Commission Regulation (EU) No 601/2012 of 21 June 2012 on the monitoring and reporting of greenhouse gas emissions pursuant to Directive 2003/87/EC of the European Parliament and of the Council (Text with EEA relevance) (repealed)

CHAPTER III

MONITORING OF EMISSIONS OF STATIONARY INSTALLATIONS

SECTION 2

Calculation-based methodology

Subsection 3

Calculation factors

Article 34

Use of laboratories

1 The operator shall ensure that laboratories used to carry out analyses for the determination of calculation factors are accredited in accordance with EN ISO/IEC 17025, for the relevant analytical methods.

2 Laboratories not accredited in accordance with EN ISO/IEC 17025 may only be used for the determination of calculation factors where the operator can demonstrate to the satisfaction of the competent authority that access to laboratories referred to in paragraph 1 is technically not feasible or would incur unreasonable costs and that the non-accredited laboratory meets requirements equivalent to EN ISO/IEC 17025.

3 The competent authority shall deem a laboratory to meet the requirements equivalent to EN ISO/IEC 17025 within the meaning of paragraph 2 where the operator provides, to the extent feasible, in the form of and to a similar level of detail required for procedures pursuant to Article 12(2), evidence in accordance with the second and the third subparagraph of this paragraph.

With respect to quality management, the operator shall produce an accredited certification of the laboratory in conformity with EN ISO/IEC 9001, or other certified quality management systems that cover the laboratory. In the absence of such certified quality management systems, the operator shall provide other appropriate evidence that the laboratory is capable of managing its personnel, procedures, documents and tasks in a reliable manner.

With respect to technical competence, the operator shall provide evidence that the laboratory is competent and able to generate technically valid results using the relevant analytical procedures. Such evidence shall cover at least the following elements:

- a management of the personnel's competence for the specific tasks assigned;
- b suitability of accommodation and environmental conditions;

- d where applicable, management of sampling and sample preparation, including control of sample integrity;
- e where applicable, development and validation of new analytical methods or application of methods not covered by international or national standards;
- f uncertainty estimation;
- g management of equipment, including procedures for calibration, adjustment, maintenance and repair of equipment, and record keeping thereof;
- h management and control of data, documents and software;
- i management of calibration items and reference materials;
- j quality assurance for calibration and test results, including regular participation in proficiency testing schemes, applying analytical methods to certified reference materials, or inter-comparison with an accredited laboratory;
- k management of outsourced processes;
- 1 management of assignments, customer complaints, and ensuring timely corrective action.