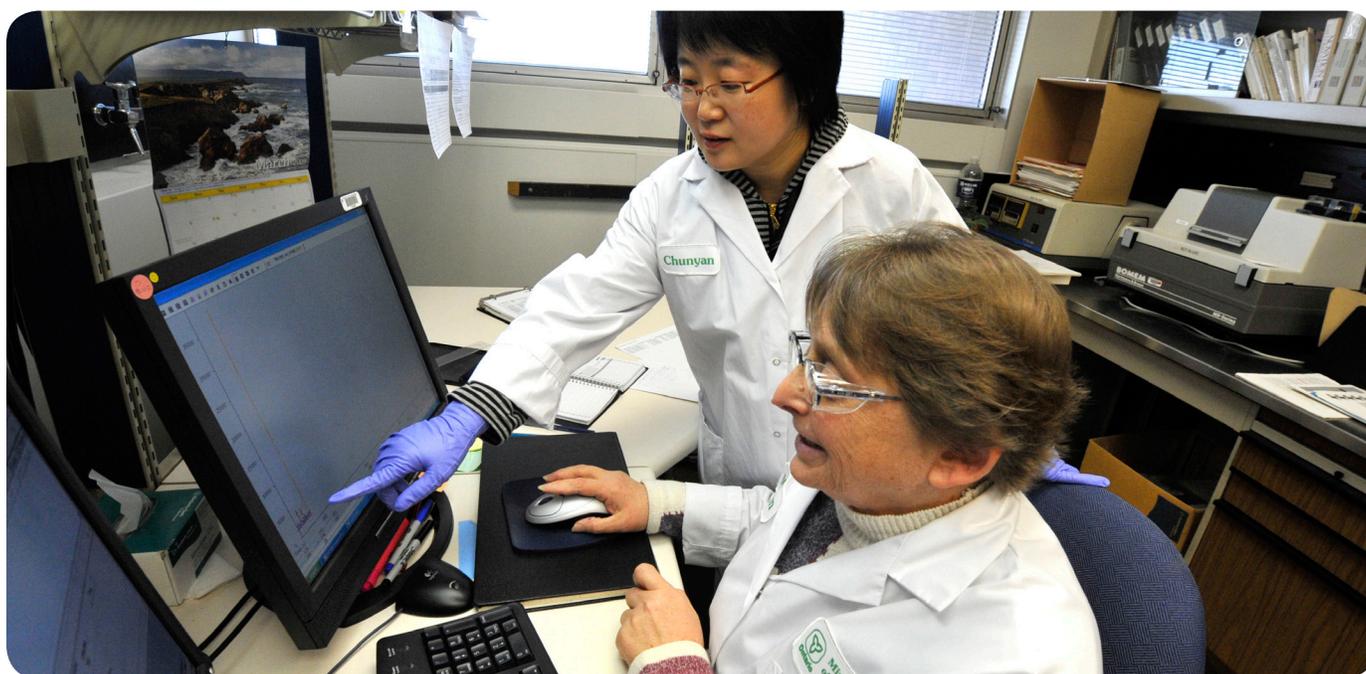


APPLICATION OF THE RISK METHODOLOGY USED FOR MEASURING LICENSED AND OUT-OF- PROVINCE DRINKING WATER TESTING LABORATORY INSPECTION RESULTS



The Ministry of the Environment (MOE)'s drinking water testing laboratory inspection program is an important aspect of our drinking water safety net. The ministry and its partners share a common commitment to excellence and we continue to work toward the goal of 100 per cent regulatory compliance.

The ministry has a rigorous and comprehensive inspection program for licensed and out-of-province laboratories that analyze Ontario drinking water. The program objective is to determine the compliance of these laboratories with requirements under the Safe Drinking Water Act (SDWA) and associated regulations.

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It is the responsibility of the licensed or out-of-province drinking water laboratories to ensure that they are in compliance with all applicable legal requirements.

This document describes the new risk rating methodology, which will be applied to the findings of MOE drinking water laboratory inspection results commencing April 1, 2012. The primary goal of this assessment is to encourage on-going improvement of compliant laboratories.

The MOE will review the risk rating methodology every three years.

The Ministry's Drinking Water Laboratory Inspection Protocol contains up to 12 inspection modules and consists of approximately 370 regulatory questions. Those protocol questions are also linked to definitive guidance that ministry inspectors use when conducting drinking water laboratory inspections. The questions address a wide range of regulatory issues, from administrative procedures to adverse water quality reporting. Additionally, the inspection protocol contains a number of non-regulatory questions. These best practice questions are not risk rated. Also, questions that are part of the "other inspection findings" module are currently not risk rated. It is possible for a laboratory to have a required action as part of this module with no change to their risk rating.

A team of laboratory and drinking water specialists in the ministry have assessed each of the inspection protocol regulatory questions to determine the assigned risk of the laboratory not complying with each regulatory requirement. This assessment is based on established provincial risk assessment principles, with each question receiving a risk rating referred to as the **Question Risk Rating**. Based on the number of areas where a laboratory is deemed to be non-compliant during the inspection, and the significance of these areas to administrative and health consequences, a risk-based inspection rating is calculated by the ministry for each drinking water laboratory.

It is important to note that an inspection rating that is less than 100 per cent does not necessarily mean that the laboratory is not analyzing drinking water improperly or not reporting data as required. It provides laboratories with information they can use to make better decisions and improve laboratory compliance. To that end, the ministry

will continue to work with the laboratories to ensure they know what to do to achieve full compliance.

The new inspection rating reflects the inspection results of the drinking water laboratory for each inspection cycle. At least two inspection cycles are carried out per year. Since different inspection modules may be employed for every inspection cycle, the inspection ratings are not comparable year-to-year. The rating record does encourage continuous improvement and allows laboratories to identify specific areas requiring attention.

Determining the Risk Rating for Drinking Water Testing Laboratories

The risk management approach used for licensed and out-of-province drinking water laboratories is aligned with the Government of Ontario's Risk Management Framework. Risk management is a systematic approach to identifying potential hazards; understanding the likelihood and consequences of the hazards; and taking steps to mitigate the risks if necessary and as appropriate.

The Risk Management Framework provides a formula to be used in the determination of risk:

$$\text{RISK} = \text{LIKELIHOOD} \times \text{CONSEQUENCE}$$

(of the consequence)

Every regulatory question in the inspection protocol possesses a likelihood value (L) for an assigned consequence value (C) as described in **Table 1** and **Table 2**.

TABLE 1:	
Likelihood of Consequence Occurring	Likelihood Value
0% - 0.99% (Possible but Highly Unlikely)	L = 0
1 – 10% (Unlikely)	L = 1
11 – 49% (Possible)	L = 2
50 – 89% (Likely)	L = 3
90 – 100% (Almost Certain)	L = 4

The consequence values (1 through 6) are selected to align with other risk-based programs and projects currently under development or in use within the ministry as outlined in **Table 2**.

The Question Risk Rating for each regulatory inspection question is derived from an evaluation of every identified consequence and its corresponding likelihood of occurrence:

- All levels of consequence are evaluated for their potential to occur
- Greatest of all the combinations is selected.

TABLE 2:	
Consequence	Consequence Value
Minor Administrative Consequence	C = 1
Medium Administrative Consequence	C = 2
Major Administrative Consequence	C = 3
Minor Health Consequence	C = 4
Medium Health Consequence	C = 5
Major Health Consequence	C = 6

The Question Risk Rating quantifies the risk of non-compliance of each question relative to the others. Questions with higher values are those with a potentially more significant impact on drinking water safety and a higher likelihood of the consequence occurring. The highest possible value would be 24 (4×6) and the lowest would be 0 (0×1).

Table 3 presents a sample question showing the risk rating determination process.

TABLE 3:					
Does the laboratory have an authorized adverse reporting Policy/Procedure?					
Risk = Likelihood × Consequence					
C=1	C=2	C=3	C=4	C=5	C=6
Minor Administrative Consequence	Medium Administrative Consequence	Major Administrative Consequence	Minor Health Consequence	Medium Health Consequence	Major Health Consequence
L=4 (Almost Certain)	L=4 (Almost Certain)	L = 1 (Unlikely)	L=4 (Almost Certain)	L=2 (Possible)	L=1 (Unlikely)
R = 4	R = 8	R = 3	R = 16	R = 10	R = 6

Application of the Methodology to Laboratory Inspection Results

Based on the results of a drinking water laboratory inspection, an **overall inspection risk rating** is calculated. During an inspection, inspectors answer the questions that relate to regulatory compliance and input their responses as “yes,” “no” or “not applicable” into the Ministry’s Laboratory and Waterworks Inspection System (LWIS) database. A “no” response indicates non-compliance. The maximum number of regulatory questions asked by an inspector varies by: laboratory (i.e., licensed, unlicensed) and type of inspection (i.e., annual 1, annual 2, focused, etc.)

The risk ratings of all non-compliant answers are summed and divided by the sum of the risk ratings of all questions asked (maximum question rating). The resulting inspection risk rating (as a percentage) is subtracted from 100 per cent to arrive at the **final inspection rating**.

Reporting Results to Drinking Water Testing Laboratories

A summary of inspection findings for each laboratory is generated in the form of an Inspection Rating Record (IRR). The findings are grouped into the 12 possible modules of the inspection protocol, which would provide the laboratory with information on the areas where they need to improve.

The 12 modules are:

1. **General**
2. **Chain of Custody**
3. **Data Retention**
4. **Drop-off Depots**
5. **DWIS**
6. **Projects**
7. **Reporting**
8. **Sample Handling**
9. **Subcontracting**
10. **Methods**
11. **Drinking Water Testing Compliance**
12. **Other Inspection Findings**

The laboratory will receive an IRR with each inspection report. The IRR is confidential to each laboratory and is not publicly reported. However cumulative results will be part of the annual report on drinking water by the Chief Drinking Water Inspector.

For further information, please contact:

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