



Primacy Revision Application

The Arsenic Rule

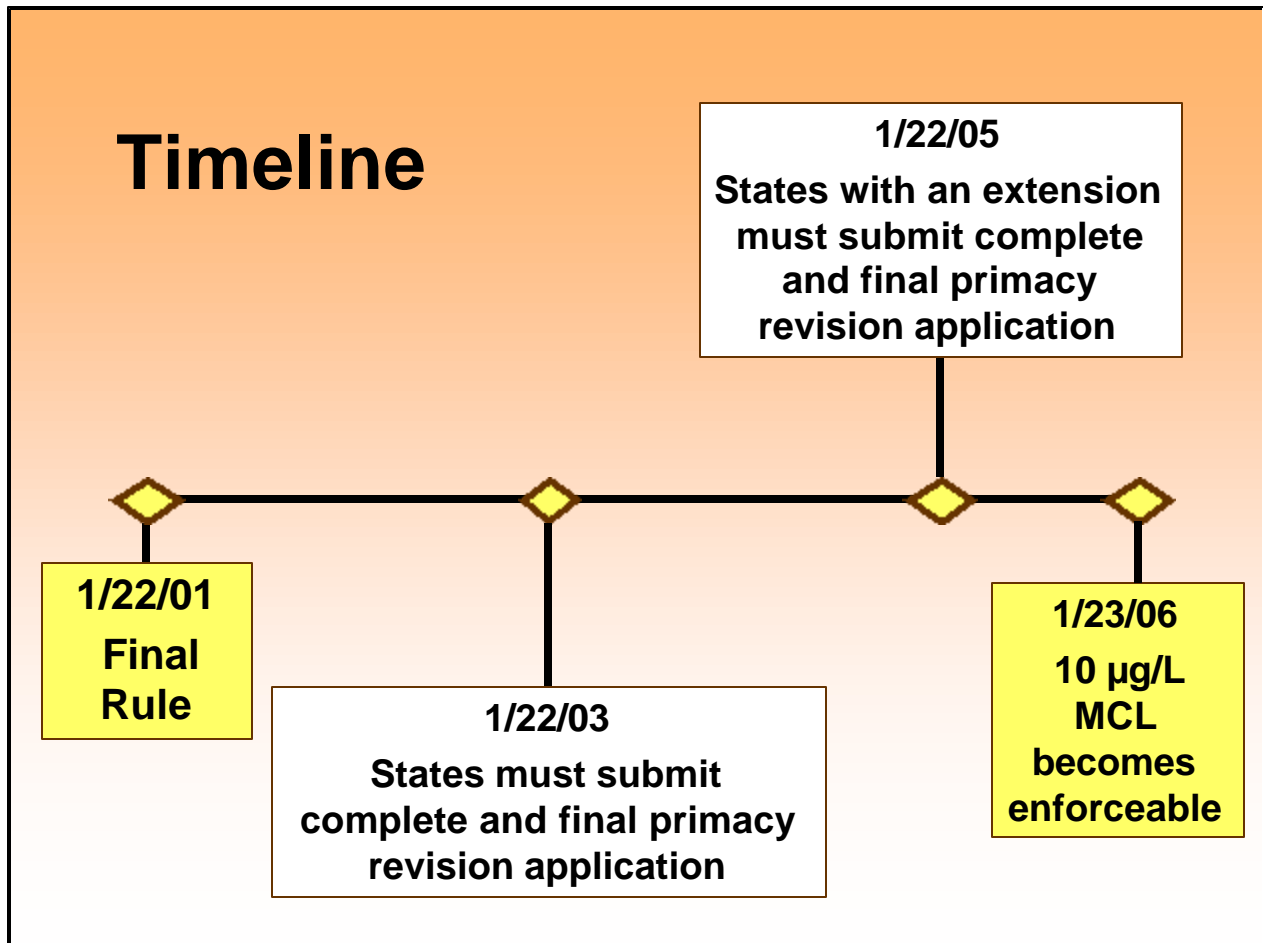
- This presentation will review the general and special primacy revision requirements of the Arsenic Rule. The 1996 Amendments to the Safe Drinking Water Act (SDWA) updated the process for States to obtain and/or retain primacy. On April 28, 1998, EPA promulgated the Primacy Rule (63 FR 23361) to reflect these statutory changes.
- 40 CFR 142 sets out the requirements for States to obtain and retain primacy for the Public Water System Supervision (PWSS) program. Under 40 CFR 142, Subpart B, States must have:
 - ✓ Regulations that are no less stringent than the federal regulations.
 - ✓ Adopted and be implementing procedures for the enforcement of State regulations and maintain an inventory of public water systems (PWSs) in the State.
 - ✓ Programs to conduct sanitary surveys of the systems in the State, to certify laboratories that will analyze water samples required by the regulations, and to ensure that new or modified systems will be capable of complying with State primary drinking water regulations
 - ✓ An EPA certified laboratory that will serve as the State's "principal" lab.
 - ✓ Adequate enforcement authority to compel water systems to comply with NPDWRs, including:
 - The authority to sue in court and to assess civil or criminal penalties for violations of State regulations and public notification requirements;
 - The right to enter and inspect water system facilities; and,
 - The authority to require systems to notify the public of any system violation of the State requirements and to require systems to keep records and release them to the State; and,
 - ✓ Adequate record keeping and reporting requirements, adequate variance and exemptions as stringent as EPA's, if the State chooses to allow variances or exemptions, and an adequate plan to provide for safe drinking water in emergencies like a natural disaster.
 - ✓ Adopted authority to assess administrative penalties for violations of their approved primacy program.
- *Throughout this presentation, the terms "State" or "States" are used to refer to all types of primacy agencies including U.S. territories, Indian Tribes, and EPA Regions.*

Major Points



- **Components of Primacy Revision Application**
 - Attorney General's Statement
 - Special Primacy Requirements
 - Waivers
 - Monitoring Plan
 - New System Monitoring
- **Bundling**

- Pursuant to 40 CFR 141.12(b)(1), States must submit a complete and final request for approval of program revisions to adopt a new or revised EPA regulation. Requests must be submitted to the EPA Administrator no later than 2 years after promulgation of a regulation.
- After a State submits a complete and final revision package, EPA has 90 days to review the package; if and when EPA approves the application, the State will have primary implementation and enforcement authority.
- Two of the primacy revision application's main components are:
 - A State Attorney General's statement, which certifies that the State has the authority to implement the Rule and that either the State does not have audit privilege or immunity laws or that, if it has the privilege or laws, they will not impact the State's ability to implement the Rule.
 - A description of how systems will comply with the Special Primacy Requirements. The special primacy requirements of the Arsenic Rule require States to discuss waivers, revisions to monitoring plans, and an approach for ensuring that new systems will meet the Rule's requirements.
- Due to the closeness of the deadlines to submit primacy packages, EPA is encouraging States to bundle (i.e., combine and submit one primacy application package) the Arsenic Rule, the Variance and Exemptions Rule, and the Radionuclides Rule.



- The Final Arsenic Rule was promulgated on January 22, 2001.
- States have 2 years from the date of promulgation to submit their primary revision applications (by January 22, 2003) (40 CFR 142.12(b)(1)).
- States may apply for a 2-year extension. Extensions can be a valuable tool for States that are unable to put an application together by the original deadline. States need to apply for an extension by January 22, 2003 (40 CFR 142.12(b)(1)).
- A State must demonstrate that it is requesting the extension because it cannot meet the original deadline for reasons beyond its control, despite a good faith effort to do so (40 CFR 142.12(b)(2)). The application must also demonstrate at least one of the following:
 - The State currently lacks the legislative or regulatory authority to enforce the new or revised requirements;
 - The State currently lacks adequate program capability to implement the new or revised requirements; or,
 - The State is requesting the extension to bundle (group) two or more program revisions in a single legislative or regulatory action.
- The State must agree to meet certain conditions during the extension period (40 CFR 142.12(b)(3)). These conditions are negotiated by each EPA Region and the State during the extension approval process, are decided on a case-by-case basis, and are included in an extension agreement (40 CFR 142.12(b)(3)).
- EPA has 90 days to review and approve or disapprove a complete and final primacy revision application (40 CFR 142.12(d)(3)(i)).
- On January 23, 2006, the revised arsenic maximum contaminant level (MCL) becomes enforceable.

Components of Primacy Revision Application



- **Primacy revision checklist**
- **Text of Primacy Agency's regulations**
- **Primacy revision crosswalk**
- **Reporting and record keeping**
- **Special primacy requirements**
- **Attorney General's Statement**

- There are 2 types of requests that States may submit to EPA:
 - A Draft Request—A State may submit a draft request for EPA review and tentative determination. The request should contain drafts of all required primacy application materials. In order to allow sufficient time for review and response to any comments and program deficiencies, a draft request should be submitted to EPA within nine months of rule promulgation.
 - A Complete and Final Request—This submission must include:
 - The primacy revision checklist (40 CFR 142.10), which lists the materials that a complete application must contain;
 - The text of or a citation to the State's regulations (40 CFR 142.12(c)(1)(i));
 - The primacy revision crosswalk, which is a side-by-side comparison of the federal requirements and the corresponding State authorities, including citations that demonstrate adequate authority to meet the requirements;
 - A discussion of how the State will comply with any new record keeping or reporting requirements (40 CFR 142.14 and 142.15);
 - A discussion of how the State will comply with the Special Primacy Requirements (40 CFR 142.16); and,
 - A statement by the State Attorney General that the laws and regulations adopted by the State to carry out the program revision were duly adopted and are enforceable (40 CFR 142.12(c)(1)(iii)).

State Primacy Revision Checklist

Required Program Elements	Revision to State Program	EPA Findings/Comments
40 CFR 142.2 and 142.10	Primary enforcement-Definition of PWS*	
40 CFR 142.10(a)	Regulations no less stringent	
40 CFR 142.10(b)(1)	Maintain inventory	
40 CFR 142.10(b)(2)	Sanitary survey program	
40 CFR 142.10(b)(3)	Laboratory certification program	
40 CFR 142.10(b)(4)	Laboratory capability	
40 CFR 142.10(b)(5)	Plan review program	
40 CFR 142.10(b)(6)(i)	Authority to apply regulations	
40 CFR 142.10(b)(6)(ii)	Authority to sue in courts of competent jurisdiction	
40 CFR 142.10(b)(6)(iii)	Right of entry	
40 CFR 142.10(b)(6)(iv)	Authority to require records	
40 CFR 142.10(b)(6)(v)	Authority to require public notification	
40 CFR 142.10(b)(6)(vi)	Authority to assess civil and criminal penalties	
40 CFR 142.10(b)(6)(vii)	Authority to require CWSs to provide CCRs**	
40 CFR 142.10(c)	Maintenance of records	
40 CFR 142.10(d)	Variance/exemption conditions (if applicable ***	
40 CFR 142.10(e)	Emergency plans	
40 CFR 142.10(f)	Administrative penalty authority*	
40 CFR 142.16(j)	Special primacy requirements, waiver criteria, monitoring plan	
40 CFR 142.16(k)	Special primacy requirements, new systems, new sources, monitoring requirements	

* New requirement from the 1996 Amendments. Regulations published in the April 28, 1998 Federal Register.

** New regulations published in the August 19, 1998 Federal Register.

*** New regulations published in the August 14, 1998 Federal Register.

- This is a copy of the State Primacy Revision Checklist for the Arsenic Rule.
- The first column contains a list of the subsections in 40 CFR 142 revised by the Final Arsenic Rule. The second column contains a short description of these program elements.
- In the third column, the State must identify the program elements revised in response to new federal requirements (40 CFR 142.12(c)(1)(i)). If an element has been revised, the State should enter “Yes” in this column and submit appropriate documentation. For non-revised elements, the State need only list the appropriate State citation and date of its adoption.
- During the application review process, EPA will insert findings and comments in the fourth column.
- A blank checklist is available in the Arsenic State Implementation Guidance on EPA’s web site at www.epa.gov/safewater.

State Primacy Revision Crosswalk

FEDERAL REQUIREMENT	FEDERAL CITATION	STATE CITATION (DOCUMENT TITLE, PAGE NUMBER SECTION/PARAGRAPH)	DIFFERENT FROM FED REQUIREMENT? EXPLAIN ON SEPARATE SHEET
SUBPART A - GENERAL			
§141.2 DEFINITIONS			
Point-of-entry treatment device (POE)	§141.2		
Point-of-use treatment device (POU)	§141.2		
§141.6 EFFECTIVE DATES			
Except as provided in paragraphs (a) through (k) of this section, and in 141.80 (a)(2), the regulations set forth in this part shall take effect on June 24, 1977.			
The regulations set forth in §§141.11(d); 141.21(a), (c) and (i); 141.22(a) and (e); 141.23(a)(3) and (a)(4); 141.23(f); 141.24(e) and (f); 141.25(e); 141.27(a); 141.28(a) and (b); 141.31(a), (d) and (e); 141.32(b)(3); and 141.32(d) shall take effect immediately upon promulgation.	§141.6(c)		
The arsenic MCL listed in §141.62 is effective for the purpose of compliance on January 23, 2006. Requirements relating to arsenic set forth in Secs. 141.23(i)(4), 141.23(k)(3) introductory text, 141.23(k)(3)(ii), 141.51(b), 141.62(b), 141.62(b)(16), 141.62(c), 141.62(d), and 142.62(b) revisions in Appendix A of subpart O for the consumer confidence rule, and Appendices A and B of subpart Q for the public notification rule are effective for the purpose of compliance on January 23, 2006. However, the consumer confidence rule reporting requirements relating to arsenic listed in Sec. 141.154(b) and (f) are effective for the purpose of compliance on February 22, 2002.	§141.6(j)		
Regulations set forth in Secs. 141.23(i)(1), 141.23(j)(2), 141.24(f)(15), 141.24(f)(22), 141.24(h)(11), 141.24(h)(20), 142.16(e), 142.16(j), and 142.16(k) are effective for the purpose of compliance on January 22, 2004.	§141.6 (k)		

- The Primacy Revision Crosswalk must be completed by States in order to identify State statutory or regulatory provisions that correspond to each federal requirement.
- The first column contains the text of EPA’s regulation. The second column contains the citation.
- In the third column, the State should enter the citation where comparable text may be found in its regulations.
- In the fourth column, the State should note whether its regulatory language or provisions differ from the federal regulations. If the State’s provisions differ from federal requirements, the State should explain on a separate sheet of paper how its requirements are no less stringent than the federal regulation.
- The Primacy Revision Crosswalk is available as Appendix J to the Arsenic State Implementation Guidance on EPA’s web site at www.epa.gov/safewater.

Special Primacy Requirements



- **Implementation Guidance**
 - Note: Guidance Often Goes Beyond Minimum
- **Requirements = “Must”**
- **Guidance = “May” or “Should”**

- In several places, both the Arsenic State Implementation Guidance and this presentation make suggestions and offer alternatives that go beyond the federal minimum requirements. EPA provides this information and guidance to assist States during the primacy revision application process and the implementation of the Arsenic Rule.
- In both the Implementation Guidance and this presentation:
 - “Must” is used to indicate legally binding requirements.
 - “May” and “should” indicate recommendations and requirements that are not legally binding. EPA and State decision-makers retain the discretion to adopt approaches on a case-by-case basis that differs from guidance where appropriate.

Special Primacy: Requirements



- **Arsenic Final Rule §142.16 special primacy requirements**
 - §142.16(j)(1) Waivers
 - §142.16(j)(2) Monitoring plan
 - §142.16(k) New systems and new sources

- In the Final Arsenic Rule, EPA revised the special primacy requirements of 40 CFR 142.16(e) including:
 - The waiver provisions in 40 CFR 142.16(j)(1). States must provide details of their waiver program, if any.
 - The monitoring plan requirements in 40 CFR 142.16(j)(2). States must describe their monitoring program plan for the revised MCL, including how the State will ensure that all systems monitor by the regulatory deadline.
 - The new systems and new sources requirements in 40 CFR 142.16(k). States must establish initial monitoring requirements for new systems and new sources, including the time frame in which new systems will demonstrate compliance with the revised MCL
- EPA recognized that, for already regulated contaminants, States could indicate that they will use the existing approved waiver programs and monitoring plans.
- Under the Final Arsenic Rule, the contents of a State request for approval of a program revision in 40 CFR 142.12(c) and the revised special primacy requirements in 40 CFR 142.16(j) and 40 CFR 142.16(k) are subject to EPA review and approval.

§142.16(j)(1): Arsenic Waivers



- **If Primacy Agency chooses to issue waivers:**
 - Describe procedures - application requirements, review process for “use” or “susceptibility” waivers, evaluation criteria, and any other documentation

Or

- Use existing or update waiver program approved under the organic and inorganic National Primary Drinking Water Regulations (NPDWR) (i.e. the Phase II/V Rules)

- If a State chooses to issue a waiver from monitoring requirements in 40 CFR 141.23, 141.24, and 141.40 [which include the requirements for inorganic contaminants (IOCs), synthetic organic contaminants (SOCs), volatile organic contaminants (VOCs)], the State must describe the procedures and criteria it will use to review waiver applications and issue waivers.
- States wanting to issue monitoring waivers may satisfy the special primacy requirement in 40 CFR 142.16(j)(1) by:
 - Describing their waiver program, including their application requirements, review process for “use” or “susceptibility” waivers, evaluation criteria (submitting any other relevant documentation);
 - Explaining any revisions to the existing State waiver criteria approved under the Phase II/V Rules; or,
 - Noting in their primacy revision package that the same procedures approved under the Phase II/V Rules will be used to issue waivers for arsenic.

Guidance: Use Existing Waiver Program



- **Submit documentation that existing waiver program will be used**
- **Submit any revisions to existing waiver program**

- EPA recommends that States that already have a waiver program approved under the Phase II/V Rules use or revise that program.
- In their primacy revision application, the State may either:
 - Submit documentation that it will continue to use its existing waiver program; or,
 - Submit any revisions to the existing waiver program.
- Since the existing program may have been approved almost 10 years ago, EPA is encouraging States to review their criteria and requirements to ensure they are adequate based on changes to PWS inventory.

Guidance: Develop a new Waiver Program



- **To move to reduced monitoring**
 - Use waiver
 - Not appropriate for arsenic
 - Used, manufactured, or stored in zone of influence
 - Susceptibility waiver
 - System-by-system waiver
 - Analytical results
 - Vulnerability assessment

- States that do not have a waiver program approved under the Phase II/V Rules and that wish to establish a waiver program for the Arsenic Rule will need to describe their proposed waiver program.
- In their primacy revision application, States need to include information about the type of waivers that will be issued.
 - ✓ EPA suggests that issuing a use waiver is not appropriate for arsenic because it is naturally occurring. Use waivers are only appropriate for man-made or -stored contaminants when a State can be confident that the contaminant has not been used, manufactured, or stored in a water system's zone of influence.
 - ✓ Susceptibility waivers may be more appropriate for the Arsenic Rule. To apply for a susceptibility waiver, a system needs to conduct a thorough vulnerability assessment of the source water to determine its susceptibility to contamination. Systems with no known susceptibility to contamination may be granted a susceptibility waiver. Vulnerability assessments should include information on:
 - Previous analytical results;
 - Proximity to sources of contamination;
 - Environmental persistence, fate, and transport of the contaminant; and,
 - How well the source is protected.
- States may wish to review the Phase II/V waiver guidance when developing their waiver program for the Arsenic Rule.
- EPA also completed a study, A Review of Contaminant Occurrence in Public Water Systems (EPA 816-R-99-006), that can be an effective tool for States in reviewing their drinking water monitoring programs. States can use the results of the data analysis to reevaluate their waiver program and monitoring schedules, to identify potentially vulnerable systems.

§142.16(j)(1): Monitoring Plan



- **A Primacy Agency must submit a monitoring plan that will ensure all systems complete the required monitoring by the regulatory deadlines**
 - States may develop a new plan
- **Or**
- States may note that they will use the same plan as they submitted for Phase II/V
- **Plan must be enforceable under State law**

- 40 CFR 142.16(j)(2) requires that States submit a monitoring plan that ensures all systems will complete the required monitoring by the regulatory deadlines.
 - States may develop a new plan; or,
 - Note that they will use the plan submitted for the Phase II/V Rules. Modifications to the plan to accommodate the new arsenic requirements should be explained.
- The State must also demonstrate that the monitoring plan is enforceable under State law (40 CFR 142.16(j)(2)).

Guidance: Monitoring Plan



- **Can phase-in monitoring over the 3-year compliance period based on system size or source of water**
- **Can require one-third of systems to monitor each year of the 3-year compliance period**

- Some States may choose to phase-in monitoring over the three year compliance period based on system size or source of water. Other States may simply require one-third of their systems to monitor during each year of the three-year compliance period.
- States have the discretion to establish and implement a monitoring plan that, based on specific State and system characteristics, ensures that all systems monitor at the required frequency for the required contaminants.

§142.16(k): New Systems



- **A Primacy Agency must submit initial monitoring requirements for new systems that begin operation after Jan. 22, 2004:**
 - How monitoring schedule will assure drinking water is protective of public health
 - Specify the time frame by which public water system (PWS) must demonstrate compliance

- 40 CFR 142.16(k) requires States to establish initial monitoring requirements for new systems and systems using a new source. According to the Final Arsenic Rule, “new” means a system or source that begins operation after January 22, 2004.
- States must explain their initial monitoring schedules, how these monitoring schedules ensure that new PWSs and systems using a new source will be in compliance with monitoring requirements, and also specify the time frame in which new systems will demonstrate compliance with the MCLs.
- For States that have existing monitoring programs for new systems and for systems that are using a new source, 40 CFR 142.16(k) requires States to explain the monitoring schedule and how the State will ensure that all new systems and systems using a new source will comply with the revised arsenic MCL and monitoring requirements.
- States can determine monitoring schedules for new systems on a case-by-case basis. In their primacy revision applications, States should explain the factors that are considered.

Guidance: New Systems



- **Recommend 1 sample for all contaminants prior to PWS operation**
- **Ensure initial monitoring frequency targets contaminants of concern**
 - Pesticide monitoring: Consider seasonal variation
 - Geologically abundant IOCs

- EPA recommends that States, when developing or modifying an initial monitoring program for new systems and systems using a new source, require systems to sample at least once for all contaminants prior to commencing operation.
- In addition, the monitoring program should reflect the contaminant(s) of concern for that State, known contaminant use, historical data, and vulnerability. Because of varying contaminant uses and sources, some contaminants occur at higher levels in some regions of the country than in other regions. Additionally, the concentrations of some contaminants are known to show clear seasonal peaks, while others remain constant throughout the year.
- For example, some States may be concerned with atrazine and require multiple samples during a specified vulnerable period (e.g., May 1 - July 31), while another State may only require the minimum number required by federal law.
- Alternatively, another State may be concerned about trichloroethylene, because of use, manufacture, or disposal of this solvent, and require four quarterly samples.
- For more information on assessing the potential spatial and temporal distributions of currently regulated contaminants, States are encouraged to consult *A Review of Contaminant Occurrence in Public Water Systems* (EPA 816-R-99-006).

Attorney General's Statement



- **All applications must include AG Statement**
 - Certifying Primacy Agency regs are adopted and enforceable
 - Primacy Agency does not have audit privilege and immunity laws or if they do:
 - They do not prevent Primacy Agency from meeting requirements of the Safe Drinking Water Act (Options in Imp. Guidance)
- **If audit and privilege statement submitted with previous application**
 - Indicate date of previous submittal
 - AG must certify that Primacy Agency audit laws have not changed since the date of that submittal

- The complete and final primacy revision application must include an Attorney General's statement certifying that State regulations were duly adopted and are enforceable (40 CFR 142.12(c)(1)(iii)).
- The Attorney General's statement must certify that the State does not have an audit privilege or immunity law, or, if it has such a privilege or law, that it does not prevent the State from meeting the requirements of the SDWA.
 - An audit privilege or immunity law gives a State enforcement discretion authority. In general, audit privilege and immunity laws grant immunity to regulated entities that uncover, report, and correct environmental problems discovered through self audits. Such a privilege or law may mean that the State does not have regulations at least as stringent as the federal regulations.
- If the Attorney General's certification was submitted with a previous primacy revision package, the State should indicate the date of submittal and the Attorney General needs only to certify that the status of the audit laws has not changed since the prior submittal.
- An example of an Attorney General statement for the Arsenic Rule is included in the Arsenic State Implementation Guidance on EPA's web site at www.epa.gov/safewater.

Bundling State Primacy Packages



- **Combine documentation into one Primacy Revision Application Package for**
 - Arsenic Rule
 - Radionuclides Rule
 - Variance and Exemption Rule
 - Others?

- “Bundling” is the grouping of two or more primacy program revision applications in a single application.
- Based on the Arsenic Rule’s date of promulgation (January 22, 2001), it may be possible for a State to bundle its primacy revision application for the Arsenic Rule with revision applications for other rules, including the Radionuclides Rule, and the Variance and Exemption Rule.

Benefits of Bundling



- **Reason to issue an extension**
- **Limit transactional costs**
 - One document to develop and submit for approval
 - Only have to go to Attorney General once
 - Monitoring plan special primacy requirements for arsenic and radionuclides are similar

- Under 40 CFR 142.12(b)(2)(i), a State may qualify for an extension for its primacy revision application if it is requesting the extension to group two or more program revisions. The State must also demonstrate that it is requesting the extension because it cannot meet the original deadline for reasons beyond its control, despite a good faith effort to do so (40 CFR 142.12(b)(2)).
- EPA is strongly encouraging bundling, because it can save States time and money:
 - The State would need to develop only one document for approval.
 - The State would only need to go to the Attorney General once.
 - If the State bundles rules with similar monitoring requirements (such as the Arsenic Rule and the Radionuclides Rule), the State could combine monitoring schedules.