



Oregon

Environmental Laboratory Accreditation Program



Department of Agriculture, Laboratory Division
Department of Environmental Quality, Laboratory Division
Oregon Health Authority, Public Health Division

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July 6, 2011

TO: All ORELAP Accredited Laboratories

Re: Primary NELAP Accreditation – Implementation of the 2009 TNI Standard

This letter is to notify all Primary NELAP accredited and applied laboratories of the Oregon Laboratory Accreditation Program (ORELAP) of the implementation plan for the 2009 TNI Standard. Originally, the ORELAP planned to implement the 2009 TNI Standard on July 1, 2011. Unfortunately, the Rule implementing the 2009 TNI Standard has been delayed and is not yet approved by the legislature. As soon as the Rule approval is granted, the ORELAP will implement the full 2009 TNI Standard. This should occur by August 1, 2011.

On-site Assessment Plan:

The implementation delay will most likely not affect most accredited laboratories because the assessments scheduled for most laboratories will occur after the ORELAP officially adopts the 2009 TNI Standard. However, for those laboratories that must participate in an on-site assessment during this interim period, the ORELAP will continue to assess laboratories to the 2003 NELAC Standard. All laboratories will be notified regarding the version of the Standard that will be used during the assessment. Should laboratories move toward implementation of the new 2009 TNI Standard prior to August 1, 2011, these laboratories will not be penalized during an on-site assessment or other assessment of data, sample receiving, or reporting procedures.

PT Implementation Plan:

Effective July 1, 2011, the ORELAP will use the 2009 TNI Standard to score and accept PT (Proficiency Testing) studies; this includes reporting to the laboratory LOQ. When reporting "< LOQs" for PT results, laboratories must use the lowest LOQ reported to any client. Please note that if a reported LOQ is greater than the PTRL (PT Reporting Limit), the ORELAP may request the analytical data and calibration records to ensure that these results were reported correctly and appropriately. ORELAP may also require proof (by written request or during the onsite assessment) that the laboratory does not report client samples below these LOQ values reported in the PT studies. If during this data review, the ORELAP determines that PTs were not reported appropriately, these results will be invalidated and will not be used as part of the laboratory's PT history.

**** The ORELAP would like to remind all laboratories that all Drinking Water laboratory LOQs are expected to be at or below the PTRL for WS PT studies.**

Note of Caution for Laboratories Holding Secondary Accreditations in Other States (NELAP or otherwise):

Due to various State statutory requirements not all Accreditation Bodies (ABs), including some NELAP ABs, are currently implementing the 2009 standard regarding PT reporting and scoring. At this time, some ABs require laboratories to report PT results down to the PTRL. Even though a result is scored "acceptable" according to the 2009 TNI standard, the AB may not accept a PT result in the case where a laboratory's LOQ is > the PTRL, the PT result is reported "<" the laboratory LOQ, and the assigned value is greater than zero.

Laboratories holding secondary accreditations should be aware of the PT requirements in those states where they hold accreditation. It is expected that for most parameters and most laboratories this will not be a concern, however it will be up to the labs to be aware of their requirements in other States. In these situations, ORELAP recommends that laboratories opt to report PT results to the PTRL rather than their LOQ in order to meet the requirements of their secondary accreditations with the following limitations.

Should you have any additional questions or concerns regarding laboratory accreditation, please contact me at Gary.K.Ward@state.or.us or 503-693-4122.

Sincerely,



Gary K. Ward
ORELAP Administrator
Oregon State Public Health Laboratory
Oregon Health Authority