Baltic Marine Environment Protection Commission

Working Group on the State of the Environment and Nature Conservation

Schwerin, Germany, 11-15 April, 2016

STATE & CONSERVATION 4-2016, 2MA-15

Document title	Revision of COMBINE text: Part B Annex B1-B5
Code	2MA-15
Category	CMNT
Agenda Item	Revision of HELCOM monitoring
Submission date	14.04.2016
Submitted by	Estonia

Background

This document contains proposed updates to HELCOM COMINE text on Part B Annex B1-B5 submitted by Estonia. Annex 1 contains the text proposal with track changes and Annex 2 contains a clean version.

Action requested

The Meeting is invited to take note of the information and agree on the proposal.

Revision of COMBINE-text: Part B Annex B1-B5

SWEDEN:

Common comments:

- Revision aims for Annex B1-B5, how are the plans for Part B B1-B7?
- Sweden is interested to follow the plans, please contact Norbert Häubner (norbert.haubner@havochvatten.se)

Specific comments:

Quality manual and SOPs:

- Laboratories/agencies/institutes…. must have an accredited quality system"
    - Requirement of accreditation could be hard and unreasonable expensive for small laboratories, but we support to require a transparent documentation of routines for quality management
    - Laboratories which are not accredited for the respective parameters should follow the ISO/IEC 17025
    - It should be possible to define for the laboratories if they follow ISO/IEC 17025 in detail, but should as a minimum requirement describe in a pre-defined frequency what has been done to assure high quality standards (SwAM has extracted a minimum requirement from the ISO/IEC 17025 for the national monitoring programmes, which could be provided if needed)
    - For bigger laboratories, with sufficient resources, should accreditation be mandatory, observed by SWEDAC (or similar institutions in other CPs)
    - Proposal for additional text: *For smaller laboratories or experts performing marine monitoring there may be exceptions allowed to the general rule of having an accredited quality system, due to an unreasonably high cost for keeping the accreditation. Those smaller performers must, however, use a well-documented and traceable quality assurance system according to at least the most applicable parts in ISO/IEC 17025 (which should be specified).*
- Validation of analytical methods:
    - The last two sentences are repetitive: "The following parameters should be considered…The range…" , should be compared with B4 Validation of analytical methods – possible to mention here:
        - Selectivity
        - Sensitivity
        - Limit of detection, Limit of quantification
        - Range
        - Accuracy
        - Measurement uncertainty
- Quality audit:
    - Important to point out follow-up systems and measures as part of the ongoing improvement
    - Proposal for additional text (copied from Annex B-3 5.2 and 6.7: *Whenever a non-conformity that may jeopardise the result of a calibration, test or inspection is discovered, the corresponding activity should be halted until the appropriate corrective action has been taken and has been shown to lead to satisfactory results. In addition, results that may have been affected by the non-conformity should be investigated and customers*

informed if the validity of corresponding calibration, test or inspection certificates/reports is in doubts. The purpose of (such) reviews is to ensure that the audits and the corrective actions are contributing to the continuing effectiveness of the quality management system as a whole.

LATVIA:

In HELCOM STATE meeting contracting parties were requested to comment issue on international accreditation for laboratories performing monitoring. Our opinion is that the accreditation should be required, but not internationally. It is too strong and not needed. The usual way after all is that there is a national body that is issuing accreditation status to laboratories and thereafter performs overseer role. This body is then accredited internationally.

GERMANY:

As laid down in the Outcome of the meeting, Poland and Sweden were of the view that the request for laboratories to have an accredited quality system was formulated too strictly.

This view is supported by Germany. Our national quality assurance expert, Ms. Petra Schilling, suggests to change the wording in the first paragraph under the Heading „Quality manual and SOPs“ by adding a sentence as follows:

“Laboratories/agencies/institutes performing marine monitoring (both sampling and laboratory analyses) must have an accredited quality system based on requirements of ISO/IEC 17025 “General requirements for the competence of testing and calibration laboratories”. If no formal accreditation is possible, the effectivity of the quality system has to be checked regularly by an external and independent authority during external audits. The quality system should be formalized …“

The reason for this is that particularly biological investigations are often carried out by small companies or associations or even by single experts. For these, it is often not possible to undergo a formal accreditation due to the extra work involved (not enough personnel) and the relatively high costs. Thus highly renounced experts would be excluded from the work if accreditation is mandatory. Giving the option of using external audits as formulated above would keep them in.

In order to avoid having to update the whole Manual after new editions of the standards have become available, I suggest to leave out the date in the citation of the relevant standard and to include the following wording:

"Note: For undated references of European Standards, the latest edition of the referenced document (including any amendments) applies."

Annex 1

Proposal of the text to substitute Part B Annexes B1-B5 of the COMBINE manual

Quality assurance and control

Quality manual and SOPs

Laboratories/agencies/institutes performing marine monitoring (both sampling and laboratory analyses) must have an accredited quality system based on requirements of ISO/IEC 17025 "General requirements for the competence of testing and calibration laboratories". The quality system should be formalized in a quality manual, which must be maintained and kept up-to-date.

For smaller laboratories or experts performing marine monitoring there may be exceptions allowed to the general rule of having an accredited quality system, due to an unreasonably high cost for keeping the accreditation. Those smaller performers must, however, use a well-documented and traceable quality assurance system according to at least the most applicable parts in ISO/IEC 17025 (which should be specified).

Standard Operating Procedures (SOPs) are Quality Management (QM) documents, which have to meet the ISO/IEC 17025 requirements. Laboratories/agencies/institutes performing marine monitoring should have documented SOPs and are obliged to follow these procedures.

Validation of analytical methods

Analytical methods need to be validated or revalidated before their introduction into routine use, whenever the conditions change for which the method has been validated (e.g., an instrument with different characteristics or samples with a different matrix), and whenever the method is changed and the change is outside the original scope of the method.

According to the ISO/IEC 17025 the laboratories/agencies/institutes shall confirm that they can properly operate standard methods before introducing the tests or calibrations. When some changes are made in the validated nonstandard methods, the influence of such changes should be documented and, if appropriate, a new validation should be carried out. The laboratory shall validate nonstandard methods, laboratory designed and developed methods, standard methods used outside their intended scope, and amplifications and modifications of standard methods to confirm that the methods are fit for their intended use. Validation includes specification of requirements, determination of method characteristics, a check that the requirements can be fulfilled by using the method, and a statement on validity. The following parameters should be considered for validating standard and in-house developed methods:

- Selectivity
- Sensitivity
- Limit of detection, Limit of quantification
- Range
- Accuracy
- Measurement uncertainty

~~limit of detection, limit of quantitation, accuracy, selectivity, linearity, repeatability or reproducibility, robustness, and linearity. The range and accuracy of the values obtainable from validated methods (e.g. the uncertainty of the results, detection limit, selectivity of the method, linearity, limit of~~

~~repeatability and/or reproducibility, robustness against external influences and/or cross – sensitivity against interference from the matrix of the sample/test object), as assessed for the intended use, shall be relevant to the assessment needs.~~

Quality audit

A laboratory/agency/institute performing marine monitoring shall periodically and in accordance with a predetermined schedule and procedure, conduct internal audits of its activities to verify that its operations continue to comply with the requirements of the quality system (ISO/IEC 17025). These audits should check that the quality management system fulfils the requirements of ISO/IEC 17025, whichever is applicable, or other relevant criteria documents, i.e. that there is conformity. These audits should also check whether or not the requirements stated in the organisation's quality manual and related documents are applied at all levels of work. The non-conformities found in internal audits give valuable information for the improvement of the organisation's quality system and should thus be used as input to management reviews.

Whenever a non-conformity that may jeopardise the result of a calibration, test or inspection is discovered, the corresponding activity should be halted until the appropriate corrective action has been taken and has been shown to lead to satisfactory results. In addition, results that may have been affected by the non-conformity should be investigated and customers informed if the validity of corresponding calibration, test or inspection certificates/reports is in doubts. The purpose of (such) reviews is to ensure that the audits and the corrective actions are contributing to the continuing effectiveness of the quality management system as a whole.

Formatted: Font: Not Italic

General remarks on sampling

According to the ISO/IEC 17025 requirements, the sampling programme should include the following:
1) a predetermined sampling plan that takes into account the specific purpose of the investigations, including the contaminants to be determined, their expected concentration range, and the type of matrix to be analysed;
2) sample collection by personnel trained in the sampling techniques and procedures specified;
3) maintenance of the sample integrity by
- using sampling devices that have been found to be suitable for the particular purpose,
- avoiding contamination of samples from the use of unclean equipment,
- using transportation procedures that ensure that the composition of the sample or the concentrations of the variables are not altered;

4) instructions for labelling the sample specifying its identity;
5) a record that demonstrates an unbroken control over the sample from collection to its final disposition.

Detailed guidelines on sampling in different matrices will be dealt with each separate variable measured in the frames of the HELCOM coordinated monitoring program. Recommendations from other bodies or working groups will be taken into consideration when available.

REFERENCE

ISO/IEC 17025~~ (2005)~~: General requirements for the competence of testing and calibration laboratories

Note: For undated references of European Standards, the latest edition of the referenced document (including any amendments) applies.

Formatted: Font: +Body (Calibri), Not Bold

Annex 2

Proposal of the text to substitute Part B Annexes B1-B5 of the COMBINE manual

Quality assurance and control

Quality manual and SOPs

Laboratories/agencies/institutes performing marine monitoring (both sampling and laboratory analyses) must have an accredited quality system based on requirements of ISO/IEC 17025 "General requirements for the competence of testing and calibration laboratories". The quality system should be formalized in a quality manual, which must be maintained and kept up-to-date.

For smaller laboratories or experts performing marine monitoring there may be exceptions allowed to the general rule of having an accredited quality system, due to an unreasonably high cost for keeping the accreditation. Those smaller performers must, however, use a well-documented and traceable quality assurance system according to at least the most applicable parts in ISO/IEC 17025 (which should be specified).

Standard Operating Procedures (SOPs) are Quality Management (QM) documents, which have to meet the ISO/IEC 17025 requirements. Laboratories/agencies/institutes performing marine monitoring should have documented SOPs and are obliged to follow these procedures.

Validation of analytical methods

Analytical methods need to be validated or revalidated before their introduction into routine use, whenever the conditions change for which the method has been validated (e.g., an instrument with different characteristics or samples with a different matrix), and whenever the method is changed and the change is outside the original scope of the method.

According to the ISO/IEC 17025 the laboratories/agencies/institutes shall confirm that they can properly operate standard methods before introducing the tests or calibrations. When some changes are made in the validated nonstandard methods, the influence of such changes should be documented and, if appropriate, a new validation should be carried out. The laboratory shall validate nonstandard methods, laboratory designed and developed methods, standard methods used outside their intended scope, and amplifications and modifications of standard methods to confirm that the methods are fit for their intended use. Validation includes specification of requirements, determination of method characteristics, a check that the requirements can be fulfilled by using the method, and a statement on validity. The following parameters should be considered for validating standard and in-house developed methods:

- Selectivity
- Sensitivity
- Limit of detection, Limit of quantification
- Range
- Accuracy
- Measurement uncertainty

Quality audit

A laboratory/agency/institute performing marine monitoring shall periodically and in accordance with a predetermined schedule and procedure, conduct internal audits of its activities to verify that its operations continue to comply with the requirements of the quality system (ISO/IEC 17025). These audits should check that the quality management system fulfils the requirements of ISO/IEC 17025, whichever is applicable, or other relevant criteria documents, i.e. that there is conformity. These audits should also check whether or not the requirements stated in the organisation's quality manual and related documents are applied at all levels of work. The non-conformities found in internal audits give valuable information for the improvement of the organisation's quality system and should thus be used as input to management reviews.

Whenever a non-conformity that may jeopardise the result of a calibration, test or inspection is discovered, the corresponding activity should be halted until the appropriate corrective action has been taken and has been shown to lead to satisfactory results. In addition, results that may have been affected by the non-conformity should be investigated and customers informed if the validity of corresponding calibration, test or inspection certificates/reports is in doubts. The purpose of (such) reviews is to ensure that the audits and the corrective actions are contributing to the continuing effectiveness of the quality management system as a whole.

General remarks on sampling

According to the ISO/IEC 17025 requirements, the sampling programme should include the following:
1) a predetermined sampling plan that takes into account the specific purpose of the investigations, including the contaminants to be determined, their expected concentration range, and the type of matrix to be analysed;
2) sample collection by personnel trained in the sampling techniques and procedures specified;
3) maintenance of the sample integrity by

- using sampling devices that have been found to be suitable for the particular purpose,
- avoiding contamination of samples from the use of unclean equipment,
- using transportation procedures that ensure that the composition of the sample or the concentrations of the variables are not altered;

4) instructions for labelling the sample specifying its identity;
5) a record that demonstrates an unbroken control over the sample from collection to its final disposition.

Detailed guidelines on sampling in different matrices will be dealt with each separate variable measured in the frames of the HELCOM coordinated monitoring program. Recommendations from other bodies or working groups will be taken into consideration when available.

REFERENCE

ISO/IEC 17025: General requirements for the competence of testing and calibration laboratories

Note: For undated references of European Standards, the latest edition of the referenced document (including any amendments) applies.