APA-1

TRANSMITTAL SHEET FOR NOTICE OF INTENDED ACTION

Control 335 Department or Agency **Environmental Management**
Rule No. **335-7-2-.17**
Rule Title: **Cryptosporidium Monitoring and Compliance**
____ New **X** Amend ____ Repeal ____ Adopt by Reference

Would the absence of the proposed rule significantly harm or endanger the public health, welfare, or safety?	**YES**
Is there a reasonable relationship between the state's police power and the protection of the public health, safety, or welfare?	**YES**
Is there another, less restrictive method of regulation available that could adequately protect the public?	**NO**
Does the proposed rule have the effect of directly or indirectly increasing the costs of any goods or services involved and, if so, to what degree?	**NO**
Is the increase in cost, if any, more harmful to the public than the harm that might result from the absence of the proposed rule?	**NO**
Are all facets of the rulemaking process designed solely for the purpose of, and so they have, as their primary effect, the protection of the public?	**YES**

****

Does the proposed rule have an economic impact?	**NO**

If the proposed rule has an economic impact, the proposed rule is required to be accompanied by a fiscal note prepared in accordance with subsection (f) of Section 41-22-23, Code of Alabama 1975.

****

Certification of Authorized Official

I certify that the attached proposed rule has been proposed in full compliance with the requirements of Chapter 22, Title 41, Code of Alabama 1975, and that it conforms to all applicable filing requirements of the Administrative Procedure Division of the Legislative Reference Service.

Signature of certifying officer Marilyn Elliott

Date **March 21, 2016**

APA-2

ALABAMA DEPARTMENT OF ENVIRONMENTAL MANAGEMENT
WATER DIVISION

NOTICE OF INTENDED ACTION

Agency Name: Alabama Department of Environmental Management

Rule No. & Title: 335-7-2-.17 Cryptosporidium Monitoring and Compliance (Amend)

Intended Action: The Alabama Department of Environmental Management proposes to amend rule 335-7-2-.17

Substance of Proposed Action:

The Department proposes to make administrative corrections in this rule.

Time, Place, Manner of Presenting Views:

Comments may be submitted in writing or orally at a public hearing to be held at 1:00 PM, May 13, 2016, in the ADEM Main Hearing Room, 1400 Coliseum Boulevard, Montgomery, Alabama 36110.

Final Date for Comment and Completion of Notice: May 13, 2016

Contact Person at Agency: Christy Monk, (334) 394-4364

Lance R. LeFleur
Director

335-7-2-.17 *Cryptosporidium* Monitoring and Compliance. The requirements of the following subparagraphs apply to all community, NTNC and TNC water systems utilizing surface water and/or ground water under the direct influence of surface water.

(a) Wholesale systems must comply with the requirements of this rule based on the population of the largest system in the combined distribution system.

(b) Systems must conduct the following monitoring on the schedule listed in subparagraph (d) of this rule unless the system will provide a total of at least 5.5-log of treatment for *Cryptosporidium*:

1. Systems serving 10,000 or more people must sample their source water for *Cryptosporidium*, *E. coli*, and turbidity at least monthly for 24 consecutive months.

2. Systems serving fewer than 10,000 people must sample their source water for *E. coli* at least once every two weeks for 12 consecutive months unless the system notifies the Department that it will monitor for *Cryptosporidium* as described in the subnext paragraph (b)3. of this rule. The system must notify the Department no later than 3 months prior to the date the system is otherwise required to start *E. coli* monitoring.

3. Systems serving fewer than 10,000 people must sample their source water for *Cryptosporidium* at least twice per month for 12 consecutive months or at least monthly for 24 months if they meet one of the following conditions based on the *E. coli* monitoring conducted:

(i) For systems using lake/reservoir sources, the annual mean *E. coli* concentration is greater than 10 *E. coli*/100 mL.

(ii) For systems using flowing stream sources, the annual mean *E. coli* concentration is greater than 50 *E. coli*/100 mL.

(iii) The system does not conduct *E. coli* monitoring as described in subparagraph (b)2. of this rule.

(iv) Systems using ground water under the influence of surface water must comply with the requirements of subparagraph (b)3. of this rule based on the *E. coli* level that applies to the nearest surface water body or the system must comply based on the requirements that apply to systems using lake/reservoir sources.

(c) Systems may sample more frequently than required under this rule if the sampling frequency is evenly spaced throughout the monitoring period.

(d) Systems must begin the monitoring required in this rule no later than the month beginning with the date listed in this table:

Population	Begin first round of monitoring by:	Begin second round of monitoring by:
≥ 100,000	October 1, 2006	April 1, 2015
50,000 to 99,999	April 1, 2007	October 1, 2015
10,000 to 49,999	April 1, 2008	October 1, 2016
< 10,000 monitor for *E. Coli*	October 1, 2008	October 1, 2017
< 10,000 & monitor for *Cryptosporidium* *	April 1, 2010	April 1, 2019

* Applies to systems that meet the conditions of subparagraph (~~2~~b)(~~e~~)3. of this rule.

(e) After completion of the second round of source water monitoring, systems must conduct another round of source water monitoring as outlined in this rule every 9 years.

(f) If a system chooses to provide at least 5.5-log treatment for *Cryptosporidium*, rather than start source water monitoring, the system must notify the Department in writing no later than the date the system is otherwise required to submit a sampling schedule for monitoring under this rule. Alternatively, a system may choose to stop sampling at any point after it has initiated monitoring if it notifies the Department in writing that it will provide at least 5.5-log treatment. Systems must install and operate technologies to provide this level of treatment by the applicable treatment compliance date in rule 335-7-6-.20.

(g) Systems with water plants operating only part of the year must conduct source water monitoring in accordance with this rule, but with the following modifications:

1. Systems must sample their source water only during the months that the plant is in operation unless the Department specifies another monitoring period based on plant operational practices.

2. Systems with plants that operate less than six months per year and that monitor for *Cryptosporidium* must collect at least six *Cryptosporidium* samples per year during each of two years of monitoring. Samples must be evenly spaced throughout the period that the plant is in operation.

(h) A system that begins using a new source of surface water or ground water under the influence of surface water or has a ground water source redesignated as ground water under the influence of surface water must begin monitoring according to subparagraph (b) of this rule within 3 months of using the new source or within 3 months of having a ground water source redesignated as under the influence of surface water. These requirements apply to any surface water or ground water under the influence of surface water system that begins operation after the monitoring start date applicable to the system's size in ~~sub~~paragraph (d) of this rule. The water system must begin a second round of source water monitoring no later than six years following the initial bin classification or determination of the mean *Cryptosporidium* level. After the second round of monitoring the water system must begin monitoring required in ~~sub~~paragraph (e) of this rule.

(i) Failure to collect any source water sample required under this ~~section~~ rule in accordance with the sampling schedule, sampling location, analytical method, approved laboratory, and reporting requirements is a monitoring violation.

(j) Systems may use monitoring data collected prior to the applicable monitoring start date in ~~sub~~paragraph (d) of this rule to meet the initial source water monitoring requirements in this rule. This data may be substituted for an equivalent number of months at the end of the monitoring period. All data submitted under this subparagraph must meet the following requirements:

1. The sample results and analysis must have been done according to EPA approved methods and be accepted by the Department.

2. The sampling location must meet the conditions in ~~sub~~paragraphs (r) through (u) of this rule.

3. A system may submit previously collected samples to meet the requirements of ~~sub~~paragraph (d) of this rule even though corresponding *E. coli* and turbidity samples are not available. A system that submits *Cryptosporidium* samples without *E. coli* and turbidity samples is not required to collect additional *E. coli* and turbidity samples when the system completes the requirements for *Cryptosporidium* monitoring.

4. Previously collected *Cryptosporidium* sample data must have been collected no less frequently than each calendar month on a regular schedule, beginning no earlier than January 1999. Sample collection intervals may vary for the conditions specified in ~~sub~~paragraph (n) of this rule if the system provides documentation of the condition when reporting monitoring results.

5. The Department may approve previously collected data where there are time gaps in the sampling frequency if the system conducts additional monitoring, specified by the Department, to ensure that the data used to comply with the initial source water monitoring requirements of ~~sub~~paragraph (d) of this rule are seasonally representative and unbiased.

6. Systems may submit previously collected data where the sampling frequency within each month varied. If the *Cryptosporidium* sampling frequency varied, systems must follow the monthly averaging procedure in subparagraph (x)5. of this rule, as applicable, when calculating the bin classification.

7. Systems that request the use of previously collected monitoring results must report the following information by the applicable dates listed below. Systems serving at least 10,000 people must report this information to EPA and to the Department. Systems serving fewer than 10,000 people must report this information to the Department.

(i) Systems must report that they intend to submit previously collected monitoring results for use. This report must specify the number of previously collected results the system will submit, the dates of the first and last sample,

and whether a system will conduct additional source water monitoring to meet the requirements of this ~~section~~rule. Systems must report this information no later than the date the sampling schedule under ~~sub~~paragraph (d) of this rule is required.

(ii) Systems must report previously collected monitoring results, along with the associated documentation listed below no later than two months after the applicable date listed in ~~sub~~paragraph (d) of this rule for the first round of monitoring.

(I) For each sample result, systems must report the applicable data elements in ~~sub~~paragraph (w) of this rule.

(II) Systems must certify that the reported monitoring results include all results the system generated during the time period beginning with the first reported results and ending with the final reported result. This applies to samples that were collected from the sampling location specified for source water monitoring under this ~~section~~rule, not spiked, and analyzed using the laboratory's routine process for the analytical methods using an EPA approved method.

(III) Systems must certify that the samples were representative of a plant's source water(s) and the source water(s) have not changed. Systems must report a description of the sampling location(s), which must address the position of the sampling location in relation to the system's water source(s) and treatment processes, including points of chemical addition and filter backwash recycle.

(IV) For *Cryptosporidium* samples, the laboratory or laboratories that analyzed the samples must provide a letter certifying that the quality control criteria specified in the methods were met for each sample batch associated with the reported results. Alternately, the laboratory may provide bench sheets and sample examination report forms for each field, matrix spike, initial precision and recovery (IPR), ongoing precision and recovery standard (OPR), and method blank sample associated with the reported results.

(iii) If the Department determines that a previously collected data set submitted for use was generated during source water conditions that were not normal for the system, such as a drought, the Department may disapprove the data. Alternately, the Department may approve the previously collected data if the system reports additional source water monitoring data, as determined by the Department, to ensure that the data set used under ~~sub~~paragraphs (x) and (y) of this rule represents average source water conditions for the system.

(iv) If a system submits previously collected data that fully meets the number of samples required for initial source water monitoring under ~~sub~~paragraph (b) of this rule and some of the data are rejected due to not meeting the requirements of this ~~section~~rule. The system must conduct additional monitoring to replace rejected data on a schedule approved by the Department. A system is not required begin this additional monitoring until two months after notification that data have been rejected and additional monitoring is necessary.

8. Analytical Methods:

(i) *E. coli* sample analysis. The analysis of *E. coli* samples must meet the analytical method and approved laboratory requirements of 40 CFR 141.704 through 141.705.

(ii) *Cryptosporidium* sample analysis. The analysis of *Cryptosporidium* samples must meet the criteria in 40 CFR 141.707(c).

(k) Following the completion of initial source water monitoring under this ~~section~~ rule and each subsequent round of source water monitoring, a system that plans to make a change to its disinfection practice must create a disinfection profile and benchmark as outlined in the rule 335-7-6-.11 and submit the proposed changes along with the disinfection profile to the Department for approval.

1. In lieu of conducting new monitoring for disinfection profiling, systems, with Department approval, may elect to meet the following requirements:

(i) Systems that have at least one year of existing data that is substantially equivalent to data collected under the provisions of rule 335-7-6-.11 may use this data to develop disinfection profiles if the system has neither made a significant change to its treatment practice nor changed sources since the data were collected. Systems may develop disinfection profiles using up to three years of existing data.

(ii) Systems may use disinfection profile(s) previously developed under rule 335-7-6-.11 in lieu of developing a new profile if the system has neither made a significant change to its treatment practice nor changes sources since the profile was developed. Systems that have not developed a virus profile must develop a virus profile using the same monitoring data on which the Giardia lamblia profile is based.

(l) Systems required to conduct source water monitoring under this ~~section~~ rule must submit a sampling schedule that specifies the calendar dates when the system will collect each required sample.

1. Systems must submit sampling schedules no later than three months prior to the applicable date listed in ~~sub~~paragraph (d) of this rule for each round of required monitoring and three months prior to monitoring required under ~~sub~~paragraph (e) of this rule.

2. Systems serving at least 10,000 people must submit their sampling schedule for the initial round of source water monitoring under ~~sub~~paragraph (d) of this rule to EPA electronically. If a system is unable to submit the sampling schedule electronically to EPA, the system may use an alternative approach for submitting the sampling schedule that is approved by EPA.

3. All sampling schedules must be submitted to the Department.

4. If EPA or the Department does not respond to a system regarding its sampling schedule, the system must sample at the reported schedule.

(m) Systems must collect samples within two days before or after the dates indicated in their sampling schedule (i.e. within a five day period around the schedule date) unless one of the following conditions applies:

1. If an extreme condition or situation exists that may pose danger to the sample collector, or that cannot be avoided and causes the system to be unable to sample in the scheduled five-day period, the system must sample as close to the scheduled data as is feasible unless the Department approves an alternative sampling date. The system must submit an explanation for the delayed sampling date to the Department concurrent with the shipment of the sample to the laboratory.

2. If a system is unable to report a valid analytical result for a scheduled sampling date due to equipment failure, loss of or damage to the sample, failure to comply with analytical method requirements, including the quality control requirements or the failure of an approved laboratory to analyze the sample, then the system must collect a replacement sample.

(n) Any replacement samples must be collected no later than 21 days after receiving information that an analytical result cannot be reported for the scheduled date unless the system demonstrates that collecting a replacement sample within this time frame is not feasible or the Department approves an alternative resampling date. The system must submit an explanation for the delayed sampling date to the Department concurrent with the shipment of the sample to the laboratory.

(o) Systems that fail to meet the criteria of ~~sub~~paragraph (n) of this rule for any source water sample required to be collected must revise their sampling schedules to add dates for collecting all missed samples. Systems must submit the revised schedule to the Department for approval.

(p) Systems required to conduct source water monitoring for *Cryptosporidium* must collect samples from each plant that treats surface water or ground water under the influence of surface water. When multiple plants draw from the same influent, such as the same pipe or intake, the Department may approve one set of monitoring results to be used to satisfy the monitoring requirements for all plants.

(q) Systems must collect source water samples prior to chemical treatment, such as coagulants, oxidants, and disinfectants, unless it is not feasible to collect the sample before chemical addition and the chemical treatment is unlikely to have a significant effect on the analysis of the sample, the system may request to collect the sample after chemical addition. The system must receive written approval before taking the samples after chemical addition.

(r) Systems that recycle filter backwash water must collect source water samples prior to the point of filter backwash water addition.

(s) Systems that use bank filtration as pretreatment to a filtration plant must collect source water samples from the well (i.e., after bank filtration). Use of bank filtration during monitoring must be consistent with routine operational practices. Systems collecting samples after a bank filtration process may not receive treatment credit for the bank filtration under rule 335-7-6-.22.

(t) Systems with plants that use multiple water sources, including multiple surface water sources and blended surface water and ground water sources must collect samples as specified below. The use of multiple sources during monitoring must be consistent with routine operational practice.

1. If a sampling tap is available where the sources are combined prior to treatment, systems must collect samples from this tap.

2. If a sampling tap where the sources are combined prior to treatment is not available, systems must collect samples at each source near the intake on the same day and must comply with one of the following for sample analysis:

(i) Systems may composite samples from each source into one sample prior to analysis. The volume of sample from each source must be weighted according to the proportion of the source in the total plant flow at the time the sample is collected.

(ii) Systems may analyze samples from each source separately and calculate a weighted average of the analysis results for each sampling date. The weighted average must be calculated by multiplying the analysis result for each source by the fraction the source contributed to the total plant flow at the time the sample was collected and then summing these values.

(u) A description of the sampling location must be submitted to the Department with the sampling schedule. This description must address the position of the sampling location in relation to the system's water source(s) and treatment processes, including pretreatment, points of chemical treatment, and filter backwash recycle. If the Department does not respond to a system regarding sampling location(s), the system must sample at the reported location(s).

(v) Systems must report results from the source water monitoring required under this ~~section~~ rule to the Department no later than 10 days after the end of the first full month when the sample is collected.

1. All systems serving a population of at least 10,000 must report the results from the initial source water monitoring to EPA electronically no later than 10 days after the end of the month when the sample is collected. If a system is unable to report monitoring results electronically, the system may use an alternative approach that is approved by EPA.

2. Systems must report the following data elements for each *Cryptosporidium* analysis:

Data Element
1. PWS ID
2. Facility ID
3. Sample collection date
4. Sample type (field or matrix spike)
5. Sample volume filtered (L), to the nearest ¼ L
6. Was 100% of the filtered volume examined
7. Number of oocysts

(i) For matrix spike samples, systems must also report the sample volume spiked and estimated number of oocysts spiked. These data are not required for field samples.

(ii) For samples in which less than 10 liters is filtered or less than 100% of the sample volume is examined, systems must also report the number of filters used and the packed pellet volume.

(iii) For samples in which less than 100% of sample volume is examined, systems must also report the volume of resuspended concentrate and volume of this resuspension processed through immunomagnetic separation.

3. Systems must report the following data elements for each *E. coli* analysis:

Data Element
1. PWS ID
2. Facility ID
3. Sample collection date
4. Analytical method number
5. Method type
6. Source type (flowing stream, lake/reservoir, GWUDI)
7. *E. coli*/100 ml
8. Turbidity *

* Systems serving fewer than 10,000 people that are not required to monitor for turbidity under subparagraph (b)2. of this rule are not required to report turbidity with their *E. coli* results.

(w) Following each round of source water monitoring required under this ~~section~~rule, systems must calculate a *Cryptosporidium* bin concentration for each plant for which monitoring was required. Calculation of the bin concentration must use the *Cryptosporidium* results reported under this ~~section~~ rule and must follow the following procedures:

1. For systems that collect a total of at least 48 samples, the bin concentration is equal to the arithmetic mean of all sample concentrations.

2. For systems that collect a total of at least 24 samples, but not more than 47 samples, the bin concentration is equal to the highest arithmetic mean

of all sample concentrations in any 12 consecutive months during which *Cryptosporidium* samples were collected.

3. For systems serving a population less than 10,000 that monitor for *Cryptosporidium* for only one year (i.e., collect 24 samples in 12 months), the bin concentration is equal to the arithmetic mean of all sample concentrations.

4. For systems with plants operating only part of the year that monitor fewer than 12 months per year, the bin concentration is equal to the highest arithmetic mean of all sample concentrations during any year of *Cryptosporidium* monitoring.

5. If the monthly *Cryptosporidium* sampling frequency varies, systems must first calculate a monthly average for each month of monitoring. Systems must then use these monthly average concentrations, rather than individual sample concentrations, in the applicable calculation for bin classification in subparagraphs (x)1. through 4. of this rule.

(x) Systems must determine their bin concentration using the following table and the *Cryptosporidium* bin concentration calculated under subparagraphs (x)1. through 4. of this rule:

For systems that are	**Concentration**	**Bin Classification**
Required to monitor for *Cryptosporidium*	*Cryptosporidium* <0.075 oocysts/L	Bin 1
	0.075 oocysts/L ≤ *Cryptosporidium* < 1.0 oocysts/L	Bin 2
	1.0 oocysts/L ≤ *Cryptosporidium* < 3.0 oocysts/L	Bin 3
	Cryptosporidium ≥ 3.0 oocysts/L	Bin 4
Serving <10,000 population and NOT required to monitor for *Cryptosporidium*	NA	Bin 1

(y) Systems must report each bin classification as required by this rule to the Department for approval no later than 6 months after the system is required to complete source water monitoring based on the schedule in this ~~section~~rule. The bin classification report to the Department must include a summary of source water monitoring data and the calculation procedure used to determine bin classification. Failure to comply with this paragraph is treatment technique violation.

(z) Systems must provide the level of additional treatment for *Cryptosporidium* specified in rule 335-7-6-.19 for the bin classification as determined under this rule and according to the schedule in rule 335-7-6-.20. Systems must provide the level of treatment required in rule 335-7-6-.19 based upon the highest bin classification determined in any round of source water monitoring. Systems that make significant changes to their watershed to lower *Cryptosporidium* levels in the source water, and are not utilizing the watershed

control program to meet treatment requirements, may request to be placed in a lower bin classification if additional monitoring is conducted to ensure the lower bin classification is warranted. The bin reclassification must be based upon monitoring conducted in accordance with subparagraph (b) of this rule. Department approval is required for a system to be placed into a lower bin classification.

(aa) Analytical Methods: Analysis of all samples of *Cryptosporidium, E. coli* and turbidity for requirements contained in this rule shall comply with the approved EPA methodology found in 40 CFR 141.704 and by a laboratory certified by EPA or the Department.

Author: Dennis D. Harrison.
Statutory Authority: Code of Alabama 1975, §§ 22-23-33, 22-23-49, 22-22A-5, 22-22A-6.
History: January 22, 2008.
Amended: May 26, 2009; January 18, 2011; XXXX XX, 2016.