GUIDANCE ON THE IMPLEMENTATION OF THE WATER SUPPLY (WATER QUALITY) REGULATIONS 2016 IN ENGLAND AND THE WATER SUPPLY (WATER QUALITY) REGULATIONS 2010 (as amended) IN WALES

The Regulations

Part 5 – Monitoring Additional Provisions

Regulation 16:
Collection and analysis of samples

Appendix 16.1:
Regulation 16: Analysis of samples

PART 5 – MONITORING ADDITIONAL PROVISIONS

Regulation 16 – Collection and analysis of samples

16.1 Regulation 16 specifies the minimum quality requirements for the taking, handling, storage and analysis of samples taken for the regulatory monitoring of water supplies. These requirements are set out in regulations 16(2) and 16(5). Regulation 16(4) sets out the requirement for the retention of records to demonstrate that the sampling, transport, storage and analysis of each sample complied with the requirements. Other paragraphs cover definitions and the procedure for authorising the use of alternative methods for microbiological analysis.

16.2 Regulation 16(2) requires that samples taken must be representative of the quality of water at the time of sampling. Sampling facilities at suppliers' assets must be designed, maintained and operated to ensure that samples taken represent the quality of the water being supplied from the asset at the time the sample is taken. Fittings approved under the Water Regulations Advisory Scheme (WRAS) should be used as appropriate.

16.3 Companies should use the BS_EN_ISO-5667 series of documents and *The Microbiology of Drinking Water (2010) - Part 2 – Practices and procedures for sampling* to form the basis for their own internal sampling manuals and design standards for companies' own sampling facilities. The Inspectorate expects companies to adopt the procedures and practices specified in these publications, which set down the standards required for best practice.

16.4 The department for Business Innovation and Skills (BIS) has appointed the United Kingdom Accreditation Service (UKAS) as the sole accreditation body in the UK for the purposes of assessing drinking water testing facilities and sampling arrangements in accordance with ISO/IEC 17025 and the Drinking Water Testing Specification (DWTS). Information Letter 05/2013 introduced the mandatory requirement that laboratories should obtain UKAS accreditation under ISO/IEC 17025 to DWTS for **all** sampling, transport and analysis of drinking water that falls within the scope of the Regulations, with effect from May 2016.

16.5 Companies should seek to obtain accreditation to ISO/IEC 17025 for sampling activities that fall within the scope of a company's laboratory quality management system, for example samples taken by samplers employed by the laboratory itself, or by the water company to take compliance samples for all regulatory parameters. The Inspectorate has proposed that certification under ISO/IEC 17024 is an acceptable alternative for individuals who take samples but who are not employed by a laboratory or by the company for routine regulatory sampling, for example distribution operatives and treatment works technicians for whom water quality sampling for a limited range of parameters is one of their duties. At the present time there are no certification schemes for sampling in operation, and the Inspectorate is in discussion with companies and UKAS to establish a way forward.

16.6 Accreditation to DWTS provides assurance to the Inspectorate that companies are complying with all the requirements of regulation 16 and, in line with the principles of better regulation, allows the Inspectorate to adopt a lighter touch approach to regulating sampling and analytical procedures.

16.7 Any samples taken by a company used to establish compliance with regulation 4 (wholesomeness), including samples taken in accordance with, or to demonstrate compliance with, the requirements of Parts 3 to 8 of the English and Welsh regulations

and **any other purpose** to determine whether a public drinking water supply is wholesome, should be covered either by the company's DWTS accreditation for sampling and laboratory analysis, or 17024 certification, whichever is appropriate. This includes samples taken as part of investigations into suspected offences committed under sections 72 and 73 of the Water Industry Act 1991.

16.8 The Inspectorate recognises that in some circumstances it may not be possible to take a sample or carry out a laboratory analysis in accordance with the company's accreditation, for example when investigating unknown contaminants using GCMS. Therefore, if a company is investigating a water quality issue and has not, or is unable to use a sampling procedure or analytical method covered by its DWTS accreditation, then this should be made clear in any report submitted to the Inspectorate. Companies are expected to maintain an awareness of and use sub-contract laboratories that can provide accredited sampling and analysis as appropriate for parameters that are beyond the scope of its laboratory's accreditation.

16.9 In the absence of accreditation to DWTS for radioactivity parameters, the analytical methods should be covered by ISO 11929.

16.10 Regulation 16(2)(d) requires that all samples are analysed as soon as possible after they have been taken, by and under the supervision of a competent person using suitable equipment. Detailed advice on this part of the Regulations is given in Appendix 16.1.

16.11 Regulation 16(3) extends the scope of the term "laboratory" to a person who may undertake analysis at the time when, and place at which, the samples are taken. Therefore the requirements of regulations 16(4), (5) and (6) cover analysis carried out on site, for example by samplers and treatment works operatives using portable testing equipment, and on-line analysers used to monitor the performance of water treatment processes, where the results or data obtained are used for any purpose as described above in paragraph 16.7.

16.12 If a company provides results or data to the Inspectorate, for any regulatory purpose, that is obtained using an instrument or method that is not covered by the company's accreditation or certification, then this must be made clear in any accompanying report.

16.13 Regulation 16(4) requires companies to maintain records for 5 years which demonstrate that the results of samples taken for regulatory purposes comply with the requirements of regulation 16, including paragraphs 5 and 6, which specify the methods to be used for microbiological analyses and the requirements for analytical trueness (accuracy), precision and limits of detection for chemical analyses. As explained in paragraph 16.6 above, accreditation to DWTS will provide assurance to the Inspectorate that companies are complying with all the requirements of regulation 16, along with having appropriate analytical quality control systems in place, which will allow the Inspectorate to adopt a lighter touch approach to regulating analytical procedures. Refer also to regulation 34, which covers the retention of records of any electronic monitoring (e.g. continuous analysers).

16.14 If a company wishes to adopt a new analytical method for any regulatory purpose, then the method should be subject to validation as approved by the relevant Standing Committee of Analysts, and, subject to that approval, the company should then obtain accreditation under DWTS before the method is used. The Inspectorate is represented on the SCA and, therefore, if these requirements are complied with, the company will be deemed to be complying with regulations 16(7), (8), (9) and (10), whereby the Inspectorate, acting on behalf of the Secretary of State or Welsh Ministers, is required to approve the use of any new analytical method.

16.15 Regulation 16(11) allows the Inspectorate to revoke any authorisation given under regulation 16(7), with 3 months' notice to the company.

APPENDIX 16.1: REGULATION 16 – ANALYSIS OF SAMPLES

A1 Training of analysts

A1.1 Water companies or their analytical contractor should produce a comprehensive analyst training manual and programme to cover all aspects of analysis.

A1.2 Once trained, all analysts' performance should be monitored and subject to regular audit. Monitoring and audit procedures, criteria for satisfactory performance and policy on retraining should be documented.

A1.3 A training record should be produced for each analyst detailing the training given, with dates and assessment of competence to perform the task, results of any audits, any retraining or further training given and any re-assessment of that competence.

A1.4 Guidance on the competence requirements of analysts, their supervisors and laboratory technical and quality management required to comply with regulation 16(2)(d)(i) is given in Information letter 08/2007.

A2 Suitability of equipment

A2.1 In addition to equipment being of the type specified in the analytical procedure, it must comply with each of the following requirements before it can be regarded as suitable for the purpose:

(i) located and used in appropriate conditions;

(ii) maintained according to the manufacturer's recommendations or auditable equivalent procedures;

(iii) have a current calibration that is both valid and traceable to national and international standards;

(iv) be used in accordance with the manufacturer's operating instructions or auditable equivalent procedures; and

(v) demonstrably comply with all system suitability and analytical quality control criteria.

A2.2 General advice on calibration is given in 'Guidelines for Calibration in Laboratories' which is available on the DWI web site (www.dwi.gov.uk).

A2.3 Sub-paragraph (e) of regulation 16(2) requires that all analysis, including field tests, must be subject to a system of analytical quality control (AQC) sufficient to demonstrate that the requirements of regulation 16(5) have been complied with for each analysis. For microbiological parameters either the specified method or an approved alternative must be used in conjunction with the practices and procedures given in 'The Microbiology of Drinking Water (2002)'.

A2.4 Appropriate systems of AQC for all other parameters will include:

- Performance testing of the analytical system;

- Routine internal AQC; and

- External AQC (proficiency testing), if a suitable scheme is available.

A2.5 Sub-paragraph (e)(ii) of regulation 16(2) requires that a laboratory's system of AQC is subject to independent checking by a person who has been approved by the Secretary of State for that purpose.

A3 Initial Performance testing

A3.1 Each laboratory or field testing organisation is required to have tested the performance of the analytical methods used for each parameter or each determined constituent of a parameter, and to have demonstrated that the system is capable of meeting the requirements set out in paragraph 16(5) and Schedule 4 before that system is used for routine analysis of compliance samples. Performance testing should cover the entire analytical procedure, including any sample preparation and concentration steps. Testing must be carried out in a manner emulating that used routinely, without taking special precautions which would not generally apply to achieve optimum performance.

A3.2 An analytical method is the specific combination of laboratory, analysts, instrumentation and analytical procedure used to analyse the sample, including any sample preparation or pre-treatment steps. Provided all analysts have been trained to the same standard and their competence has been assessed using the same criteria they can be regarded as equivalent for the purposes of initial performance testing of the analytical method.

A3.3 The analytical method should be subjected to testing of its trueness, precision and limit of detection, including spiking recovery and resilience against possible interferences. The minimum acceptable specifications for performance testing are given below. The design of tests and calculation of performance characteristics should be in accordance or consistent with the guidance given in 'A Manual of Analytical Quality Control for the Water Industry'(NS30).

A3.4 A laboratory using an analytical method which is not referenced to a fully validated authoritative method will be expected to demonstrate that the method has been fully documented and tested to the standard currently expected of an authoritative reference method. It should demonstrate that the following have been established:

(i) the required tolerances of all measurements undertaken within the method (volumes, temperatures, masses, etc.);

(ii) the forms of the determinand measured, including speciation;

(iii) the effect of interferences has been widely investigated and quantified; and

(iv) significant sources of error have been identified and adequate means of controlling them documented.

A3.5 Further guidance is given in section 4 of NS30. In the past, some reference methods may have been validated to a lower standard than is now required by bodies such as the Standing Committee of Analysts. The data available, plus the body of experience of use of these methods should be assessed when deciding whether the methods are suitable.

A3.6 For most parameters, the minimum specification for the performance characteristics to be determined is as follows.

Estimate the within-laboratory total standard deviation of individual analytical results for blanks, standard solutions, samples and spiked samples on at least 5 separate days (further advice on number of batches and period of testing is given below). The number of replicate determinations of each solution in each batch should be the same and not less than two. The trueness for standard solutions, mean spiking recovery and standard deviation of spiking recovery should also be determined.

A3.7 The range of the standard solutions tested should include the regulatory prescribed concentration or value wherever possible, but in all cases the whole calibrated range of the method must be covered subject to allowance for ensuring that all measurements fall within the calibrated range. This implies that a minimum of two different standard solutions must be included in the performance tests. All standard solutions should be prepared immediately prior to analysis for each batch, either from the pure substance or a stock solution which is known to be stable for the period of the tests.

A3.8 All estimates of standard deviation used to estimate limit of detection or precision, or used in significance tests must have at least 10 degrees of freedom.

A3.9 The sample, or, if necessary, samples, and spiked sample(s) selected for use should represent the type or types of drinking water normally analysed. The same bulk sample(s) should be used throughout the tests. Samples should be spiked immediately before analysis for each batch. The spiking standard should either be known to be stable for the period of the tests or be prepared as for standard solutions.

A3.10 Where there is a choice of key instruments, including electrodes and chromatographic columns, each combination used should be regarded as a separate analytical method. In such cases the following guidance is given.

A3.11 For identical instruments full validation is required of each method except where the results of limited testing of the instruments under the conditions used in the analytical method have demonstrated that there is no statistically significant (at the 95% confidence level) difference in performance between the instruments, in which case only one method requires full validation. The tests should be performed on a minimum of five separate days and include the analysis of typical real samples and spiked samples. If the internal AQC record subsequently shows a significant difference in performance between methods each system should then be fully validated. Alternatively, independent data may be available to demonstrate the equivalence of items such as chromatographic columns.

A3.12 For instruments which are not identical, full validation is required for each analytical method.

A3.13 Laboratories should note that 5 batches of duplicate analyses do not give 10 degrees of freedom. While many combinations of number and size of batch may give 10 degrees of freedom or more, a minimum of 11 batches is required to guarantee that number of degrees of freedom, irrespective of the number of replicates included in the batch. Laboratories are therefore strongly recommended to adopt 11 batches of duplicates as their minimum specification. The formula for calculating degrees of freedom is given on page 57 of NS30.

A3.14 For methods where the discrimination of the method is insufficient to record values other than zero for most blank determinations the within-batch standard deviation of either the low standard or the within-batch standard deviation of the sample may be used to calculate the limit of detection. Alternatively, a very low standard solution, at a concentration approximately two to three times the expected limit of detection when using the best currently available method, may be used as a surrogate blank. Similarly, a natural sample spiked at a similar low level may, if necessary, be used as a surrogate natural sample. Some methods, particularly those involving simple titrations or the use of comparators, may be incapable of measuring any within-batch differences. In such cases, the limit of detection should be quoted as the lowest measurable concentration or value.

A3.15 The bulk sample may not always be stable over the entire period of testing, resulting in an artificially high estimate of between-batch standard deviation. This instability may be recognised by a distinct trend in results for the sample over the period of testing and a between-batch standard deviation which, statistically, is significantly greater (at the 95% confidence level) than would be expected from the estimates obtained for the standard solutions. In such cases, a surrogate between-batch standard deviation should be calculated using procedure (a) on page 53 of NS30. Where the instability is so great that the estimate of within-batch standard deviation is significantly affected, it may be possible to improve stability by ageing of the sample. Where ageing is either impractical or ineffective in reducing sample instability sufficiently to avoid a statistically significant effect on the estimate of within-batch standard deviation, procedure (b) on pages 53 and 54 of NS30 should be used.

A3.16 The period of testing should be continuous and not unduly long. Not more than 2 batches may be analysed on any one day. When 2 batches are analysed on the same day all instruments used should be shut down to overnight conditions, daily reagents freshly prepared and all test solutions freshly prepared between the first and second batches.

A3.17 For physical parameters for which values are not truly additive, spiking recovery tests may yield little useful information and need not be done. It is not possible to either analyse a blank or do spiking recovery tests for hydrogen ion. For these parameters the calibrated range (or ranges) must include the full range of values encountered and the PCV (the full PCV range for hydrogen ion), as samples cannot be diluted.

A3.18 In the following paragraphs re-evaluation means the investigation of the analytical system and its performance to determine whether the most recent validation or revalidation of the analytical system remains appropriate. Re-evaluation may include, as necessary, assessment of the cumulative effect of minor changes to the analytical method, review of internal and external AQC and corrective action followed by limited testing to demonstrate that correct performance has been re-established.

A3.19 In the following paragraphs, revalidation means the redetermination of the performance characteristics of the analytical system as described above.

A3.20 The performance characteristics of an analytical method should be revalidated whenever a significant change has occurred such as a change in:

(i) the analytical procedure used;

(ii) the key equipment used;

(iii) the laboratory environment; or

(iv) change of staff carrying out the procedure. This does not include routine changes which normally occur within the laboratory which are supported by appropriate training and properly trained supervisors.

A3.21 The significance of any change should be assessed by a competent analyst, and any decision that a change is not significant should be supported by the results of limited but adequate testing.

A3.22 When a change of premises occurs, it is not always possible to revalidate all analytical methods before they are used. In such cases, it is essential that methods which on transfer also undergo a change of one of the types (i), (ii) and (iv) above are revalidated before they are used, as should those which are known to be susceptible to changes in laboratory environment e.g. ammonium and trihalomethanes. Other analytical methods should normally be revalidated within 3 months of relocation.

A3.23 Analytical methods should also be re-evaluated and if necessary revalidated whenever the results of routine AQC (internal or external) indicate that a statistically significant deterioration in performance has occurred which cannot be corrected, or that there is a significant discontinuity in the routine AQC record, whether due to a failure to perform routine AQC or disuse of the analytical method. Laboratories may also wish to re-evaluate the performance characteristics whenever routine AQC indicates that a statistically significant improvement in performance has occurred. Statistical significance should normally be assessed at the 95% confidence level.

A3.24 Analytical methods which are used infrequently should not require full revalidation when they are used, provided a greater degree of internal AQC is employed than that recommended for routinely used systems. A suitable procedure is given in recommendation (iv) of the Harmonised Guidelines for Internal Quality Control in Analytical Chemistry Laboratories ISO/IUPAC/AOAC, Pure and Applied Chemistry, vol 67, No 4, pp 649-666, 1995 (The AQC Guidelines).

A3.25 When an analytical method has been in continuous use for several years, typically between 3 and 5 years without revalidation, the system should be re-evaluated, and the need for revalidation of the performance characteristics considered.

A4 Routine Internal AQC

A4.1 As a minimum, the laboratory should use a control solution that contains a known concentration at or close to the PCV for each parameter or determined constituent of a parameter for each analytical method, except as provided for below. The term "close to the PCV" should be interpreted as meaning the PCV ± 25%. The PCV for a determined constituent of a parameter is the PCV for the parameter. The frequency of use of control solutions must be at a frequency of >5% of samples and subject to a minimum of one per batch of analyses for batches of less than 20 samples. All control solutions should be subject to the full analytical procedure that is used for analysing samples and analysed with each batch of analyses.

A4.2 For permanent laboratory tests a "batch of analyses" should be regarded as a group of measurements or observations of standards, samples and/or control solutions which

have been performed together in respect of all procedures, either simultaneously or sequentially, by the same analysts using the same reagents, equipment and calibration.

A4.3 For field tests a "batch of analyses" should be regarded as a group of measurements or observations of standards, samples and/or control solutions which have been performed on the same day by the same analysts using the same reagents, equipment and calibration.

A4.4 In the following cases the guidance on selection of control solutions given above is not appropriate:

(i) the PCV represents a concentration or value outside the normal analytical range of a particular method;

(ii) there is no PCV;

(iii) the PCV is descriptive;

(iv) the PCV is a minimum; or

(v) the PCV is a range.

A4.5 In these cases, as a minimum, a control solution with a known concentration or value within both the calibrated range of the method and the range of interest should be used.

A4.6 When a wide range of concentrations or values is calibrated which includes the PCV, but the overwhelming majority of drinking water samples have concentrations or values which are within a narrow band of the calibration range for which control at the PCV is inappropriate, as a minimum, two control solutions should be used, one with a known concentration or value at or close to the PCV and the other with a known concentration or value within the range of interest.

A4.7 As a minimum, all the results obtained from all control solutions should be used to plot, for each solution or calculated quality control characteristic, a Shewhart chart which is used to decide whether a method is in statistical control. When other types of chart are used, including those using statistics calculated from individual values, the laboratory or other organisation should demonstrate that its arrangements effect adequate statistical control over the systematic error, and both the within-batch and between-batch components of random error, though not necessarily as separate items.

A4.8 Further guidance on the construction and use of control charts is given in NS30, the AQC Guidelines and “Guidance on the Interpretation of Aspects of Analytical Quality Control (AQC)” which is available from the Drinking Water Inspectorate.

A4.9 The laboratory or other organisation should; have properly documented policy and procedures for routine AQC that stipulate what action or actions should be followed when an out of control condition is shown to exist, include a definition of an out of control condition and detail the records to be made when such a condition exists. These documents should be consistent with the guidance given in the documents referenced above. The results of analyses obtained using a method not in statistical control, should not be released except in exceptional circumstances, when each result so released should carry an appropriate commentary in all records and reports. The circumstances in which such results can be released should be fully documented and state that the cause of the out of control condition should first be identified and shown not to affect the results of analysis of samples intended for release.

A4.10 The procedures should also include regular and frequent examination and review of all charts and include guidance for checking and investigating significant trends or changes in either random or systematic error, and for correct operation of the chart. The minimum examination and review periods for each chart should depend on the frequency with which datum points are produced but should not be less frequent than monthly for examination and annually for review. The examination and review should be carried out by a suitably qualified and competent person who is not directly involved in the analysis, such as the laboratory quality manager. There should be appropriate rules for assessing revised control limits.

A5 External AQC

A5.1 The laboratory should participate in an appropriate external AQC scheme for each parameter or determined constituent of a parameter for which an appropriate scheme is available. The laboratory should also have a properly documented procedure for investigating and recording all failures notified by the organiser of a scheme.

A5.2 Guidance on the suitability of a scheme is given in "The International Harmonised Protocol for the Proficiency Testing of (Chemical) Analytical Laboratories" M Thompson, R Wood, Journal of AOAC International, Vol 76, No 4, 1993.

A5.3 In line with the recommendations of this document, laboratories are recommended to participate in schemes distributing drinking water samples of appropriate matrix and which conform to the relevant parts of the protocol. Samples should contain or be spiked with concentrations of interest (approximate range PCV/10 to twice the PCV) and with appropriate speciation where this is of interest. When, in respect of any parameter, a laboratory participates only in schemes which do not meet all the recommended criteria it will be expected to demonstrate that it is participating in the most appropriate scheme currently available.

A6 Regulation 16(3)

A6.1 This regulation includes any organisation or person carrying out regulatory analysis in the definition of a laboratory. This includes all analyses carried out as field tests. Advice on the use of on line monitors is included above at paragraphs 19.13-19.19.

A7 Regulation 16(4) Retention of records

A7.1 This regulation requires a water company to make and retain all records necessary to establish that all the requirements of regulation 16 have been complied with in respect of each analysis carried out.

A7.2 The records required include:

(i) instrument installation, commissioning, maintenance and repair records, including any instrument log or diary;

(ii) basic calibration records (including proof of traceability), system suitability checks and any other record necessary to demonstrate the suitability of any equipment used at the time of the analysis;

(iii) the analytical procedure used;

(iv) method performance testing data, including raw data and a full record of any re-evaluation of the method;

(v) routine internal and external AQC data, including charts, investigations of out of control conditions and corrective action; and

(vi) raw data for the whole analytical run.

A7.3 Items (i) and (ii) above should be retained for not less than three years after the equipment has been decommissioned and disposed of. Calibration records should be retained for not less than three years after either disposal of the equipment or disposal of the calibration item, whichever is the longer.

A7.4 Items (iii) and (iv) above should be retained for not less than three years after the last analysis to which they relate.

A7.5 Items (v) and (vi) above should be retained for not less than three years.

A8 Regulation 16(5)

A8.1 This regulation sets the required standard for quality of analysis or, in the case of microbiological parameters, the method to be used.

Microbiological parameters

A8.2 Sub-paragraph (a) requires that the methods specified in column (2) of Table A1 in Schedule 4 must be used, unless an alternative has been approved. See regulations 16(7) to 16(11) below.

Hydrogen ion

A8.3 All pH measurements must have a trueness of 0.2 pH units and a precision of 0.2 pH units. Suitability of any analytical method used must be established before it is used to analyse samples. See *Initial performance testing* above. On commencement of use, the analytical method must then be continuously subject to routine internal and external AQC. See *Routine Internal AQC* and *External AQC* above.

Odour and Taste

A8.4 A method with a precision of 1 dilution number at 25°C must be used.

A8.5 Methods A1-A3 respectively in the publication The Determination of Taste and Odour in Drinking Waters (2010) in the series Methods for the Examination of Waters and Associated Materials should be used. Performance characteristics cannot be determined for these parameters, nor is there currently available a suitable scheme of external AQC. One sample, which is expected to have a dilution number greater than zero, should be analysed in duplicate with each batch of samples put through the full procedure. The difference between the two results should be plotted on a control chart and used to provide information precision of analysis of samples. All out of control conditions should be investigated and appropriate action taken. Further advice on the use of difference control charts is given in section 5.3.3 (pages 59 to 70) of NS30.

Parameters with no PCV or a descriptive PCV only

A8.6 The parameters residual disinfectant (free and/or total chlorine) and total organic carbon have no numerical value for the PCV and therefore do not appear in Table 2 in Schedule 4. The general guidance given below for all other parameters is appropriate, but satisfactory target values for limit of detection, precision and trueness need to be set by the laboratory. This should be done on the basis of fitness for purpose. Unless the water company is able to demonstrate that less stringent targets are appropriate the target values given below will be regarded as describing fitness for purpose for these parameters.

(i) Residual Disinfectant:

Trueness	The greater of 10% of the result or 0.05 mg Cl/l
Precision	The greater of 10% of the result or 0.05 mg Cl/l
Limit of Detection	0.05 mg Cl/l or the minimum concentration specified as either a target value or an action level at any of the water company's treatments works or in its distribution system, whichever is the lower concentration.

Guidance on calibration and AQC for chlorine measurement is given in Information letter 03/2005 .

(ii) Total organic carbon (TOC)

Trueness	The greater of 10% of the result or 0.25 mg C/l
Precision	The greater of 10% of the result or 0.25 mg C/l
Limit of Detection	0.5 mg C/l

All other parameters

A8.7 The performance requirements are given in Table A2 in Schedule 4 in terms of the maximum permitted deviation of the method for trueness and precision and the maximum value for the limit of detection. These terms are defined in regulation 16(6). For the purposes of these regulations, the precision quoted is numerically equal to twice the total within laboratory standard deviation of individual results.

A8.8 Methods that measure the parameter as defined, and are capable of achieving the stated performance should be selected. Due regard must be given to the effect of interferences. In general, the methods published by the Standing Committee of Analysts in the series 'Methods for the Examination of Waters and Associated Materials' will be capable of the required performance, but laboratories should ascertain this before using any particular method.

A8.9 A laboratory using an analytical method which is not referenced to a fully validated authoritative method, will be expected to demonstrate that the method has been fully documented and tested to the standard currently expected of an authoritative reference method. It should demonstrate that the following have been established:

(i) the required tolerances of all measurements undertaken within the method (volumes, temperatures, masses etc.);
(ii) the forms of the determinand measured, including speciation;

(iii) the effect of interferences has been widely investigated and quantified; and

(iv) significant sources of error have been identified and adequate means of controlling them documented.

A8.10 Further guidance is given in section 4 (pages 31 to 48) of NS30. In the past, some reference methods may have been validated to a lower standard than is now required by bodies such as the Standing Committee of Analysts. The data available plus the body of experience of use of these methods should be assessed when deciding whether these methods are suitable.

A8.11 Table A2 in Schedule 4 only specifies precision and trueness at the PCV. At other concentrations or values the requirement is either the percentage figure given in Table A2 or one half of the value or concentration represented by that percentage figure at the PCV, whichever is the larger.

A8.12 For example, for aluminium the trueness and precision requirements are 10% at the PCV (200 μg/l). This equates to an absolute value of 20 μg/l at the PCV. The target for concentrations less than 100 μg/l (one half of the PCV) is one half of this, 10 μg/l (standard deviation 5 μg/l). For all concentrations above 100 μg/l the target is 10% of the result (standard deviation 5%). At one half of the PCV the target is the same whichever way it is calculated. A worked example for bromate is given below.

Worked example for the bromate parameter

Limit of Detection

Target 25% of PCV i.e. for bromate 2.5 μg/l

Calculated as 5 x within batch SD for blank or low standard surrogate blank or 3 x within batch SD of a natural sample or low spiked sample.

Precision

Target the greater of 25% of mean result or 25% of 0.5 x PCV i.e. for bromate 25% of mean or 1.25μg/l

This applies to all solutions

Trueness

(i) Standards

Greater of 25% of true value or absolute target of 25% of 0.5 x PCV i.e. for bromate 25% of prepared value or 1.25 μg/l

(ii) Natural samples

Not applicable

(iii) Spiked natural samples
Mean recovery of spike the greater of 25% of added spike or 25% of 0.5 x PCV i.e. for bromate 25% of added spike or 1.25 μg/l

A8.13 The suitability of any analytical system used must be established before it is used to analyse samples. See *Initial performance testing* above. On commencement of use, the analytical system must then be continuously subject to routine internal and external AQC. See *Routine Internal AQC* and *External AQC* above.
Guidance on the suitability of methods for the preparation of samples for analysis of metals, sample and sample extract preservation and storage requirements is given in Information letter 12/2005.

A8.14 Performance of a method is satisfactory if either all the relevant criteria are met for all solutions or any difference between the target and the estimate is not significant at the 95% confidence interval.

A9 Regulation 16(6)

A9.1 This regulation defines the terms 'limit of detection', 'precision' and 'trueness'.

A9.2 Either of the methods of estimating the 'limit of detection' given may be used. The estimate of standard deviation used must be calculated from the initial performance testing data using ANOVA. An F-test may be used to determine whether a failure to achieve the target limit of detection is statistically significant.

A9.3 'Precision' is twice the total within laboratory standard deviation. It must be calculated from the initial performance testing data using ANOVA. An F-test may be used to determine whether a failure to achieve the target precision is statistically significant.

A9.4 'Trueness' must be determined using the calculated value of a standard solution or added spike as the true value, and the mean value calculated from the initial performance testing data using ANOVA. A t-test may be used to determine whether a failure to achieve the target trueness is statistically significant, provided precision is satisfactory.

A10 Use of Reporting Limits instead of the limit of detection

A10.1 Analytical reporting limits (RLs) are values or concentrations, other than limits of detection (LODs), that are used by laboratories, and sometimes Water Companies, as a cut off below which all results for a particular test are reported as being less than that value or concentration. They should not be used for parameters that are defined as the sum of the detected concentrations of the constituent compounds, e.g. total pesticides, trihalomethanes, polycyclic aromatic hydrocarbons.

A10.2 RLs are sometimes used instead of the determined LODs because the LOD has a value or concentration that is not compatible with the laboratory's or company's policy on reporting results, because it has more significant figures than are reported. This practice is only acceptable if the RL adopted is the LOD rounded up to the last reporting figure, and the RL is only applied to the final calculated result (including any conversion to regulatory units). Examples of acceptable and unacceptable RLs are given below.

Examples of inappropriate use of reporting limits

LOD	Maximum permissible LOD	RL[1,2]	Reason given for adopting RL
0.31	2.5	2.5	Equals maximum permissible LOD and will not need revising if LOD changes
0.65	1	2	Set as a common RL for all determinands in the analysis suite

[1] Using these RLs on the public record instead of the actual result of analysis would contravene the reporting requirements.

[2] Applying these RLs to intermediate results (e.g. to nitrite and total oxidised nitrogen results before calculating the nitrate result) would contravene the requirements of regulation 16. The calculation is part of the analytical method.

Examples of appropriate use of reporting limits

LOD	Number of decimal places reported for results close to the LOD[3,4]	Appropriate RL
0.141	3	0.141
0.141	2	0.15
0.141	1	0.2

[3] The number of decimal places reported should always be related to method performance.

[4] The examples of number of decimal places reported are given for demonstration of appropriate reporting limits only and do not reflect any view on the appropriate number of significant figures to report.

A11 Regulations 16(7) to 16(11)

A11.1 Where a method of analysis is specified in Table A1 in Schedule 4 (the prescribed method), laboratories must use the specified method unless an alternative method has been authorised (approved), in which case the authorised alternative may be used subject to any conditions given in the authorisation. An alternative method may not be used until written authorisation has been given to the appropriate water company.

A11.2 A laboratory wishing to use an alternative method that has not been approved, must make an application through the relevant water company, for authorisation of the method. Such application must be made in writing to the Drinking Water Inspectorate and must include a full description of the method to be used along with results of tests demonstrating both the reliability of the method and its equivalence to the prescribed method.

A11.3 More detail of the information and testing requirements and criteria are given in 'The Microbiology of Drinking Water'. An expert group of microbiologists from Member States is to be established to provide advice to the Commission on technical issues such as performance testing of alternative microbiological methods.

A11.4 An alternative method will only be authorised if it is adequately documented and the results of tests demonstrate to the Drinking Water Inspectorate's satisfaction that

results obtained using the method, are at least as reliable as those produced by the use of the prescribed method.

A11.5 The Drinking Water Inspectorate may make any authorisation subject to such conditions as it considers appropriate, e.g. limitation of the types of sample matrix it may be used to analyse or specify extra quality control requirements. Authorisation may be general or granted to a specific water company. It may also be revoked at any time, by notice in writing to any water company to which authorisation has been given. At least three months' notice will be given of any revocation.

A12 Additional Information

A12.1 In addition to the guidance given above and in the documents referenced in the Annex and the Introduction to the Guidance, advice on different aspects of AQC is given in a number of other documents, many of which are referenced within the reference documents. Further sources of relevant information are:

- 'Guidelines for Calibration in Laboratories', which is available on www.dwi.gov.uk.
- 'A Manual of Analytical Quality Control for the Water Industry'(NS30).
- Harmonised Guidelines for Internal Quality Control in Analytical Chemistry Laboratories ISO/IUPAC/AOAC, Pure and Applied Chemistry, vol 67, No 4, pp 649-666, 1995 (The AQC Guidelines).
- "Guidance On The Interpretation Of Aspects Of Analytical Quality Control (AQC)"
- "The International Harmonised Protocol for the Proficiency Testing of (Chemical) Analytical Laboratories" M Thompson, R Wood, Journal of AOAC International, Vol 76, No 4, 1993.
- "The Determination of Taste and Odour in Drinking Waters 2010" in the series Methods for the Examination of Waters and Associated Materials (HMSO)
- "Quality Control Charts in Routine Analysis", Gardner M J, Water Research Centre, November 1996, WRc Ref: CO 4239
- BSI Draft for Development "Water Quality – Guide to analytical quality control for water analysis" BSI Ref: DD ENV ISO 13530:1999 (CEN Ref: ENV ISO 13530:1998 E. ISO Ref: ISO/TR 13530:1997(E)).
- "Quality Control Charts in Routine Analysis", Gardner M J, Water Research Centre, November 1996, WRc Ref: CO 4239.
- "The Microbiology of Drinking water 2002" and relevant updates in the series Methods Of Examination of Waters and Associated Materials. (http:\www.environment-agency.gov.uk/nls)

Revision notes:

Version	Revision	Date
1.0	First major version covering the 2016 Regulations	July 2016
1.1	Typing errors corrected in para 16.11 & 16.13	April 2017
1.2		
1.3		
1.4		
1.5		