

RESPONSE TO COMMENTS – LABORATORY CERTIFICATION REGULATIONS: 310 CMR 42.00

November 4, 2016

310 CMR 42.05(1)(b)			
Existing Regulation: List of certified matrices includes “Cyanide” for potable water.			
	COMMENT	RESPONSE	COMMENTER
1	Total Cyanide and Available Cyanide should be separated out on the list of certification matrices, disciplines and categories. Further, the Department should offer certification for Free Cyanide.	The comment has been noted. However, MassDEP did not propose a change to this specific section of the regulation and thus it is not subject to revision at this time. It should be noted that federal drinking water regulations at 40 CFR Part 141 are written for “cyanide”, not for the individual cyanide species.	Mike Delaney (MWRA)
310 CMR 42.08(3)(g)			
Existing Regulation: <u>Reagents, Standards, Media</u> : Consumable supplies, such as, but not limited to, reagents, standards and media must not be used beyond their expiration date.			
	COMMENT	RESPONSE	COMMENTER
2	In order to conserve resources, minimize waste and assist in pollution prevention, I suggest using the NELAC/TNI approach to the expiration of reagents and standards found in 5.5.6.4 a) of the 2003 NELAC standard which states "The laboratory shall retain records for all standards, reagents, reference materials and media including the manufacturer/vendor, the manufacturer's Certificate of Analysis or purity (if supplied), the date of receipt, recommended storage conditions, and an expiration date after which the material shall not be used unless its reliability is verified by the laboratory."	The comment has been noted. However, MassDEP did not propose a change to this specific section of the regulation and thus it is not subject to revision at this time. For clarification: The reliability of standards and reagents, beyond their expiration date, is uncertain. Analyses performed using expired standards, reagents or supplies result in data that may not be legally defensible. The MassDEP Laboratory Certification Program is designed, in part, to ensure that laboratory practices are followed that result in the production of analytical data usable for compliance assessment and/or enforcement purposes.	Don D’Anjou (Granite State Analytical Laboratory)
310 CMR 42.08(5)(a)6a			
Proposed Regulation: “For instruments with a calibration curve that has been set by the instrument manufacturer, the laboratory shall verify the calibration curve using a minimum of three calibration check standards that bracket the expected concentration range. The check standards shall represent low, medium, and high concentrations and include a standard at the minimum reporting level (MRL). If the result of the calibration check does not agree within 10% of the assigned value of each check standard, instrument recalibration must be performed.”			

Earlier in the regulations, the MRL is defined as: "Minimum Reporting Level means the minimum concentration that can be reported as a quantitated value for a target analyte in a sample following analysis."

	COMMENT	RESPONSE	COMMENTER
3	<p>This requirement is excessive. It should be handled more like an initial calibration/continuing calibration approach. The factory calibration serves as the initial calibration and the check standard serves as a continuing calibration. If the continuing calibration works, the instrument is still working.</p> <p>Also, the 10% requirement at the Minimum Reporting Level (MRL) is too tight. What is the basis for this requirement? The EPA LCMRL approach uses a 50% requirement at the MRL.</p>	<p>MassDEP maintains that the 10% limit for the check standards is appropriate. Analysis of quality control samples across the calibration range of the instrument permit the analyst to use a calibration that has been pre-set by the manufacturer. Use of the pre-set calibration is intended to be applicable only in circumstances where the instrument has demonstrated exceptionally consistent response and linearity. Limits of 10% are cited for the determination of the dynamic range of instruments in the 21st edition of <i>Standard Methods for the Examination of Water and Wastewater</i> Section 4020B.1c. Section 4020B.2b of the 22nd edition of <i>Standard Methods</i> requires limits of 10%, over the calibration range, for calibration verifications. Use of a single continuing calibration standard, at the mid-point, would not provide documentation regarding the slope of the manufacturer's calibration. A single mid-point standard could be found to fall within acceptance criteria, while the termini of the calibration have shifted resulting in data of suspect quality.</p> <p>A failure of the calibration check samples requires that the laboratory prepare and analyze daily calibration standards. Daily calibration would be appropriate for a method that demonstrates variability at points within the working range of the instrument.</p> <p>310 CMR 42.08(5)(a)6ai requires that all instruments be calibrated immediately prior to analysis using a blank and three calibration standards that bracket the expected concentration range. The proposed regulation is intended to permit an exception to this requirement only in the event that an instrument, programmed by the manufacturer, has exhibited exceptionally stable performance.</p>	Michael Delaney (MWRA)

310 CMR 42.08(5)(a)1.d

Existing Regulation: Record Maintenance: The record maintenance procedures section of a laboratory's QA Plan shall include the procedures for creating, controlling, and maintaining the following records:

- i. Raw data (including, but not limited to, laboratory notebooks, instrument printouts, and electronic records);
- ii. Chain-of-custody records;
- iii. Calculations;
- iv. Quality control data; and
- v. Reports

	COMMENT	RESPONSE	COMMENTER
4	The section should define specifically which equipment requires a maintenance logbook.	The comment has been noted. However, MassDEP did not propose a change to this specific section of the regulation and thus it is not subject to revision at this time. For clarification, the laboratory's QA Plan must list all major pieces of analytical and support equipment in use and that have corresponding maintenance logbooks.	Mike Delaney (MWRA)

310 CMR 42.08(5)(a)6.d.ii

Existing Regulation: An in-line meter may be used to check reagent-grade water provided that it is calibrated annually.

	COMMENT	RESPONSE	COMMENTER
5	The section should be moved to 310 CMR 42.08(5)(c)12 because it applies to the reagent-grade water system.	The comment has been noted. However, MassDEP did not propose a change to this specific section of the regulation and thus it is not subject to revision at this time. For clarification: The reagent water requirements at 310 CMR 42.08(5)(c)12 apply to water to be used in microbiological analyses. 310 CMR 42.08(5)(a)6.d.ii specifies the requirements for conductivity meters under the general quality assurance/quality control requirements for the laboratory. Inclusion of the regulation in the general requirements section of the regulations is appropriate as it specifies that the regulation applies to the use of conductivity meters used to monitor the reagent grade water system in both the microbiological and chemistry laboratories.	Mike Delaney (MWRA)

310 CMR 42.08(5)(a)7e			
Existing Regulation: Designates the information that is required to be included on a chain-of-custody form.			
	COMMENT	RESPONSE	COMMENTER
6	This section on Sample Collection, Preservation and Handling should be revised to allow new, electronic, paperless technology.	The comment has been noted. However, MassDEP did not propose a change to this specific section of the regulation and thus it is not subject to revision at this time. For clarification, the current regulation does not prohibit the use of electronic, paperless technology. The section indicates that the information must be included, but does not specify how the information is to be maintained.	Mike Delaney (MWRA)
310 CMR 42.08(5)(b)1e			
Proposed Regulation: Designates the information required in the event that manual integrations are used for a chromatogram.			
	COMMENT	RESPONSE	COMMENTER
7	This new section on integrating chromatographic peaks is a good addition to improve data integrity. It should be revised to explicitly allow maintaining electronic documentation of integrations.	The proposed regulation does not prohibit the use of electronic documentation.	Mike Delaney (MWRA)
310 CMR 42.08(6)			
Proposed Regulation: Requires annual ethics training for all laboratories.			
	COMMENT	RESPONSE	COMMENTER
8	MWRA endorses this new requirement on annual laboratory ethics training. MassDEP should give some guidance on how much training time is expected to be needed to cover the required topics.	Laboratories may develop in-house training or use resources available on the internet to meet this requirement. There are a number of Power-point presentations that may be downloaded from the internet for free and used by any laboratory. It is not necessary for laboratory staff to attend fee-based training classes or hire a third party to provide this training. The amount of training required, and the content, will vary significantly from full, fee-for-service laboratories to single employee, single analyte process-control laboratories. Because of this variability, the amount of time required to provide this training would likely range from 1 to 3 hours.	Mike Delaney (MWRA)
9	MWWA suggests that for municipal laboratory personnel the only required ethics training should be the bi-annual training required by the state under Chapter 28 of the Acts of 2009, the ethics reform law. Since this law already imposes education and training requirements on public employers and public employees regarding ethics and conflict of interest, it would be costly for communities to have their employees undergo two different kinds of ethics training. MWWA requests MassDEP amend this section to specify that	The state ethics training applicable to municipal public laboratory employees, mandated by Chapter 28 of the Acts of 2009, does	Jennifer Pederson (MWWA)

	<p>municipal laboratory personnel will only have to comply with Chapter 28 of the Acts of 2009 to be in compliance with this section of the regulations.</p>	<p>not address the unique nature of the laboratory environment where data integrity is essential. Although state ethics training is important, it is general in nature and focuses on acceptance of gifts, or conflicts of interest relating to employment. For drinking water analyses, laboratory practices can have direct and serious ramifications with respect to public health. There is immense pressure for laboratory analysts and management staff to produce data quickly and cost effectively. Further, pressure exists to report results that are free of reported quality defects and that fall within regulatory requirements. In Massachusetts, there have been at least 8 documented cases in both the public and private sector of laboratory staff (or water supply operators) manipulating data or samples to make it appear that regulatory requirements were met, when in fact they were not. This section ensures that all laboratory employees are routinely reminded, through training, that the integrity of the laboratory data and protection of human health are of the utmost importance. It is essential that laboratory staff be provided with ethics training that covers the types of actions that may be considered fraudulent, or otherwise improper in a laboratory setting.</p>	
10	<p>Regarding Section 310 CMR 42.08(6), we appreciate that the proposed amendment is written to allow for laboratories to create and conduct laboratory ethics training programs in-house. We ask that the final language of the revised CMR maintains the ability for certified laboratories to create and conduct these training programs in-house. As a small business, it would likely be a significant expense if the logistics of the training program required the use of a third party.</p>	<p>Laboratory ethics training typically includes the following situations/practices:</p> <ul style="list-style-type: none"> • Fabrication, falsification, or misrepresentation of data; • Improper clock setting (time traveling) or improper date/time recording; • Unwarranted manipulation of samples, software, or analytical conditions; • Misrepresenting or misreporting QC samples; • Concealing a known analytical or sample problem; • Concealing a known improper or unethical behavior or action; and • Failing to report the occurrence of a prohibited practice or known improper or unethical act to the appropriate 	<p>Zach Lovatt (Northeast Environmental Laboratory, Inc.)</p>

		<p>laboratory or contract representative, or to an appropriate government official.</p> <p>The National Environmental Laboratory Approval Program (NELAP), administered by The NELAC Institute (TNI) requires annual ethics training for all laboratories. Annual ethics training for laboratory staff is the national standard.</p> <p>The EPA <i>Manual for the Certification of Laboratories Analyzing Drinking Water</i>, Supplement 1 to the Fifth Edition encourages laboratories to have an ethics policy and implement a fraud detection and deterrence policy/program. These MA state requirements in 310 CMR 42.08(6) support and conform to this EPA position.</p>	
<p>310 CMR 42.08(5)(c)11.a Existing Regulation: When quality control samples are available, each analyst shall analyze at least one quality control sample per year for the categories to be certified.</p>			
	COMMENT	RESPONSE	COMMENTER
11	<p>This section should be clarified to indicate what kind of quality control samples are required and whether these are separate from the proficiency test samples used to maintain certification.</p>	<p>The comment has been noted. However, MassDEP did not propose a change to this specific section of the regulation and thus it is not subject to revision at this time.</p> <p>For clarification: Quality control samples may be any “known” samples included in an analytical batch, or proficiency test samples. While proficiency test samples would meet the regulatory requirement, it is not necessary for each analyst to perform a proficiency test study.</p>	<p>Mike Delaney (MWRA)</p>
<p>310 CMR 42.12 Proposed Regulation: Major addition – Regulates specific situations or circumstances where certification could be downgraded or revoked.</p>			
	COMMENT	RESPONSE	COMMENTER
12	<p>MWRA endorses the major revisions to this section. These are important revisions needed to deal with the small number of laboratories that might try to take advantage of the certification process for unreasonable financial gain.</p>	<p>310 CMR 42.12(2)(a)2 and 310 CMR 42.12(3)(a)2 [as well as 310 CMR 42.13(5)] all include language regarding the timely reporting of data for compliance samples. A number of options have been discussed and discarded by the MassDEP Laboratory Advisory</p>	<p>Mike Delaney (MWRA)</p>

	<p>However, MassDEP needs to be sensitive to honest laboratories that might have difficulty getting paid by some clients or primary laboratories. If laboratories are obliged by this regulation to always submit their lab reports to clients, primary laboratories or regulators, they might lose their leverage to get paid. Timely reporting should always be required when there are MCL violations, but MassDEP shouldn't take away a laboratory's ability to do business in situations that aren't MCL violations. Once a laboratory has sent the report, it can have difficulty getting paid for this service.</p>	<p>Committee, in an attempt to ensure that compliance data are not held hostage at laboratories for any reason. Laboratories have been found to hold data for any number of reasons including internal management issues at the laboratory, or payment issues with sub-contractors or other entities. This is problematic for the MassDEP Drinking Water Program with respect to the monitoring of public water supply safety. It has also been a problem for drinking water system operators. Data that included an MCL violation have been held for lack of payment from a sub-contract laboratory. The intent of the regulation is to promote (and enforce if necessary) communication and cooperation among the laboratory, public water suppliers/water supply operators, and any laboratories performing compliance analysis work.</p>	
13	<p>310 CMR 42.12(3)(a)2-Proposed regulation relating to causes for revocation of certification specifically "Failure to report compliance data to a public water system, the Department, or other responsible party in a timely manner or interfering with the reporting of such data produced by other entities. "In a timely manner" is very vague. We note that even within the Department, the definition of timely is not consistent from region to region. Further, it is not the responsibility of the laboratory to report to the Department. It is strictly the public water supply's responsibility.</p>	<p>The current regulation at 310 CMR 42.13(5) does specify that all MCL exceedances must be reported within 24 hours. The regulations are silent as to any reporting requirements in the event that samples are not found to have MCL violations. There are no current regulations that prohibit laboratories from accepting samples for analysis and then holding analytical data for a prolonged period. However, failure to report compliance data within required timelines, whether or not there is an MCL violation, prevents compliance with Federal and State regulations, interferes with MassDEP's oversight of public water supplies, and thereby has the potential to endanger public health.</p>	<p>Bob Bentley (Analytical Balance Corporation)</p>
14	<p>42.12(2)(a)2.; 42.13(5)(d) and similar - The intention to force laboratories to produce data where financial obligations have not been met either by the water system or by the primary laboratory would result in the further degradation of the financial stability of the laboratory community. A mechanism with which to report non-payment issues to MassDEP in order to expedite payment and data release might be warranted. (Also as previously mentioned in the LAC meeting, "timely manner" must be defined).</p>	<p>The EPA <i>Manual for the Certification of Laboratories Analyzing Drinking Water</i> (fifth edition) includes the following statement in Section 14.3 of Chapter III: A laboratory should be downgraded from certified, provisionally certified or interim certified status to "not certified" for a particular contaminant analysis for the following reasons:</p> <ul style="list-style-type: none"> • Reporting proficiency testing (PT) data from another 	<p>Don D'Anjou (Granite State Analytical)</p>

		<p>laboratory as its own;</p> <ul style="list-style-type: none"> • Falsification of data or other deceptive practices; • Failure to use the analytical methodology specified in the regulations; • For provisionally certified laboratories, failure to successfully analyze a PT sample or any other unknown test sample for a particular contaminant within the acceptance limits specified; • For provisionally certified laboratories, failure to satisfy the Certification Authority that the laboratory has corrected deviations identified during an on-site evaluations; • For provisionally certified laboratories, persistent failure to report compliance data to the public water system or the State drinking water program in a timely manner thereby preventing compliance with Federal and/or State regulations and endangering public health. Data which may cause the system to exceed an MCL should be reported as soon as possible. • Refusal to participate in an on-site evaluation conducted by the Certification Authority. <p>Note that the reasons include failure to report analytical data in a timely manner.</p> <p>This regulation does put additional responsibility on the certified laboratory. Other business options, such as cash on delivery of samples, prior to accepting work from problem clients, could be considered to reduce this burden. The laboratory's contract with the public water supplier should specify reporting timelines. The laboratory is under no obligation to accept samples from entities that have a poor payment history; however, in the event that samples are accepted, the laboratory has also accepted the responsibility for reporting the analytical data in accordance with</p>	
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		<p>required timelines.</p> <p>The following minor regulation revision will be included to clarify the intent of the regulations and alleviate concerns relating to the phrase “timely manner”: for 310 CMR 42.12(2)(a)2 and 310 CMR 42.12(3)(a)2, change the phrase “timely manner” to “in a manner so as to meet prescribed reporting timelines”.</p>	
<p><u>310 CMR 42.13(5)(a) and 310 CMR 42.13(5)(b)</u> Modification of Existing Regulations:</p> <p><u>310 CMR 42.13(5)(a)</u>: Following completion of sample analysis, a certified laboratory shall notify its clients of the results of all samples that exceed any EPA- or Department-established maximum contaminant level (MCL), maximum residual disinfectant level, or reportable concentration or that identify the presence of microbiological organisms in potable water. Notification must clearly indicate that a regulatory limit has been exceeded. The date, time, and manner of notification must be documented and kept on file.</p> <p><u>310 CMR 42.13(5)(b)</u>: A laboratory that accepts potable water samples for analysis must notify its client public water system of the results of all samples that exceed a regulatory limit. Such notification must be given within 24 hours of the analysis of the sample whether or not the laboratory accepting the sample subcontracted the analysis to another laboratory.</p>			
	COMMENT	RESPONSE	COMMENTER
15	<p>310 CMR 42.13(5)(a) – This is a broad statement in that it does not call out any MCL violation but merely states microbiological organisms. Since laboratories can and do analyze for more than coliform and <i>E. coli</i> (e.g., heterotrophic plate count, <i>Pseudomonas</i>, iron bacteria, amongst others), it seems that this statement needs to be more specific. We note that presently (under 310 CMR 22), even coliform does not constitute an MCL violation but would seemingly need to be reported to our clients under this dictum.</p>	<p>The revised regulations removed the specification to report “within 24 hours of obtaining valid data”; the revised regulations also added Section 310 CMR 42.13(5)(f), which specifies that preliminary data, or data for which data quality objectives were not met, must be reported with a case narrative describing any factors affecting data usability.</p> <p>Validation of analytical data for <u>routine</u> samples (i.e., those not indicating an MCL exceedance) may take place over the course of several days. However, for samples associated with an MCL exceedance for a public water supply, public health may be placed at risk while waiting for analytical data to undergo routine final validation and release. Laboratories that choose to accept drinking water samples must have in place procedures to identify potential MCL exceedances in real time, and then expedite the</p>	<p>Bob Bentley (Analytical Balance Corporation)</p>
16	<p>310 CMR 42.13(5)(a); 42.13(5)(b) – Many chromatographic methods are sufficiently complex that validating data within 24 hours of sample analysis (injection) may not be routinely achievable. Consequently, the previous language "Within 24</p>	<p>Validation of analytical data for <u>routine</u> samples (i.e., those not indicating an MCL exceedance) may take place over the course of several days. However, for samples associated with an MCL exceedance for a public water supply, public health may be placed at risk while waiting for analytical data to undergo routine final validation and release. Laboratories that choose to accept drinking water samples must have in place procedures to identify potential MCL exceedances in real time, and then expedite the</p>	<p>Don D’Anjou (Granite State Analytical)</p>

	<p>hours of obtaining valid data" should be restored in order to avoid rushes to judgment and potential false positives or negatives by a laboratory trying to meet a 24-hour deadline without fully validating the data. Additionally, it may be an unnecessary burden to impose upon the laboratories the requirement to notify its clients of any and all MCL violations within 24 hours of sample analysis unless the violation is an acute risk to the public (i.e., <i>E. coli</i>, nitrate, nitrite) where 24-hour notification obviously must be mandatory.</p>	<p>validation and reporting of the exceedance analytical data within 24 hours of the completion of analysis; expedited data validation and reporting can be completed within a regular 8-hr workday even for the most complex analytical methods.</p> <p>Laboratories do not regulate water supplies and cannot determine the MCL violations that constitute risks to the public, and those that do not. Laboratories do not possess the complete history of a water supply, or the susceptibility of the population served. The impact of an MCL violation is determined by the Department and therefore it must be reported as soon as possible, consistent with the EPA <i>Manual for the Certification of Laboratories Analyzing Drinking Water</i> (fifth edition) (see above) and the Department's responsibilities under the Federal Safe Drinking Water Act.</p> <p>To address commenter's concerns, the following revised language will be included in the amended regulations:</p> <p><u>310 CMR 42.13(5)(a)</u> Upon obtaining valid data, a certified laboratory shall notify its clients of the results of all samples that exceed any EPA- or Department-established maximum contaminant level (MCL), maximum residual disinfectant level or reportable concentration, or that identify the presence of regulated microbiological organisms in potable water. Notification must clearly indicate that a regulatory limit has been exceeded. The date, time, and manner of notification must be documented and kept on file.</p> <p><u>310 CMR 42.13(5)(b)</u> A laboratory that accepts potable water samples for analysis must notify its client public water system of the results of all samples that exceed a regulatory limit. Data indicating exceedances of regulatory limits must be validated and the</p>	
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		<p>validated data reported as soon as possible, not to exceed 24 hours after the completion of sample analysis. Such notification must be given within 24 hours of the completion of analysis of the sample, whether or not the laboratory accepting the sample subcontracted the analysis to another laboratory.</p> <p><u>Rationale for these revisions to the amended regulations:</u> Proposed changes to 310 CMR 42.13(5)(a) include addition of “regulated” to the microbiological reporting requirements to clarify that only regulated organisms must be reported to the Department. The phrase “following completion of sample analysis” has been removed from this section and restored to “obtaining valid data”; however, a cap on the amount of time permitted (i.e., 24 hours) to determine that data are valid and report the validated data has been added to 310 CMR 42.13(5)(b).</p> <p>Proposed changes to the amended 310 CMR 42.13(5)(b) specify that data are to be validated and reported within 24 hours of the completion of sample analysis. For protection of public health, an extended period of time for data validation beyond that indicated is not appropriate for compliance samples where an MCL exceedance exists.</p>	
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310 CMR 42.13(5)(d)
Proposed Regulation: Laboratories accepting samples to be analyzed for the purpose of determining regulatory compliance must ensure that analytical data are reported in a timely manner to meet their clients’ reporting requirements. A laboratory that has had regulatory compliance samples subcontracted to it by another laboratory must release analytical data to the client laboratory before the client laboratory’s reporting deadline.

	COMMENT	RESPONSE	COMMENTER
17	If a lab subcontracts samples to another laboratory with little time left before the client deadline, the sub lab may not have sufficient time to analyze the sample before the due date. Labs often subcontract samples at the last minute due to instrument issues or holding time constraints. This wording could leave the sub lab at fault if the original lab does not	Reporting timelines must be arranged between laboratories at the time that samples are subcontracted. In the event that a subcontract laboratory is unlikely to meet the client laboratory’s reporting deadline, the terms of the contract must clearly state the timeline that will be met. The client laboratory is then free to accept the terms, and thereby accept responsibility for the	Kimberly LaPlante (Eurofins Spectrum Analytical Laboratory)

	<p>give the sub lab enough time to complete the analysis before the client deadline.</p>	<p>missed timeline, or to negotiate with other laboratories that may be able to meet the original timeline requirement.</p> <p><u>Language changes to the amended 310 CMR 42.13(5)(d):</u> Laboratories accepting samples to be analyzed for the purpose of determining regulatory compliance must ensure that analytical data are reported in a timely manner to meet their clients' reporting requirements. A laboratory that has had regulatory compliance samples subcontracted to it by another laboratory must release analytical data to the client laboratory within the timeline arranged by the laboratories.</p> <p><u>Rationale for revision of amended regulations:</u> The proposed change more clearly indicates that the primary laboratory is responsible for ensuring that timelines are met; however, the sub-contract laboratory must release data to the primary laboratory within agreed upon timelines. It is not an acceptable practice to hold data beyond the contract specified timelines.</p>	
<p>310 CMR 42.13(5)(f) Proposed Regulation: Preliminary data and data for which data quality objectives were not achieved must be accompanied by a case narrative describing quality control outliers or any other factors affecting data usability.</p>			
	<p>COMMENT</p>	<p>RESPONSE</p>	<p>COMMENTER</p>
<p>18</p>	<p>MassDEP should not allow certified laboratories to “cherry pick” what results they report to their clients, but this section is too vague to achieve that goal. It needs to be removed or carefully rewritten.</p>	<p>The data impacted by this regulation are solely those where the data are preliminary, or have a data quality outlier, and they are reported (e.g., notification of a potential MCL exceedance). The regulation requires that such data be flagged; it does not require that all lab data be reported. For example, a laboratory that invalidates an analytical batch, due to quality control failures, need not report such data in the event that the sample is re-analyzed and the subsequent analysis shows no such data quality concerns. This disclosure permits the end user of the data to consider the reliability of the data, prior to taking action based upon them.</p>	<p>Mike Delaney (MWRA)</p>
<p>19</p>	<p>It is not clear why the Department is asking for a case narrative on preliminary data which most likely is not being reported. Preliminary data is just that – preliminary. We suggest that this is overly broad.</p>		<p>Bob Bentley (Analytical Balance Corporation)</p>

		The following minor language revision will be added to clarify the intent of this regulation: If preliminary data, or data for which data quality objectives were not achieved are reported, they must be accompanied by a case narrative describing quality control outliers or any other factors affecting data usability.	
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310 CMR 42.13(10)(b)
Proposed Amendment to Existing Regulation: A Department-certified laboratory must supply a copy within 30 **calendar** days of receipt of documents from its director, supervisor, and owner holding greater than 5% equity. The documents include a citation of violations or settlement agreement issued by any local, state, or federal government agency naming the individual and documents evidencing a civil or criminal conviction of that individual involving operations of any other environmental laboratory certified or accredited by EPA or any state. The Department-certified laboratory must ensure that its director, supervisor, and owner are required to submit a copy to it within 30 **calendar** days of receipt of such documents by the individual.

The amendment to the regulation clarifies that notification is to be made within 30 **calendar** days. No additional requirements were made to the types of documents to be provided to the Department.

	COMMENT	RESPONSE	COMMENTER
20	This is a very broad statement. If a laboratory was to receive a notice from the Internal Revenue Service about underpayment of taxes, for example, it seems that the department is interested in this although the relevance to the laboratory's certification is specious. Further, if an OSHA inspection report mentioned that a laboratory had restrooms having round rather than U-shaped toilet seats, it seems the Department would also be interested in this while this obviously has no relevance to the laboratory's certification. If a laboratory were to hire a new director or supervisor who had a citation in the past five years, is this considered a requirement? If the supervisor merely worked at a laboratory which was cited but was not named, is this a requirement?	The comment has been noted. However, MassDEP's only change to this specific section of the regulation was to clarify that the 30-day timeline should be counted using calendar days. Thus, the only comments that may be considered at this time would be related to the addition of the calendar day clarification to the 30-day timeline.	Bob Bentley (Analytical Balance Corporation)

310 CMR 42.12(2)(a)5 and 6 and 310 CMR 42.12(3)(a)10 and 12
Proposed Regulations: These proposed sections indicate that reporting sample results for analyses for which the laboratory is certified, without indicating whether or not the analyses were conducted in accordance with Department Certification standards, may result in downgrading of certification status.

	COMMENT	RESPONSE	COMMENTER
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21	In Section 42.01(2), the section states that all analyses are assumed to have been conducted in accordance with the certification standards unless there is a statement to the contrary. It seems that section 42.01(2) renders the associated sections in 310 CMR 42.12 and 310 CMR 42.13 unnecessary.	The regulations cited serve different purposes: 40 CFR 42.01(2) is the applicability section of the regulations. 310 CMR 42.12(2)(a)5 and 6 as well as 310 CMR 42.12(3)(a)10 and 12 provide clarification, and regulatory authority, as to the actions that may be taken by the Department in the event that laboratories do not clearly indicate where analyses were performed in compliance with 310 CMR 42.00, and where they were not.	Bob Bentley (Analytical Balance Corporation)
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310 CMR 42.13(6)

Proposed Amendment to Existing Regulation: The amendment adds the following language: Changes affecting the availability of properly operating equipment to perform analyses for which the laboratory is certified must be reported in writing to the Department within seven calendar days of the change.

	COMMENT	RESPONSE	COMMENTER
22	Please clarify how long of a time frame must equipment be down before MassDEP is notified? For example, if a lab has one ICP/MS instrument and it goes out of service for 1 day; does that require notification? Seven days before notification?	<p>The proposed regulations required notification of circumstances where an instrument is, or will be, out of service for an extended period of time. There are no notification requirements for an instrument being out of service for fewer than seven calendar days.</p> <p>The proposed regulation amendment requires clarification, as the intent is not clearly communicated. Instruments routinely go out of service for a few days for routine maintenance or repairs. Due to scheduling issues and the cost of rush service, it is possible that an on-site visit for a service technician may not be scheduled within seven calendar days.</p> <p>The proposed revision of the amendment to the regulation extends the period of time which an instrument may be out of service to 14 days. The revised language also clarifies that the timeline begins at the time that the instrument first went out of service.</p> <p>The following language revision will be added to clarify the intent of this regulation: Changes affecting the availability of properly operating equipment to perform analyses for which the laboratory is certified, where the equipment has been, or will be,</p>	Kimberly LaPlante (Eurofins Spectrum Analytical Laboratory)

		unavailable for a period of 14 calendar days or more, must be reported in writing to the Department within 14 calendar days of the onset of the change to the instrument's operational status.	
310 CMR 42.17(2)(a)			
Proposed Regulation:			
<u>Violations.</u> Without limitation, it shall be a violation of 310 CMR 42.00 for any person to:			
(a) Fail to comply with any order of the Department.			
	COMMENT	RESPONSE	COMMENTER
23	I recommend appending language for clarification to "Fail to comply with any order of the Department" such as "pursuant to the implementation of the requirements of 310 CMR 42.00". The original statement appears too all encompassing and could lead to abuse of power.	This is standard language added to all MassDEP regulations by the MassDEP Office of General Counsel (OGC). Note that orders issued by MassDEP are subject to appeal if their scope or findings are perceived to be excessive.	Don D'Anjou (Granite State Analytical)
310 CMR 42.20(5)(b)			
Proposed Regulation: For acceptance limits of proficiency test samples....± 30 percent of the true value for chlorite; and ± 30 percent of the true value for bromated.			
	COMMENT	RESPONSE	COMMENTER
24	Bromated should be "bromate".	This is a typographical error that will be corrected.	Mike Delaney (MWRA)