Chapter 9 The Role of Laboratories

Contents

Chapter 9 The Role of Laboratories

9.1 Overview

Environmental laboratories conduct a wide variety of tests for water providers, including chemical, physical, and microbiological tests of raw, treated, and distributed water. Depending on the size and complexity of its system, a water provider might have anywhere from dozens to thousands of water tests conducted on a weekly basis. The laboratories' test results provide data to support informed planning and decision making regarding the multi-barrier approach, including strategies for source protection, water treatment, and the protection of the distribution system.

Laboratory testing also plays a critical role in determining whether contaminants are present in the system.[1] In this regard, water providers adopt monitoring strategies that are oriented both to assessing the performance of the multi-barrier system (and thereby preventing contamination) and to identifying and reacting to contaminants after they have entered the system. The prompt and reliable reporting of test results by laboratories is especially important in relation to the latter type of monitoring, when other barriers have failed and dangerous contaminants have entered the distribution system.

This chapter focuses on microbiological testing, because the issues that require attention are primarily in this area.

9.2 Water Testing Laboratories in Ontario

The majority of microbiological testing of municipal water systems is provided by private or municipally owned laboratories. Provincial government laboratories currently provide few testing services for municipalities; the laboratories of the Ministry of the Environment (MOE) and the Ministry of Health and Long-Term Care (Ministry of Health) were either closed or stopped providing such

[1] As discussed in Chapter 8, the most effective type of monitoring is real-time monitoring, such as in the case of real-time chlorine residual monitoring. Real-time monitoring is not currently available for microbiological testing, but it may be in the future. Because of the advantages to water systems, the development and implementation of such real-time testing should be encouraged.

testing in 1996.[2] The latter ministry's public health laboratories still play a significant role in testing water samples from non-municipal water systems and private wells.

Approximately 79 environmental analytical laboratories in Ontario carry out microbiological drinking water analyses.[3] The number of private laboratories that provide environmental testing increased during the 1990s; currently, approximately 55 are privately owned.[4] Their role grew dramatically after the wholesale withdrawal of provincial government laboratories from routine testing services and the consequent privatization[5] of microbiological testing services in 1996. Since then, the great majority of municipalities – those that do not own and operate their own testing laboratory – rely on private laboratories for microbiological testing. Larger water providers, such as the municipal water departments of Ottawa, Toronto, and Waterloo, commonly have in-house laboratories for water sampling and analysis, although they will contract out testing for some uncommon or hard-to-detect contaminants.[6]

9.2.1 The Current Regulation of Laboratories

In the Part 1 report of this Inquiry, I described the historical role of the MOE and Ministry of Health laboratories in testing drinking water. When water testing was privatized in 1996, private sector laboratories were not regulated by the provincial government. There were no established criteria governing quality of testing, no requirements regarding the qualifications or experience

---

[2] Before this, provincial government laboratories at both the MOE and the Ministry of Health provided a number of testing services to municipalities, including microbiological analyses of drinking water. Ontario, Ministry of the Attorney General, 2002, *Report of the Walkerton Inquiry, Part 1: The Events of May 2000 and Related Issues* (Toronto: Queen's Printer), pp. 370–371.

[3] There is little current quantitative published information on the capacity and capability of Ontario's analytical laboratories. These figures are based on interviews with senior private and public sector laboratory experts by J.E. Pagel. See J.E. Pagel, 2002, "An overview of drinking water testing laboratories in Ontario," Walkerton Inquiry Commissioned Paper 21, p. 4.

[4] Of the 79 water testing laboratories in Ontario, besides the 55 that are private, 11 laboratories are municipal, 1 is a hospital lab, and 12 belong to the Ministry of Health. Ibid., pp. 4–5.

[5] "Privitization," as I said in the Part 1 report of this Inquiry, refers to the government's 1996 discontinuation of all routine microbiological testing for municipal water systems – a move that resulted in the large majority of municipal systems turning to private sector laboratories for routine water testing. Ontario, Ministry of the Attorney General, p. 368.

[6] Pagel, p. 20.

of laboratory personnel, and no provisions for the licensing, inspection, or auditing of such laboratories by the government.[7]

In August 2000, the government passed Ontario Regulation 459/00, which requires the mandatory accreditation of environmental laboratories conducting specified tests of drinking water. The regulation also established a certification process for accredited laboratory analysts, who are now the only people allowed to test drinking water in Ontario.

The provincial government's approach to the licensing of clinical laboratories, which test specimens taken from humans (such as blood or stool specimens), provides a useful contrast. Since the early 1970s, clinical laboratories have been regulated under the *Laboratory and Specimen Collection Centre Licensing Act*.[8] Under section 9(1) and 9(11) of the Act, all laboratories that test human specimens are licensed by the provincial government through renewable 12-month licences. The government can revoke or refuse to renew a licence on a number of grounds, including the laboratory's failure to meet the standards set out in a provincial laboratory proficiency testing program. Under this program, the provincial government sets the standards to be met, and the Ontario Medical Association has been designated to carry out proficiency testing for clinical laboratories.[9] Further, the regulations under the Act prescribe the educational and experience qualifications required for laboratory personnel, the establishment of a quality control program, and the maintenance of records and submission of reports to the Province.[10]

9.3 Accreditation

The Ontario accreditation program for environmental laboratories is based on ISO/IEC[11] 17025, "General Requirements for the Competence of Testing and Calibration Laboratories." Accreditation requires a detailed on-site inspection and a continuing demonstration of the laboratory's competence to perform certain types of tests. Site audits and proficiency testing are currently carried

[7] Ontario, Ministry of the Attorney General, p. 367.
[8] *Laboratory and Specimen Collection Centre Licensing Act*, R.S.O. 1990, c. L.1.
[9] It is a condition of the licence that laboratories submit to proficiency testing; ibid., s. 9(14). Laboratory inspections are performed by the Ministry of Health Laboratory Services Branch staff.
[10] R.R.O. 1990, Reg. 682, "Laboratories"; and R.R.O. 1990, Reg. 683, "Specimen Collection Centres"; under the *Laboratory and Specimen Collection Centre Licensing Act*, R.S.O. 1990, c. L.1.
[11] International Organization for Standardization and International Electrotechnical Commission, respectively.

out by the Canadian Association for Environmental Analytical Laboratories (CAEAL).[12] The Standards Council of Canada (SCC) grants accreditation based on CAEAL's recommendation and conducts an annual audit of the program.[13]

A separate laboratory accreditation program exists for clinical laboratories in Ontario: the Quality Management Program for Laboratory Services, established under an agreement between the Ministry of Health and the Ontario Medical Association (OMA).[14] Accreditation under this program, as in the case of CAEAL, is based on an ISO standard.[15]

In relation to environmental laboratories, the SCC and CAEAL define accreditation as "the formal recognition of the competence of a laboratory to carry out specific tests."[16] To be accredited, laboratories are required to undergo proficiency testing, based on interlaboratory comparisons, twice a year for the relevant type(s) of testing, and to undergo site audits every 2 years.[17] Further, laboratories are required to comply with ISO/IEC standard 17025, with required corrective actions, and with CAEAL's code of ethics and publicity guidelines.[18]

---

[12] CAEAL, formed in 1989, is a non-profit organization whose members include approximately 450 environmental analytical laboratories, from both the public and private sectors, and private individuals. SCC and CAEAL, 2001, "Accreditation of laboratories in Canada with a focus on drinking water testing laboratories," p. 6; and CAEAL, n.d., "Canada's accredited environmental laboratories: A user's guide from the Canadian Association for Environmental Analytical Laboratories (CAEAL)."

CAEAL assessments of a laboratory's technical proficiency are typically carried out by teams of two to four assessors over a period of 3 to 4 days. There are 86 trained assessors in the CAEAL/SCC program, 47 of whom are employed by federal, provincial, and municipal regulatory authorities. Most assessors are from larger laboratories or from government. SCC and CAEAL, p. 3.

[13] The SCC is a federal Crown corporation created by an Act of Parliament in 1970. Its mandate is "to promote efficient and effective voluntary standardisation in Canada, where standardisation is not expressly provided for by law." The SCC represents Canada at international standards organizations such as the ISO and the International Laboratory Accreditation Cooperation (ILAC). *Standards Council of Canada Act*, R.S. 1985, c. S-16, s. 4(1). See also SCC and CAEAL, pp. 3, 5; and CAEAL, n.d.

[14] This program is one year into a five-year program that will result in external quality assessment of test performances in clinical laboratories.

[15] International Organization for Standardization, 2002, Technical Programme, ISO/DIS 15189.2, *Medical Laboratories: Particular Requirements for Quality and Competence* (Geneva: ISO).

[16] A laboratory becomes accredited by "providing evidence that they have: the personnel with the skills and knowledge; the environment with the facilities and equipment; the quality control; and the procedures, in order to produce competent test results." SCC and CAEAL, p. 1.

[17] Ibid., pp. 1, 3, 4.

[18] Ibid., p. 1.

In Part 1 of the Inquiry, I heard evidence about the organization of the accreditation program and the types of review that CAEAL auditors carry out. I was impressed by the thoroughness of the verification process and the capacity to identify areas for improvement at individual laboratories. Although a quality assurance program adds time, effort, and cost to laboratory operations, the improvements in reliability, validity, and record keeping more than offset the increased expenditure.[19] As such, drinking water testing should be performed only by accredited laboratories, as currently required under Ontario Regulation 459/00.

Recommendation 41: The provincial government should phase in the mandatory accreditation of laboratories for all testing parameters, and all drinking water testing should be performed only by accredited facilities.

The current requirement for accreditation relates only to specified tests on drinking water. A laboratory is not required to be accredited in order to test for certain chemical and radionuclide parameters. These tests are, however, directed at ensuring the safety of drinking water, and in my view the requirement for accreditation should be expanded to all testing parameters for drinking water. The Province should phase in this expansion according to a reasonable timetable, and with reference to the breadth of accreditation requirements in other provinces.[20] Overall, the MOE, as part of its oversight role, should ensure that adequate verification of laboratory testing takes place, whether through the requirements of MOE licensing (discussed below) or CAEAL accreditation.[21]

9.4 The Role of the Regulator

Recommendation 42: The Ministry of the Environment should license and periodically inspect, as required, environmental laboratories that offer drinking water testing; as with water treatment operations, continuing accreditation should be a condition of licence.

---

[19] Pagel, pp. 6–11; and CH2M HILL Canada Limited and Diamond Management Institute, 2002, "A total quality water management system for Ontario: The model water utility," Walkerton Inquiry Commissioned Paper 19, p. 100.

[20] Pagel, pp. 22–25.

[21] For example, the MOE should ensure that proper quality assurance occurs through proficiency testing, testing comparisons between laboratories, and the use of blind samples. The MOE should also require the use of standardized methods as appropriate, as I recommend in Chapter 8.

Although accreditation is a necessary step in ensuring the proficiency of testing laboratories, it is not by itself sufficient. The purpose of accreditation is to provide a means of assessing the competence of a laboratory in a given field of testing. It is not to review and verify the individual laboratory's knowledge of, and compliance with, regulatory standards. The Province therefore cannot rely on accreditation alone as a means of overseeing water testing laboratories.

The provincial government should therefore regulate water testing laboratories in the following manner. The MOE Laboratory Services Branch, using provincial standards, should license and if necessary inspect laboratories to ensure that they comply with provincial standards under Ontario Regulation 459/00, the Drinking Water Standards, and other applicable regulatory instruments. Inspections should be done only as often as required and should include unannounced inspections. The MOE's Investigations and Enforcement Branch should also be available to address any breaches of provincial standards. As recommended in Chapter 13, enforcement should be strict in this area.

I do not think the Province needs to adopt an oversight program for environmental laboratories that is nearly as extensive as the one that exists for water systems. The issues that arise in the testing of water samples are much less complex than the management and operation of even the least complex water system. The chain of custody for a water sample has fewer links, or critical control points, than does the comprehensive series of multi-barriers through which drinking water must flow before it can be considered safe for human consumption. The most important issues for a laboratory are ensuring that proper procedures are followed in tracking water samples, conducting tests, and reporting results to the water providers and provincial authorities.

This is not to say that environmental testing does not play an important role in monitoring drinking water quality.[22] Rather, the requirements in terms of oversight for laboratories are simply less than for water systems. For these reasons, I do not see the need for an extensive inspections program for environmental laboratories, so long as the accreditation program is functioning effectively.[23]

---

[22] Although testing results must be considered in relation to such issues as an operating agency's strategies for source protection, treatment, and distribution, the accuracy and timeliness of laboratory results can be characterized as vital to drinking water safety in the case of the barrier of monitoring.

[23] Inspections should be prioritized, in my opinion, according to the areas in which the MOE most expects difficulties to arise based on the history of the laboratory, the results of accreditation audits, the types of tests performed, the types of water systems served, and other relevant factors.

To the extent that it is necessary to assert its regulatory presence, the MOE should not duplicate the types of verification provided as part of accreditation.

9.4.1 Laboratory Reporting Requirements

In the Part 1 report of this Inquiry, I discussed the importance of ensuring the proper reporting of adverse water quality results to the MOE, the Medical Officer of Health, the operator, and the public. The Province addressed the need for a legally enforceable regulation in Ontario Regulation 459/00, which requires laboratories to notify the MOE, the Medical Officer of Health, and the operating agency of adverse results. In addition, the regulation includes requirements for public reporting. These requirements should remain in place.

From the perspective of the laboratory, a clearly defined method of reporting adverse results within the organization, and to external entities, should exist. This requires familiarity with the regulatory system and its requirements and open lines of communication among the treatment facility, the laboratory, the MOE, and the Ministry of Health. Guidelines that establish a time frame for reporting testing results will aid in this dialogue, as will the clear labelling of samples subject to testing under Ontario Regulation 459/00.

9.5 Improvements to the Accreditation Program

As I indicated above, the accreditation program in Ontario strikes me as an effective, well-run program.[24] That said, I think it is important that the program be fully transparent.

Recommendation 43: The results of laboratory accreditation audits should be provided to the Ministry of the Environment and should be publicly available.

For reasons of transparency, and to support the regulatory role I described above, the results of audits of laboratories for accreditation purposes should be

[24] The Ontario Medical Association, which is responsible for implementing an accreditation program for clinical laboratories, indicated at the Inquiry that the CAEAL program is "excellent" and that it complies with ISO standards, although the program could use some improvement in certain areas. Dr. A. Schumacher, for the Ontario Medical Association, Walkerton Inquiry Submission (Public Hearing, September 20, 2001), transcript pp. 83–85.

provided to the MOE and should be publicly available.[25] Laboratories should not be subject to privacy regulations or constrained by commercial confidentiality when dealing with samples under Ontario Regulation 459/00. Instead, they should be accountable to and act in the public interest at all times.[26]

In addition, to the extent possible, accreditation should verify the competence of a laboratory with respect not only to drinking water testing, but also to the pre- and post-testing phases of laboratory services, including the collection and transport of samples, sample handling and preparation, and the analysis and interpretation of results.[27] A chain of custody should exist for all samples, so that any sample is traceable throughout the process.[28] Efforts to adapt and expand accreditation to pre- and post-analytical phases are reportedly occurring under ISO auspices.[29]

9.6 The Role of Provincial Laboratories

9.6.1 Ministry of the Environment Laboratory Services Branch

The role of the MOE Laboratory Services Branch in relation to safe drinking water is primarily twofold. First, the branch provides routine testing services to the MOE in support of its regulatory functions including support for the inspections and enforcement functions. In my view it is important that the MOE continue to provide this function. While there may be an argument for contracting out routine testing services, such capability is useful for the government in effectively discharging its role as the regulator of private laboratories, including, as discussed above, the periodic inspection of private

---

[25] I was informed by CAEAL during the Part 2 public hearings that this requirement exists in British Columbia. R. Wilson, for the SCC/CAEAL, Walkerton Inquiry Submission (Public Hearing, September 20, 2001), transcript pp. 144–145.

[26] In this regard, CAEAL should ensure that its code of ethics permits CAEAL auditors to release information received as part of an audit to meet this requirement and to otherwise release information where it is in the public interest.

[27] I recognize that many aspects of pre- and post-testing phases – such as sampling practices, recording information, and interpreting samples in the context of a water system – are the primary responsibility of the operating agency of a water system. However, the laboratory should be expected to demonstrate that it has been informed of these aspects by the operating agency and to maintain appropriate documentation.

[28] Likewise, standardized formats should exist for tabulating results and presenting information.

[29] Dr. H. Richardson, for the Ontario Medical Association, Walkerton Inquiry Submission (Public Hearing, September 20, 2001), transcript pp. 84, 107.

laboratories. In my view an effective inspector must have a solid understanding of what is being inspected. Such an understanding is fostered by a continuing government presence in the area.

The second role of the Laboratory Services Branch is to develop and regularly re-evaluate testing protocols. At the risk of over-simplifying, this includes developing the tests necessary for water-treatment system operators to meet their monitoring obligations. A related role, which stems from the expertise in testing protocol, is the provision of expert advice to routine testing laboratories when peculiar results are obtained. The chemistry behind such tests is often complex and the expert advice available from the Laboratory Service Branch serves a valuable function.

I was told by a number of parties in Part 2 of the Inquiry that the expertise within the Laboratory Services Branch as well as the equipment available has been allowed to deteriorate over the last 10 to 15 years and that if this trend continues the branch's valuable role in the evaluation and development of testing protocols will become impaired.

The implicit question is the degree to which the function should be continued within the MOE and whether it is reasonable to rely on expertise that exists elsewhere. Although I have noted above that expertise in testing protocol serves a valuable function in relation to drinking water, a detailed review of this function – which extends well beyond drinking water into the full range of tests related to MOE activities – is beyond my mandate. It would seem to me to be appropriate for the government to conduct an evaluation of the benefits of keeping this function within the MOE and if it concludes that it is worthwhile to ensure that it is provided with adequate resources.

I also envision the Laboratory Services Branch playing a role in relation to the licensing and inspection of environmental laboratories and the oversight of the SCC/CAEAL accreditation program, as discussed above.

9.6.2 Ministry of Health and Long-Term Care Laboratories

The Ministry of Health's public health laboratories have an integral role to play in the provincial public health system by providing screening programs and specialized testing for outbreak identification, by supporting case

management and outbreak investigations, and by participating in outbreak management teams for major outbreaks.

In terms of drinking water testing, one of the functions of public health laboratories is to carry out, free of charge, tests of samples submitted by private citizens who deliver water samples to local public health agencies for microbiological testing. Public health agencies should assist private citizens in understanding both the test results and the limitations of the testing.

Public health laboratories employ certified medical laboratory technicians and are not required to be accredited under the SCC/CAEAL accreditation program for tests carried out by members of the College of Medical Laboratory Technologists of Ontario.[30] Those laboratories should be required to be accredited for water testing in the same way as other laboratories are; that is, according to consistent test protocols and requirements for proficiency testing. Whether this is implemented through the SCC/CAEAL program or another accreditation program, I leave for the Province to determine.

9.7 Miscellaneous Submissions

During Part 2 of the Inquiry, I received a number of submissions regarding the role of private and public sector (especially provincial government) laboratories in relation to the microbiological testing of water samples. These included submissions by some that the Province should reverse its decision to privatize laboratory testing and, by others, that private laboratories are more competent than their public counterparts. I do not see a need, for reasons related to drinking water safety, to rely exclusively on either private or public laboratories to perform the microbiological testing of drinking water samples. Therefore, I do not consider it necessary, for reasons of safety, for the government to reverse its 1996 privatization decision. That said, all laboratories must be subject to effective supervision, both through an accreditation program and through regulatory oversight.

It was submitted to the Inquiry by one private laboratory that it is preferable for municipalities not to conduct water tests in-house because of a possible conflict of interest. I do not see this as a problem. Ensuring drinking water safety is a shared objective of the managers of both municipal water systems

[30] O. Reg. 459/00, s. 2(2).

and municipal laboratories. If laboratory staff are professional and well-trained and if their management systems are verified by accreditation and provincial oversight, then this will permit consistent, high-quality testing. Further, having its own laboratory gives a municipality greater control over the nature and timing of its testing and allows for better communication and cooperation among water system managers, public health officials, and laboratory staff.

Another submission made at the Inquiry was that small or remote municipalities do not have access to affordable testing services. In this regard, the Ontario Municipal Water Association (OMWA) and the Ontario Water Works Association (OWWA) recommended that municipalities be permitted to do their own presence/absence coliform testing in-house, with the condition that it be done by a water quality analyst and that a proportion of samples be analyzed by a certified lab. According to the OWWA/OMWA, such testing costs less than using accredited laboratories and the results are available more quickly. Municipalities should be encouraged to carry out in-house testing to complement or check tests done by outside laboratories. However, to maintain consistent safety standards province-wide, municipalities should not be permitted to substitute such tests for tests done by accredited laboratories according to the minimum regulatory requirements.

The OWWA/OMWA also argued that to reduce overall costs and equalize costs between urban and rural areas, laboratory services for small and remote municipalities should either be provided by or paid for by the Province. I disagree. The cost of laboratory services is part of the full cost of water services. If a small or remote municipality is unable to afford those services, it is also unlikely to be able to afford other elements of the cost of safe water, not to mention municipal programs and services generally. In those exceptional cases, I recommend in Chapter 14 that the Province make subsidies available only according to defined affordability criteria.