ENVIRONMENTAL PROTECTION

COMPLIANCE AND ENFORCEMENT

OFFICE OF QUALITY ASSURANCE

Notice of Action on Petition for Rulemaking

N.J.A.C. 7:18-5.5

Regulations Governing the Certification of Laboratories and Environmental Measurements

Request for Amendments to the Requirements for Quality Assurance/Quality Control Program

Petitioner: David A. Bossie for In-Situ, Inc.

Take notice that the Department of Environmental Protection (Department) has determined to deny the petition for rulemaking described below, filed by David A. Bossie (petitioner) and received by the Department on March 27, 2017. Notice of receipt of the petition was published in the May 15, 2017, New Jersey Register (49 N.J.R. 1251(a)).

The Petition

The petitioner requests that the Department amend the Regulations Governing the Certification of Laboratories and Environmental Measurements, N.J.A.C. 7:18 (Laboratory Certification Rules). Specifically, petitioner requests that the Department amend N.J.A.C. 7:18-5.5(c)1 regarding quality control checks for dissolved oxygen instruments to allow the calibration of optical dissolved oxygen sensors to be checked less frequently than the calibration of membrane-based dissolved oxygen sensors. The existing rule provides:

(c) A laboratory performing chemical testing shall conduct the quality control checks specified in the applicable [Department Sanctioned Analytical Methods], and the following additional checks:

1. The laboratory shall calibrate dissolved oxygen instruments against air or air saturated water before each use or weekly, whichever is less frequent. The laboratory shall test dissolved oxygen instruments weekly using the Winkler method (azide modification) 4500-OC set forth in SM-18 or ASTM method D88-92(A), or another Winkler method promulgated by the [US Environmental Protection Agency].

N.J.A.C. 7:18-5.5(c)1.

The petitioner claims that the existing rule is antiquated and was designed to identify inaccurate instruments that use membrane technology to measure dissolved oxygen. The petitioner states that the membrane, or Clark Cell, method uses a thin, flexible membrane that is notorious for undergoing surface-chemistry changes, and that these changes necessitate frequent calibration and quality assurance checks. In contrast, petitioner indicates that dissolved oxygen sensors that use optical technology (such as those that petitioner's company manufactures and sells or rents) are extremely stable, and that validation studies demonstrate changes in calibrations of as little as <0.1 mg/L over one year, which is the recommended calibration period for such devices. The petitioner states that the Winkler method (a titration used to check that a dissolved oxygen sensor is properly calibrated) has associated errors that can lead to greater uncertainty than the optical dissolved oxygen sensor. Petitioner indicates that weekly tests of optical dissolved oxygen sensors are unnecessary and a waste of environmental consultant time

and resources. Petitioner suggests that tests of optical dissolved oxygen sensors be required quarterly, rather than weekly.

The petitioner asserts that one goal of the petition is the reduction of waste. Petitioner states that the proposed amendment will help alleviate the waste associated with performing Winkler titrations, which is not limited to the small amount of physical waste from the reagents used in the titration, but includes the waste associated with the entire quality assurance process. Petitioner indicates that a New Jersey environmental consultant already has a significant paperwork load associated with complying with New Jersey Administrative Code requirements, and that lessening this paperwork is one type of reduction of waste, albeit a small one. Further, petitioner states that when a weekly Winkler titration is required, every week petitioner's company must perform the titration and ship the dissolved oxygen sensor to its customers overnight, which wastes fuel, time and money. Petitioner asserts that the waste of fuel is significant: a truck must drive to In-Situ, Inc. in Colorado, then drive the package to the airport where a plane flies it to New Jersey; another truck then takes the package from the airport to the customer's office. Petitioner claims that the time a consultant spends getting the weekly dissolved oxygen sensor delivery and then driving to the worksite and installing the new sensor is time that could be better spent on work that will have a more lasting, valuable environmental impact.

Petitioner's other stated reason for requesting amendment to the rules is to reduce the financial burden the regulation places on In-Situ, Inc., and its New Jersey customers. Petitioner states that this financial burden would be worthwhile if the Winkler titration added any value to the quality control process for optical dissolved oxygen sensors; however, it adds nothing when the sensor uses optical technology.

Petitioner provides suggested rule language to implement the requested amendment, and asserts that the Department has adequate statutory authority to make the amendment requested.

The Department's Response to the Petition

The Department does not agree with the petitioner that the rule amendment presented in the petition will achieve the goals that petitioner enumerates, which are improving environmental protection, reducing waste, and reducing the financial burden on certified laboratories in New Jersey. Rather, the Department finds that changing the frequency with which the Winkler titration is performed to test the sensor to a frequency that is not related to the interval between calibrations would reduce the quality control associated with dissolved oxygen testing. The existing rule requires an instrument to be calibrated before each use or weekly, whichever is less frequent, a requirement that petitioner does not contest. The Winkler testing is a check of the sensor's calibration and, as discussed below, also occurs weekly or less frequently, depending on how often the sensor is used. The existing rule's required Winkler testing correlates to the frequency of the required calibration. Regardless of sensor type, the existing rule's calibration checks remain justified due to both the field use of dissolved oxygen sensors as well as the propensity for human calibration error. Further, any waste associated with the calibration checks is minimal. Lastly, the costs and inconveniences petitioner finds to be associated with checking the calibration of optical dissolved oxygen sensors are avoidable; as discussed below, the existing rule does not require a New Jersey certified laboratory (which is a term that can include consulting firms) that purchases or rents an optical dissolved oxygen sensor from In-Situ, Inc., to send the equipment back and forth to In-Situ, Inc., for the required Winkler test.

In his petition, petitioner discusses two types of dissolved oxygen sensors: membrane-based and optical. Membrane-based, or "Clark Cell" sensors use a membrane-covered electrochemical detector to measure oxygen ions in water. An optical dissolved oxygen sensor uses a chemical film attached to the tip of an optical cable, which measures oxygen based on the film's fluorescence when exposed to water. Dissolved oxygen sensors are generally just one component of multi-meter instruments that also have the ability to test for other parameters, such as pH, in addition to testing for dissolved oxygen.

The Department's rules require that the calibration of dissolved oxygen instruments, regardless of type, be tested weekly using the Winkler method. The Department interprets the rule to require weekly Winkler testing when the instrument is being used at least once during the week in question. If a certified laboratory is not using the instrument as often as weekly, then testing would occur when the instrument is used. During the required testing, both the dissolved oxygen sensor and the Winkler method are used to independently measure the amount of dissolved oxygen in a sample of water. The values obtained from the dissolved oxygen sensor (whether Clark Cell or optical) are then compared to the values obtained from the Winkler method. The difference between these values must be less than 0.3 mg/L. If the difference is greater, then the sensor must be recalibrated. Sensors are not calibrated to the result of the Winkler titration; rather, the test is a check of the dissolved oxygen sensor's calibration. A sensor is calibrated to a separate known standard. The comparison tests the precision of the sensor, and ensures that the sensor has been calibrated correctly and/or that a prior calibration has held.

The Winkler method has been in use for many years, but it remains an appropriate method of testing the calibration of both membrane-based and optical dissolved oxygen sensors.

Petitioner appears to acknowledge that the Winkler method is an appropriate and necessary test of calibration, since the petitioner does not suggest eliminating all Winkler method calibration testing for optical dissolved oxygen sensors, but rather, suggests reducing the frequency of such testing.

Although N.J.A.C. 7:18-5.5(c)1 was promulgated prior to the development of modern optical dissolved oxygen sensor technology, the Department still finds the required calibration checks to be both necessary and appropriate for optical dissolved oxygen sensors that are in use at least weekly. Petitioner cites the results of validation studies to support his assertion that optical dissolved oxygen sensors are extremely stable, and implies that the changes in calibration observed over the course of a year are so slight as to obviate the need for the weekly calibration testing of these instruments. However, standard validation testing in a laboratory does not replicate the way that multi-meter instruments are handled in the field, such as to measure dissolved oxygen in surface water bodies, or in effluent from a treatment works. The transit and jostling of these meters inherent in their use at one or more sites in ambient conditions undoubtedly increases the chances that the calibration of one or more components (for example, pH or dissolved oxygen) will not hold. Also, on several occasions, consulting firms have mentioned to the Department that rented equipment is not as well cared for as owned equipment, making frequent testing of dissolved oxygen sensor calibration even more important.

Further, standard validation studies do not replicate the propensity for human error in instrument calibration. The Department has found that many of the deficiencies seen in audits of dissolved oxygen sensors (both membrane-based and optical) involve improper calibration of the instrument. In fact, one of petitioner’s arguments for decreasing the frequency of Winkler testing as a calibration check is the Winkler test's susceptibility to analyst error; however, the

Winkler method is one of In Situ, Inc.'s approved methods for the calibration of its optical dissolved oxygen sensors. (See In-Situ, Inc. Method 1002-8-2009 Dissolved Oxygen Measurement by Optical Probe, Section 10.1, available at https://in-situ.com/support/documents/in-situ-method-1002-8-2009-dissolved-oxygen-do-measurement/.) Therefore, due to both the unpredictability of the field handling of these instruments as well as the propensity for human calibration error, reducing the frequency of quality control testing for optical dissolved oxygen sensors is not justified.

As stated above, the Winkler titration verifies the calibration. If the frequency of the Winkler titration is reduced to a frequency that does not correspond to calibration, then not every calibration would be verified. In this regard, petitioner's suggested frequency of quarterly calibration testing seems arbitrary. Such a decrease in testing would clearly decrease environmental protection, as Winkler titration at the same frequency as calibration adds a level of credibility or defensibility to the dissolved oxygen sensor's results obtained after each calibration and, therefore, to the laboratory's data.

In addition to citing the stability of optical dissolved oxygen sensors, the petitioner also asserts that the Department's regulations result in waste beyond the small amount of physical waste that results from an actual Winkler titration. Specifically, the petitioner points to the paperwork associated with Winkler testing, as well as wasted time, resources, and costs associated with the weekly transportation of optical dissolved oxygen sensors between New Jersey and Colorado for the purpose of testing their calibration.

The Department disagrees with petitioner, and finds that physical and paperwork waste under the existing rule is so minimal that there is no need to lessen it. Winkler titrations involve a small volume of reagents (as petitioner notes), which require no special method of disposal.

Similarly negligible are the paperwork requirements associated with the performance of Winkler titrations, and, again, petitioner appears to recognize that any reduction would amount to a small alleviation of waste. The number of certificates of analysis required for Winkler test titrants would likely remain the same, regardless of whether the titration is performed weekly or quarterly. Further, once test results are obtained, the Department does not mandate a specific recording method; a simple notation of the results in a logbook, which takes very little time, would be sufficient. If petitioner is concerned about physical paper waste, the Department notes that it allows for records related to Winkler titrations to be stored electronically.

The Department also disagrees with petitioner's claims regarding the waste and costs associated with the repeated transport of dissolved oxygen sensors, and finds such waste and costs to be entirely avoidable. The Department's rules do not require that the equipment vendor be the entity to test a dissolved oxygen sensor's calibration. A laboratory that rents or purchases an optical dissolved oxygen sensor can perform the Winkler titration itself, as many times as necessary, in far less time than it would take to ship the sensor. In fact, the shipping of sensors after checking their calibration could very well be counter-productive to ensuring their proper calibration, as such calibration may not hold in transit. Assuming a laboratory elects to obtain its equipment from a Colorado-based vendor, such as In-Situ, Inc., the only shipping between New Jersey and Colorado that would be necessary is, as for any vendor from any location, the shipment for the laboratory to initially obtain the equipment and then, if rented, for the customer to return it at the end of the rental period. Even this transit waste could be lessened if the laboratory selected a local New Jersey-based vendor or other vendor in closer geographic proximity. Therefore, the Department declines to decrease quality control standards for dissolved oxygen sensors by reducing the frequency of required quality control testing to reduce

the costs that petitioner identifies, many of which are unnecessary. A laboratory could use a less wasteful and less expensive method of checking the calibration of dissolved oxygen sensors than the process petitioner describes.

Therefore, in accordance with N.J.S.A. 52:14B-4(f) and N.J.A.C. 1:30-4.2, after careful consideration of the petition, the Department has determined to deny the petition for rulemaking.

A copy of this notice has been mailed to the petitioner as required by N.J.A.C. 1:30-4.2.