Environmental Data Quality Assurance Regulation

Intentions Paper Series

For the Revision of the
Environmental Data Quality
Assurance Regulation (EDQAR)

EDQAR Revision Update:

A Summary of Responses to the Public Consultation

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Glossary of Terms

Term/Acronym		Definition
Authorization	…	An order, permit, licence, approval or certificate issued under an enactment administered by the minister
ENV	…	British Columbia Ministry of Environment and Climate Change Strategy
CALA	…	Canadian Association for Laboratory Accreditation
CDC	…	Centre for Disease Control
CEM(S)	…	Continuous Emissions Monitoring System
CS e-link	…	ENV group email server
Director	…	Means a person employed by the government and designated in writing by the minister as a director of waste management or as an acting, deputy or assistant director of waste management
Directory	…	Directory of Qualified Laboratories
DW	…	Drinking Water
EA	…	Environmental Assessment
ECCC	…	Environment and Climate Change Canada
EDQAR	…	Environmental Data Quality Assurance Regulation
EMA	…	Environmental Management Act
EWQA	…	Enhanced Water Quality Assurance Program
IEC	…	International Electrotechnical Commission
ILAC	…	International Laboratory Accreditation Cooperation
IP	…	Intentions Paper
ISO	…	International Organization for Standardization
ISO/IEC 17025	…	*General requirements for the competence of testing and calibration laboratories*
ISO/IEC 17011	…	*Conformity assessment -- Requirements for accreditation bodies accrediting conformity assessment bodies*
ISO/IEC 17043	…	*Conformity Assessment – General requirements for proficiency testing*
MRA	…	Mutual Recognition Agreement or Arrangement
PT	…	Proficiency Test/ing
QA	…	Quality Assurance
QA/QC	…	Quality Assurance / Quality Control
SCC	…	Standards Council of Canada
SI	…	Système international d'unités
WSER	…	Wastewater Systems Effluent Regulations

1 Introduction

The Environmental Data Quality Assurance Regulation (EDQAR) was enacted in 1990 to ensure environmental data for use under the Environmental Management Act (EMA) is accurate and reliable. The EDQAR is the primary means through which British Columbia (BC) controls the quality of environmental data produced for programs operated under the EMA.

An interjurisdictional review (IR) of data quality assurance practices in place across Canada found that BC is the only jurisdiction that does not designate the ISO/IEC 17025 standard as a qualification criterion. The IR provides defensible evidence from several studies which demonstrate that accredited laboratories out-perform non-accredited laboratories. One of those studies involved comparisons of over a million PT results. The authors of the IR provide several recommendations to enhance the effectiveness of the EDQAR; predominant among them is the formal adoption of the ISO/IEC 17025 standard as a qualification criterion.

The findings of the IR, proven quality assurance practices used in other jurisdictions and interim solutions developed to resolve issues arising from functional gaps in the current regulation were used to develop draft revisions of the EDQAR. Those draft revisions were articulated in an intentions paper (IP) which was posted for public review and comment on the ministry's website for the period October 17, 2018 to December 17, 2018.

This public consultation included two public meetings held on November 26, 2018 and November 30, 2018.

This report provides a summary of the responses received as part of this consultation process. The ministry has reviewed and considered all input in its drafting of revisions of the EDQAR.

The public consultation process and the initial draft of this document were produced by JRD Consulting Company's James R. Downie, Principal. JRD Consulting was contracted by the ministry to manage the public consultation. Prior to publication this document revised by the Ministry of Environment and Climate Change Strategy.

2 Background to the Public Consultation

2.1 Intentions Paper

An intentions paper entitled "Update to British Columbia's Environmental Data Quality Assurance Regulation" provides background information, ministry's proposals to update the EDQAR, as well as the process to provide comments to the ministry. This document was posted for public review and comment on the ministry's website for the period October 17, 2018 to December 17, 2018.

The document can be accessed at: https://www2.gov.bc.ca/assets/gov/environment/research-monitoring-and-reporting/monitoring/emre/edqar_intentions_paper.pdf. In addition to the intentions paper, a response form was assembled and was made available on the website to assist in the submission of comments to the ministry. The form can be accessed at: https://www2.gov.bc.ca/assets/gov/environment/research-monitoring-and-reporting/monitoring/emre/edqar_response_form.pdf.

2.2 Public Consultation Process

The period for public consultation opened on October 17, 2018. On this date, a notice regarding the posting and the intention to update the EDQAR was transmitted by email to persons, agencies, and organizations. Specifically, notice was provided to:

- Active permittees
- Air/stack monitoring organizations
- All B.C. municipalities, regional districts, and Health Authorities
- All First Nations and the First Nation Health Authority
- All laboratories listed in the Directory of Qualified Laboratories
- National laboratory organizations such as the Standards Council of Canada (SCC), Canadian Association for Laboratory Accreditation (CALA) and the Canadian Council of Independent Laboratories (CCIL) and their membership
- Representatives of the federal government and all provinces and territories
- Select national/provincial environmental associations and environmental groups and their membership
- Relevant B.C. environmental associations and industry groups and their membership
- CS e-link – a ENV email group for waste management contacts.

In all, the notice was provided to approximately 3,000 recipients representing a broad cross-section of government, laboratory, industry, and relevant associations.

The ministry hosted public webinars on November 26, 2018 and November 30, 2018. The webinars included a presentation based on the information provided in the intentions paper and an opportunity for attendees to pose questions to ministry personnel regarding the proposed updates. These sessions were attended by 78 groups. Access to the recordings of the public meetings were also provided.

In addition to the formal consultation process, information regarding the ministry's plan for the update to the EDQAR was presented informally to several groups and individuals by ministry personnel.

3 Public Response

A total of twenty (20) response submissions were received, of which three were "no comment". Of the remaining 17 submissions:

- Laboratories (4)

- Municipalities (3),
- Industry (3) - including representatives of the mining and forest products sectors
- Associations (4)
- Government (1)
- No affiliation (2)

A summary of the responses is arranged and presented consistent with the 'response form'. The complete set of responses were considered in the development of revisions.

3.1 General Questions

The response form begins with an opportunity to answer three general questions as shown in the blue panel below.

Response Form Question G1-3:

G1. Overall, please indicate your level of support for the proposed revisions to the EDQAR described in the intentions paper:

Please select one box from the scale below (1= Not at all supportive; 6= Extremely supportive)

	1	2	3	4	5	6	
Not at all supportive	☐	☐	☐	☐	☐	☐	Extremely supportive

G2. What are the reasons for your choice?

G3. Do you have any general comments about the ministry's proposed revisions to the EDQAR?

Although these general questions were intended to gauge the overall support for the EDQAR updates, most respondent comments were focussed on the proposed adoption of laboratory accreditation.

3.1.1 Overall Response to Proposed Updates

Of the 17 submissions received 16 responded to the question regarding support for the update to the EDQAR, and the majority (14/16) expressed a strong score[1] or opinion in favour of laboratory accreditation. Two of the submissions were not in favour of this direction for the EDQAR Update, and one supported laboratory accreditation with a caveat.

3.1.1.1 Support for the Proposal

Statements and scores related to the proposed changes to the EDQAR were the overwhelming theme for this question. Many respondents expressed the value of accreditation in terms of "consistent, accurate, and reliable data" and "increased confidence in the data". Other terms used are "levels the playing field", "align the BC system with an international standard", and "overdue relative to other jurisdictions". In the

[1] It should be noted that not all submissions completed the scoring section of the questions.

case of one municipal laboratory, support was expressed for the accreditation of commercial laboratories, but recommended that municipal laboratories be exempt due to perceived cost.

In one case, the respondent suggested that the ministry develop in-house expertise to audit and qualify laboratories and that this approach would offer significant benefits compared to commercial laboratory accreditation. This submission is explored further under "Additional Comments".

A Sample of Supportive Respondent Comments

"The proposed revisions to the EDQAR are overdue relative to other jurisdictions."

"strongly supports the initiative to require all laboratories providing testing data in support of environmental regulation to be accredited to the ISO/IEC 17025 standards."

"believe strongly that accreditation to the international standard ISO/IEC 17025 General Requirements for the Competence of Testing and Calibration Laboratories is vital to ensure that the environmental testing performed in the province of British Columbia is accurate and performed in a competent manner."

3.1.1.2 Concerns or Opposition to the Proposal

Concerns were expressed most strongly by the forest products sector. From this sector we received two submissions, including an association representing 14 pulp and paper mills and 17 forest products organizations. Their feedback reported that they feel that the current process in the EDQAR offers adequate assurance of data quality. In their submission, they provide a lengthy list of reasons why they feel this is the case, including:

- Operation of pulp and paper in-house labs and CEMs must be in accordance with the terms and conditions of waste discharge permits, thus imposing a higher degree of assurance and control than a non-permitted laboratory.
- Laboratory, stack and CEM sampling procedures must follow the BC Field Sampling Manual; Laboratory analytical procedures must follow the BC Environmental Laboratory Manual
- Laboratory QA/QC program must align with recommendations in the BC Environmental Laboratory Manual.
- Laboratory must be CALA registered and participate in proficiency testing
- Laboratory must undergo annual inspection by ENV Inspections staff, including participation in a split sampling program
- CEM performance must be audited twice yearly by ENV and pass said audit
- CEM maintenance and uptime must be as per BC Field Sampling Manual

They also point out the overlap between the ISO standards 9001, 17025, and 14001, and that in many cases the requirements are a duplication of their permit requirements. Finally, the forest products respondents express concern about the cost of achieving accreditation to the ISO/IEC 17025 standard.

As mentioned above, one municipal submission suggested that municipal laboratories should be exempt from the requirement for accreditation due to the perceived cost of accreditation.

A Sample of Opposed or Concerned Respondent Comments

"We are of the opinion that our current management practises create an environment for testing excellence as seen by our CALA results. The requirement for third party certification of our labs to ISO 17025 will be valueless in terms of improvement of our testing results. However, it will ensure a significant elevation in our testing costs."

"the proposed changes to EDQAR will result in duplicative and unwarranted changes to pulp and paper facility laboratory operation, including substantive increases to the cost of doing business… are not applicable to the pulp and paper sector or wood processing industry, either due to: a) the nature of our laboratory work and/or b) the existence of adequate checks and balances to assure the quality of laboratory results."

"We disagree that municipal labs should be accredited. Accreditation costs are prohibitive"

3.2 Response to Proposed Requirement for Laboratory/Test Accreditation

The remainder of questions presented in the response form are focused on specific proposals. The following four questions relate specifically to the proposed requirement for accreditation to the ISO/IEC 17025 standard.

Response Form Question 1:

1.1 Please indicate your level of support for the proposal to require formal accreditation for the laboratory/test methods that generate test results for ministry programs.

Please select one box from the scale below (1= Not at all supportive; 6= Extremely supportive)

	1	2	3	4	5	6	
Not at all supportive	☐	☐	☐	☐	☐	☐	Extremely supportive

1.2 What are the reasons for your choice in question 1.1?

1.3 Do you have any other comments regarding the ministry's intention to require ISO/IEC 17025 accreditation for laboratories and test methods that produce analytical data for ENV programs?

1.4 Do you support the suggested wording to be used for the update to the EDQAR related to laboratory accreditation? Please offer suggestions for alternate wording if warranted.

As mentioned above, many comments provided for question G1-3 are in fact also applicable to Question 1.

Response to Question 1.1

For those respondents that completed this section of the response form (10/17), the majority expressed support for laboratory accreditation. Some respondents deferred their comments to question G1-3 in response to this question.

Response to Question 1.4

Where comments were made on the suggested wording (Question 1.4) for the EDQAR related to accreditation (7/17), all were in support of the proposed wording.

3.2.1 Overall Response to the Proposal for Laboratory/Test Accreditation

As noted above, the majority of respondents (9/10) providing scores or opinions to question 1.1 were in favour of the addition of the requirement for laboratory accreditation to the EDQAR.

3.2.1.1 Support for the Proposal

Statements and scores related to the proposal to require accreditation to the ISO/IEC 17025 standard were overwhelmingly positive.

Sample of Supportive Respondent Comments

"Laboratory accreditation is the only practical way to ensure that laboratories are competent to perform the work (testing) they do."

"The ACPBC strongly supports laboratory accreditation as the best means to ensure the quality of the analytical data that the Ministry will rely upon for decision making. There really is no alternative to the required reliability."

"Specifically, both SCC and CALA believe strongly that accreditation to the international standard ISO/IEC 17025 General Requirements for the Competence of Testing and Calibration Laboratories is vital to ensure that the environmental testing performed in the province of British Columbia is accurate and performed in a competent manner."

3.2.1.2 Concerns or Opposition to the Proposal

As noted above, one municipal respondent expressed concern about the cost of accreditation to small laboratories. The dissenting opinion from the forest products sector with respect to laboratory accreditation is provided under Question G1-3 above. There was also one respondent that separated accreditation between routine and non-routine tests (see below).

A Sample of Opposed or Concerned Respondent Comments

"Costs are prohibitive to small municipal labs."

"I support formal accreditation for tests that are commonly performed in BC (those pertaining to typical permits and common contaminants), but not for obscure tests that are rarely requested, e.g. for evaluation of a specific potentially contaminated site"

3.3 Response to the Proposed Scope of Application

The next question posed in the response form deals with the 'scope' of application.

Response Form Question 2:
2.1. Do you support the scope of application for laboratory/test accreditation that is being for the generation of all regulatory data to which it can be applied for ENV programs? If not, please explain why.

3.3.1 Overall Response to the Proposed Scope of Application

A response to this question was provided by 9/17 respondents, although two were off-topic. While the majority (4/7) are in favour of the proposed scope in the intentions paper, strong opinions were expressed (3/7) that the scope was too broad to be realistic, in particular in respect of spills and emergencies and non-routine parameters. One respondent proposed an alternate approach to non-routine parameters that is explored further in the Discussion Paper associated with this report.

3.3.1.1 Support for the Proposal

Although the majority of respondents supported the proposed scope in the intentions paper, strong and lucid arguments were made in support of exceptions to the blanket application of the requirement for laboratory accreditation.

A Sample of Supportive Respondent Comments

"Yes. There should be no exceptions for data submitted to the Ministry irrespective of urgency or transient conditions as might occur in a spill. Unreliable data has no utility in decision-making. Accredited laboratories are best placed to avoid delivery of unreliable data to the Ministry."

3.3.1.2 Concerns or Opposition to the Proposal

Concerns were expressed about the applicability of formal laboratory accreditation for non-routine parameters and also the timeliness of response that might be compromised if an industry had to respond quickly to a spill or emergency. The suggestion being that response may be delayed while the permittee seeks out an accredited laboratory for a parameter, the character of which cannot be foreseen. These are valid concerns that may be addressed by the suggestion of a respondent to consider accreditation for

method development and non-routine tests. This possibility is explored in the Discussion Paper associated with this report.

A Sample of Opposed or Concerned Respondent Comments

"There are concerns of the restrictiveness and potential risks of application of the regulation to "all test data", specifically for spills and emergencies. Consider the rare scenario where there is a spill or an emergency. It is a facility's and permittee's responsibility to characterize the nature or extent of a spill as quickly and completely as reasonably possible. Some of this data may be critical in informing decisions on how to minimize risk or consequence of an emergency. Further, the character of spills cannot always be anticipated. If a permittee's typical lab is not accredited for a specific test that would characterize a spill, the permittee must then find another laboratory that is accredited or use other provisional measures. This may delay the process of receiving data that could inform risk and consequence management decisions."

"We feel it is unrealistic to expect accredited laboratories to also seek accreditation for every individual compound and testing method, particularly for non-routine analyses. B.C. is unique in that it regulates over 600 compounds, compared to about 100 in most other provinces. It simply doesn't make financial sense for our member laboratories to gain accreditation for all these different tests. Also, to gain accreditation for a test requires several months, well beyond the timeframe required to perform the testing.
Perhaps one solution might be an approach used by the Standards Council of Canada, which currently offers accreditation for method development and non-routine tests which ensures a defensible process is employed. We encourage the Ministry to include such an option."

"No, there are numerous analyses/parameters for which accreditation cannot easily be obtained, e.g. those without a reference method or no PT program available"

3.4 Response to the Proposed Phase-in Period

Question 3 of the response form asks respondents to comment on the proposed 2 year phase-in period.

Response Form Question 3:
3.1. Do you have any comments regarding the ministry's intention to have a phase-in period of two years for the new requirements including laboratory/test accreditation?

3.4.1 Overall Response to the Proposed Phase-in Period

In terms of the phase-in period, 9/17 respondents provided comments on this question, with 5/9 suggesting that two years is a reasonable period, 3/9 suggesting that two years may be difficult for small laboratories or labs that would face a significant expansion in scope. One respondent suggested that the period be as short as could be accommodated.

3.4.1.1 Support for the Proposal

Respondents in favour of the proposed two-year phase in period in the intentions paper were generally in agreement with this time frame. Comments generally were not expansive in rationale.

A Sample of Supportive Respondent Comments

"A phase in period of two (2) years is reasonable. Based on personal experience this is sufficient time for non-accredited laboratories to become accredited."

"SCC believes this time period is appropriate, as it coincides with the typical accreditation cycle"

"Two years seems reasonable, anything less would be very difficult for small labs to achieve"

3.4.1.2 Concerns or Opposition to the Proposal

Concerns expressed were mainly associated with the suitability of the proposed phase-in period on small laboratories that may have limited resources due to budgetary constraints.

A Sample of Opposed or Concerned Respondent Comments

"A two-year transition period for the requirement for formal laboratory accreditation for the small laboratories might not be a sufficient timeframe due to possible budgetary constraints. Consequently, the MOE might want to consider a longer phase-in period."

"The Ministry's "two year" requirement may be underestimating the amount of work required by some laboratories, particularly with labs on a current two-year accreditation renewal cycle that may have to increase the scope of their accreditation by as much as 3-5 times."

"There is a need for exception for small labs"

3.5 Response to the Proposal for Qualification by Proficiency Testing

The questions presented in this section of the response form provided an opportunity for respondents to weigh in on the option to qualify laboratories by proficiency testing in some circumstances.

Response Form Question 4:

4.1 Please indicate your level of support for the retention of laboratory qualification via proficiency testing as practiced by the EDQAR for use in special circumstances.

Please select one box from the scale below (1= Not at all supportive; 6= Extremely supportive)

	1	2	3	4	5	6	
Not at all supportive	☐	☐	☐	☐	☐	☐	Extremely supportive

4.2 What are the reasons for your choice in question 4.1?

4.3 It is proposed that a laboratory seeking to utilize laboratory qualification by proficiency testing be required to provide a rationale for the accommodation, receive approval of the Director and that approval will be for a limited time period. Please comment on the proposal

3.5.1 Overall Response to the Proposal for Qualification by Proficiency Testing

The matter of retention of laboratory qualification via proficiency testing was commented on by 12/17 respondents.

3.5.1.1 Support for the proposal

Respondents in favour of the option (5/12) cited that it will provide an alternative option to full accreditation. Others considered it to be a low-cost alternative to accreditation. The forest products industry, which is generally opposed to the overall proposed changes to the EDQAR, support retention of the current EDQAR laboratory qualification requirement "CALA register and participate in proficiency testing".

All respondents in favour of the option supported the proposed requirement to impose strict conditions on this accommodation.

A Sample of Supportive Respondent Comments

"Laboratories need to operate with efficiency and economies of scale. Labs do not want to have to work with more than one Accrediting Body (AB). If our current AB cannot meet all of our new accreditation requirements, and based on assessment of risk, proficiency testing for only some tests should be considered. Yes, a rationale should be provided. If there is a recurring approval, it must be done so in a timely way if done as frequently as every two years."

"When laboratory qualification via proficiency testing (instead of accreditation) is deemed beneficial, enhanced laboratory qualification should also include a review and assessment of the laboratory's historical quality assurance/quality control records, with the MOE establishing criteria for acceptable performance of quality assurance/quality control results."

"Allows us to meet requirements of testing (proficient) without high cost of accreditation"

"Case by case, it may be required. I think formal testing should always be preferred… Totally makes sense. A lab should be able to explain the reasons"

3.5.1.2 Concerns or Opposition to the Proposal

The majority (8/12) of respondants were opposed to this option, providing potent arguments why this proposed element of the updated EDQAR should be dropped. The following arguments were provided by respondants:

- Maintains two standards and puts additional onus on the ministry to review an accommodation request.
- Direct accreditation costs for small laboratories are not onerous, so they should not require an exemption. There should be no dilution of the standards when decisions are being made about the environment and the health of our citizens.
- Discretionary provisions like this could be subject to abuse – political or otherwise.
- Qualification by PT is inferior to laboratory accreditation.

A Sample of Opposed or Concerned Respondent Comments

"The Ministry proposes that laboratories claiming "hardship" be exempted from meeting the accreditation requirement. CCIL is opposed to such exemptions. Direct accreditation costs for small laboratories are not onerous. And more importantly, there should be no dilution of the standards when decisions are being made about our environment and the health of our citizens."

"CALA is "not at all supportive" of laboratory qualification via proficiency testing alone. CALA cannot envision situations where laboratory qualification via PT alone would be required and therefore does not support the retention of laboratory qualification via PT as practiced by the EDQAR… Discretionary provisions like this could encourage laboratory owners\senior managers to use political influence\connections to encourage the approval of their laboratories. This potentially undermines what the Ministry is trying to accomplish by updating the EDQAR. After approval for one laboratory is granted based only on PT it invites the addition of other laboratories (if PT only is adequate for laboratory ABC how can the Ministry say it isn't good enough for laboratory XYZ……..)."

"Proficiency testing (PT) as a basis for laboratory qualification should be phased out to ensure that going forward ALL the data submitted to the Ministry and maintained for future decision-making be on the same reliability footing. The main problem with PT is that it inherently relies on the undocumented supposition that a process is constant over time. ISO/IEC 17025 opens the workings of a defined process to external scrutiny to ensure that the supposition of continued reliable performance is supported by audited procedures and practices within the lab."

"SCC believes full accreditation is the only appropriate option; To that end, it would be the recommendation of both SCC and CALA that the exceptions to formal accreditation proposed in section 5.1.4 of the Intentions Paper, whereby laboratories can apply for approval from the Ministry simply through proficiency testing, not be included in the final draft of regulation…that the benefits of formal accreditation are more important to producing accurate test results, ensuring quality test data, and protecting the health of both the environment and of the general public."

3.6 Response to the Proposal Regarding Online/Continuous Measurement

Section 5.1.5 of the IP proposes that environmental test data generated by online/continuous measurement have an element of quality management to ensure a high level of confidence in the data. While the provision for laboratory/test accreditation does not extend to online/continuous monitoring, certain elements of quality management are proposed in the EDQAR update revisions.

The following question was asked regarding online/continuous measurement:

Response Form Question 5:
5.1 Do you have any comments or suggestions regarding the proposed revisions for online/continuous measurements that generate test data for ministry programs?

3.6.1 Overall Response to the Proposal to Impose Quality Management

A total of 7/17 respondents provided comments on the online/continuous monitoring proposals in the intentions paper. The most common position was concern about duplication with the requirements of the BC Field Sampling Manual which is typically cited in waste discharge authorizations.

3.6.1.1 Support for the Proposal

Respondent comments in favour of the proposed changes to the EDQAR (2/7) did not provide a rationale for their position.

A Sample of Supportive Respondent Comments

"The proposed revisions for online/continuous measurements seem reasonable."

"Quality management makes good sense"

3.6.1.2 Concerns or Opposition to the Proposal

Responses to the proposal regarding online monitoring (4/7) include concerns regarding the potential duplication of effort with respect to the requirements of the BC Field Sampling Manual. The respondents consider an online monitoring/quality assurance program that aligns with the requirements of the BC Field Sampling Manual is already in a high state of technical and operational quality making additional requirements under the EDQAR redundant.

A Sample of Opposed or Concerned Respondent Comments

"The intentions paper is very vague as it relates to continuous air monitoring… All of these air monitoring instruments are already included in the existing comprehensive ENV audit/performance testing program conducted twice annually…We are of the opinion that our current programs provide excellent operational performance and result accuracy. Again, we believe that given our use of such trained trades employees

in conjunction with our facilities' ISO 9001 and ISO 14001 registration, that there are no material improvements to be realised relating to our continuous monitoring."

"Proficiency testing might not be available and suitable in all instances of on-line/continuous measurement. Also note that continuous monitors are covered in the BC Field Sample [Sic] Manual. This may present a duplication in requirements."

"More specifically:

1. *Operation of pulp and paper in-house labs and CEMs must be in accordance with the terms and conditions of waste discharge permits, thus imposing a higher degree of assurance and control than a non-permitted laboratory.*

a. Laboratory, stack and CEM sampling procedures must follow the BC Field Sampling Manual
…
f. CEM performance must be audited twice yearly by MOE and pass said audit
g. CEM maintenance and uptime must be as per BC Field Sampling Manual"

3.7 Response to Proposed Provision for Laboratories New to B.C.

A provision proposed in the intentions paper to mitigate barriers to trade would allow a laboratory new British Columbia to qualify by proficiency testing for a two year period during which the laboratory would achieve accreditation.

Response Form Question 6:
6.1. Please comment on the provision in the proposed EDQAR revisions for laboratories new to B.C.

6.2. Do you have any comments regarding the use of laboratory qualification via proficiency testing or the two-year period for accreditation to be achieved in this process?

3.7.1 Overall Response to Proposed Provisions for Laboratories new to B.C.

The provision in the EDQAR update for laboratories new to B.C. attracted comments from 7/17 of the respondents. The comments reflected a split between those that support the proposal and those with concerns.

3.7.1.1 Support for the Proposal

Comments in favour of the proposal reflected the proposed two-year period as reasonable or useful as an interim measure.

A Sample of Supportive Respondent Comments

"While a two-year timeframe for laboratories new to BC to be accredited is reasonable, will the Ministry require these laboratories to indicate up-front to clients that they are not ISO 17025 accredited and/or not accredited for the analyses being requested?"

"As already noted, CALA does not support the qualification of laboratories based on PT alone. However, this appears reasonable as an interim measure that is only applied to laboratories new to B.C."

"The proposed provision for new laboratories is reasonable."

3.7.1.2 Concerns or Opposition to the Proposal

Comments with concerns for the proposal were based either on opposition to the use of PT alone for laboratory qualification, with opposition to the proposal to use PT to temporarily qualify laboratories new to B.C. as an extension of that. An alternate perspective is opposition after the initial two-year transition period is passed.

A Sample of Opposed or Concerned Respondent Comments

"We would not support qualification based on PT alone past the two-year phase in period."

"As our responses elsewhere show, we oppose PT in lieu of full accreditation once the initial period has passed."

3.8 Response to the Proposal for Special Provisions

The intentions paper outlines a proposal to apply special provisions in cases where accreditation and proficiency testing is not available for a given parameter, or to be used in unforeseen circumstances. Question 7 of the response form asks respondents if they have any comments or suggestions regarding the proposed revisions.

Response Form Question 7:
7.1 Do you have any comments or suggestions regarding the proposed special provisions for the revised EDQAR?

3.8.1 Overall Response to the Proposal for Special Provisions

In terms of the proposal for special provisions, 11/17 respondents made comments. There is general agreement with the need for provisions for special circumstances, and several respondents pointed out the resource challenges that such a program will present. One respondent pointed out a program that might address this concern, and this is explored in the Discussion Paper associated with this report.

3.8.1.1 Support for the Proposal

The proposal to have a provision for special circumstances in the update to the EDQAR was supported by 9/11 respondents. Many of these agreed with the need to address circumstances where laboratory accreditation is not a good fit. Several pointed out the resource needs for such a technical process and these comments were noted for further discussion.

A Sample of Supportive Respondent Comments

"As referenced above, special provisions will be necessary for unforeseen spills and emergencies."

"For newly developed methods for compounds of emerging interest, or for specialty analysis, accreditation may not be practical, and there needs to be an allowance for this. "

"With this in mind the Special Provisions §5.1.7 will be commonly used and the way in which these provisions are applied can have significant impact on the laboratory community."

"These special provisions will be fairly common, and BC ENV will need to assign a dedicated individual or committee to assess each situation and make a suitable decision."

3.8.1.2 Concerns or Opposition to the Proposal

Concerns were expressed by 4/11 respondents, although some supported the provision but pointed out concerns with the related resources required to deliver the requirement. In this case, the respondents pointed out several resource considerations or impacts that should be considered as this provision to the EDQAR update is finalized. An alternate approach that may address the resource challenges presented by one respondent. This alternate approach is explored more fully in the Discussion Paper associated with this report.

A Sample of Opposed or Concerned Respondent Comments

"With this in mind the Special Provisions of 5.1.7 will be commonly used and the way in which these provisions are applied can have significant impact on the laboratory community.
- Who will be responsible for determining when analytes are related as mentioned in the section Where [Sic] accreditation and proficiency testing is not available? What qualifications will this person have to adequately evaluate if the analytes are related?
- When accreditation is not available for the analyte or related analytes the laboratory is required to submit qualifying information to support the quality of the test results. Who is going to be assessing the quality of the work? What qualification will this individual or group have to assess the validity of the determinations?"

"These special provisions will be fairly common, and BC ENV will need to assign a dedicated individual or committee to assess each situation and make a suitable decision."

"B.C. is unique in that it regulates over 600 compounds, compared to about 100 in most other provinces. It simply doesn't make financial sense for our member laboratories to gain accreditation for all these different tests. Also, to gain accreditation for a test requires several months, well beyond the timeframe required to perform the testing...Perhaps one solution might be an approach used by the Standards Council of Canada, which currently offers accreditation for method development and non-routine tests which ensures a defensible process is employed. We encourage the Ministry to include such an option."

"SCC believes that accreditation is always available, and we have policies in place for when PT is not"

3.9 Response to Measures Proposed to Assure Compliance

The EDQAR update proposes several options for laboratory qualification including formal accreditation, proficiency testing performance, and with the use of special provisions. Measures are proposed to ensure an adequate level of oversight is in place which would allow ENV to assess the effectiveness of the EDQAR update and ensure that it achieves the targeted objectives.

Response Form Question 8:
8.1. Please comment on the provision in the proposed EDQAR revisions for accreditation verification (Section 6.1).

8.2. Please comment on the provision in the proposed EDQAR revisions for accreditation updates and proficiency testing performance notifications (Sections 6.2 and 6.3).

3.9.1 Overall Response to Compliance Assurance Measures

Question 8 of the response form garnered comments from 10/17 of respondents. Responses included both supportive feedback and concerned feedback.

3.9.1.1 Support for the Proposal

Respondents in favour of the provision (5/10) spoke generally about accreditation verification as reasonable and an expectation of accredited laboratories.

A Sample of Supportive Respondent Comments

"We are open to verification. Part of being an accredited lab"

"The provisions for accreditation updates and proficiency testing performance notifications appear reasonable."
"It would be beneficial to specify if laboratory accreditation verification will be performed by the MOE staff and at what frequency. Metro Vancouver supports the provision in the proposed EDQAR revisions for

accreditation updates and proficiency testing performance notifications to municipalities & regional districts."

3.9.1.1 Concerns or Opposition to the Proposal

Concerns expressed by respondents (4/10) reflected challenges in managing the information and resource impacts, in particular:

- PT results for accredited laboratories are managed by the accrediting body and should not be an element for submission to the ministry. This comment has been noted for further discussion.
- The resources to manage this amount of data by the ministry, and the suggestion that this can be better managed by the laboratories themselves in consultation with their clients.

A Sample of Opposed or Concerned Respondent Comments

"Accreditation bodies must ensure that PT performance is satisfactory for continued accreditation. Submission of PT results to ENV is unnecessary and could lead to confusion. It might also be perceived as an attempt to interfere in an accreditation bodies decision to award accreditation that is consistently recognized."

"How does the Ministry plan on managing this large amount of data? Will there be parties assigned the responsibilities of reviewing PT programs, PT data, PT failures and subsequent corrective actions along with interacting with the laboratories? An alternative would be to have the laboratories notify their clients and/or the Ministry of any suspensions or withdrawn accreditation. This is better aligned with the Ministries focus on accreditation rather than PT performance and reduces the burdens on the Ministry and laboratories. Accreditation depends on successful PT where they are available so focusing on the accreditation will naturally include the PT requirements that the ministry desires to uphold."

"Section 6.1 Accreditation Verification proposes to require permittees to notify ENV of changes in use of third-party labs and to be responsible for submission of accreditation and PT information. PPEF feels that this expectation is duplicative with the Ministry of Environment's current, and recommended continuing, practice of maintaining a listing of all labs that maintain "qualified" status under B.C. regulation, including submission of proof of such status. Additionally, the PPEF fails to see the purpose or value associated with the proposed requirement to 'notify' of changes in external laboratory as lacking purpose and value."

3.10 Additional Comments and Ministry Responses

The final opportunity for public feedback provided in the response form asks for any additional comments as shown below.

Response Form Question:
Do you have any additional comments or suggestions for the Ministry regarding the proposed revisions to the regulation?

Due to the timing of the EDQAR's revision process, ***Ministry Responses*** were prepared and provided after the replacement regulation was deposited and therefor reflect the requirements of the finalized regulation and not those that were presented as proposals during the consultation process.

Additional Comment 1

"It remains unclear whether permittees must notify the Ministry of a change in laboratories used for obtaining results for permitted parameters. We urge the Ministry to provide clarity on how the revisions will apply to laboratories that have all permitted parameters accredited."

Ministry Response

Authorization holders are required to have a qualified laboratory analyze their samples for the parameters specified in their authorization. Authorization holders are not required to notify ENV of their intended testing laboratory. Authorization holders are free to have any laboratory/ies analyze their samples as long as they are qualified to analyze those parameters.

Additional Comment 2

"Proposed Suggestions for the Accreditation of Small industrial or Commercial laboratories supporting specific industrial operations by the;

1. Designation of a PT and assessment program that addresses specific parameters and their concentrations relevant to the scope of laboratory operation,

a) For small industrial labs and or commercial small labs with few staff supporting industrial operations, MOE may want to consider to create an alternative PT and Assessment category that are based on a risk based QA audit program, encompassing a PT program and an assessment process that are process based whereby the audit scope is based on the scope of the laboratory operation rather than based on a general laboratory assessment profile.

b) Both the PT and assessment audits (inspections) could potentially be directed and carried out by either external auditors or preferably by MOE audit staff (an audit team similar to the air audit team operated on a cost recovery formula) who understand the work performed by the laboratory and who also understand the risk to compliance within the laboratory and the impact these risks have on permits. An initial audit plan would have to be developed for each lab which then will define both the PT and audit/assessment criteria to be followed thereafter.

c) The initial risk-based audits should identify what needs to be audited and then both the PT and the audits(assessments) then to be tailored on the feedback from these audits for the development of a documented audit plan. The audits can be based on methods used for routine and repetitive tests and focus on laboratory activities or methods of highest risk, i.e. sample prep. etc. If the laboratory is found to be undertaking low risk activities and there is little or no effect on the compliance, the frequency of audit schedule(cycle) could potentially be reduced thereby reducing the assessment costs. This approach could also be adopted to field operational labs supporting compliance.

I believe that this new type of approach to lab accreditation would be unique to BC and it potentially could be a more suitable and less expensive alternative for the auditing of small industrial/commercial labs undertaking specific lab analyses supporting compliance monitoring. I believe this approach would also be welcomed by both industry and small labs and it would also be a benefit to the Ministry as it may be more effective tool to fulfill the original intent of the EDQA Regulation than the current intended "one shoe fit all" accreditation approach. In addition, by implementing this approach and incorporating an MOE audit team, the Ministry would also build an all-important in-house technical expertise to accurately and effectively assess environmental laboratories on a continual basis."

Ministry Response

Thank you for this well-thought process for consideration. While we agree that such a process is desirable for the reasons you point out, it is a challenge to accomplish for the following reasons:

- The scope of accreditation is determined by the testing laboratory not the accreditation body or ENV. This allows the laboratory to determine which parameters to include.
- It is resource intensive at a time when government resources are exceedingly limited.
- This is the business of accrediting bodies, and they are better positioned - technically and administratively - to carry it out than the ministry.
- Use of accrediting bodies for this purpose is cost neutral to the people of B.C.

Additional Comment 3

"CCIL would like to see more clarity around which regulations, permits and licenses require accredited testing."

Ministry Response

In general accredited testing will be required for any parameter listed in an authorization. Authorizations include orders, permits, approvals or certificates issued under an enactment administered by the minister. Authorization holders are required to have a qualified laboratory analyze their samples for the parameters specified in their authorization.

Additional Comment 4

"CALA strongly supports the proposed revisions to the EDQAR that require the accreditation of laboratories to ISO/IEC 17025 by an Accreditation Body (AB) that operates according to ISO/IEC 17011 (evidenced by the fact that the AB is a signatory to the ILAC MRA."

Ministry Response

Thank you for your support.

Additional Comment 5

"What will be the process to ensure that prescriptive elements in the BC Lab Manual do not interfere with or prevent the use of accredited laboratory performance-based methods for submission of results to ENV?"

Ministry Response

The assessors will understand that the prescriptive elements in the BC Lab Manual take precedence and will take this into consideration during assessments.

Additional Comment 6

"Section 2.1 The proposed requirement to submit analytical results within 45 days does not align with data submission timeframes identified in facility permits and should therefore not apply to data associated with permit-mandated monitoring."

Ministry Response

An authorization holder must provide the results of the qualified laboratory's analysis as a) specified in the authorization, b) a director, or c) within 5 days after the analysis is completed.

Additional Comment 7

"In reference to Figure 1, PPEF would like to point out that difference in consecutive failures between accredited and non-accredited labs was less than 0.5%. This very small difference hardly seems sufficient to warrant the imposition of substantial operational changes and costs."

Ministry Response

Yes, this observation is correct. It is part of a trend to improved performance that has been pushed by the advent of laboratory standards – both for accredited and non-accredited laboratories (to their credit). It is also a valid observation to see that accredited laboratories also demonstrate PT failures and loss of accreditation from time to time. It is important to understand that the elements being put in place by the update to the EDQAR – ISO/IEC 17025 accreditation in particular – is a *system* improvement that will achieve better confidence in all test results being received by the ministry, and improve decision-making for the protection of the people and environment of B.C.

Additional Comment 8

"It is unclear how the proposed EDQAR revisions would apply to consultants/contractors retained by the forest products sector companies for the purpose of conducting regulatory/permit air emissions sampling and testing. All sampling and analysis must follow permit or regulatory prescribed methodologies (i.e. USEPA Method 5), including QA/QC, and as such should be exempt from the EDQAR proposed changes."

Ministry Response

The requirement for testing by accredited laboratories applies to 'discrete environmental samples' which are defined as "an environmental sample collected for analytical testing or processing by a laboratory".

Additional Comment 9

"Finally, it is important for ENV to understand that although some facilities (such as solid wood) are able to use contract laboratories or consultants, this is not a viable option to replace all testing presently conducted in an in-house laboratory. The extra handling and time delays, alone, associated with remote shipping and off-site analyses pose a notable risk to diligent environmental performance management."

Ministry Response
The ministry recognizes the challenge presented by remote facilities. This is the reason we encourage you to consider becoming accredited.

Additional Comment 10
"Thank you for the opportunity to comment. We look forward to the updated regulation as a step forward in ensuring the protection of the public and the health of the environment."

Ministry Response
Thank you for your support.

Additional Comment 11
"None, other than our positions in the attached letter"

Ministry Response
Thank you for your submission.

Additional Comment 12
"Large-scale, remote production facilities need to maintain compliance with an updated EDQAR and to be available to support immediate, short turn-around time (24 hours) testing requirements for emergencies. A goal of EDQAR should be continuous improvement, and this should be in balance with:
- mitigating risk to the environment; and
- degree of enforcement.

As described in Question 2.1: Consider the exceptionally rare event of a suspended PT parameter that must be analyzed in a timely manner. Consideration should be given to what options a remote production facility will have if a third-party laboratory is not available with an accredited method within a reasonable distance for a reasonable turnaround time."

Ministry Response
As noted above, the ministry is sensitive to the challenges the update to the EDQAR may present to remote testing facilities. It is important that your organization consider accrediting your remote testing facility in order that the logistical challenges can be met in a reliable way and would encourage you to explore the costs of accreditation. It is also important to consider the local circumstances and "due diligence" to prepare for challenges that may present themselves from time to time. The ministry is prepared to work with all permittees in achieving the essential element of the EDQAR update – improved confidence in test results submitted to the ministry.

Appendix A

Response Form Questions

Response Form Questions

The following questions are based on the ministry's policy intentions paper for revising the Environmental Data Quality Assurance Regulation (EDQAR). The intentions paper can be downloaded from the ministry website at:

https://www2.gov.bc.ca/assets/download/2A0BD92BA0434A588975861AADDB34E4

General Questions

The ministry has a duty to protect human health and the environment, and the best decisions can only be made with objective and reliable test results. The EDQAR will be strengthened to incorporate a formal laboratory standard for the qualification of laboratories, leading to improved confidence and reliability of test results. It will also facilitate reaching "equivalency agreements" with other levels of government, which will lead to increased efficiency and cost savings.

G1. Overall, please indicate your level of support for the proposed revisions to the EDQAR described in the intentions paper:

Please select one box from the scale below (1= Not at all supportive; 6= Extremely supportive)

	1	2	3	4	5	6	
Not at all supportive	☐	☐	☐	☐	☐	☐	Extremely supportive

G2. What are the reasons for your choice?

G3. Do you have any general comments about the ministry's proposed revisions to the EDQAR?

PROPOSED UPDATE

1. Laboratory/Test Accreditation

Section 5.1.1 of the EDQAR Intentions Paper (IP) sets out to make formal accreditation a requirement for test data destined for submission to ENV to satisfy monitoring requirements or other purposes under the EMA. Accreditation provides formal recognition of the competence of a laboratory to perform tests in conformance with a formal laboratory standard – ISO/IEC 17025.

1.1 Please indicate your level of support for the proposal to require formal accreditation for the laboratory/test methods that generate test results for ministry programs.

Please select one box from the scale below (1= Not at all supportive; 6= Extremely supportive)

	1	2	3	4	5	6	
Not at all supportive	☐	☐	☐	☐	☐	☐	Extremely supportive

1.2 What are the reasons for your choice in question 1.1?

1.3 Do you have any other comments regarding the ministry's intention to require ISO/IEC 17025 accreditation for laboratories and test methods that produce analytical data for ENV programs?

1.4 Do you support the suggested wording to be used for the update to the EDQAR related to laboratory accreditation? Please offer suggestions for alternate wording if warranted.

2. Scope of Application

Section 5.1.2 of the IP sets out that formal laboratory/test accreditation should be a requirement for all test data destined for submission to ministry programs.

2.1. Do you support the scope of application for laboratory/test accreditation that is being for the generation of all regulatory data to which it can be applied for ENV programs? If not, please explain why.

3. Phase-In Period

In Section 5.1.3, the EDQAR update is considering a two-year update period for the new requirements, including the requirement for formal laboratory/test accreditation. During the transition period, the prior requirement for laboratory qualification is to be maintained.

3.1. Do you have any comments regarding the ministry's intention to have a phase-in period of two years for the new requirements including laboratory/test accreditation?

4. Laboratory Qualification by Proficiency Testing

While the ministry has a strong preference for formal laboratory/test accreditation for test results in its programs, it is recognized there may be circumstances where it will be beneficial to qualify laboratories using the current EDQAR requirement for proficiency testing.

4.1 Please indicate your level of support for the retention of laboratory qualification via proficiency testing as practiced by the EDQAR for use in special circumstances.

Please select one box from the scale below (1= Not at all supportive; 6= Extremely supportive)

	1	2	3	4	5	6	
Not at all supportive	☐	☐	☐	☐	☐	☐	Extremely supportive

4.2 What are the reasons for your choice in question 4.1?

4.3 It is proposed that a laboratory seeking to utilize laboratory qualification by proficiency testing be required to provide a rationale for the accommodation, receive approval of the Director and that approval will be for a limited time period. Please comment on the proposal to set strict conditions on the use of this accommodation.

5. Environmental Test Data Generated by Online/Continuous Monitoring

Section 5.1.5 of the IP proposes that environmental test data generated by online/continuous measurement have an element of quality management to ensure a high level of confidence in the data. While the provision for laboratory/test accreditation does not extend to online/continuous monitoring, certain elements of quality management are proposed in the EDQAR update revisions.

5.1 Do you have any comments or suggestions regarding the proposed revisions for online/continuous measurements that generate test data for ministry programs?

6. Provision for Laboratories New to B.C.

The proposed amendment to the EDQAR include a provision for laboratories new to B.C. in order that the requirement for laboratory/test accreditation not be seen as a barrier to trade. The provisions include utilizing laboratory qualification via proficiency testing as an interim requirement to demonstrate data quality and a two-year period for laboratory/test accreditation to be achieved.

6.1. Please comment on the provision in the proposed EDQAR revisions for laboratories new to B.C.

6.2. Do you have any comments regarding the use of laboratory qualification via proficiency testing or the two-year period for accreditation to be achieved in this process?

7. Special Provisions

Section 5.1.7 of the IP proposes several special provisions to take into consideration special circumstances that the ministry may face with respect to laboratory testing. This includes (but is not limited to) the following potential situations:

- Accreditation and proficiency testing for a parameter is not available;
- Laboratory of special skill or expertise; and
- An “If all else fails” provision for unforeseen circumstances.

7.1 Do you have any comments or suggestions regarding the proposed special provisions for the revised EDQAR?

8. Assuring Compliance

Section 6 of the IP sets out compliance and enforcement provisions that will enable ENV to confirm that the changes proposed in the EDQAR update are implemented within the environmental sector.

8.1. Please comment on the provision in the proposed EDQAR revisions for accreditation verification (Section 6.1).

8.2. Please comment on the provision in the proposed EDQAR revisions for accreditation updates and proficiency testing performance notifications (Sections 6.2 and 6.3).

9. Additional Comments

Do you have any additional comments or suggestions for the Ministry regarding the proposed revisions to the regulation?

Please add comments on other aspects of the Intentions Paper to completely address any concerns you may have. All comments will be read and considered.

Thank you very much for your comments and feedback.