socially complex and multidisciplinary; the solutions will affect many groups, with technology innovation playing an increasingly important role. It is necessary to adopt a systematic approach to solve the current problems, and stakeholders must be included. In addition to solving environmental problems, the goal is to help communities. EPA supports water technology clusters because they have adopted a systematic approach, bringing together a wide variety of stakeholders from various sectors affected by similar regional water challenges who are able to respond to these complex challenges. The Cincinnati water technology cluster began in 2010 when EPA brought together water industry stakeholders in the Ohio River Valley—this cluster officially became Confluence in 2011. Mr. Kadeli provided examples of the great progress made in water technology innovation, noting that it is important to engage a broad group of stakeholders to address an issue, beginning with defining the problem and ultimately delivering results. The outcome is a collective vision with mutually beneficial goals that enables all parties to mobilize resources to realize stronger, more enduring solutions. Mr. Kadeli encouraged collaboration among clusters, which will benefit all.

Instructions and Preparation for Afternoon Facilitated Group Discussion

Maggie Theroux, Senior Cluster Development Specialist, ORD, EPA

Ms. Maggie Theroux provided instructions to the participants regarding how the afternoon facilitated group discussion would be administered.

Building a Credible Testing Program—Overview of Testing Issues in Water Technology Commercialization

Teresa Harten, Team Lead, EPA Cincinnati Water Cluster, ORD, EPA

Ms. Teresa Harten explained that technology purchasers, regulators, vendors and financiers rely on technology testing for a variety of reasons, including making decisions, writing regulations, attracting funding and improving technology. Credible testing is performed by an objective third-party testing organization with stakeholder involvement and is fair, transparent and peer reviewed. Selection of those technologies that will be tested may be driven by users' challenges, vendors and innovation, or an organization's expertise. Many questions regarding stage of technology development and fairness must be considered and answered during the process, which should be transparent. Testing organizations also must consider issues of outcome, branding and financing. Test plan development includes determining which entities to involve as well as test scoping (e.g., balancing speed and cost with completeness and certainty). Ms. Harten described a case study (arsenic removal technology verifications and arsenic demonstration program) to illustrate scoping. The range of testing programs includes voluntary testing, mandatory testing, industry standards compliance, state-only programs and industry-led programs. It may be feasible to explore a network of testing organizations with reciprocity among the organizations; connecting the network to an international system and/or other networks provides another avenue of exploration.

Questions/Answers and Discussion

Although the EPA Environmental Technology Verification (ETV) Program performed customized testing, there may be a method to benchmark, share and obtain insights about the technologies. Are ETV case studies available? The protocols and test plans are available on the ETV website, as well as three volumes of case studies, which focus on environmental and human health outcomes by technology categories.

Who paid for the arsenic technology demonstrations? Congress mandated the program, so tests were government-funded with a very specific \$20-million appropriation. The program was unique in that the government purchased the technologies. (www.epa.gov/nrmrl/wswrd/dw/arsenic/where.html.)

Are regional variations in ETV protocols allowed? Although certain parts are standardized, there is some ability to modify the protocols.

The future role of a network of testing organizations may be expanded to verify certain protocols that are being used onsite. There is a definite need to examine new models.

PANEL DISCUSSION: NATIONAL AND STATE TESTING AND LABELING PROGRAMS

Moderator: Ned Bartlett, Partner, Bowditch & Dewey, LLP (New England Water Innovation Network)

WaterSense® Overview of Certification and Labeling ***Veronica Blette, WaterSense® Branch Chief, OW, EPA***

Ms. Veronica Blette explained that WaterSense® is a labeling program for commercial-ready water technologies to foster innovation. It is not an incubator. It smartly uses resources (EPA, manufacturers, licensed certifying bodies, retailers and other partners) to provide independent third-party credibility, certifying that EPA criteria have been met. WaterSense® uses a variety of factors, such as national water savings, water efficiency and independent certification, to determine which products to label. To date, 11,000 products have been labeled, including lavatory faucets, irrigation controllers, tank-type toilets and new homes. Since 2006, WaterSense® labeled products are estimated to have saved 487 billion gallons of water, reduced water-related energy consumption by 64.7 billion kilowatt hours, and saved consumers \$8.9 billion in water and energy bills. The goal is to reach \$1 trillion in savings by the end of the current year.

The product-certification process includes 274 manufacturing partners across six product categories, six accredited and EPA-licensed certifying bodies, and three internationally recognized accreditation bodies. Each group has different roles, responsibilities and credentials. The responsibilities of manufacturers include designing and submitting compliant products, abiding by WaterSense® guidelines, and contracting with accredited and licensed certifying bodies. Among their responsibilities, certifying bodies must evaluate the manufacturers' production processes, maintain a list of certified products and provide the list to EPA, and conduct annual surveillance and product retesting. Accreditation bodies evaluate, accredit and oversee certifying body capability and competence to certify products to the WaterSense® certification system and specifications. WaterSense® responsibilities include developing and maintaining certification system requirements and specifications; policing use of the label and protecting the trademark; and marketing the label to consumers, utilities and designers.

Ms. Blette described the steps of the product-certification process, which begins with a manufacturer partnering with EPA and applying to a certifying body for certification. After the certifying body conducts the product evaluation, the body authorizes the manufacturer to use the WaterSense® label and notifies EPA, which maintains an online registry of labeled products. The certifying body continues to conduct ongoing conformity assessment. The cost of the process is market-driven, and the Agency is not involved in transactions between the manufacturer and certifying body. The program benefits manufacturers as it helps them to market and sell water-efficient products. Through 2012, manufacturers have reported that more than 119 million labelled products have been shipped.

Michigan Water Technology Testing Program

Gil Pezza, Director, Water Technologies Initiative, Michigan Economic Development Corporation

Mr. Gil Pezza focused on the activities undertaken in Michigan surrounding water technologies. He noted that having too much water creates a feeling of complacency in many, which makes it difficult to rally for support around this issue. To successfully obtain support in the economic development community, it is key to illustrate that water technologies benefit the economy and create jobs. In Michigan, water technology innovation drivers and needs include economic development initiatives, regional strategies centered around water or the “Blue Economy,” the state’s mandate to protect and preserve its waters, market opportunities, attraction of water-dependent companies, end users, and regulation. One of Michigan’s Water Technologies Initiative focal points is facilitating pilot tests of innovative technologies. Technologies have been end-user driven, and Michigan’s strategy for financing has been *ad hoc* based on each project. Operation and maintenance funds from utilities that could be applied to pilot projects were identified in some cases, and cost-sharing occurred in others. Regional plans involving innovation technologies—similar to those of Oakland and Macomb counties in Michigan—have been developed. Mr. Pezza pointed out that fragmentation in the water industry has prevented the formation of advocacy groups to lobby for prioritization of funds for water. One manner by which to accomplish this is to focus on water technologies to bring together environmental organizations and industry. It is necessary to create a nexus between academia and end users via engineering consulting firms and prioritize state-level water issues by shattering state agency “silos” and developing a consensus plan around water with all of the various regions in the state. Mr. Pezza recommended creating a virtual water team to align the strategy and establishing a funding mechanism to jump start water technology programs. Development of a market strategy also is needed.

Questions and Answers

What are your observations about the innovation of U.S. companies and entrepreneurs compared to those in Israel? U.S. companies and entrepreneurs are just as good, but Israel has a different innovation environment; entrepreneurs there are allowed to fail before further innovating and getting funded. Companies should engage their state’s department of environmental quality (or the equivalent) before performing a pilot project.

NSF International: Testing and Certification

C. Bruce Bartley, Senior Technical Reviewer, Global Water Programs, Filtration Division, NSF International

Mr. Bruce Bartley explained that NSF International is a global, independent public health and safety organization whose mission is to protect and improve human health. It began in 1944 when the University of Michigan School of Public Health received a grant from the Coca-Cola Company to develop standards for soda fountain sanitation and overcome regulatory barriers. The organization involves and engages the three groups that drive standards—industry, consumers and regulators. NSF International standards and certification are recognized by the American National Standards Institute (ANSI) and internationally. The organization’s Global Water Program tests and certifies products related to residential and public water. Certification to the NSF standard ensures that products meet regulatory requirements for the United States and Canada and is a mark of distinction. Customers are assured that the product is safe for use in drinking water and performs as advertised. Certified products are entered into an online directory of certified drinking water system products. The cost of certification depends on the standard and testing facility location, approximately \$2,500–\$7,500 annually and \$2,500–\$50,000 for testing.

Questions and Answers

Are the water reuse standards for residential or commercial use? The standards are aimed at residential use; industry can choose residential or commercial certification at the time of testing.

How did NSF International build reciprocity with other countries? It was a long and arduous process.

In those cases that a state body oversees the water program, would the state adopt the NSF protocol? States have a number of options depending on the political and regulatory environment present. NSF International surveys states regarding their policies every 2 years in an ongoing process because of the constantly changing regulations and policies.

Does the NSF International process lend itself to innovative product certification? Innovative or not, any technology dealing with water most likely needs to go through the process. NSF International handles each case individually as it is received at the applied research center. There are enough standards and protocols available that most products fit within one.

Washington State's Technology Assessment Protocol—Ecology (TAPE) Emerging Technologies Program

Kurt Marx, Assistant Director for Clean Water Innovation, Center for Urban Waters, University of Washington Tacoma

Mr. Kurt Marx explained that TAPE is the state of Washington's stormwater treatment certification program for emerging treatment technologies for sediment, metals, phosphorus and oil. Permitting is the driver for the program, which is referenced in regard to emerging technologies in the *Stormwater Management Manual for Western Washington*. The state's Department of Ecology wants and needs new stormwater treatment technologies to meet permit requirements and protect and improve water quality; TAPE fills this need by allowing proven treatment systems to be utilized before the manual is updated, approximately every 5 years. The program also provides vetted, consistent third-party performance data to users. There are three certification levels with new development and redevelopment requirements for treating stormwater; the program does not apply to retrofits or to industrial stormwater permits, which must meet numeric effluent benchmarks. The TAPE program has approved 13 technologies, with 15 additional technologies active in various stages of the program. TAPE approval is a marketing tool for those companies that participate, and jurisdictions outside of the state of Washington have benefited from the program. Water clusters can play a role in helping early-stage companies bring their innovative water technologies to the marketplace by locating test sites, minimizing costs and encouraging reciprocity. One of the biggest challenges for technology companies is to find a testing/installation location.

Questions and Answers

Stormwater removal at airports (i.e., reducing open water that might attract birds) is a significant market; does this use fall under industrial uses under the TAPE program? TAPE does not apply to industrial permitting and is limited to technologies for removal of sediment, metals, phosphorus and oil; it meets a narrow regulatory field (state regulatory requirements).

Leaders Innovation Forum for Technology (LIFT) Technology Evaluation Program

Jeff Moeller, Director of Water Technologies, Water Environment Research Foundation (WERF)

Mr. Jeff Moeller explained that LIFT is an initiative of WERF and the Water Environment Federation (WEF) that moves technology into practice more quickly. LIFT focuses on new technologies with the goal of accelerating innovation. The initiative includes a technology evaluation program, a people and policy program, and an informal forum for research and development managers. The end-user driven program includes a working group, which has grown from 25 facility-owner members to more than 250, and a volunteer experts pool comprised of consultants, academics, equipment manufacturers and other stakeholders. The LIFT Technology Evaluation Program provides a credible, well-documented vetting system to screen new technologies, mitigates the risk and cost of innovative technology deployment, facilitates collaboration for evaluating and testing new technologies, and provides peer-reviewed information about these technologies.

The LIFT Technology Scan Program provides a platform for vendors to introduce technologies; 28 new technologies have been submitted since the pilot launched in November 2013. After LIFT's call for new and innovative technologies, providers submit technology applications. WERF assembles panels of experts and practitioners to review applications. Selected technologies are invited to present to LIFT audiences that are appropriate to their technology readiness levels to garner interest in early adoption of the technology. WERF also helps develop and manage independent, peer-reviewed technology evaluations. Results and data are shared following the collaborative pilots, demonstrations and testing, which occur at testing and demonstration facilities/sites with individualized quality assurance project plans. The program focuses on demonstration and evaluation, rather than certification and validation, and shares the costs and risks of technology innovation through partnerships.

Clusters can work with LIFT in several ways, including via the following avenues:

LIFT Technology Scan. Clusters that are working with technology providers should encourage these providers to apply to the LIFT Technology Scan Program to help advance their technologies.

Collaborative Technology Demonstration/Evaluation Project. Many wastewater facilities that are WERF subscribers are located in water clusters. These subscribers, in conjunction with a cluster, can initiate a collaborative demonstration project process via a request letter to WERF at any time. Through this process, WERF will work with the facility and cluster to identify additional agencies interested in partnering to fund the demonstration and conduct an independent technology evaluation.

Peer Review of Demonstration/Evaluation Project. A WERF utility subscriber, in conjunction with a cluster, can request to utilize WERF's expert peer-review process for a new technology demonstration project it is conducting, which lends national credibility to the results. WERF currently is conducting peer reviews of several biosolids-to-energy technologies in the San Francisco Bay area.

Questions and Answers

Some technologies in the water market have historically been applied to one sector but now have the opportunity to be applied in a new sector; these are not new technologies but existing technologies with new uses. Currently, there is no platform to increase the visibility of these products. Can LIFT play a role in this? Yes, LIFT can play a role in this and is interested in technologies from other sectors. Increasing visibility of technology in new sectors is a great discussion topic for this group.

The New Jersey Corporation for Advanced Technology (NJCAT)

Richard Magee, Technical Director, NJCAT

Dr. Richard Magee explained that the New Jersey Department of Environmental Protection (NJDEP) was the impetus for establishing NJCAT in 1997 as a public-private partnership to accelerate emerging environmental and energy technology deployment. Its technology verification program moved NJCAT forward; NJCAT does not perform technology testing but rather conducts an evaluation program to verify innovative environmental and energy technology performance claims using independent third-party laboratory and field demonstration performance data. A vendor seeking an innovative technology certification contacts NJCAT or NJDEP, and a preliminary assessment of the technology is performed. The vendor submits the technology performance claims and supporting data to NJCAT, which uses established protocols to verify the claims and sends the verification report to a peer-review team and NJDEP. The final report must be approved by the NJCAT Board of Directors and submitted to NJDEP for certification. The program expedites the use of new technology by NJDEP regulatory programs, and information about the technology is included in NJCAT and NJDEP outreach and education programs. Technologies are included in the appropriate state bid specifications, which increases the possibility of selection. Dr. Magee noted that many states use the New Jersey Stormwater Management Rules, which drive the verification and certification process by stipulating that manufactured treatment devices may be

used to meet regulatory requirements provided the pollutant removal rates are verified by NJCAT and certified by NJDEP. The recent economic situation has caused NJDEP to modify the process to rely on laboratory testing because of the challenges and associated costs of field testing.

Panel Discussion

Mr. Ned Bartlett summarized the themes of the panel presentations, including the variety of drivers (economic, regulatory, end user); reciprocity; and limitations on geographic jurisdiction and market share.

Mr. Pezza noted that one challenge of the water technology sector is that the technologies are too expensive; cost is a driver. Dr. Magee said that manufacturers and product developers were responsible for testing and verification costs. Mr. Pezza said that other industries (e.g., automotive industry) have successfully accomplished bringing affordable products to the marketplace, and applying the core competencies of successful industries to the water technology industry (i.e., cross-fertilization of competencies among industries) would be beneficial.

Mr. Bartlett asked the participants about the potential role of water clusters in providing affordable technology innovation. Mr. Richard Seline mentioned the balance around the public sector dictating what the market will adopt. Some technologies have next-generation market value that goes unrealized. Mr. Bartlett noted that the pharmaceutical industry excels at off-label uses of its products, but the water sector has not been successful in this area.

Mr. Egils Milbergs thought that one role of water clusters could be to facilitate the sharing of users' experiences with technologies in a system in which actual users provide reviews and performance ratings. Mr. Bartlett summarized that the water clusters could establish an information-sharing clearinghouse. Ms. Blette agreed that this would be helpful because utilities often do not adopt innovative technologies out of fear of risks; reading reviews from their peers would help alleviate that fear. Mr. Marx noted that these experiences already are being recorded via certain programs but are not always shared. Dr. Magee commented that it is difficult to obtain follow-up on a technology's field performance. Also, the lack of field testing required in some programs will cause the loss of a great deal of practical information.

Dr. Gilinsky stated that the issue of reciprocity needs to be solved, and the cluster format could provide the solution. Ms. Ebie Holst noted that testing criteria will evolve, and there always will be regional components, but a "version control" mechanism needs to be established so that the "stamp of approval" speaks to the time in history that a product was verified. A list of certification criteria necessary for each state would provide developers with a blueprint for developing technologies that can be used in multiple jurisdictions. Although Dr. Gilinsky did not think that most states had a clear picture of their specific needs, Dr. Magee noted that some know their critical issues (e.g., Virginia and phosphorus). Some developers try to cater to certain states' needs. Mr. Greg Carroll said that reciprocity is a great concept, but states are reluctant to embrace automatic reciprocity. An interim goal toward the long-term goal of reciprocity could be to collect a body of testing information so that states can make their own decisions. EPA's ORD is working with Ohio, Kentucky and Indiana to develop a joint protocol for ultraviolet (UV) testing.

Ms. Kirsten Melberg explained that the city of New Orleans is wanting to quantify the economic and social benefits of technologies in addition to the environmental factors. She wondered whether any other groups had begun to quantify these benefits. Mr. Pezza said that it is difficult to develop metrics to quantify green infrastructure. Water clusters must explain the benefits, such as job creation and increased quality of life, to states and municipalities. Water technologies offer these benefits, but this must be proven before developers can obtain investments. His most difficult struggle within his organization is explaining the immediacy of the direct impacts. Ms. Melberg said that her organization has begun to develop a matrix to determine these measurements; she welcomes any advice other clusters may have. Mr. Pezza said that Michigan's economic development plan may be of some help, and he offered to share

it. Mr. Moeller said that the city of Portland (Oregon) has made a significant effort in attempting to quantify green infrastructure benefits, and Mr. Bartlett added that the city of Philadelphia is heavily into green infrastructure.

Mr. Seline said that his organization is attempting to determine the total procurement capacity (technology only) of the 4,300 water authorities in Texas, and he wondered whether other organizations had attempted anything similar. Ms. Blette said that surveys conducted under the Safe Drinking Water and Clean Water Acts might provide this information. She also noted that technology costs are high because technologies must be built to meet different states' specifications. Reciprocity is important, but technologies that lend themselves to this should be selected.

Dr. Magee commented that many venture capitalists have moved away from environmental technologies because of the continually changing regulatory environment.

PANEL DISCUSSION: OPERATING AND MAINTAINING A TECHNOLOGY TESTING CENTER

Moderator: Dean Amhaus, President and Chief Executive Officer, The Water Council

Massachusetts Alternative Septic System Test Center

George Heufelder, Director, Barnstable County Department of Health and the Environment

Via teleconference, Mr. George Heufelder explained that the Massachusetts Alternative Septic System Test Center is operated by the Barnstable County Department of Health and the Environment and has approximately 25 locations for the onsite septic system technology testing it has been performing since 1999. The center is funded via vendors and grants, and Barnstable County contributes staff time. Activities are numerous and include product testing, facilitation of research and development of proprietary products, research on nonproprietary treatment strategies, and work with vendors to develop data for obtaining approvals from various jurisdictions. Potential clients generally contact the center via telephone to discuss the available range of services. If the client does not know which testing protocol is needed, the center discusses the goals and expectations, advises the client of the options, drafts and conducts a sampling plan, and compiles the report. If the client knows the appropriate testing protocol, the center clarifies goals and expectations, advises the client of the options, drafts and conducts a sampling plan, and compiles the report. If an NSF protocol is required, the client is advised to contact NSF International directly.

Onsite wastewater testing centers require attention 365 days a year, and directors must ensure that clients develop reasonable expectations for their efforts and expenditures. It is important to meet with the regulator to ensure that the vendor has been understood accurately. Regulators in some states may stop the process based on their interpretations of state policies. Mr. Heufelder encouraged early-stage companies to know the universe of their competitors' products and understand the regulatory frameworks under which products will be approved. It also is important to hire a staff member who can describe the product to a broad range of audiences. Also, dealing with regulators requires patience. Test centers can assist with developing sampling plans at various stages of product development, work with regulators to clarify information requirements, and compile data and performance reports for the various purposes.

Questions and Answers

What arrangements does the center have with wastewater utilities? Are universities involved? There are no arrangements with wastewater utilities, of which there are only three or four public treatment plants on Cape Cod, but the center monitors 1,400 systems with various technologies via a Web-based recording system to help municipalities track their performance.

Does the center's model provide for maintenance via fees collected, or are other sources of funding necessary? The operation can be administered entirely on client fees.

How many devices are connected to the cloud? What is the future of cloud-connected devices? The center encourages cloud-based monitoring devices, but there is not a great deal of activity in this area currently.

International Center for Water Technology and Center for Irrigation Technology

David Zoldoske, Director, International Center for Water Technology, California State University, Fresno (Fresno State)

Dr. David Zoldoske stated that the water cluster centered in Fresno, California, was established in April 2001 and identified three key areas of need in its strategic plan, which are to increase exports, develop a workforce and establish a hydraulic testing laboratory. Using industry, Fresno State, EPA and the U.S. Economic Development Administration as resources, the cluster raised more than \$6 million for laboratory equipment and facilities. With these funds, the Water and Energy Technology Incubator—which includes almost 9,000 square feet of dedicated laboratory space—was built on the campus of Fresno State and is the basis for the water cluster efforts. Dr. Zoldoske displayed images of several components of the facility, including some of the few test pumps located west of the Mississippi River and a degasser. An energy project in conjunction with the city of San Jose (California) is expected to have a return on investment within 4 to 6 years. The International Association of Plumbing and Mechanical Officials-certified/ANSI laboratory provides services for fee, including WaterSense® and witness testing and product development. The center has adopted a policy of reporting only successful data so that negative data are not used against developmental products. Dr. Zoldoske noted that the San Joaquin Valley economic development model includes water and energy as key components. The water cluster and the center work as partners, and the center helps businesses to succeed while promoting innovation. In conclusion, Dr. Zoldoske pointed out the importance of using laboratory and field data to tell the whole story.

Questions and Answers

Does the center's model provide for maintenance via fees collected, or are other sources of funding necessary? The initial efforts were more opportunistic than programmatic, but now it is much more programmatic, with a \$4-million budget that includes some state support. The laboratory makes up approximately 15 to 20 percent of the program, which is involved in a wide variety of projects, including work in disadvantaged communities. The model ensures that the laboratory has synergies, and workforce investment funding helps manage the water cluster. Integration of the various components, including several start-up companies, provides support to the laboratory.

How many devices are connected to the cloud? What is the future of cloud-connected devices? Recently, the Pacific Gas and Electric Company provided nearly \$500,000 to establish the Agriculture Water Energy Center, which focuses on collection of farm energy and water management. Some vendors work in the cloud, bringing in amazing, inexpensive sensor technologies. There has been a rapid, tectonic shift in the ability to collect data inexpensively.

Can any of the sensors be adapted to the wastewater sector? This should be possible, especially given the discussion regarding cross-pollination of technologies across sectors.

Does the cluster still administer an export program? The cluster worked with Mexico, Brazil, Argentina and Chile for 6 years on export of irrigation technologies. The cluster has reapplied for funds, but the political landscape has changed, emphasizing a shift toward trade with China rather than South America, and vendors are hesitant to trade with China for intellectual property reasons. The prior funding supported about 50 percent of the costs to market products in South America. If there is a shift away from an emphasis on China to more palatable countries for vendors, the cluster will re-examine its options. California terminated its export program, so that avenue no longer is an option.

INDIVIDUAL PRESENTATIONS

Emerging Technology—A State’s Permitting Perspective

Jeff Davidson, Environmental Manager, Division of Drinking and Ground Waters, Southwest District Office, Ohio EPA

Mr. Jeff Davidson described some of the conventional “wisdoms” surrounding emerging technology, which no longer apply. Dealing with aging water plants and distribution systems is a significant challenge, as water mains are reaching their life expectancy, tanks were designed for water quantity rather than quality, and regulatory concerns have changed since their construction. Emerging contaminants have resulted in new regulations for surface, drinking and ground water, but these regulations place a stress on plants not designed for them. This provides a challenge for emerging technologies to solve. Mr. Davidson mentioned the following emerging contaminants: harmful algal blooms, pharmaceuticals, personal care products, cryptosporidium, legionella, viruses, disinfection byproducts and hexavalent chrome.

There are a number of source water quality and quantity issues (e.g., arsenic, Lake Erie algal blooms, nutrient loading), and emerging technologies must perform across a wide range of water quality conditions and operational challenges to be viable. Also, it is necessary to ensure a proper correlation between technology complexity and operator expertise. Monitoring cannot be completely reliant on automation to determine that the required inactivation is being achieved. Well-defined, simple operating protocols for performing routine maintenance, troubleshooting operational issues, making adjustments, and obtaining and installing replacement parts must be established. To ensure a system is sustainable, infrastructure must be operable following decades of use, and water utilities cannot be reliant on a single vendor for the long-term maintenance of proprietary technology. States also require contingencies for when the technology fails or is out of service for routine and nonroutine circumstances, and states and water utilities must have accurate information on the full cost of the technology over its entire life cycle. Consumer expectations for water keep increasing, and utilities must meet these demands. Standards and limitations of residual disposal also must be considered. Mr. Davidson concluded that there are many considerations beyond the efficacy of the treatment that must be considered before technology is employed, particularly at smaller public water systems.

Questions and Answers

There are many qualitative regulations; is there a value to quantitative regulations? The Midwest increasingly is moving in this direction. Source water protection is a major issue, and the quantity issue accompanies it. Obtaining water that is affordable to treat will drive quantitative regulations.

What is the trend regarding procurement of new technologies? Engineering consultants probably are the biggest direct consumer in terms of information. The American Water Works Association (AWWA) and Ohio EPA established a technology committee with consultants, water system representatives and state regulators to discuss problems and how to solve them. The engineers brought forward information and data about available, new technologies. Technologies are re-evaluated on a routine basis to determine whether piloting can be decreased and other demonstration data can be accepted; this is an attempt to increase the feasibility of introducing new technologies.

How are procurement methodologies playing out in terms of the pace of innovation? They are vetted by the regulators more than they have been in the past now that there is more of a push for technology adoption.

Can you provide a case study of an emerging technology introduced to your office? What are the criteria for introducing new technologies? Are new technologies vetted across the state? Arsenic is the best example. The regulation changed, so the office engaged in a 2-year process to review NSF International,

EPA and other states' information on arsenic technologies. The new regulation drove the need to turn to emerging technologies. The technology committee provides a great deal of input as well.

Sometimes a district is attempting to solve an issue for which the state does not have an answer, so the district takes the lead in researching and proposing a solution, and then the results are adopted across the state.

What is most helpful for states to implement new technologies? It is important that the technologies that are applied be appropriate for the situation and not cause negative unintended consequences.

Imagine H₂O—Experience in Permitting and Testing
Scott Bryan, Chief Operating Officer, Imagine H₂O

Mr. Scott Bryan explained his organization's path-to-market programming. The business program encourages innovation with an annual competition that identifies promising water innovations and emerging businesses. The competition's top 12 companies advance to the Imagine H₂O accelerator, which promotes winning ideas through in-kind resources, mentorship, investor introductions and beta customers. Imagine H₂O's Accelerator Hub Partners Program currently includes five water clusters and expects to grow during the current year. The program provides clusters with resources for local entrepreneurs and opportunities to leverage the Imagine H₂O competition to engage the innovation community. Mr. Bryan described a case study regarding nontraditional financing, illustrating that the key to success is to utilize local resources, capital and expertise. He encouraged clusters to help entrepreneurs move beyond pilot projects, which are not always scalable or financially sustainable. Pilots can be an important step but do not comprise a sound business model; beta customer engagements are superior. There is more room in the water sector for business innovation versus technology innovation. Clusters can be a resource in helping entrepreneurs work with market partners to understand the ultimate needs of end users and customers. Mr. Bryan encouraged clusters to commit resources toward implementation opportunities rather than simply focusing on marketing activities. Entrepreneurs also should engage with regulators so that they understand the regulatory framework that guides product adoption. The water sector contains a complex network of consultants, competitions, agencies, universities and so forth, which need to make themselves available and more understandable for entrepreneurs. It is important for entrepreneurs to focus on end-user agreement; clusters can encourage entrepreneurs to engage the end user.

Questions and Answers

What is your opinion of crowdsourcing? It is an interesting concept in general, but it is not seen often in the water sector. There is a growth opportunity in the water sector, but the general public does not understand water technologies, which is critical for crowdsourcing success.

There is a body of evidence that entrepreneurs, innovators and investors are trying to disrupt regulated markets in an attempt to build innovative solutions. Can you comment on this? Some developers love regulations and can build a successful business based on them, but there is a lack of clarity in certain areas (e.g., greywater, direct potable reuse) that must be addressed before a wave of innovation enters the sector. Although entrepreneurs and investors are not comfortable with the regulatory environment in these areas, they are finding opportunities to monetize other areas within the water industry.

WORKING LUNCH

Discussion on Financing of Testing Facilities and Technologies

Earl Jones, Member, Liberation Capital (New England Water Innovation Network), and Paul O’Callaghan, Chief Executive Officer, BlueTech Research

Mr. Earl Jones introduced the discussion, noting that money entering the water sector is decreasing. The current advice is for funders to begin in industrial water and then transition to municipal water. Today’s dialogue is important because it is necessary to move the sector away from spawning 20-year “overnight” successes. The U.S. investment gap in the water sector is \$250 billion, and problems are accelerating. The single largest problem facing the sector is financing. Regulations provide difficulties for developers. Finally, solving the challenge of reciprocity would be beneficial.

Mr. Paul O’Callaghan noted that the sector has many real challenges with no simple solutions. He explained that BlueTech Research maps the water innovation landscape within four core practice areas: water reuse and alternative water, energy and resource recovery, unconventional fossil fuels and water, and smart water. The company tracks innovations, licensing and patents to map the sector in three ways: thematically, from a technological perspective and by application. Energy and resource recovery is a major investment theme in which BlueTech sees activity. Mr. O’Callaghan observed that the overall objective of technology verification is to accelerate the adoption of solutions that meet client needs. Innovation must meet client needs and should deliver its own value. Investors and developers should recognize that the purpose of the water sector is not to deliver double-digit returns to investors; it is to deliver water services in an efficient manner. Companies with technologies or solutions that meet client needs can be successful, and there are examples of this. Entrepreneurs should adapt, however, to reflect market realities, as opposed to expecting the water sector to change to meet their needs.

Mr. O’Callaghan provided a graphic representation of two “overnight success stories after 20 years.” These case studies included UV technology and ultrafiltration membranes. Early adopters are a key element needed to help companies advance on the technology S-curve. He displayed another graph of the revenue stages of BlueTech Innovation Tracker companies within the water sector, explaining that there are a large number of companies at the prerevenue and early revenue stages. Next, there is a high rate of attrition as companies attempt to move through the “valley of death” and reach a revenue bracket of \$1 to \$10 million. Companies can stabilize in the \$1 to \$10 million range; the next step is to scale up to reach a revenue range of \$50 to \$100 million. Companies must move past the pilot project stage successfully by gathering the right data, testing on the appropriate waste stream, obtaining independent third-party validation, and linking pilots to the next steps in the commercial process. Many companies do not do this. One of the best uses of seed funding is to fund a demonstration facility at or near full scale, ideally with a “flagship” client located relatively near the company’s main office. Early adopters are an important component of success. Verification is good, but performance is highly dependent on test conditions, which vary.

When vetting a technology, BlueTech Research reviews available data, determining whether it has been proven and at what scale and in what conditions. Fragmentation occurs in testing and validation—as it does in the water industry as a whole—as a result of different technologies, applications, scales and clients. Buyer confidence can be increased by sharing information among peers via the WEF discussion forums, conference papers, and possibly crowdsourcing and social media. Other potential models include the European Union ETV Pilot Programme, which covers water, waste and energy, and Canada’s nonprofit foundation, Sustainable Development Technology Canada™, a successful demonstration support initiative.

Discussion

Mr. Pezza wondered whether some water technologies are more attractive to investors. Mr. Jones said that venture capitalists look at those with interesting returns on investment. Technologies that require increased capital are less attractive. Sensors and similar technologies have a great deal of cachet right now.

A participant asked about the best financial model given the 20-year S-curve. Mr. Jones thought that the “headwind” in the marketplace is getting the product to market, particularly in the United States, which has a fragmented regulatory landscape. It is important to assess the product’s channel to the market rather than whether the product is the best.

Mr. Davidson asked how to “sell” wastewater technology to the public. Mr. Jones responded that the United States has not done an effective job with public outreach surrounding water. It is necessary to educate the public that treatment comes with a cost. Singapore is a model for excellent public outreach about water. Mr. O’Callaghan agreed that Singapore has done a great job making the field of water exciting to the public, noting that education on this topic must be more accessible. Mr. Seline added that a crisis sharpens the public’s focus around an issue, and this year, the “water wars” and the question of which entities “own” water have entered the public’s consciousness. It is a public commodity, and this crisis provides the opportunity to educate. The most significant challenge is convincing water purveyors that innovative technologies are viable technologies.

Mr. Jones commented that collaboration among municipalities would create leverage. It is necessary to think beyond technology innovation to organizational innovation. Yesterday’s solutions will not meet today’s or tomorrow’s problems.

Dr. Zoldoske was unsure how to reconcile the fact that local municipalities are required to solve their water issues while being regulated from above.

PANEL DISCUSSION: EXPERIENCES OF BUSINESSES IN THE TESTING, APPROVAL AND PERMITTING PROCESS

Moderator: Stephen McKnight, Vice President of Community and Market Assessments, Fourth Economy Consulting (Water Economy Network)

Mr. Steven McKnight introduced the session, asking participants to consider what actions water clusters can take to add value to the testing process.

Experience With an Alternate Test Procedure Study for an Automated *Escherichia coli*/Total Coliform Method

Peter Gallant, Vice President of Regulatory Affairs, ENDETEC Sensor Group, Veolia Water Solutions and Technologies

Dr. Peter Gallant described the ENDETEC method, an automated microbiology method that can provide early alerts when water is contaminated by coliform bacteria. The company sought EPA approval for compliance testing under the Total Coliform Rule. There are business benefits to EPA approval because EPA has become the “gold standard” in countries around the world; key benefits of this approval include investability, credibility and market access. Dr. Gallant briefly described his company’s experience with EPA’s Alternate Test Procedure process, noting the excellent responsiveness of EPA staff. Despite this responsiveness, the process is lengthy, and for investors and startups, time is the enemy. Investors will not fund any product with regulatory risk, so multiyear delays can have a devastating effect on venture capital.

Dr. Gallant learned many lessons throughout the process, including the fact that EPA approval is just the beginning of bringing a product to the marketplace. It also is important to engage states and understand the regulatory framework because allowable methods vary by state. Accreditation requirements may present significant barriers to automated microbial methods. Dr. Gallant recommended that EPA consider adopting or establishing global standards for method performance for as many analytical methods as possible and establish standard protocols and performance-based standards (e.g., Method 334). Clusters should develop support resources to enable early-stage companies to mitigate regulatory risk. EPA and clusters together should consider developing a “presubmission” program to provide feedback and a roadmap to approval. He fears that the desired goal of instant notification of microbial water contamination may not be realized in the current landscape.

Questions and Answers

What is the cost of applying the technology to surface waters? A semiquantitative system for surface water is available, but automated methods do not compete on cost. Surface water testing under the Beaches Environmental Assessment and Coastal Health Act of 2000 is moving to polymerase chain reaction (commonly known as PCR) rather than automated testing.

Innovative Septic System Technology Testing and State Permitting

Jim Bell, Executive Vice President, Bio-Microbics, Inc.

Mr. Jim Bell explained that his company is a global supplier of innovative water, wastewater and storm-water treatment technologies. Its prime market is developing decentralized wastewater technologies. Current NSF/ANSI onsite residential wastewater standards include Standard 40 and Standard 245, and the new NSF Standard 350 deals with commercial and residential water reuse. The company has been testing to NSF standards since 1996; this decision was driven by the states, some of which require meeting a national standard in a manner that also meets state requirements. Costs for NSF testing begin at \$50,000, with annual certification fees ranging from \$6,000 to \$15,000, but it is essential to test to the standards because all product sales are regulatory driven. Testing to NSF standards is the first step in obtaining state approvals. Overcoming the fragmented regulatory landscape is difficult because states are entrenched after 40 years of maintaining jurisdiction. This cannot be corrected, but there is a need to understand the problem. Progress can be made in the emerging market of water reuse, and data sharing may help with state reciprocity.

Questions and Answers

Is this the only system certified for NSF Standard 350? This system was the only one tested that used ANSI itself as a certifier. Other technologies have used ANSI certifiers to test to NSF standards.

Can you elaborate on the push toward data sharing? The *EPA Memorandum of Understanding Regarding Cooperation in Decentralized Wastewater Management* between the State Onsite Regulators Association (SORA) and the National Onsite Wastewater Recycling Association, Inc. (a trade association) addresses data sharing. A session at the upcoming SORA meeting will allow the regulators to agree, with industry present, on the parameters that will allow data sharing among states. These will be presented to EPA. Another group may serve as the central repository for this information.

Experiences of Businesses Obtaining the WaterSense® Label for Irrigation Controllers

Brent Mecham, Industry Development Director, Irrigation Association

Mr. Brent Mecham explained that Smart Water Application Technologies (SWAT), established in 2002, is a collaborative effort between municipal water providers and the irrigation industry that is managed by the Irrigation Association. The mission is market transformation, and SWAT created a testing protocol to validate manufacturer claims for smart controllers following the ISO standard-setting process. SWAT

does not provide certification, only testing results. The SWAT testing protocol is used as the basis for EPA's WaterSense® labeling program with a few modifications; EPA testing provides another validation. The labeling process can provide many challenges, such as the need for the right weather conditions, which can create a significant cost to small manufacturers. Irrigation controllers have had slow growth, as the market has not embraced them, but drought and EPA's WaterSense® have become motivators for adoption. SWAT results have been used as the basis for product rebates, and WaterSense® labeling has become an alternate source for providing rebates. Soil moisture sensors, flow sensors, sprinklers and nozzles, and valves may be investigated in the future. SWAT also is working through ANSI standards developers to take the testing protocols to the next level to facilitate adoption by others.

Questions and Answers

Has there been pushback regarding recycled water and its application on the landscape? Green codes are attempting to remove urban irrigation from the potable water supply, but the definition of the term “potable” is an issue. A significant issue is the potential health hazard from plumbing codes that require a purple pipe be used for all alternate water sources because of confusion that may arise from the various treatment levels of the different water sources. Recycled water often is very useful for landscape irrigation if the quality is sufficient to not harm plants.

Delivering Next-Generation Stormwater Technologies by Harnessing the Power of Collaborative Effort

Robert Adair, President, Convergent Water Technologies

Mr. Robert Adair stated that his company breaks down barriers to innovation, delivers solution-oriented distribution and enables innovators to reach a national market. Next-generation stormwater technologies, including a high-performance modular biofiltration system, mostly are iterative technologies. It is necessary to institutionalize innovation. Stormwater is an industry in the making; drainage and flood control have evolved to include habitat protection and restoration and rainwater reuse, so the stormwater moniker no longer is accurate. The green infrastructure paradigm is driven by necessity, and a lack of national standards is a hindrance for the stormwater sector. The current timeline (2 to 3 years) and cost (\$250,000 to \$700,000) of testing should not be a hindrance to introducing new technologies; a better testing regime is needed to meet critical objectives. The variety of regulations also decreases the ease of moving technologies to the market. Mr. Adair advocates for a national verification program, Stormwater Testing and Evaluation of Products and Practices (STEPP). STEPP would allow laboratory verification to trigger market access, field monitoring results to trigger certification, and stormwater permits to drive universal acceptance. Stormwater companies should think more like technology companies in regard to innovation.

Biosolids Class A/B Designation Through EPA Pathogen Equivalency Committee Process ***Fred Mussari, Vice President of Research and Development, BCR Environmental Corporation***

Dr. Fred Mussari stated that innovation in biosolids treatment is necessary because infrastructure is aging, underfunded and facing significant cost escalations. Landfill capacity, increasing regulations and escalating energy use also drive the need for innovation. BCR Environmental Corporation's core principles ensure that the company's actions are simple, environmentally responsible, economically viable and sustainable. There are fundamental economic barriers to the majority of the market when considering new biosolids treatment technologies, and most approved solutions do not have sustainable economics at scale. The company views regulators as true partners in the permitting process, with national approval and broad market adoption as the ultimate goal.

Venture capitalists will not take the risk of building full-scale facilities to obtain regulatory approval for a new process, but there is a mechanism to obtain approval for pathogen-reduction technologies. The EPA Pathogen Equivalency Committee is a multidisciplinary volunteer committee that established a straight-

forward process for approval. The theoretical approval process for biosolids treatment methods is simple compared to the practical process. EPA approval is critical to early adoption and innovation success (business velocity). To improve the adoption process, Dr. Mussari recommended that a Vector Attraction Reduction Equivalency Committee be implemented to facilitate innovation. Also, better communication is needed between EPA and state permitting authorities. Protection of public health and the environment while developing new processes that are economically viable should be the primary goal. The process of gaining regulatory approval for new biosolids treatment processes can be difficult but is necessary if new technologies are to gain broad acceptance. Shortcutting the approval process in an effort to drive innovation may have unintended consequences.

Panel Discussion

Mr. Milbergs thought that it is important to experiment with different types of regulatory solutions across the country as a way to navigate the regulations and provide room for innovation. Dr. Gallant said that his company has suggested that the traditional laboratory accreditation framework be adapted to become field-based accreditation that still is based on federal approvals of the methods.

Mr. Seline asked Mr. Carroll whether EPA has a set of waivers to accelerate technology adoption in crisis situations that could serve as a model for the adoption of innovative technologies. Mr. Carroll responded that although this is not his area of expertise, he is aware of a waiver process for the best available treatment technology to be applied when the standard cannot be met. His peers at EPA Headquarters deal more with waivers.

Mr. McKnight summarized that it is critical for clusters to understand the regulatory process, policy environment, market drivers and cost so that a course of action can be developed that decreases uncertainty and builds relationships with industry partners undertaking the process.

INDIVIDUAL PRESENTATION

Ontario, Canada—Perspective and Approach to Water Technology Testing ***Brian Mergelas, Chief Executive Officer, WaterTAP***

Dr. Brian Mergelas stated that Ontario has a significant number of water assets, including 102 water-related research institutes, groups and centers. The province also has several assets in terms of testing technologies. Ontario's technology acceleration is aimed at building capacity for water companies, connecting end users to solution providers at the right time, and creating an environment for innovation. Barriers to innovation include limited access to testing facilities, regulatory disincentives, financial issues and the perceived risk of implementation. The Ontario Clean Water Agency is the largest in the province, operating approximately 500 facilities. The agency tracks more than 60 companies with innovative technologies and services and matches them to clients based on need. The Southern Ontario Water Consortium (SOWC) brings together academia and industry to increase access to testing facilities and includes six nodes that make it possible to perform testing: water treatment, wastewater treatment, ecotoxicology, watershed management, sensor development, and water and wastewater analysis.

Showcasing Water Innovation is Ontario's \$17-million program that funds 32 projects to promote innovative and cost-effective management of community water resources; innovative projects save money. A new process of multisite approvals has been established that is based on multisite approvals for mobile treatment facilities. In this process, the technology proponent holds the Environmental Compliance Approval (ECA), and the facility owner authorizes testing, acknowledging that effluent limits still will be met. A new Comprehensive Certificate of Approval process allows pre-approval to accelerate innovation, which the old process inhibited. For SOWC approvals, companies and researchers can access facilities with no ECA requirement, and multisite approvals can be used. The Regional Public Works

Commissioners of Ontario organization represents the 16 largest water providers in Ontario and facilitates the sharing of best practices.

Dr. Mergelas agreed with earlier presenters that reliance on pilot projects can hinder success and noted the importance of peer-to-peer groups in the adoption of innovative technologies. Underutilization is another issue that must be addressed. Sharing best practices among the water clusters would be beneficial, in addition to sharing best practices among utilities. Furthermore, testing protocols provide a common language for innovation. One of WaterTAP's roles is to help coordinate efforts in the water sector, creating visibility for technology companies and educating end users about opportunities to perform tests and share results. WaterTAP also helps to foster better communications among end users to decrease risk in the adoption of new technologies.

Questions and Answers

How many of the companies involved are startups? There are approximately 180 small companies, but it is difficult to determine whether they are true startups. Among the 900 companies, there are a few large companies, some midsize companies and a great number of small companies. The effort helps companies that have some commercial traction.

Is there an opportunity present to collaborate outside of the province? WaterTap's role is to engage with other clusters. Building bridges among the clusters and engaging with other clusters to promote water technology companies is beneficial for all.

Do you see clusters as collaborators rather than competitors? Clusters have the same goals, to solve the world's water problems, so collaboration benefits everyone.

How supportive is the Ontario government? The government has been very supportive and created an organization to bring together activities and efforts already in place. Although WaterTAP's outreach is heavily subsidized, it provides services for fees. Without the subsidies, WaterTAP would have to increase its fees.

How does WaterTAP guide companies whose products may not be "ready for prime time"? The MaRS Centre for Impact Investing deals with early-stage companies, so WaterTAP would recommend that the company spend more time in MaRS. Also, the Ontario Centres of Excellence engage companies earlier in the process than WaterTAP. The companies that WaterTAP helps have some commercial traction, with WaterTAP helping to refine their product.

How are companies identified and over what period of time? Are all companies Ontario-based? Companies were identified through a water asset map created from commercial databases and interviews. The program is funded by the province, so the primary driver is a mandate to improve Ontario's economy.

Often the largest cost of the accreditation is the time spent in the learning process. Can you describe the multisite verification process? There is a broader challenge for companies to be able to obtain a permit that recognizes that once a process has been demonstrated by one municipality, it should be easier to work with other municipalities. A technology is considered proven in Ontario when it has been installed successfully in three independent sites for 3 years.

FACILITATED DISCUSSION SESSION: BEST PRACTICES AND CHALLENGES REGARDING WATER TECHNOLOGY TESTING FACILITIES, PROGRAMS AND REQUIREMENTS

Led by: Maggie Theroux, Senior Cluster Development Specialist, ORD, EPA

The desired outcome of the facilitated discussion was a list of best management practices (BMPs) and challenges regarding water technology testing facilities, programs and requirements to help water cluster leaders determine where and how they can have an impact.

The participants broke into six small groups to brainstorm BMPs and challenges and then met as a whole to discuss them.

Identified, Categorized BMPs

Engage/Communicate

- Peer-to-peer communication.
- Utility engagement in early technology.
- Engaging the entrepreneurial ecosystem in clean water solutions.
- Identifying stakeholders early and engaging them transparently.
- Engaging stakeholders/end users to identify and leverage testing facilities.
- Partnering with industry, end users and academia.
- Ensuring that consulting engineer organizations are included in the dialogue.
- Communicating effectively with consulting engineers.
- Leveraging whenever possible.

Test

- Testing roadmaps by application leading to a cluster/testing organization by application.
- Articulating “dos” and “don’ts” for testing projects (e.g., define needed data).
- Piloting early/field testing.
- Establishing protocols for tests that are relevant to the community.
- Verifying and validating data for end-user need and regulatory requirements.
- Participating in an ISO effort to create a technology verification standard.
- Laboratory specialization.
- Multisite permitting.

Know

- Identifying social, environmental and economic goals.
- Getting a grasp of BMPs.
- Knowing your regulator and communicating early.
- Providing advice (e.g., guidance manual) to early-stage companies.
- “It’s about the market, ‘stupid’.”

Match

- Matching technology needs with industry/regulatory requirements.

Track

- Keeping a score card with success and nonsuccess stories.
- Storing and communicating data.

- Retooling procurement from design/product-based to performance based.
- Implementing lean and continuous improvement in the regulatory system for predictability and efficiency.
- “What will fill the void?”

Identified, Categorized Challenges

Funding

- Funding for regulator-relevant demonstration.
- Funding midstage; market penetration; “valley of death.”
- Scalability (laboratory scale → pilot plant → full scale): Alliances and partnerships are needed to help depending on project scale because some larger companies may be innovative but still have a funding gap.

End Users

- More end-user management.
- How to involve end users in defining system and product requirements (voice of the customer).
- Lack of identification of needs and processes (i.e., do not develop technologies that are in search of a solution).

Standards and Reciprocity

- Lack of recognized standards across states for regulatory acceptance.
- Transjurisdictional issues.
- What is the pathway to more national standards, testing criteria and protocols?
- Regulatory uncertainty.
- Complex manufacturing/regulatory approval process; high cost; lengthy timeframe.
- The need to create best approval coordination for 50 states and 10 provinces with the long-term goal of reciprocity.
- How to promote continued innovation in an existing technology without burdening the developer with a new, extensive round of testing time and cost.

Knowledge Sharing

- Centralized knowledge-sharing forum.
- National database of testing programs and test beds.

Uncategorized

- Risk transfer.
- How to enable and adopt a “systems” holistic approach to water management (e.g., data, sensors).
- The need for water technology organizations to have techniques to quantify economic impacts.
- Marketing laboratory services to create awareness.
- How to address ETV legacy in state regulations.
- Where the product is in the development cycle: Where is the company on the commercial pathway? Does the cluster have the ability to help? If a cluster has limited resources, should it help those products further along in the development process? Does the cluster know of other resources to which it can refer the developer?

Discussion

Participants requested a list of those individuals who have implemented BMPs, including their contact information, so that it would be easy to reach out if there were questions about how to implement certain BMPs. Participants could volunteer to be points of contacts for the BMPs with which they have experience. This would make the list more meaningful and evidence-based.

Participants suggested that Dr. Mergelas provide a Webinar on BMPs.

A participant commented that he views challenges on different levels: individual; mezzo (organizational, institutional); and meta, which is the level of meaningful outcomes. It is necessary to think about the challenges at various levels, which then need to be woven together (input to process to outcome). The challenges being discussed mostly are process challenges.

Some challenges are exacerbated in certain areas (e.g., funding from utilities vs. industry), so the problem must be examined as a whole.

Voting

Considering that the ultimate goal of a water cluster is to expedite innovative technology to the market and provide solutions to utilities, the participants voted on which challenges are most likely to impede this goal. Each of the six small groups was given three votes, and multiple votes were allowed to be given to one item.

The following categories received the following number of votes:

- Standards and reciprocity—*6 votes*
- Funding—*5 votes*
- End users—*3 votes*
- Knowledge sharing—*3 votes*
- How to enable and adopt a “systems” holistic approach to water management—*1 vote*

As the participants discussed the top vote-getters, the concept of reciprocity evolved into the lack of data sharing. This issue also includes a lack of discussion among states (i.e., peer-to-peer communication) regarding long-term experiences based on good science and data. Data should be viewed objectively; no value judgments should be imposed on data. There also are different data needs, and it is necessary to ensure the quality assurance/quality control of data.

When discussing the lack of national standards, participants thought that it was necessary to create best approval coordination but were unsure about the pathway to accomplish this when considering the political process and how to engage stakeholders. A roadmap must be defined. What is the landscape from approach to approach or desired outcome to desired outcome? It varies among technology types (wastewater, drinking water, etc.). There are standards relative to performance and to type of protocol. The stormwater sector would benefit from NSF Standards 40 and 350. Some sectors in the water industry have parts of standards on a national scale, and this needs to occur across all sectors. It is critical to know the end point when developing standards.

Following the discussion period, participants were asked to comment about their opinions on the facilitated discussion and workshop; they offered the following insights:

Pros

- The small group interaction and facilitated discussion were beneficial.

- The timekeeping was great.
- The speaker/attendee variety was excellent.

Cons

- Logistically, the space was awkward for meeting in small groups.
- More time and clearer criteria should have been provided for the group brainstorming session.
- Voting should have been done individually rather than by group.
- The facilitated discussion groups could have been aligned with the panel and speaker topics.
- Full sentences describing each of the BMPs and challenges should have been required to increase clarity.

Ms. Theroux stated that the next step is to share the identified BMPs and challenges within each cluster and network to further validate them.

DISCUSSION SESSION: DRAFT AGENDA FOR NEXT MEETING

Led by: Alan Vicory, Chair, Confluence Board of Directors and Principal, Stantec Consultants

Ms. Gutierrez stated that the water technology cluster leaders had agreed to a series of three meetings; this was the first. The next meeting will take place at the AWWA Annual Conference and Exposition (ACE) in June in Boston. The third meeting will take place at the end of September at WEF's Annual Technical Exhibition and Conference (WEFTEC) in New Orleans.

Participants noted the challenge of meeting for an entire day during a larger conference, which is why the current plan is to meet on the last day of ACE. There is a great opportunity to leverage AWWA and other key decision makers who will be present at the conference. There will be a large market showplace (Innovation Pavilion), and CEOs and manufacturers will be present. It will be beneficial to discuss with them how they can help clusters as partners as well as to obtain buy-in from them. The opportunity to engage with other stakeholders is useful, and water cluster effectiveness can be increased by learning how clusters can be of service to various stakeholders. Cluster representatives also can attend the meetings or sessions of various groups (e.g., manufacturers or utilities councils). Meeting at the beginning of the conference rather than the end will increase energy.

If the focus of the next meeting will be on the cluster network, the meeting should be held separate from a larger conference. A 2-day retreat would be most advantageous for this. Mr. Seline explained that he had convened a group of clusters to discuss vital issues, but because it was held at a larger conference, 25 key individuals from outside of the clusters were present to provide crucial input throughout the day as well.

In regard to logistics at ACE, a room has been reserved for the group at the end of the conference, but it could be changed to the Sunday the conference begins (June 8). Water cluster can present themselves at the Innovation Pavilion being organized by Imagine H₂O and AWWA, which is an opportunity to increase visibility. Booths will be available to a few clusters at a reduced fee, and companies from four clusters already are represented at the pavilion. The conference has good programming (e.g., piloting, best practices sessions) for clusters.

The participants discussed the potential formats for the next meeting. One participant suggested holding a half-day meeting at the beginning of the conference to include an introduction to manufacturers. Another participant described a meeting in which each participant had given a 3-minute TED-type talk to stimulate discussion; this could be a model for the next meeting.

Another suggestion was to meet in smaller groups for a 2-hour discussion on various topics. It is important to accommodate the diversity of interests and expertise of the group and satisfy all expectations.

Leaders can take ownership of an issue identified at this meeting (e.g., knowledge-sharing platform) and discuss them in small groups prior to ACE. These small groups could brainstorm solutions to the various issues and report to each other during the water cluster meeting at ACE. The small groups also could meet outside of the larger water cluster leaders group while attending ACE and report to the larger group. There needs to be a top-down framework, but within the framework there must be organic flexibility depending on motivation, interest and expertise.

One way to move some of the issues forward prior to the next meeting is to leverage efforts. Under the LIFT program, WEF and WERF are co-funding a project entitled, "Creating the Space to Innovate." The project will include a series of dialogs and a summit, and some of the issues covered relate to those discussed during this meeting. There may be an opportunity for representatives from this group to participate in this effort

A participant would like more discussion on the operation of water clusters (e.g., how financed, administered) at the next meeting.

There is the possibility of a tour of a decommissioned pilot plant near Boston.

For the WEFTEC meeting in New Orleans, the clusters could organize a conference session to solicit broader participation. Mr. Barry Liner explained that a room is reserved for the water cluster leaders on Sunday, September 29, with lunch available. If the water cluster leaders would like to plan a program for that time/location, it is possible. At the prior year's conference, programming introduced a networking session. There also will be an Innovation Showcase Pavilion co-hosted by WEF, Imagine H₂O and BlueTech Research, with receptions on Monday and Tuesday evenings, and there are a few 10-foot-by-10-foot booths available to innovation partners.

Mr. Alan Vicory thanked EPA for organizing the meeting. Ms. Gutierrez thanked her staff members for organizing and the participants for attending and adjourned the meeting at 5:55 p.m.

MARCH 26, 2014

Participants were offered the opportunity to tour EPA's Test and Evaluation Facility in Cincinnati, Ohio.

APPENDIX A

U.S. EPA Water Technology Innovation Cluster Leaders Meeting Participants List

Cheryl Abrams

U.S. Environmental Protection Agency

Robert Adair

Convergent Water Technologies

Evelyn Allen

Southern Ontario Water Consortium

Dean Amhaus

The Water Council

William Ball

University of Cincinnati

Ned Bartlett

Bowditch & Dewey, LLP
New England Water Innovation Network

Bruce Bartley

NSF International

Jim Bell

Bio-Microbics, Inc.

Veronica Blette

U.S. Environmental Protection Agency

Seth Brown

Water Environment Federation

Scott Bryan

Imagine H₂O

Bonnie Buthker

Ohio Environmental Protection Agency

Greg Carroll

U.S. Environmental Protection Agency

Ryan Connair

U.S. Environmental Protection Agency

Jeff Davison

Ohio Environmental Protection Agency

Julius Enriquez

U.S. Environmental Protection Agency

Peter Gallant

Veolia Water Solutions and Technologies

Ellen Gilinsky

U.S. Environmental Protection Agency

Jon Grant

WaterTAP Ontario

Sally Gutierrez

U.S. Environmental Protection Agency

Michelle Haan

U.S. Environmental Protection Agency

Bill Hagstrand

NorTech Water

Teresa Harten

U.S. Environmental Protection Agency

Evelyn Hartzell

U.S. Environmental Protection Agency

Roy Haught

U.S. Environmental Protection Agency

Greg Heitzman

Louisville Metropolitan Sewer District

Ebie Holst

Clean WaterNet

Erik Hromadka

Global Water Technologies

Earl Jones

Liberation Capital
New England Water Innovation Network

Lek Kadeli

U.S. Environmental Protection Agency

Melinda Kruyer

Confluence

Kristen LeBaron

The Scientific Consulting Group, Inc.

Barry Liner

Water Environment Federation

Ron Lovan

Northern Kentucky Water District

Brenda Lucas

Southern Ontario Water Consortium

Richard Magee

New Jersey Corporation for Advanced
Technology

Kurt Marx

Center for Urban Waters at the University of
Washington Tacoma

Steve McKnight

Water Economy Network

Brent Mecham

Irrigation Association

Kirsten Melberg

New Orleans Water Innovation

Brian Mergelas

WaterTAP Ontario

Egils Milbergs

Center for Accelerating Innovation

Jeff Moeller

Water Environment Research Foundation

Michael Murphy

Massachusetts Clean Energy Center

Fred Mussari

BCR Environmental

Sarah Neiderer

District of Columbia Water and Sewer Authority

Paul O'Callaghan

BlueTech Research

Helle Petersen

Central Valley Business Incubator

Gil Pezza

Michigan Economic Development Corporation

Glenn Schrader

University of Arizona

Richard Seline

Regionnovate LLC

Chi Ho Sham

The Cadmus Group, Inc.

Harry Stone

Battelle

Maggie Theroux

U.S. Environmental Protection Agency

Alan Vicory

Confluence

Donna Vincent Roa

BlueTech Research

Abby Waits

U.S. Environmental Protection Agency

David Zoldoske

International Center for Water Technology at
California State University, Fresno

APPENDIX B

U.S. EPA Water Technology Innovation Cluster Leaders Meeting Program Summaries

In advance of the Water Technology Innovation Cluster Leaders Meeting, EPA distributed short summaries of several testing and labeling programs as background resource materials for the workshop. This appendix contains those summaries as they were distributed to the meeting participants.¹

This appendix contains summaries for the following programs:

- Federal Insecticide, Fungicide and Rodenticide Act (FIFRA)
- Leaders Innovation Forum for Technology (LIFT) Technology Evaluation Program
- New Jersey Energy and Environmental Technology Verification Program
- Pathogen Equivalency Committee (PEC) Process
- Technology Assessment Protocol–Ecology (TAPE)
- Toxic Substance Control Act (TSCA)
- U.S. EPA Clean Water Act (CWA) Alternative Testing Procedure (ATP) Program for Drinking Water
- U.S. EPA Clean Water Act (CWA) Alternative Testing Procedure (ATP) Program for Water Quality
- WaterSense®

¹ Although these program summaries were prepared with input from representatives of the testing programs, EPA cannot guarantee the accuracy of the summaries and does not accept any responsibility or liability for their accuracy, content, completeness, legality or reliability.

Federal Insecticide, Fungicide and Rodenticide Act (FIFRA)

Mandatory Registration program for antimicrobial disinfection technologies in the United States	Administered by EPA OCSPP, Antimicrobials Division Cost: \$11,577 plus chemical or product registration fees Time: Up to several years http://www2.epa.gov/pesticide-registration/antimicrobial-pesticide-registration
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Overview

Technologies that claim to have antimicrobial effects are regulated as pesticides under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). Water technologies/devices that, for example, claim to perform microbial disinfection are subject to regulation under FIFRA, which is administered by EPA's Office of Chemical Safety and Pollution Prevention (OCSPP), Antimicrobials Division. There are two classifications: (1) if the antimicrobial technology uses chemicals, then it is regulated and must be registered or (2) if a mechanical device claims antimicrobial effects without a specific chemical added to the device, then it is regulated and does not need to be registered. EPA needs to understand what the manufacturer is claiming regarding antimicrobial activity and how the device functions (chemical or mechanical) to make that determination. For ultraviolet (UV) drinking water technologies, their approval is handled by EPA's Office of Water and the UV Guidance Manual applies. If the technology uses nanomaterials then it is also regulated by the Toxic Substance Control Act.

Process

For registration, the manufacturer should first visit the website listed above and then email the contact to request a presubmission meeting to determine whether registration is necessary. The presubmission meeting is free, and it is usually scheduled within 6 weeks of contacting the division. It is advisable that the manufacturer hire a pesticide regulatory consultant to make sure that the technology is feasible and accurate and applicable data can be gathered to prove it.

The manufacturer is expected to submit the information requested on the website to EPA 2 weeks prior to the meeting. It is essential that applicants include a description of the proposed uses and how the product works and label claims and any planned non-pesticidal label uses (a draft label would be preferred). Presubmission information: <http://www.epa.gov/oppad001/preapplmeet010.htm>

During the meeting, risk managers and scientists review the process with the manufacturer to decide exactly what the technology is trying to do, help them decide if they want to go through this process, and make sure that they are prepared to develop a solid protocol. Only after a successful meeting will the manufacturer be invited to develop a testing protocol or use an existing protocol from EPA's database. Once a protocol gets approved and the technology/device registered, EPA redacts all identifying information and publicly posts the protocol so that it can be used and adapted by other manufacturers.

Outcome

The Agency shares the registration of new chemicals or products both online and through the public comment process.

EPA has a database of pesticides and chemicals: EPA's Pesticides Chemical Search, online at <http://iaspub.epa.gov/apex/pesticides/f?p=chemicalsearch:1>

For the hospital line of antimicrobial products, if a product fails efficacy testing after registration, then the failing product is reported to the public under the Antimicrobial Testing Program: <http://www.epa.gov/oppad001/antimicrobial-testing-program.html>

Protocol Development

Manufacturers develop their own testing protocols with review by the Antimicrobials Division or use an existing approved protocol. Testing must not only determine that the pesticide is not harmful to humans or the environment but also that the product supports the antimicrobial claims.

Cost

There is a registration service fee of \$11,577.

In addition to the service fee, there are new Chemical or Product registration fees, which are listed in the fee table: <http://www.epa.gov/pesticides/fees/>

Timeline

The process could take a few years, depending on the amount and scope of data needed.

Contact

Contact information for the Antimicrobials Division Ombudsman is listed on the website with the registration manual: <http://www2.epa.gov/pesticide-registration/pesticide-registration-manual>

Additional Information

Possible sources for a list of pesticide regulatory consultants:

- American Chemistry Council (ACC): <http://www.americanchemistry.com/>
- Chemical Specialty Products Associations (CSPA:) <http://www.cspa.org/>

LIFT Technology Evaluation Program

<p>Voluntary Evaluation and demonstration program for wastewater, stormwater, and drinking water technologies in North America</p>	<p>Administered by Water Environment Research Foundation (WERF) Cost: Project specific Time: Project specific www.werf.org/lift</p>
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Overview

The LIFT Technology Evaluation Program is a technology testing, evaluation and demonstration program administered by WERF for wastewater, stormwater and drinking water technologies. The process is driven by municipal and industrial facility owner end users. WERF municipal and industrial facility owner subscribers identify innovative technologies of interest and work collaboratively with technology providers and others to evaluate/demonstrate them and move them into practice.

Manufacturers may apply to be considered through the LIFT Technology Scan program. The technology evaluation process produces independent, peer-reviewed evaluations that can be used by facility owners and their advisors to gain confidence in the performance of new technologies and adopt them more quickly.

Evaluation Process

WERF uses LIFT Technology Scans to identify and conduct technology evaluations.

Application	Technology providers may submit their products to a Technology Scan using a standardized application form. The program is open to emerging, precommercial and newly commercialized products. Established products seeking new applications may also be considered. Conventional technologies are not eligible under the program.
Technical Review	An expert committee selected by WERF does an initial screening review of the technical content and any claims as well as the technology readiness level to confirm a likely match of the technology with its intended application.
Assessment by Interested Parties	WERF coordinates presentations of technologies deemed of interest to end users and assembles partnerships for technology pilots/demonstrations and independent, third-party evaluations.
Evaluation	WERF contracts with third parties to conduct evaluations/demonstrations to assess performance of technology processes against design claims. Evaluations are supported by the interested parties (i.e., sharing of costs and risks). Evaluations also focus on scale-up and integration into facilities to optimize technologies and speed adoption by facility owners.

Final Report and Dissemination

WERF develops peer-reviewed evaluation reports and products that are publicly available (free for subscribers) and disseminated by WERF and WEF. Technology evaluations may also be initiated under LIFT by end user facility owners who identify a technology of interest and request WERF's help in assembling collaborative partnerships and conducting an independent evaluation.

Outcome

LIFT uses a collaborative process that helps move new technologies into practice by managing risk. The outcomes of this program include:

- A credible, well-documented vetting system to screen new technologies and processes.
- Ability to more rapidly deploy new technologies and remove existing impediments.
- Mitigation of the risk and cost of innovative technology deployment through partnerships.
- Facilitation of collaboration among facilities for the evaluation and testing of new technologies.
- Peer-reviewed information about emerging technologies.

WERF does not endorse a particular technology but rather provides the results/performance data and includes the criteria that were used to evaluate performance.

Protocol Development

As the first step of an evaluation project, WERF brings together all project participants (e.g., technology provider, facility owners, independent consultants) to develop the scope and objectives for the demonstration/evaluation. All parties agree to a project Quality Assurance Project Plan (QAPP) that includes a data collection plan and experimental plan. The QAPP must be approved by WERF's peer review committee.

Cost

The cost is project specific. Costs have ranged from \$25,000 to more than \$1 million depending on the nature and scope of the testing and evaluation.

Timeline

The estimated time to complete the testing and evaluation is project specific. The time has ranged from a few months to a year or two depending on the nature and scope of the testing and evaluation.

Contact

Jeff C. Moeller, P.E.
Director of Water Technologies
635 Slaters Lane, Suite G-110
Alexandria, VA 22314
(571) 384.2104
jmoeller@werf.org

New Jersey Energy and Environmental Technology Verification Program

Mandatory

Verification program for **stormwater manufactured treatment devices** in **New Jersey**

Administered by **New Jersey Center for Advanced Technology**

Cost: \$20,000 plus testing costs

Time: Approximately 6–12 months (depends on dispute resolution, if required) plus testing time

<http://www.njcat.org/>

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Overview

New Jersey's Energy and Environmental Technology Verification (EETV) Program verifies the performance of stormwater manufactured treatment devices (MTDs). The program is administered by the New Jersey Corporation for Advanced Technology (NJCAT), which has been designated as the official third-party verification entity for the EETV Program. MTDs that complete the verification process receive certification from the New Jersey Department of Environmental Protection (NJDEP), allowing the use of that technology in the state of New Jersey.

Although this brief focuses on the verification process for MTDs, NJCAT and the EETV program also verify a variety of other environmental and energy technologies.

Verification Process

To begin the MTD verification process, manufacturers must submit an MTD Verification Application to NJCAT. NJCAT reviews the application to ensure that the planned testing program meets the NJDEP protocol requirements.

NJCAT does not perform any technology testing. Manufacturers must have their technologies tested by an independent third-party laboratory or under independent third-party supervision in their own laboratories; they then submit a performance test report to NJCAT. NJCAT evaluates the data to verify MTD performance.

Verification application

Prior to commencing the planned laboratory testing program, the manufacturer must provide an MTD verification application that provides the following information: organization information, a general description of technology, laboratory testing location, a statement of potential conflicts of interest, and a quality assurance project plan.

NJCAT will review the manufacturer's verification application to ensure that the laboratory testing will be conducted in strict accordance with the applicable laboratory testing protocol and all NJDEP requirements.

On NJCAT approval, the manufacturer commences the laboratory testing in strict

accordance with the laboratory testing protocol.

Quality control

NJCAT will review the laboratory test report for completeness and compliance with the applicable laboratory protocol. Within 30 days of receipt of the test report, NJCAT will meet in person or by telephone with the manufacturer to discuss the report and issue a preliminary opinion regarding the manufacturer's compliance with the protocol and, if not, specifying in detail the areas of noncompliance with the protocol. If outstanding issues cannot be resolved, the manufacturer may request submission of outstanding issues to a three-member review panel.

Report preparation

Once any outstanding issues with the preliminary opinion have been resolved, NJCAT will issue a final verification report within 90 days. The NJCAT-issued verification report will then be posted for a 30-day public comment period. If there are no public comment issues or the issues can be resolved, NJCAT will finalize the report and notify NJDEP that the MTD has been verified.

If any issues resulting from public comments cannot be resolved, the issues are submitted to a three-member review panel for resolution. The cost of the review panel is the responsibility of the losing party. Based on the review panel's report and NJCAT's response, the manufacturer can decide to address any unresolved outstanding issues or end the process. If all issues have been resolved, NJCAT will finalize a verification report.

Outcome

If the MTD passes the verification process, NJCAT will notify NJDEP that the final verification report has been posted on the NJCAT website. NJDEP will then certify the technology for use in the state of New Jersey. NJDEP only certifies MTDs for total suspended solids removal: 50 percent for hydrodynamic sedimentation devices and 80 percent for filtration devices.

If the MTD does not pass the verification process, NJCAT will issue the final verification report to the manufacturer. The manufacturer may resubmit the technology for verification after addressing concerns raised in the verification process.

Protocol Development

The verification process requires laboratory testing of the MTD according to the [New Jersey Department of Environmental Protection Laboratory Protocol to Assess Total Suspended Solids Removal by a Hydrodynamic Sedimentation Manufactured Treatment Device](#) or the [New Jersey Department of Environmental Protection Laboratory Protocol to Assess Total Suspended Solids Removal by a Filtration Manufactured Treatment Device](#), both dated January 25, 2013.

Testing must be conducted by or under the supervision of an independent third-party laboratory.

Cost

NJCAT's verification process requires a \$20,000 fee. Manufacturers are responsible for testing costs. Review panel costs are separate.

Timeline

The verification process can take from 6–12 months depending on: (1) the completeness and compliance of the test report, (2) the time to resolve issues with the test report, (3) the need for a test report review panel, (4) the extent of public comments, (5) the time spent on the public comment resolution process, and (6) the need for a verification review panel and the extent and complexity of the outstanding issues raised by the public commenters.

Contact

Dr. Richard S. Magee
Technical Director
973-879-3056
rsmagee@rcn.com

Pathogen Equivalency Committee (PEC) Process

Strongly suggested Review and recommendation program for sewage sludge treatment processes in a specific site (or nationwide)	Administered by a committee of U.S. EPA & other agency experts Cost: No cost for PEC application; all other costs extremely variable Time: Variable http://water.epa.gov/scitech/wastetech/biosolids/basic.cfm#benefits
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Overview

The Pathogen Equivalency Committee (PEC) consists of 10 experts from EPA and other agencies, including the Centers for Disease Control and Prevention, who review applications from applicants (often manufacturers) for new sewage sludge treatment processes seeking to establish equivalency to the currently approved processes listed in 40 CFR Part 503 Subpart D. The Committee then makes recommendations to relevant federal and/or state permitting authorities on the merits of the application. An applicant must prove that his/her process can consistently reduce pathogens to levels comparable to the reduction achieved by the listed Process to Further Reduce Pathogens (PFRPs) or Process to Significantly Reduce Pathogens (PSRPs). An equivalency determination is required of the relevant sludge/biosolids permitting authority, unless the treatment process falls under certain accepted sludge disinfection Alternatives. Equivalency is generally recommended on a site-specific basis, unless the applicant meets the requirements for the process to be considered suitable on a national level. Applicants that successfully complete the process will be subject to approval by the relevant permitting authority, after which they will be allowed to utilize their process to prepare the sewage sludge for land applications.

Application Process

Before applying, applicant should answer the following questions:

(1) Am I seeking PFRP or PSRP pathogen reduction equivalency?

- To answer this question, the applicant may need to conduct proof-of-concept studies to determine which is most applicable, as well as the parameters and matrices within which the process will operate.

(2) Does my process resemble or meet the operating conditions of any current alternatives listed in 40 CFR Part 503 Subpart D?

- If process resembles or meets the operating conditions of any of the established options available under Class A for PFRP processes or Class B for PSRP processes, an equivalency recommendation may *not* be necessary.
- If process resembles an established option but with one or more key differences, then the applicant may be able to demonstrate equivalency with minimal testing, through a comparison of operating conditions between the new process and the established one. This decision is made on a case-by-case basis by the permitting authority and/or PEC.
- If process neither meets nor resembles an established option, applicant will need to determine equivalency through testing using a Quality Assurance Project Plan (QAPP) that clearly demonstrates how the pathogen is killed, whether by pressure, temperature, pH, chemical, etc.

(3) Am I seeking site-specific or national equivalency?

- If treatment process (1) is to be used in different areas of the United States and (2) its effectiveness is independent of the variety of climatic and other conditions that might be found in differing locations, then a recommendation of national PFRP or PSRP may be useful.

Application Steps

- Step 1** Applicant contacts the appropriate state or federal permitting authority using the following website for contact info: <http://water.epa.gov/scitech/wastetech/biosolids/locator.cfm>. If PEC involvement is appropriate, the authority will coordinate with PEC. If applicant is not currently working with a specific wastewater treatment plant, he/she should contact the PEC.
- Step 2** Applicant develops a QAPP to provide a framework for the testing process, which will be reviewed and approved by the PEC using a Completeness Checklist before testing commences.
- Step 3** Applicant carries out QAPP and analyzes data.
- Step 4** Applicant completes and submits pathogen reduction equivalency application package using the detailed forms found on the website.

Testing Protocol

Equivalency can be demonstrated in one of two ways: (1) by comparing operating conditions to existing PFRPs or PSRPs or (2) by providing performance and microbiological data. In general, sludge should be sampled using accepted, state-of-the-art techniques for samples and analyzed using methods required by 40 CFR Part 503 Subpart D. The quality of data provided to PEC is extremely important, and EPA evaluates the study design, accuracy of the data, and adequacy of results for supporting the conclusions that are drawn. Full-scale operation data are most desirable but may be very difficult to obtain depending on the pathogen in question.

A PFRP is a treatment process that is able to consistently reduce sewage sludge pathogens to acceptable levels as detailed in the table below. This enables sludge to meet requirements for consideration as a Class A sewage sludge. The PEC is concerned primarily with enteric viruses and viable helminth ova reduction, because fecal coliform or *Salmonella* sp. require separate ongoing monitoring.

A PSRP is a process that consistently reduces the density of pathogens, viruses and/or parasites in mixed sludge from a conventional plant by the amounts detailed in the table below. This enables sludge to meet requirements for consideration as Class B sewage sludge. It is expected that some pathogenic microorganisms will survive PSRP treatment.

Criteria for Demonstrating Pathogen Reduction		
Mandatory Minimum Requirements		
	PSRP Equivalency	PFRP Equivalency
Process Efficiency Parameters:	≥ 2 log reduction of fecal coliform bacteria	1. ≥ 3 log reduction of total enteric viruses, and 2. ≥ 2 log reduction of viable helminth (<i>Ascaris</i> ova, and 3. ≥ 3 log reduction of fecal coliform bacteria
Process Compliance Parameters (The 40CFR503 Requirements):	< 2,000,000 MPN or CFU/g total solids (TS) of fecal coliform in the treated sludge	Organism densities in the treated sludge of: 1. < 1 pfu/4 g TS of total enteric viruses, and 2. < 1 viable helminth (<i>Ascaris</i> ova/4 g TS, and 3. < 1,000 MPN fecal coliform / g TS or 4. < 3 MPN <i>Salmonella</i> spp./4 g TS (applicant's choice)

Several optional organisms are listed in a separate table. EPA is collecting information on the fate of these microorganisms by different modes of treatment with the intent of gathering enough data to support their usefulness as surrogates in full-scale testing. *Consider including as many of the optional analyses as feasible.* The measurement of all or some of optional organisms will enhance your demonstration by increasing the level of confidence associated with the process under investigation and will be helpful later when the process is tested on a larger scale. (Criterion (3) Demonstration of Successful Scale-up.)

It is highly preferred that a process goes through the PEC equivalency review process. There are Alternatives that a process may meet to bypass this process. Alternatives 3 and 4 for Class A (PFRP) processes and Alternative 1 for Class B (PSRP) processes explain how this is possible—but there may be one or more states that do not allow this.

Please refer to the table for requirements that both PSRP and PFRP processes must meet to be recommended for equivalency. The applicant is responsible for identifying the process operating parameters (e.g., time, temperature, pH) that are necessary and sufficient for achieving reductions in pathogens needed for the process to be considered satisfactory. The applicant is responsible for utilizing a suitable laboratory and using methods approved in the QAPP and with proper QA for all testing.

Outcome

The PEC considers each equivalency application on a case-by-case basis. The committee evaluates the information on operating parameters and/or the sewage sludge that the applicant must provide. The PEC then recommends one of four decisions about the process to the permitting authority:

- (1) Full equivalency,
- (2) Conditional or restrictive equivalency,
- (3) Not equivalent, or
- (4) More information necessary.

Around the time a recommendation is issued, PEC will request that the applicant create an operation and maintenance (O&M) manual. The O&M manual may be provided to the permitting authority, but

generally stays with the PEC. It is important to note that the PEC's recommendations are typically followed but are not formally binding. The permitting authority makes the final decision on equivalency. Successful applicants are listed and described on PEC's website, and data may or may not be posted on the permitting authority's site as well. Unsuccessful applicants' data are not shared publicly.

Cost

There is no cost for applying to PEC. The applicant is responsible for all costs associated with development of a QAPP, research and completion of the application. These costs can range anywhere from \$100,000 to \$1 million, depending on the degree of complexity and detail a project requires.

Timeline

PEC review of a completed application can take 3 or more months, which may be spread over several years. This does not include the time the applicant takes to conduct proof-of-concept studies, create an acceptable QAPP, and conduct all required testing.

Contact

Laura Boczek and Bob Brobst, PEC Co-Chairs
U.S. Environmental Protection Agency
26 West Martin Luther King Dr.
Cincinnati, OH 45268
boczek.laura@epa.gov
brobst.bob@epa.gov

Technology Assessment Protocol – Ecology

Mandatory Testing and certification program for stormwater treatment technologies in Washington	Administered by Washington Department of Ecology Cost: \$12,000 plus testing costs Time: 6-30 months http://www.ecy.wa.gov/programs/wq/stormwater/newtech/index.html
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Overview

Washington's Technology Assessment Protocol – Ecology (TAPE) certifies short-detention, flow-based stormwater treatment technologies. Technologies that successfully complete the TAPE process will receive a General Use Level Designation (GULD) from the Washington Department of Ecology (Ecology).

Certification Process

To obtain certification under TAPE, manufacturers must complete an initial application, design a Quality Assurance Project Plan (QAPP), conduct testing, and submit a final Technical Evaluation Report (TER) for review by Ecology.

Initial application To begin the TAPE process, manufacturers must submit an initial application to Ecology. The initial application must include preliminary performance data for the technology, which may come from other testing programs.

Ecology and the Board of External Reviewers (BER) will review the application. If Ecology considers the technology promising, Ecology will approve the technology for a Pilot Use Level Designation (PULD) or a Conditional Use Level Designation (CULD) based on the preliminary performance data.

Both PULD and CULD are limited-duration certifications that allow the manufacturer to install the technology at a limited number of sites for testing purposes.

QAPP design After the initial application is accepted, the manufacturer must develop a QAPP to evaluate the performance of the technology. Ecology and three members of the BER will review the plan.

Field testing Once Ecology approves the QAPP, the manufacturer has 24 months to carry out the study and submit a final TER to Ecology.

Final evaluation Ecology and the BER will evaluate the TER within 3 months, then Ecology will issue a final decision. If Ecology approves the report, the technology receives a GULD, certifying it for use in the state of Washington.

Ecology will have 6 months to review the TER and issue a final determination.

Contact

Douglas C. Howie, P.E.
douglas.howie@ecy.wa.gov
360-407-6444

Toxic Substance Control Act (TSCA)

Mandatory Review program for new chemicals in the United States	Administered by EPA OCSPP, Chemical Control Division Cost: \$2,500 for PMN submission; all testing costs extremely variable Time: At least 90 days for PMN review, more for testing http://www.epa.gov/oppt/newchems/
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Overview

The new chemical review program is not for a technology, *per se*, but for a new chemical that is not already listed on the Toxic Substances Control Act (TSCA) Inventory. At least 90 days prior to manufacture or import of a new chemical for general commercial use, a Premanufacture Notice (PMN) must be filed with EPA under Section 5 of TSCA. During the review period EPA will assess the potential risk to human health and the environment from the new chemical and may take action to prevent any unreasonable risks including requiring testing before commercialization or identifying conditions to be placed on the use of the new chemical before it enters into commerce.

TSCA applies to chemicals used in water technologies that involve filtering but not those claiming to “kill” any microbes or particles. If the technology is claiming a pesticidal property such as antimicrobial disinfection, then it is regulated under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA; please see the FIFRA summary). Nanomaterials are considered chemical substances and are subject to TSCA regulation. TSCA is administered by EPA’s Office of Chemical Safety and Pollution Prevention (OCSPP), Chemical Control Division.

Process

Manufacturers must first determine if the chemical substances they wish to submit are on the TSCA Inventory. The public TSCA Inventory is available online at: <http://www.epa.gov/oppt/existingchemicals/pubs/tscainventory/howto.html>. EPA also maintains a separate confidential list of chemical substances that are on the TSCA Inventory that are not publicly available.

When a manufacturer has a new chemical that is not on the inventory, a [PMN](#) must be submitted at least 90 days prior to the manufacture or import of the chemical. Before submitting a PMN you may arrange a prenotice call with EPA. This is recommended for new technologies, such as water filtration using nanomaterials. A PMN must include information such as specific chemical identity, use and anticipated production volume. The PMN must also contain all reasonably ascertainable exposure and release information and existing available environmental health and safety test data. TSCA does not require a company to develop new data for a PMN submission, but it must submit all available or reasonably ascertainable data. For example, 85 percent of PMN submissions contain no toxicity data.

EPA will review the available data and assess the potential human health and environmental risks of the new chemical. If EPA determines that there is a potential unreasonable risk, it will take any action necessary to prevent that risk including requiring toxicity or exposure testing and could include banning the use of the chemical. EPA will usually allow the PMN submitter to market the new chemical on a

limited basis while toxicity studies are being conducted. If the technology is for water filtration, then a long-term toxicity study may be required.

Outcome

When the PMN review period is completed, the PMN submitter may commercialize the PMN substance. This may involve certain restrictions EPA has identified to prevent unreasonable risks during the PMN review period. EPA would make this action effective through a 5(e) consent order or a Significant New Use Rule. <http://www.epa.gov/oppt/newchems/pubs/cnosnurs.htm>

When the PMN submitter commences manufacture of the PMN substance, it is required to notify EPA. At that point, EPA places the chemical on the TSCA Inventory.

Protocol Development

EPA usually requires testing according to standard protocols that it will identify. If a protocol for a new test needs to be developed or the PMN submitter suggests a nonstandard protocol, EPA will work with the PMN submitter to review that test protocol. The PMN submitter will usually have to develop any new protocols.

Cost

There is a \$2,500 fee for submitting a PMN. If testing is required, there will be additional costs. Longer term tests, such as 90-day oral or inhalation studies, can cost between \$300,000 (oral) and \$700,000 (inhalation).

Timeline

At a minimum, the PMN review period is 90 days whether EPA makes any unreasonable risk findings or not. If EPA develops regulations to prevent unreasonable risks that process could take another 3–6 months. If testing must be conducted before commercialization, then that process would take as long as required to conduct the study and have EPA evaluate the results of the study and reevaluate the potential risks.

Contact

For answers to questions about procedural, technical or regulatory requirements prior to submitting a PMN, submitters can call a PMN prenotice coordinator:

David Schutz, 202-564-9262

Jim Alwood, 202-564-8974

U.S. EPA Clean Water Act (CWA) Alternative Testing Procedure (ATP) Program for Drinking Water

Mandatory Government evaluation program for alternative/new drinking water method or procedure in United States (nationwide)	Administered by U.S. EPA Cost: No cost to apply, but applicant must pay for all required testing Time: 1 to 2 years after completed application http://water.epa.gov/scitech/methods/cwa/atp/questions.cfm
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Overview

The Alternative Testing Procedure (ATP) Program for Drinking Water is a *government evaluation program* run by EPA to govern an applicant's use of alternative or new drinking water reference methods or procedures under the National Primary Drinking Water Regulations of the Safe Drinking Water Act.

ATP evaluates two types of proposals:

- (1) A modification of an EPA-approved reference method or procedure that uses the same determinative technique and measures the same analyte(s) of interest.
- (2) A proposal for a new method, which uses a different determinative technique to measure the same analyte(s) of interest as an EPA-approved reference method.

ATP evaluates new and alternative microbiological and chemical methods using separate testing protocols under one application process. Applicants are responsible for testing performance of the alternative or new method as part of their applications, but EPA can provide assistance in developing study plans. Applicants can only apply for *nationwide* use. It is *mandatory* that applicants get approval for an alternative or new method. Applicants that complete the process and have their alternative or new method approved via the expedited methods process will be able to use their method in all regulated entities and laboratories across the country.

Evaluation and Approval Process

Step 1 Applicant designs a study plan that will test that the modified method produces results better than or equal to those produced by an appropriate EPA-approved reference method for the applicable combination of analyte and determinative technique.

Step 2 Applicant submits study plan design and the application form to the ATP program at the EPA Office of Water, Office of Groundwater & Drinking Water, Technical Support Center.

The application form may be found on page 71 of the EPA Microbiological Alternate Test Procedure Protocol for Drinking Water, Ambient Water, and Wastewater Monitoring Methods, available here: <http://water.epa.gov/scitech/methods/cwa/atp/questions.cfm#askEPA>.

Step 3 The appropriate EPA body approves the study plan or makes suggestions that must be incorporated before EPA will approve the plan.

- Step 4** Applicant conducts testing using his/her own resources and following the specific plans based on analyte and determinative technique being tested.
- Step 5** Applicant develops a comprehensive study report including all data, results and conclusions, which he/she will send to the ATP program to be added to the application package.
- Step 6** EPA will consider an application complete and will begin review once the application form, study plan and study report are all in the hands of the ATP program.
- Step 7** ATP will either accept or deny the alternative or new method, and EPA will send the applicant a notification of the decision. Successful applications will then be forwarded to the expedited methods program.
- Step 8** Once the method has gone through this expedited process, it will be added to CFR 40 Part 141, Appendix A.

Testing Protocol

The ATP Program generally requires either:

- (1) A side-by-side method comparison study that compares the new method directly with a comparable EPA-approved method, or
- (2) A study that evaluates the new method's ability to meet quality control (QC) acceptance criteria of a comparable EPA-approved method, where QC criteria has been set.

The ATP program covers various EPA-approved methods for a multitude of analytes, both microbiological and chemical. For microbiological methods, the applicant should use a drinking water certified laboratory to perform the evaluation as per the ATP protocol. The testing protocol can be found online on the ATP website. For chemistry methods, however, because methods vary widely in their chemistry and procedures, it is impossible to provide general guidance for the development of a robust method. The applicant should identify critical points of each step in the procedure, address or control these points in the method, and demonstrate that acceptable method performance is attained using all procedural options specified in the method. The applicant is responsible for utilizing a suitable laboratory and using the methods approved in the study plan and in accordance with quality assurance protocols.

Outcome

If ATP recommends the approval, it is forwarded for Expedited Method Approval. Once approved, the applicant will receive documentation that he/she is approved to utilize the alternative or new method in all regulated entities and laboratories.

Cost

There is no cost for applying for an ATP. The applicant is responsible, however, for all costs associated with the application and research.

Timeline

The timeline for completing an entire application is dependent on the timeliness and quality of the applicant's work. Once an application has been accepted by the ATP program, the expedited process will enable the method to be approved and formally adopted within 1 to 2 years.

Contact

For microbiological methods:

James Sinclair

Technical Support Center

Office of Groundwater and Drinking Water

Sinclair.james@epa.gov

513-569-7970

For chemical methods:

Steven Wendelken

Chemistry Drinking Water ATP Program

Technical Support Center

Office of Groundwater and Drinking Water

wendelken.steve@epa.gov

513-569-7491

U.S. EPA Clean Water Act (CWA) Alternative Testing Procedure (ATP) Program for Water Quality

Mandatory Government approval program for alternative/new ambient water, wastewater, or sewage sludge method in United States (nationwide or limited use)	Administered by U.S. EPA Cost: No cost to apply, but applicant must pay for all required testing Time: 3 to 4 years after completed application http://water.epa.gov/scitech/methods/cwa/atp/questions.cfm
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Overview

The Alternative Testing Procedure (ATP) Program for Water Quality is a government approval program run by EPA to approve through rulemaking an applicant's alternative or new ambient water, wastewater or sewage sludge methods for use as a compliance monitoring method under the National Pollutant Discharge Elimination System (NPDES) program of the Clean Water Act (CWA).

ATP evaluates two types of proposals:

- (1) A modification of an EPA-approved reference method or procedure that uses the same determinative technique and measures the same analyte(s) of interest regulated under 40 CFR Part 136.
- (2) A proposal for a new method, which uses a different determinative technique to measure the same regulated analyte(s) of interest as an EPA-approved reference method.

For microbiological method proposals, ATP evaluates new and alternative methods using one protocol. For chemical method proposals, ATP evaluates new methods separately from alternative methods in two different protocols. Applicants are responsible for testing performance of the alternative or new method as part of their applications. EPA provides assistance in developing study plans. Applicants can apply for nationwide use (NW) or limited use (LU) approval. It is mandatory that applicants get approval for use of any alternative or new method if they want laboratories to be able to use their methods for compliance monitoring (i.e., methods in NPDES permits). Applicants that complete the NW process and have their alternative or new method added to the Code of Federal Regulations will be able to have their method used by all regulated entities and laboratories across the country. Methods approved for LU will only be applicable in the single laboratory that they are approved for.

Process for Microbiological Method Proposals

Approval Process (NW use as default)

- Step 1** Applicant designs a study plan that will test that the modified method produces results equal to or better than those produced by an appropriate EPA-approved reference method for the applicable combination of analyte and determinative technique.
- Step 2** Applicant submits NW use study plan design and three copies of the application form and the method to the ATP program at EPA Office of Water, Office of Science and Technology,

Engineering & Analysis Division, for review.

In cases of limited use applications:

- Applicants in states that have the authority to administer CWA monitoring programs will direct application materials to the Director of the State Agency issuing the NPDES permit.
- Applicants in states that do not have the authority to administer CWA monitoring programs will direct application materials to the EPA Regional ATP Coordinator.

- Step 3** The appropriate EPA body will approve the study plan or make suggestions that must be incorporated before EPA will approve the plan. The study plan must be approved before the applicant can begin testing.
- Step 4** Applicant will conduct testing using his/her own resources and following the approved study plan based on the regulated analyte and determinative technique being tested. Applicant is responsible for utilizing a suitable laboratory and using the methods approved in the study plan and in accordance with quality assurance protocols.
- Step 5** Applicant will develop a comprehensive study report including all raw data, statistical analyses, results and conclusions (and the revised method if test results show that it needs revision), which he/she will send to EPA to be added to the application package.
- Step 6** EPA will consider an application complete and will begin review once the application form, study plan, written method and study report have been received by EPA and are found to be acceptable.
- Step 7** If EPA accepts the alternative or new method, EPA will send the applicant a letter stating that the method is acceptable. The application will then be recommended to the EPA Administrator for approval through a federal rulemaking.

In cases of limited use applications: After reviewing the complete application, the appropriate State or Regional EPA ATP Coordinator will provide applicant with an official letter of approval or disapproval, and the process will be complete.

- Step 8** For NW applications, once the alternative or new method has gone through the formal rulemaking process, including a public comment period, and is approved, it will be added to CFR 40 Part 136 as an approved method for the particular regulated analyte in the matrix in which it was tested.

Testing Protocol

The ATP Program prefers either:

1. A side-by-side method comparison study that compares the new method directly with a comparable EPA-approved method for new methods, or
2. A study that evaluates the new method's ability to meet quality control (QC) acceptance criteria of a comparable EPA-approved method, where QC criteria has been set for alternative methods.

The ATP program covers various EPA-approved methods for a multitude of analytes, both microbiological and chemical. Specific testing protocols for all analytes, method formats and reference methods can be found online in three PDFs on the ATP website.

Process for Chemical Method Proposals

ATP evaluates new chemical methods separately from alternative chemical methods. Applicants may follow the same general application steps that are listed above but must take note of the following differences in testing protocols:

New Methods: A new method is a set of procedures that has been written in the 17-section standard EPA format, contains standardized QC elements and associated acceptable criteria, employs a determinative technique different from those previously approved for a measurement of a given regulated analyte, and employs a determinative technique that is as sensitive and selective as the previously approved techniques. A new method involves a change to the determinative technique, and the applicant must use the results of the validation study to develop acceptance criteria for the new combination of 40 CFR Part 136 regulated analyte and determinative technique.

Alternative Methods: An applicant may submit an application for review and recommended approval of a modified version of an approved 40 CFR Part 136 method or procedure(s) that uses the same determinative technique which measures the same 40 CFR Part 136 regulated analyte(s) of interest as the approved method. Applicants demonstrate method equivalency by meeting QC acceptance criteria associated with EPA-designated approved Part 136 methods. ATP also distinguishes between “minor modifications,” which do not change the underlying chemistry of the approved method, and “major modifications,” which involve changing the underlying chemistry of the “front end” techniques. (See Title 40 of the Code of Federal Regulations, Part 136.6.).

Alternative methods can be differentiated from new methods because an alternative method involves a change to the “front end” of the method; in other words, those procedures which prepare the sample and/or isolate the analyte(s) of interest from the sample matrix prior to identification and measurement.

New method validation *and* alternative method validation each have a three-tier process that classifies the intended use of a new method and requires a validation study that is reflective of the level of use associated with each tier:

- Tier 1** Methods may only be used by a single laboratory (limited-use) for one or more matrix types.
- Tier 2** Methods may be used by all laboratories (NW) for only one matrix type. Validation requires a 3-laboratory validation study.
- Tier 3** Methods may be used by all laboratories (NW) for all matrix types and requires a 9-laboratory validation study. The applicant is responsible for utilizing a suitable laboratory and using the methods approved in the study plan and in accordance with quality assurance protocols. Additional guidance on submission and validation of alternative methods and development of QC acceptance criteria for new methods for regulated chemical analytes including application forms may be found here:
<http://water.epa.gov/scitech/methods/cwa/atp/questions.cfm>

Outcome

Once an alternative or new method is formally approved through rulemaking for NW and added to CFR 40 Part 136, entities may use the method for compliance monitoring under the NPDES program. To be added to the CFR, the applicant’s study report (which includes all associated data) is placed in the rulemaking docket when the method is proposed as an approved method at 40 CFR Part 136 and will be accessible to the public for public comment.

In cases of limited use applications: Once an alternative or new method is approved for LU by the appropriate authority (listed above) and a letter of approval is distributed to the applicant, the method is permitted to be used in only the approved laboratory.

Cost

There is no cost for applying for an ATP. The applicant is responsible, however, for all costs associated with the application and required research.

Timeline

The timeline for completing an entire application is dependent on the timeliness and quality of the applicant's work. Once an application has been accepted by the ATP program and passed onto the EPA Administrator for approval, it can take 3 to 4 years for it to be formally adopted into the CFR.

Contact

For new and alternative microbiological methods:

Robin K. Oshiro

Engineering and Analysis Division (4303T)

U.S. EPA Office of Water, Office of Science & Technology

Oshiro.robin@epa.gov or OSTCWAMethods@epa.gov

For new and alternative chemical methods:

Lemuel Walker

Clean Water Act ATP Coordinator (4303T)

Engineering and Analysis Division

U.S. EPA Office of Water, Office of Science & Technology

Walker.lemuel@epa.gov

WaterSense®

Voluntary Labeling program for plumbing products Nationwide	Administered by U.S. EPA Cost: Variable Time: Variable http://www.epa.gov/watersense/index.html
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Overview

WaterSense® is a certification and labeling program for water efficient products and new homes that meet EPA-developed specifications. Showerheads, toilets, bathroom sink faucets, landscape irrigation controllers, urinals, pre-rinse spray valves and new homes that are at least 20 percent more efficient than standard products without sacrificing performance may be certified to use the WaterSense® label. Certified products must use the WaterSense® label for packaging and promotion.

Certification Process

WaterSense® certification is a two-step process: manufacturers must enter into a partnership agreement with EPA, then obtain certification from a third-party licensed certifying body (LCB).

Partnership Before applying for certification, manufacturers must sign a partnership agreement with EPA. The partnership agreement can be completed online at http://www.epa.gov/watersense/partners/partnership_agreement.html

Certification After signing the partnership agreement with EPA, manufacturers need to contract directly with an LCB to have their product certified. A full list of LCBs is available online at http://www.epa.gov/WaterSense/about_us/cert_bodies.html.

The LCB will test the product to verify that it meets the WaterSense® specification. The LCB will also assess production processes and review quality management systems, as necessary.

Market Surveillance Every year, EPA requires that each LCB must retest at least 15 percent of the WaterSense®-labeled products it has certified in each category to ensure that the products still meet the appropriate WaterSense® specification. Half of the products to be retested may be specified by EPA, whereas the other half are randomly chosen by the LCB.

Products may be retested only once every 3 years.

Outcome

Once certification is complete, the LCB will provide the manufacturer with WaterSense® label and logo files. The WaterSense® label can be applied to any packaging and promotional materials for the certified product. The certification does not expire but may be revoked if the product fails retesting under market surveillance (described above).

The LCB will also notify EPA that the product is certified to use the WaterSense® label. The product will be included on EPA's online registry of WaterSense®-certified products.

Protocol Development

Test protocols for WaterSense® certification are specified by EPA for each product type. These specifications must be used by LCBs to certify the appropriate product types.

When developing a test protocol for a product type, EPA will first issue a notice of intent, requesting input on technical issues. If EPA receives sufficient input, the Agency will develop a draft specification. Where possible, EPA works with voluntary standards bodies (such as ASTM International) to develop specifications. The draft specification will be released for public comment and stakeholder input, then revised and either released as a revised draft or published as a final specification.

The specifications for each product type are available online at http://www.epa.gov/WaterSense/partners/product_program_specs.html.

Cost

Certification costs vary between certifying bodies but are expected to be comparable to other certifications for plumbing products. There is no cost to enter into a WaterSense® partnership with EPA.

Retesting costs are borne by product manufacturers.

Timeline

Certification time varies between certifying bodies but is expected to be comparable to other certifications for plumbing products.

Contact

WaterSense®
U.S. Environmental Protection Agency
Office of Wastewater Management (4204M)
1200 Pennsylvania Avenue, N.W.
Washington, D.C. 20460.

(866) WTR-SENS (987-7367)
watersense@epa.gov