



Drinking Water Information Letter 3/2012

Adoption of Microbiological Methods

Purpose

1. This Information Letter sets out the requirements for validation of microbiological methods used for the analysis of drinking water and the demonstration of the equivalence of the new or modified methods introduced after **October 1, 2012** which must be achieved before such methods are adopted for use in Alberta.

Scope

2. The scope of this Information Letter is limited to accredited laboratories undertaking microbiological analysis of drinking water samples from waterworks systems regulated under the *Environmental Protection and Enhancement Act* and proposing to utilize new or modified microbiological methods of analysis of drinking water.

Background

3. To date, there has been no formal guidance provided to laboratories or other parties on the criteria required by Alberta Environment and Sustainable Resource Development to approve new or modified microbiological methods for use in Alberta to analyse drinking water samples¹.

4. Validation means a process of providing evidence that a method is capable of serving its intended purpose – to detect or quantify a specified microbe or microbial group with adequate precision and accuracy.²

5. Validation is classified as primary or secondary according to its purpose. Primary validation is an exploratory process with the aim of establishing the operational limits and performance characteristics of a new, modified or otherwise inadequately characterised method. Secondary validation (also termed “verification”) takes place when a laboratory proceeds to implement a method developed elsewhere. Secondary validation focuses on gathering

¹ s. 17(2)(h) of the Potable Water Regulation

² ISO/TR 13843:2000 section 4.2.1

evidence that the laboratory is able to meet the specifications established in primary validation.³

6. Once validation of the method has been completed, the equivalence of the new or modified method must be demonstrated. A method is considered quantitatively equivalent with another method when the average relative difference of their confirmed counts is found “not different” when following the calculations in ISO 17944:2004⁴.

7. This Information Letter sets out the requirements for adopting new methods for the microbiological analysis of drinking water samples in Alberta and is intended to clarify the position for companies wishing to propose new microbiological methods for use in such analysis as well as for laboratories intending to change their methodology after October 1, 2012.

Detail

8. Validation (primary or secondary, as required [paragraph 5 above]) will be undertaken in accordance with the procedures set out in ISO/TR 13843:2000 *Water quality – Guidance on validation of microbiological methods*⁵.

9. Once validation has been completed, equivalence between the modified or new method will be evaluated using the criteria set out in ISO 17994:2000. Details of the reference method(s) can be obtained from the Drinking Water Specialist, Alberta Environment and Sustainable Resource Development.

10. A report, or reports, detailing the validation (paragraph 8) and the equivalence assessment (paragraph 9), will be submitted to the Drinking Water Specialist, Alberta Environment and Sustainable Resource Development for consideration. The format of the report, or reports, should follow the requirements set out in ISO 17994:2000 section 8.

11. The Director of Alberta Environment and Sustainable Resource Development will respond, in writing, to the applicant, once the evaluation of the submitted material has been completed. If the method is validated, the Director has the authority under s. 17(2)(h) of the Potable Water Regulation to authorize its use.

³ ISO/TR 13843:2000 section 4.2.2, 4.2.3

⁴ ISO 17994:2000 section 3.1.1.3

⁵ Additional guidance may be found in *Method Validation of U.S. Environmental Protection Agency Microbiological Methods of Analysis* section 2.6.4.

Enquiries

12. Enquiries on this Water Policy Bulletin should be addressed to Dr Donald Reid, Drinking Water Specialist, Drinking Water and Wastewater Section, Regional Integration Branch via email at donald.reid@gov.ab.ca or by telephone at 780-644-8061.

Rescinded