Understanding and Recognizing Innovation and How to Use Technology Transfer as a Path to Sustainability

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Office of Research and Development

AGENDA

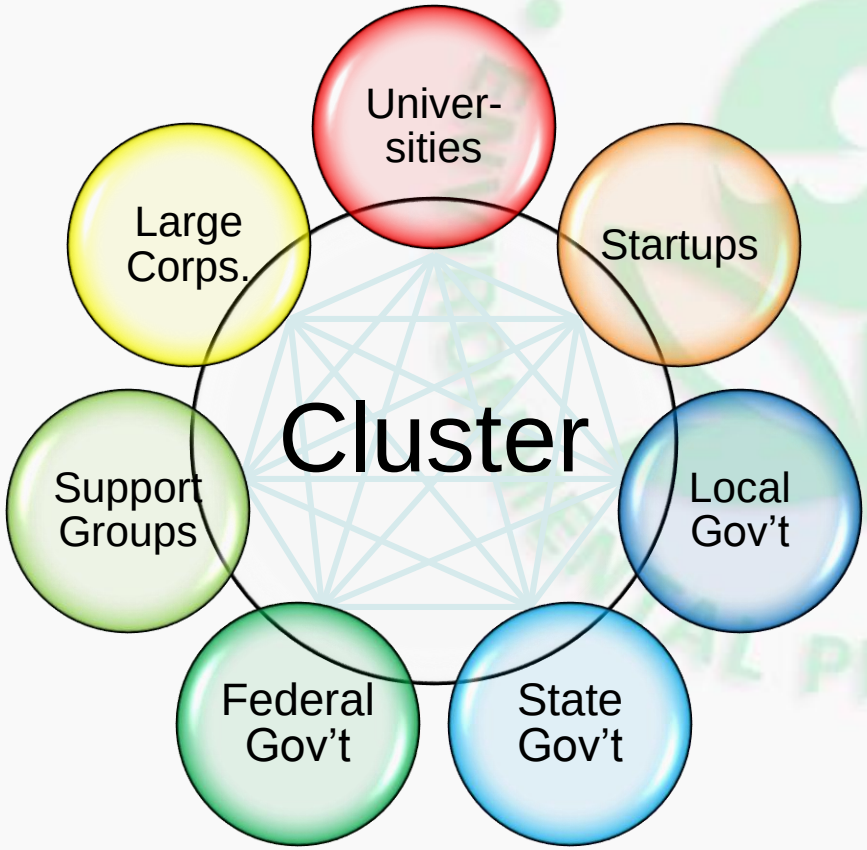
- The Water Technology Innovation Cluster
- What is the Cluster Concept
- The Government (What and How)
- Success Stories

The Water Technology Innovation Cluster

- 2011 EPA / SBA – Administrators
- $ 5 Million/5 year cluster funded in Cincinnati, Ohio
  - WHY Cincinnati

What is the Cluster Concept

Clusters are **dense, regional networks** of companies and other groups in the same industry.



Cluster organizations can:

- Connect researchers to business partners
- Connect start-ups to accelerators and other resources
- Streamline testing and approval processes
- Act as support groups for innovators, speeding the development and adoption of technologies

- Cincinnati
  - > 1000 Scientists & Engineers
  - > 500,000 ft^2 of lab space
  - 100 Years R&D
  - Patent Per Capita
  - 3 Facilities

EPA Cincinnati Water Research Facilities

Experimental Stream Facility
Milford, OH

AWBERC
Cincinnati, OH

Test and Evaluation Facility
Cincinnati, OH

Drinking Water Pilot Plants

Bio containment Laboratory

Analytical Laboratories

Regional DW, WW, and SW Patents

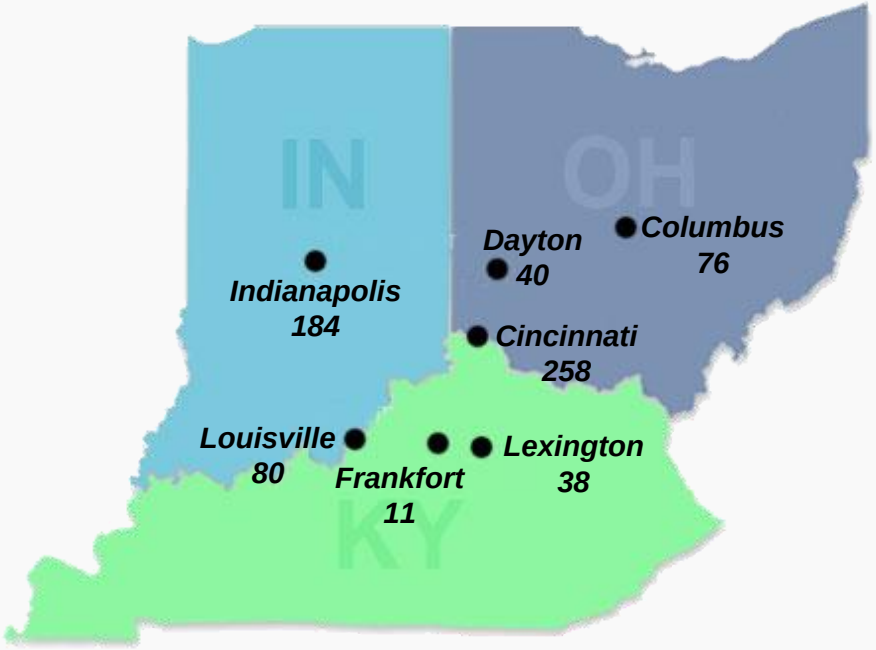
Indianapolis:
Drinking Water: 138
Waste Water: 45
Storm Water: 1

Lexington:
Drinking Water: 9
Waste Water: 26
Storm Water: 3

Louisville:
Drinking Water: 17
Waste Water: 62
Storm Water: 1

Columbus:
Drinking Water: 24
Waste Water: 46
Storm Water: 6

Dayton:
Drinking Water: 8
Waste Water: 32
Storm Water: 0



Frankfort:
Drinking Water: 3
Waste Water: 8
Storm Water: 0

Cincinnati:
Drinking Water: 96
Waste Water: 153
Storm Water: 9

Search Date: October 8, 2010
Source: USPTO, 1976-Present, Search terms: “Drinking Water”, “Storm Water” and “Waste Water”

2012 EPA internal RFP

- Over 25 proposed
- 17 Internal Technologies Selected
  - Go/No analysis
  - Technology Niche /Market Analysis

The Government (What and How)

- 1980 – Directs Government Labs to T2
  - Stevenson Wilder Act
  - Bye- Dole Act
- 1986 & Amendment
  - Federal Technology Transfer Act
    - Cooperative Research and Development Agreements
    - Priority given
      - Small Business
      - US Manufactured
    - Intellectual Property Protection
    - Licensing and Royalties

The Technology Transfer (T^2) "Commercialization" Conundrum

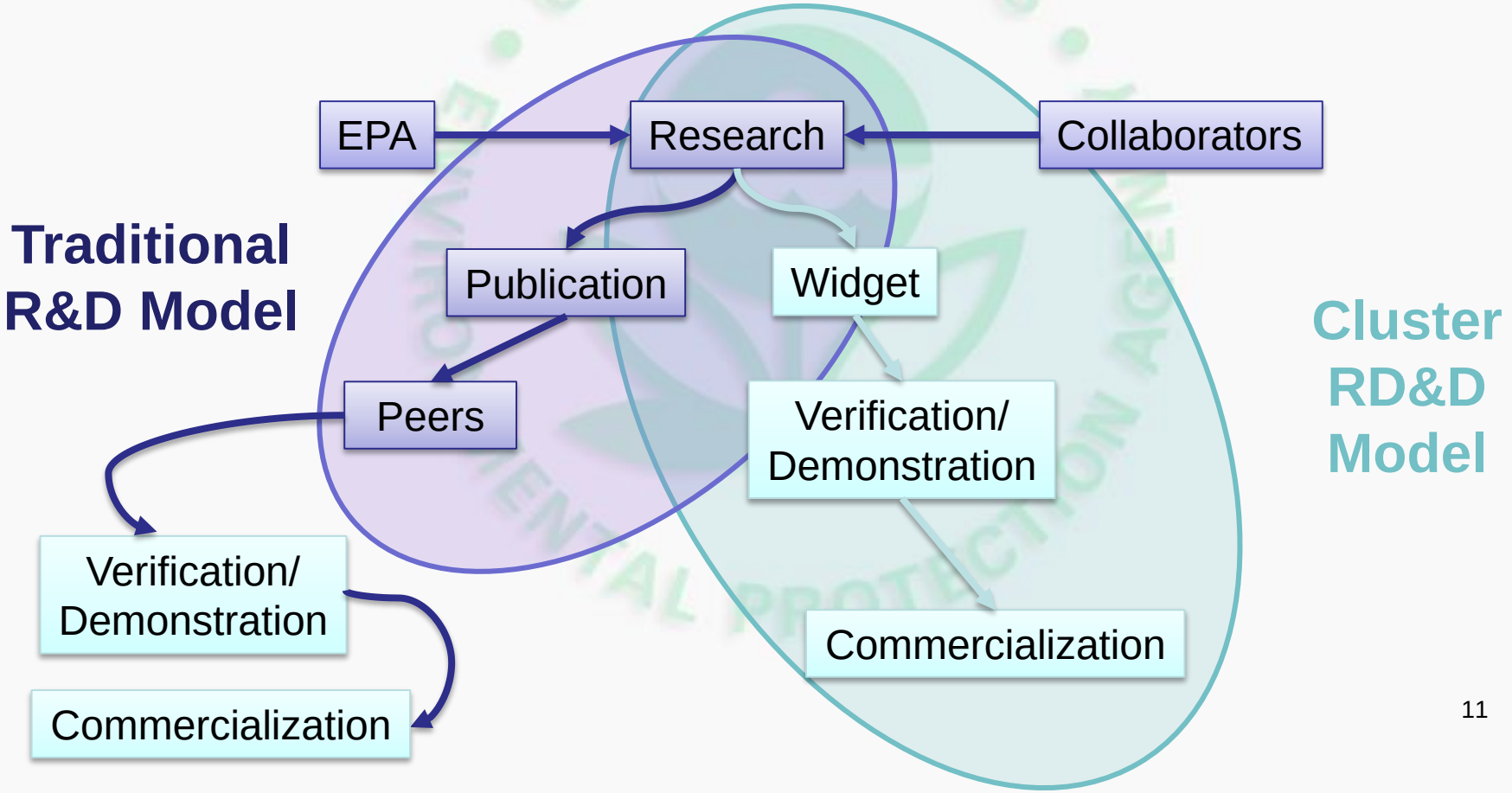
Federal labs **can**:

- Research
- Develop
- Protect IP
- Test and evaluate
- Support verification and validation

Federal labs **cannot**:

- Manufacture
- Market
- Invest

Technology Transfer Research, Development, and Deployment Model



Impact of EPA Internal Funding

Increased Collaboration

- 14 CRADAs
- 6 patent applications
- 4 license agreements
- Improved Motivation –

…from only **17** funded projects.

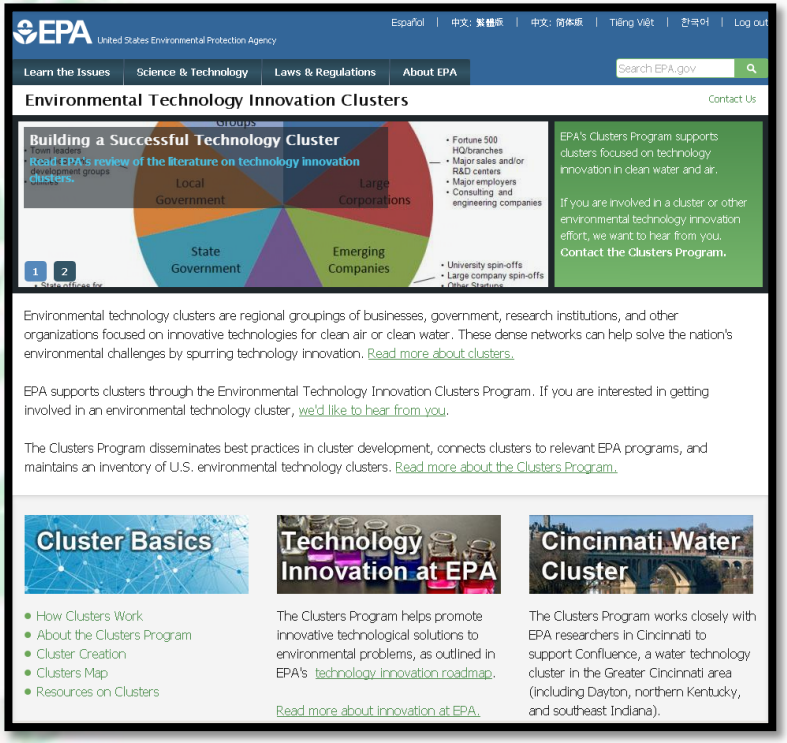
Success Story

- EPA Developed Technology
  - MST – (Government, Research and Commercial Licenses)
  - 8 new Staff in the past 2 years
- EPA – University Developed Tech
  - improve treatment efficiency & improve Water quality at reduced O&M $
  - Citi Logic – 7 utilities are using
- EPA – Private Partner Developed Tech
  - Nessie
  - Demonstrations
  - March 2016 1st License

NESSIE – “Detain H_2O”

Clusters Program Support Activities

- Connects EPA researchers to potential partners –
  - Relationship Building
- Assists researchers
  - Developing collaborative agreements
  - protecting IP vs Publication
  - Patenting & Non Disclosure Agreements
  - Discussions with potential partners
  - Designing the CRADA/SOW/QAPP
- Identify and profile water technologies
  - Internal and External
  - Go/No Go / Technology Niche Analysis
  - Path forward Analysis
  - Technology demonstration
  - Mentoring R&D Staff – “DARK-SIDE”
  - Innovation Showcases



www2.epa.gov/clusters-program

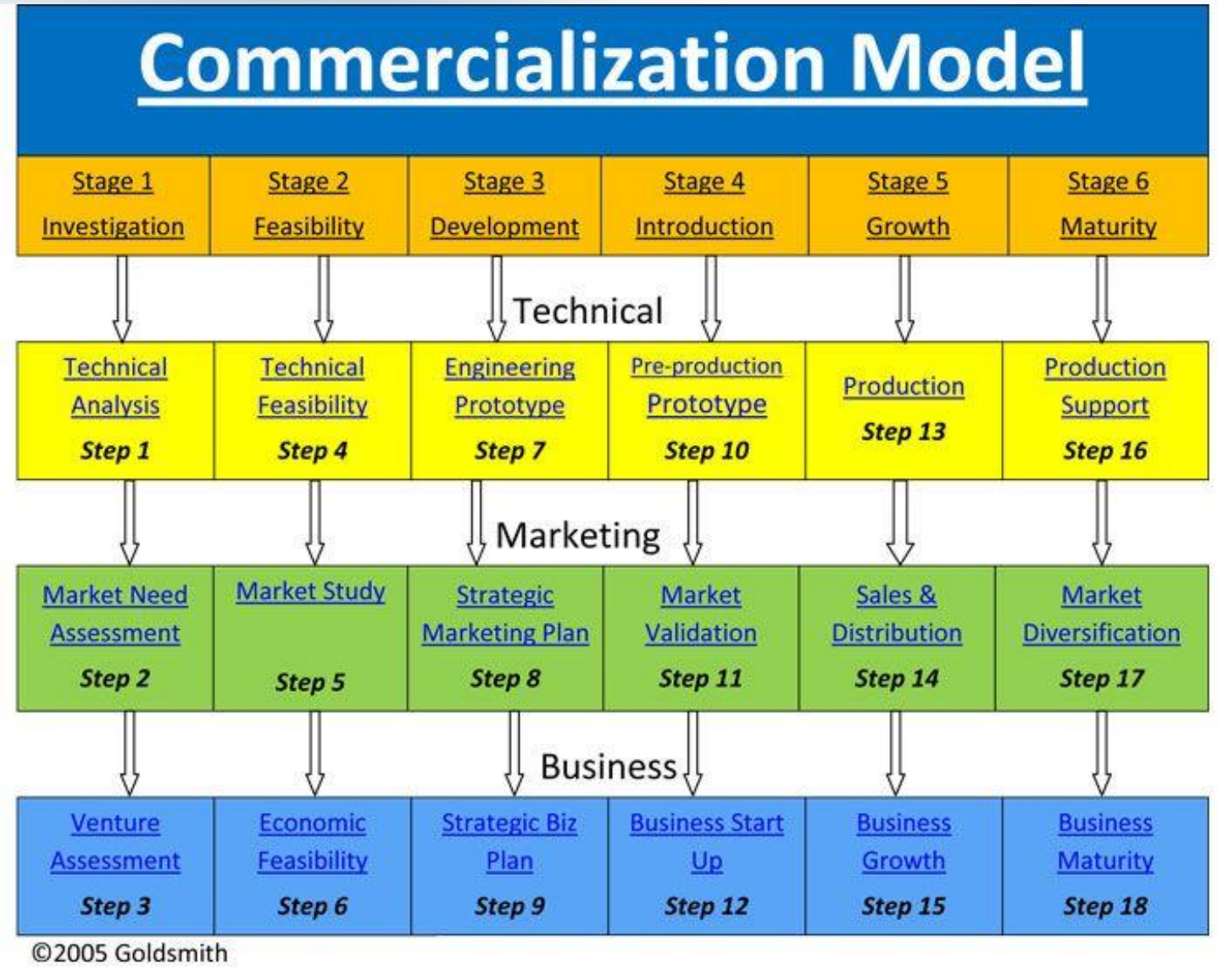
Go No/Go Analysis

- Decision support tool for management
  - Inventions/concepts to further develop
  - Which to patent
  - Which patents to maintain or abandon
  - Which are candidates for T2

- Risk / No guarantee
  - Doesn’t replace knowledge, instinct,

Technology Niche Analysis

- Decision support tool for management
  - Assess technologies for market entry
  - Strategic planning and preparation
    - Transfer technology into the private sector
    - Recognizes specific applications (niche)
    - Maps performance, ease of use, price to end user
    - Map supply chain
    - Identify potential end-users
    - Finds the appropriate insertion point for the technology
- Risk


Commercialization Model
Stage 1 Investigation
Stage 2 Feasibility
Stage 3 Development
Stage 4 Introduction
Stage 5 Growth
Stage 6 Maturity
Technical
Technical Analysis Step 1
Technical Feasibility Step 4
Engineering Prototype Step 7
Pre-production Prototype Step 10
Production Step 13
Production Support Step 16
Marketing
Market Need Assessment Step 2
Market Study Step 5
Strategic Marketing Plan Step 8
Market Validation Step 11
Sales & Distribution Step 14
Market Diversification Step 17
Business
Venture Assessment Step 3
Economic Feasibility Step 6
Strategic Biz Plan Step 9
Business Start Up Step 12
Business Growth Step 15
Business Maturity Step 18
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Mechanisms to Build a Collaboration

- Cooperative Research and Development Agreements
- Third Party Contract
- Academically Collaborate

Drinking Water Program

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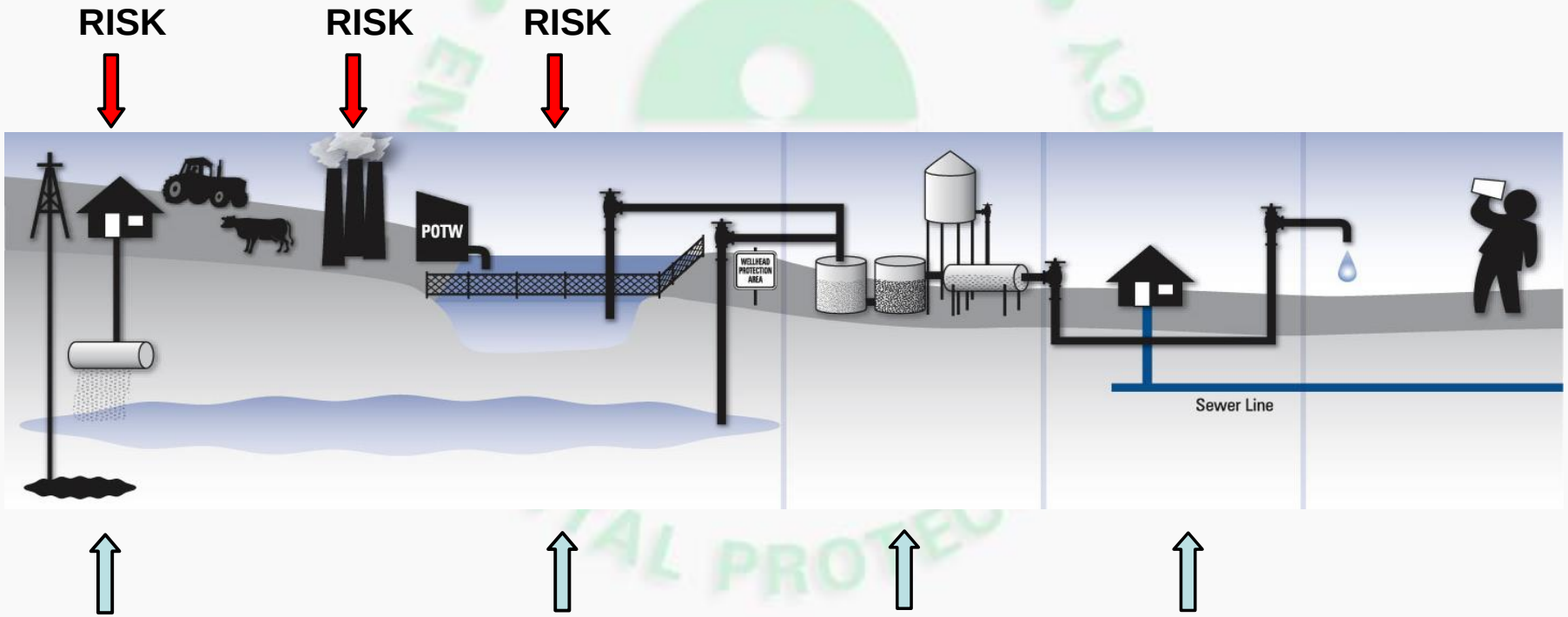
SDWA & the Operator Certification Program

- **1996 SDWA Amendments**

- The 1996 Amendments established a holistic approach to preventing contamination problems by emphasizing source water protection and enhanced water system management.

- The Capacity Development program, Operator Certification program and Drinking Water State Revolving Fund (DWSRF) were established by these amendments.

PROTECTING AMERICA'S PUBLIC HEALTH
MULTIPLE *RISKS* REQUIRE MULTIPLE *BARRIERS*



Prevent Contamination through Protection and Security Measures

TREATMENT TECHNOLOGY

MONITORING/ COMPLIANCE

OPERATOR CERTIFICATION PROGRAM

- Operator Certification programs establish minimum professional standards.

- In 1999, EPA issued Operator Certification program guidelines specifying minimum standards for certification and recertification of the operators.

- If a state does not implement an Operator Certification program, EPA must withhold 20% of its annual DWSRF capitalization grant.

- States also have the flexibility to set aside DWSRF funds for implementation of the program.

Operator Certification Guidelines

- The final guidelines were published in 1999 and included the nine Baseline Standards:
- Authorization
- Classification of Systems, Facilities, and Operators
  - EX. Virginia - Systems are classified as: Class VI, V, IV, III, II, and I (lowest level to highest level) based on number of people served or capacity (MGD), and treatment process.
- Operator Qualifications
  - EX. Virginia - Operators are classified as: Class VI, V, IV, III, II, and I (lowest to highest to match the system classifications). Successively more experience/ education is required.

Operator Certification Guidelines

- Enforcement
  - Primacy agencies must have the ability to require community and non-transient non-community water systems to comply with the regulations.
  - States must also have the ability to revoke or suspend operator certifications.
- Certification Renewal
  - EX. Virginia requires renewal on a 2 year basis. It requires Class I, II, and III operators have at least 20 continuing professional education hours for renewal of their license.
- Resources Needed to Implement the Program
  - Example sources of program funding include application fees, certification renewal fees, exam fees.
  - EPA recommends that states establish a dedicated fund for the program.
- Recertification
  - A process by which individuals with expired licenses can become recertified.

Operator Certification Guidelines

- Stakeholder Involvement
  - Public comment on rule revisions is not considered adequate stakeholder involvement.
  - In general, states have Operator Certification boards or committees made up of operators, trainers, and utility managers to review operator regulations, trends, training, etc.

- Program Review
  - EPA recommends internal reviews at least once every 3 years and external reviews at least once every 5 years.
  - Examples of items to review include regulations, exam items, budget and staffing, training needs.

EPA OVERSIGHT:

- **Annual Reports –** States submit annual Operator Certification program reports to EPA Regions. Regional Operator Certification coordinators have the responsibility for making the annual determination as to whether DWSRF funding should be withheld or conditioned based on the state program meeting the nine baseline standards.

- **Stage 1 Violations –** As part of the Stage 1 Disinfection Byproducts Rule, "each CWS and NTNCWS… must be operated by qualified personnel who meet the requirements specified by the state and are included in a state register of qualified operators." Not having a "qualified operator" is a violation the Stage 1 Disinfection Byproducts Rule and violations are tracked in SDWIS Fed.

ACTIVITIES AND KEY ISSUES:

- **Workforce –** Operators were identified by the industry as one of the mission critical positions in utilities, and predicted workforce shortages in the water sector can affect a utility's ability to reliably provide safe water.
  - Some utilities that do not practice adequate knowledge management will lose institutional knowledge as experienced operators leave the workforce.
  - The retirements may create additional challenges for small systems trying to attain and maintain TMF capacity. As larger systems lose experienced operators, they may attract small systems operators with better pay and benefits.
  - EPA partnered with AWWA and WEF to develop a Department of Labor (DOL) Water Sector Competency Model to identify the skills and knowledge needed to work in the water sector. In 2009, the model was published to DOL's website and printed in multiple journals. In 2010 EPA collaborated with AWWA and WEF on the Work for Water campaign to promote careers in the water sector and direct targeted audiences to the appropriate resources for jobs and training.

- Work for Water website: http://www.workforwater.org/

Workforce Collaborations

- EPA collaborated with industry to develop a workforce recruitment video for high school and vocational students. It has been posted on EPA's Operator Certification website and the Work for Water website.
- **MOU with Veterans Affairs**
  - To help address predicted workforce shortages in the water sector, OGWDW and OWM signed a memorandum of understanding with the Department of Veterans Affairs – Vocational Rehabilitation and Employment Service
  - Connects veterans with disabilities to water sector careers.
  - The MOU focuses on promoting water sector career opportunities to veterans while educating utilities about government programs that can help them recruit and train veterans for these jobs.
- The MOU can be found here: http://water.epa.gov/infrastructure/sustain/upload/VA-EPA-Memorandum-of-Understanding.pdf

Regulatory Development & Update

Regulatory Development Process

- EPA publishes a list every 5 years of unregulated contaminants.
  - This list is called the Contaminant Candidate List (CCL)
  - Identifies contaminantes which may require regulation and are known or anticipated to occur in public water supplies

- EPA then monitors up to 30 unregulated contaminants every 5 years.
  - The monitoring is conducted under that Unregulated Contaminant Monitoring Regulation (UCMR).
  - The contaminants selected for monitoring are largely based on the CCL.

- After reviewing relevant data, including the results of the UCMR sampling, EPA then determines whether or not to regulate at least 5 contaminants on the current CCL every 5 years.
  - This selection of a contaminate for regulation is called a Regulatory Determination.

Regulatory Development Process (cont'd)

SDWA requires EPA to make regulatory determinations for at least 5 CCL contaminants every 5 years. EPA must regulate if:

1) The contaminant may have an adverse effect on the health of persons;

2) The contaminant is known to occur or there is substantial likelihood that the contaminant will occur in public water systems with a frequency and at levels of public health concern; and

3) In the sole judgment of the Administrator, regulation of such contaminant presents a meaningful opportunity for health risk reduction for persons served by public water systems

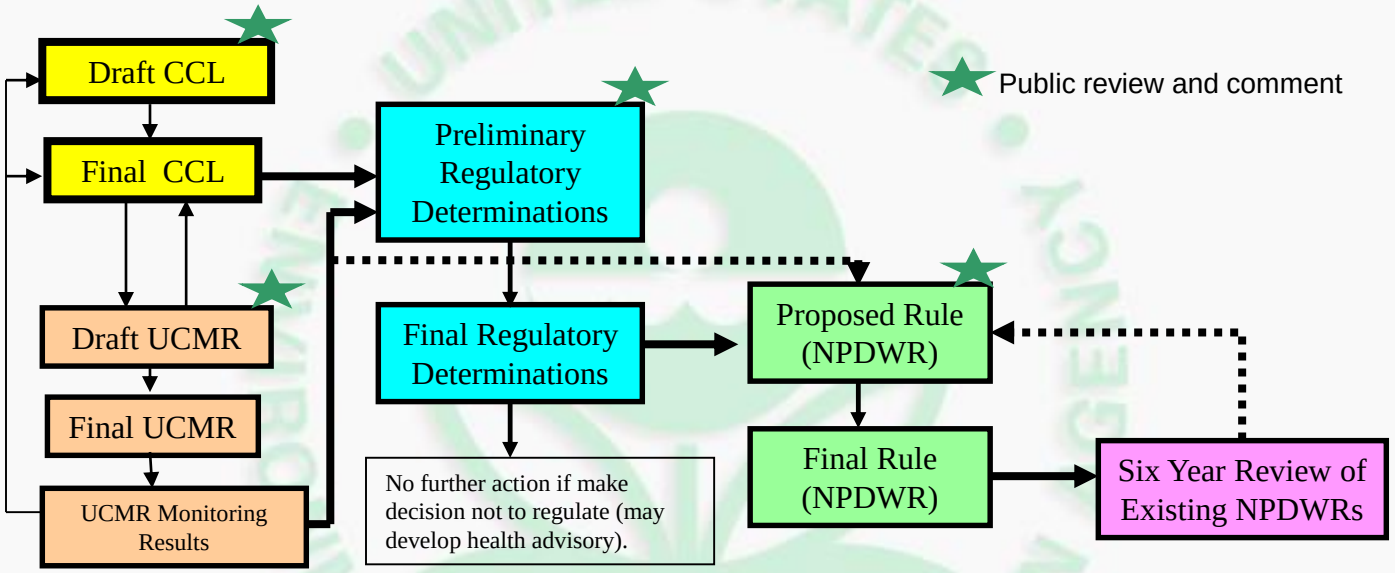
***SDWA Section 1412(b)(1)**

Regulatory Development Process (cont'd)

- After EPA has made a determination to regulate a specific contaminant.
  - EPA has 24 months to propose the regulation.
  - The proposed regulation is then published in the Federal Register and EPA solicits comments from the public on the contents of the rule.
  - EPA will then review the public comments and finalize the regulation.

- The Safe Drinking Water Act also requires EPA to review each national primary drinking water regulation at least once every six years and revise them, if appropriate.
  - As part of the Six-Year Review, EPA evaluates newly available data, information and technologies to determine if any regulatory revisions are needed.
  - Revisions must maintain or strengthen public health protection.

General Flow of SDWA Regulatory Processes



At each stage, need increased specificity and confidence in the type of supporting data used (e.g. health, occurrence, treatment).

Update on Regulatory Activities

- Some ongoing regulatory activities include:
  - Contaminant Candidate List (CCL)
  - Unregulated Contaminant Monitoring Regulation (UCMR)
  - Six Year Review
  - Lead and Copper Rule Revisions
  - Lead and Copper Oversight
  - Lead and Copper Rule Guidance Materials
  - Lead and Copper Webinars
  - Revised Total Coliform Rule
  - PFOAs/PFOS
  - Harmful Algal Blooms

Contaminant Candidate List (CCL)

- **Published draft CCL 4 - Feb 4, 2015**
  - 60-day comment period ended April 6
  - Lists 100 chemicals or chemical groups and 12 microbial contaminants
  - CCL 4 info at- http://www2.epa.gov/cct/draft-contaminant-candidate-list-4-ccl-4

- **Next Steps -**
  - Compile, consider, and analyze public comments
  - Revise CCL 4, as appropriate
  - Publish Final CCL in 2016

Third Unregulated Contaminant Monitoring Rule (UCMR 3)

- Final rule published May 2, 2012

- Monitoring is occurring from 2013-15
  - 28 chemicals and 2 viruses
  - Contaminants include hormones, perfluorinated compounds (e.g., PFOS/PFOA), VOCs, metals (including Cr^{+6} and total Cr), 1,4-dioxane, chlorate and pathogens

- Data are posted to the National Contaminant Occurrence Database (NCOD) ~quarterly (http://www2.epa.gov/dwucmr/occurrence-data-unregulated-contaminant-monitoring-rule#3)

- Will complete monitoring in 2015 and data reporting in 2016

Six Year Review

- The 1996 Safe Drinking Water Act amendments require EPA to review each existing national primary drinking water regulation (NPDWR) no less often than every six years and revise the NPDWR, if appropriate.
  - Completed the **1st** Six Year Review of 69 NPDWRs (2003)
    - The Agency made the decision to revise the Total Coliform Rule
  - Completed the **2nd** Six Year Review of 71 NPDWRs (2010)
    - The Agency identified PCE, TCE, acrylamide and epichlorohydrin as candidates for revision
  - Will complete the **3rd** Six Year Review in 2016
    - This will be the first time a Six Year Review addresses the microbial and disinfection byproduct regulations

Lead and Copper Rule Revisions

- EPA is currently in the process of revising the Lead and Copper Rule.
- EPA requested the National Drinking Water Advisory Council to form a working group to provide stakeholder input on several key rule revision issues
- In November, 2015 the NDWAC considered working group's recommendations and the recommendations of the dissenting member of the working group and the public.
- The NDWAC decided to adopt the working group's recommendations for
  - Proactive Lead Service Line Replacement programs
  - More robust public education requirements for lead and LSLs
  - Strengthening Corrosion Control Treatment requirements
  - Modify monitoring requirements to provide for consumer requested tap samples for lead
  - Tailor water quality parameters for each system and increase frequency of monitoring
  - Establish a health based household action level
  - Separate copper requirements focused on water corrosive to copper
  - Establish appropriate compliance and enforcement mechanisms
- EPA is currently considering the recommendations of the NDWAC as it continues the regulatory development process.

Lead and Copper Rule Oversight Review

- State Commissioner Letter
  - Historical EPA sent letters on February 29, 2016, requesting state commissioners confirm their implementation of the LCR is consistent EPA regulations and guidance.
  - Responses to these letters were due March 30, 2016.
  - Between fiscal years 2013-2015, a total of 2,441 public water systems, delivering water to 5.7M Americans, reported an ALE.
  - In an effort to review nationwide LCR implementation, EPA is collaborating with Regions and States to determine what actions were taken as a response to these 2,441 Action Level Exceedances.
- Action Level Exceedance Review

Lead and Copper Rule Guidance Materials

- EPA has begun updating guidance materials and issuing memos to ensure implementation with the LCR is consistent on a nationwide basis.
  - EPA released a memo in February 2016 providing recommendations on how public water systems should address the removal of cleaning aerators, pre-stagnation flushing, and bottle configuration for the purpose of the Lead and Copper Rule.
  - In March 2016, EPA released the OCCT Technical Recommendations, designed to help states and systems work through the LCR's Corrosion Control Treatment steps.
  - Between April and August of 2016 EPA has held a series of webinars aimed at education attendees in the requirements of the Lead and Copper Rule.

Lead and Copper Rule Webinars

- EPA has been conducting webinars to assist
  - Lead and Copper Rule 101 Webinar Series
    - Series of 3 webinars covering the requirements of the Lead and Copper Rule.
      - Part 1: Requirements Before and Action Level Exceedance
      - Part 2: Requirements After an Action Level Exceedance.
      - Part 3: Compliance Determination and Reporting Requirments.
  - Optimal Corrosion Control Training
    - Designed to educate participants on the contents of the new EPA guidance document on Optimal Corrosion Control Treatment Evaluation.
    - Guidance document is available at: https://www.epa.gov/dwreginfo/lead-and-copper-rule-compliance-help-public-water-systems

Revised Total Coliform Rule Purpose

- Revision of the 1989 Total Coliform Rule
- Improve public health protection by reducing the pathways through which fecal contamination and pathogens can enter the distribution system
- TCR & RTCR objectives:
  - Evaluate effectiveness of treatment
  - Determine integrity of distribution system
  - Signal possible presence of microbial contamination

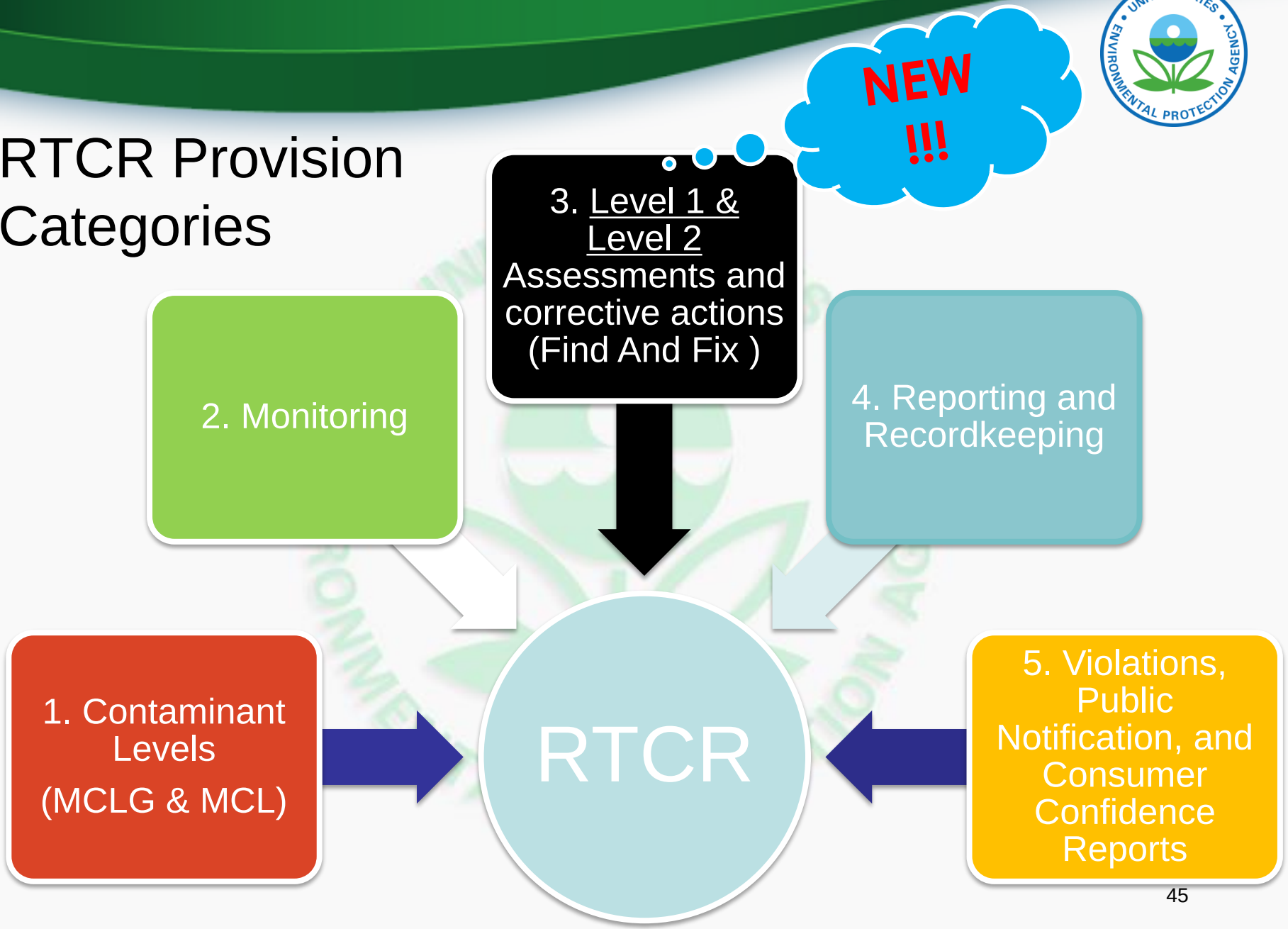
RTCR Timeline And Applicability

- **February 13, 2013:** FINAL RTCR published in Federal Register.

- **February 26, 2014:** Minor corrections published in the Federal Register.

- **April 1, 2016:** Systems and states required to comply with all rule requirements.
  - Applies to all PWSs: CWS & NCWS (transients & Non-transients); GW & SW systems; Any size population served

RTCR Provision Categories



RTCR Contaminant Levels

- Contaminant levels (MCLG and MCL) are now based on the presence or absence of E.coli

- The MCLG for *E. coli* is set at zero.
  - Same as under TCR

- The MCL for *E. coli* is based on the occurrence of a condition. So the system is not in compliance with the MCL if:
  - PWS has an *EC*+ repeat sample following a TC+ routine sample.
  - PWS has a TC+ repeat sample following an *EC*+ routine sample.
  - PWS fails to take all required repeat samples following an *E. coli*-positive routine sample.
  - PWS fails to test for *E. coli* when any repeat sample tests positive for total coliforms.

RTCR Monitoring

- Monitoring requirement are basically the same as under the TCR.
  - PWSs must have a sample siting plan for RTCR monitoring. The sample siting plan is subject to review and revisions by the state
  - All Surface Water PWSs, regardless of size, must monitor monthly
  - Ground Water PWSs serving more than 1,000 persons must monitor monthly
  - Ground Water PWSs serving less than 1,000 persons may monitor monthly, quarterly or annually.
    - The state makes the decision on which monitoring frequency it will allow and must adopt requirements for any frequency that is less than monthly.

RTCR Level 1 and Level 2 Assessment

- Level 1 and Level 2 Assessments are a new Provision

- PWSs are required to conduct a Level 1 or Level 2 assessment when certain monitoring conditions occur in their system.
  - Level 2 assessments look at same aspects as a Level 1 but with higher degree of scrutiny.
  - Level 2 Assessments must be conducted by a Primacy Agency or by a 3rd party on behalf of the Primacy Agency.

- If any “sanitary defects” are found PWS must correct within a required timeframe.

RTCR Reporting, Violations

- Reporting and Record Keeping
  - Same as under TCR with the addition of Level 1 and Level 2 Assessments.

- Violations (4 types)
  - *E. coli* MCL violation = MCL
  - Treatment Technique violations = TT
  - Monitoring violations = M
  - Reporting violations = R

- Treatment Technique Violation vs. Treatment Technique trigger
  - Failure to assess and/or correct a sanitary defect is a TT violation
  - Triggering an assessment (level 1 or level 2) is <u>not</u> a violation

RTCR Public Notification & CCR

- Public Notifications and Consumer Confidence Reports
  - Under the TCR, systems were required to include health effects language for total coliforms and fecal coliforms/*E. coli*.
  - Under the RCTR, the health effects language was updated to reflect that total coliforms are an indicator of potential contamination. The health effects language for fecal coliforms/*E. coli* has been replaced with health effects language for *E. coli* only.

Consumer Confidence Report

- Under the TCR The CCR table must include:
  - Information related to the highest monthly TC+ results (number or percentage)
  - Total number of fecal coliform/*E. coli*-positive samples.
- Under the RTCR the CCR table must include:
  - CCR table must include information on the total number of *E. coli*-positive samples
  - And must also include language that describes the number of required assessments, the corrective actions taken, and if appropriate, the number of assessments missed and corrective actions not completed

Harmful Algal Blooms

- Harmful algal blooms are overgrowths of algae in water.
  - Some produce dangerous toxins in fresh or marine water
  - Even nontoxic blooms hurt the environment and local economies.

- Harmful algal blooms are the result of:
  - Sunlight
  - Slow-moving water
  - Nutrients (nitrogen and phosphorus)
    - Nutrient pollution from human activities makes the problem worse, leading to more severe blooms that occur more of

Available Resources

- Other resources available for Operators:
  - EPA's Drinking Water Webinars
  - EPA's Small System Monthly Webinar Series
  - EPA's Drinking Water Training System
  - Department of Labor Competency Model
  - EPA's Workforce Development Workgroup
  - RTCR Guidance, Webinars, and Fact Sheets

EPA Drinking Water Training Webinars

- EPA provides training opportunities aimed at improving knowledge and skills related to the Safe Drinking Water Act.
  - Target audience is water professionals, public officials, and involved citizens.

- Upcoming training topics include:
  - Lead and Copper Tap Sampling
  - Lead and Copper Compliance Determination
  - Drinking Water State Revolving Funds
  - Tools for Operator Certification
  - Removal of Contaminants through biological treatment

- For more information visit EPA's drinking water training page:
  - https://www.epa.gov/dwreginfo/drinking-water-trainings

Small Systems Monthly Webinar Series

Challenges and Treatment Solutions for Small Drinking Water and Wastewater Systems

- EPA's Office of Research and Development and Office of Water are jointly hosting this monthly webinar series.
  - Goal is to communicate current small systems research along with Agency priorities.
  - The provides a forum for EPA to communicate directly with state personnel and other drinking water and wastewater small systems professionals.
  - The webinars will include presentations from state representatives.
  - Attendees have the option of receiving a certificate for one continuing education contact hour for each webinar.

- More information can be found at:
  - https://www.epa.gov/water-research/small-systems-monthly-webinar-series

EPA's Drinking Water Training System

- EPA is in the process of piloting a training tool supported by EPA HQ, Regions and States.
  - It is an online, self-paced computer based training system.
  - Designed to provide an overview of NPDWRs in modular format.
  - Participant creates their own curriculum based on responses to questions.
  - Curriculum progress tracked by the training system.

- Rollout will include a webinar to introduce the online training tool
  - Anticipated for wide release in Fall 2016.

RTCR Guidance, Webinars, and Fact Sheets

- RTCR Quick Reference Guide (QRG)
  - http://water.epa.gov/lawsregs/rulesregs/sdwa/tcr/upload/epa815b13001.pdf
- RTCR State Implementation Guidance – Interim Final
  - http://water.epa.gov/lawsregs/rulesregs/sdwa/tcr/upload/epa816r14004.pdf
- RTCR Assessments and Corrective Actions Guidance Manual – Interim Final
  - http://water.epa.gov/lawsregs/rulesregs/sdwa/tcr/upload/epa815r14006.pdf
- RTCR Training: 5 webinar training series
  - Recordings & slides on ASDWA website www.asdwa.org/rtcr
  - Target audience: Regions, States, and Technical Assistance Providers
- RTCR workshops and presentations. Slides on ASDWA website www.asdwa.org/rtcr
  - AWWA ACE in Boston, MA.
  - NRWA annual in-service training event in Mobile, AL
  - RCAP 2014 National Training Conference in Madison, WI.

RTCR Guidance, Webinars, and Fact Sheets

- RTCR-- A Guide for Small Public Water Systems (serving ≤ 1,000)
  - Part A: concise information -- intended as a quick reference resource
  - Part B: detailed requirements
  - Part C: checklist to help water systems determine their compliance
  - Part D: different routine frequencies available to water systems if the drinking water primacy agency allows reduced monitoring

- RTCR Transition Memorandum
  - How PWSs must comply with the TCR*
  - Primacy agency reporting of TCR violations and enforcement data to the Safe Drinking Water Information System (SDWIS/FED)*
  - How points will be assigned to the TCR and RTCR violations by the Enforcement Targeting Tool (ETT)

- RTCR Public Notification (PN) Templates

- These resources are available on the EPA RTCR Website.
  - https://www.epa.gov/dwreginfo/revised-total-coliform-rule-and-total-coliform-rule

Thank You

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