Baltic Marine Environment Protection Commission

Working Group on the State of the Environment and Nature Conservation

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STATE & CONSERVATION 3-2015

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Submitted by	Estonia
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Background

State and Conservation 2-2015 considered Table 2 of document 2MA-1-Rev.1 'Information on monitoring guidelines' and welcomed that Estonia will review and propose a general text and associated references to substitute Part B Annex B1-B5 of the current COMBINE manual. The meeting agreed that Annexes B6, B7 and B16 will not be included as separate chapters in the Monitoring Manual but that the content of the annexes will instead be considered in the guidelines of the respective monitoring sub-programmes.

This document contains a proposal to substitute Part B Annexes B1-B5 of the COMINE manual.

Action required

The Meeting is invited to take note of the information and agree on replacing the current text with this proposal.

Proposed 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.

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: 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.

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