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Requirements for laboratories testing the physico-chemical and chemical parameters of water, for the analyses performed as part of those tests and for quality assurance of laboratory operations, and the analysis reference methods[1]

Passed 25.08.2011 Annex 57

This Regulation is enacted on the basis of Section 12^1(3) of the Water Act (*Veeseadus*).

Chapter 1
Requirements for laboratories testing the physico-chemical and chemical parameters of water and for quality assurance of their operations

§ 1. Competence of laboratories

Laboratories testing the physico-chemical and chemical parameters of water ('laboratories') must meet the following requirements:
1) they must be accredited in accordance with the EVS EN ISO/IEC 17025 standard;
2) they must be accredited to use the appropriate methods of analysis (including laboratory, field and online methods);
3) they must have undergone the required interlaboratory comparative tests once a year.

§ 2. Receipt of samples at laboratories

(1) When a sample is received at a laboratory, an appropriate sampling protocol that has been put in place for the sampling methods under the relevant Regulation enacted on the basis of Section 12^1(3) of the Water Act shall be submitted with the sample.

(2) The recipient of a sample at a laboratory shall draw up a document confirming receipt and containing at least the following information:
1) the date and time the document was prepared;
2) the given name and surname of the person handing over the sample and of the recipient;
3) the conditions under which the sample was transported to the laboratory;
4) the date and the time the sample was taken;
5) the parameters to be determined.

(3) The document confirming receipt shall be signed by the person handing over the sample and by the recipient.

(4) If it becomes evident that the sample has not been taken or transported in accordance with the requirements laid down in the relevant Regulation of the Minister for the Environment enacted on the basis of Section 12^1(3) of the Water Act, a note to this effect shall be added to the analysis report to be issued by the laboratory.

(5) In the case referred to in subsection 4, the analysis results shall not be used for the purposes of water surveys within the meaning of Section 12^1(1) of the Water Act.

§ 3. Choice of method of analysis

(1) The method of analysis shall be chosen in accordance with the EVS EN ISO/IEC 17025 standard or other equivalent standards accepted at international level.

(2) If the laboratory does not use a reference method for analysing a sample, it shall use methods of analysis, including laboratory, field and online methods, which have been validated and documented in accordance with the EVS EN ISO/IEC 17025 method or other equivalent standards accepted at international level.

§ 4. Drawing up of analysis results

Analysis results shall be drawn up in accordance with the requirements of the EVS EN ISO/IEC 17025 standard or other equivalent standards accepted at international level.

§ 5. Disputing analysis results

(1) When analysis results are disputed, a parallel analysis shall be organised in another impartial laboratory that meets the requirements laid down in Section 1 of this Regulation.

(2) When resolving a dispute, preference shall be given to analysis results obtained using a reference method.

§ 6. Quality assurance and control of laboratory operations

(1) In their operations, laboratories shall apply a quality management system in accordance with the EVS EN ISO/IEC 17025 standard or other equivalent standards accepted at international level.

(2) Laboratories shall participate in the interlaboratory comparative tests referred to in Section 12^1(4) of the Water Act by:
1) participation in interlaboratory comparative tests that are carried out using the methods of analysis referred to in Section 3 of this Regulation of measurands at levels of concentrations that are representative of the chemical testing of water;
2) analysis of reference materials concerning collected samples which contain measurands at appropriate levels of concentrations in relation to the standards referred to in Section 7(1) of this Regulation.

Chapter 2
Requirements for the quality of analyses performed as part of tests of the physico-chemical and chemical parameters of water

§ 7. Minimum performance criteria for methods of analysis

(1) The minimum performance criteria for all methods of analysis shall be based on an uncertainty of measurement of 50 % or below (k = 2) and a limit of quantification equal to or below a value of 30 % of the relevant standards.

(2) For the purposes of this Regulation, ‘limit of quantification’ means a stated multiple of the limit of detection at a concentration of the determinand that can reasonably be determined with an acceptable level of accuracy and precision. The limit of quantification can be calculated using an appropriate standard or sample. It may also be obtained from the lowest calibration point on the calibration curve, excluding the blank.

(3) For the purposes of this Regulation, ‘uncertainty of measurement’ means a non-negative parameter characterising the dispersion of the quantity values being attributed to a measurand, based on the information used.

(4) For the purposes of this Regulation, ‘limit of detection’ means the output signal or concentration value above which it can be affirmed, with a stated level of confidence, that a sample is different from a blank sample containing no determinand of interest.

(5) In the absence of a relevant standard for a given parameter, or in the absence of a method of analysis meeting the minimum performance criteria set out in subsection 1, the best available techniques not entailing excessive costs shall be used.

§ 8. Calculation of mean values

(1) Where the amounts of physico-chemical or chemical measurands in a given sample are below the limit of quantification, the measurement results shall be set to half of the value of the limit of quantification concerned for the calculation of mean values.

(2) Where a calculated mean value of the measurement results referred to in subsection 1 is below the limits of quantification, the value shall be referred to as ‘less than limit of quantification’.

(3) Subsection 1 shall not apply to measurands that are total sums of a given group of physico-chemical parameters or chemical measurands, including their relevant metabolites, degradation and reaction products. In those cases, results below the limit of quantification of the individual substances shall be set to zero.

Chapter 3
Analysis reference methods

§ 9. Reference method

For the purposes of this Regulation, ‘reference method’ is a standard method of determination that is the basis for comparing other methods of analysis in accordance with the EVS EN ISO/IEC 17025 standard or other equivalent standards accepted at international level. The reference methods are set out in the Annex to this Regulation.

§ 10. Choice of reference method

When choosing a reference method, preference shall be given to a valid standard issued by the International Organisation for Standardisation or another standard issued by an internationally recognised professional organisation.

§ 11. Repeal of Regulation

Regulation No 53 of the Minister for the Environment of 16 June 2003 on the requirements for laboratories performing water surveys and the analysis reference methods (RTL 2003, 78, 1140) is repealed.

[1]Commission Directive 2009/90/EC laying down, pursuant to Directive 2000/60/EC of the European Parliament and of the Council, technical specifications for chemical analysis and monitoring of water status (OJ L 201, 1.8.2009, p. 36).

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Annex