GUIDANCE ON IMPLEMENTATION OF REGULATION 16(2)(d)(i)

1 BACKGROUND

1.1 Regulation 16(2)(d)(i) of the Water Supply (Water Quality) Regulations 2000[1] requires that samples are analysed by or under the supervision of a person who is competent to perform that task. See 3.1.

1.2 A number of audits have shown that in the past some laboratories have not always complied with this requirement in all circumstances. The following guidance is issued as a benchmark to aid water companies in understanding and implementing the requirement. When assessing competence in respect of regulation 16(2)(d)(i) the Inspectorate will check whether the competence of the relevant person or persons is demonstrated either in line with this guidance or is demonstrably equivalent. Companies opting for equivalent demonstration should be prepared to justify their arrangements and demonstrate equivalence.

2 ANALYSTS

2.1 It is recognised that some laboratories recruit school leavers and others without a formal scientific qualification and train them to undertake analytical duties with respect to regulatory drinking water analysis. The results of these analyses can have significant public health consequences. Many of these people become very proficient analysts with respect to routine work. The Inspectorate believes that where relevant such persons should be encouraged to work towards achieving the qualifications necessary to demonstrate that they are a competent person. They should also be encouraged to join an appropriate professional body as part of their continuing professional development (CPD).

2.2 Guidance on training for competence to perform an analytical procedure is given in Appendix 1 of Guidance on the Water Supply (Water Quality) Regulations 2000 and 2001. In addition to assessment by witnessing and other means objective criteria should be set and tested for all procedures. Paragraphs 2.3 to 2.9 below set out the Inspectorate's benchmark for assessing the appropriateness of such criteria. **These are not the criteria for a competent person for the purposes of Regulation 16(2)(d)(i), but they are a necessary prerequisite.**

2.3 For chemical and physical analysis this should take the form of at least three complete typical analytical runs which should additionally contain one typical sample analysed in duplicate and duplicate analysis of the same sample spiked with a concentration close to the regulatory standard. The same sample be used for each run. At least two determinations of the routine AQC sample should also be included. Testing should cover the entire analytical procedure carried out by the analyst, including any relevant sample preparation and concentration steps. The standard deviations and trueness/recovery of the AQC; the sample and the spiked sample, when calculated using analysis of variance should be consistent with the current method performance. Once trained and assessed, analysts should take part in the appropriate proficiency testing scheme.

[1] Water Supply (Water Quality) Regulations 2001 in Wales.
[2] Normally chemistry or microbiology as appropriate.
[3] Chemistry, microbiology or other scientific discipline relevant to the role.

2.4 For microbiological analysis this should take the form of split sample analysis carried out in parallel by the analyst under assessment and a trained analyst. An appropriate number of samples containing the target organism should be analysed to provide statistical confidence. Samples should be analysed on not less than two separate days and where possible should include samples containing indigenous target organisms and/or representative samples artificially seeded with chlorine-stressed environmental organisms prepared using the procedures described in 9.6.2.1 or 9.6.2.2 of Part 3 of the Microbiology of Drinking Water 2002. Positive control suspensions, negative controls and blanks appropriate to the method should be included in each batch of samples analysed. The analysts should use media, quality control suspensions and reagents prepared by a trained analyst. There should be no significant difference between the results obtained by the two analysts. In order to demonstrate ongoing competency trained analysts should participate in an appropriate external proficiency testing scheme.

2.5 Any person who has not performed the procedure for a period, not exceeding a suitable time period as justified by the laboratory for the procedure in question, should be reassessed and retested and if necessary retrained before their competence is confirmed. Minor method changes should involve formal communication to all trained and in training staff. Major method changes will involve retraining and reassessment for all relevant staff.

2.6 Competence to perform the procedure should be witnessed and assessed by an appropriate competent person in respect of the analysis being assessed. The results of each assessment should be approved by the Technical Manager or nominated deputy.

2.7 Analysts who have yet to achieve the necessary criteria should be subject to appropriate documented supervision and require independent approval of all results by a competent person or the approved trainer.

2.8 The results of all competence assessments and testing should be retained as part of the persons training record.

2.9 Once fully trained an analyst should still be supervised by a competent person. The level of supervision should be appropriate to the analyst's ability and experience.

3 COMPETENT PERSON (analyst, supervisor and/or team leader)

3.1 A competent person in the meaning of the regulations is a person who is competent to take responsibility for the work and results (the task). This may be work they have themselves carried out or work which they have supervised.

3.2 Competent persons should have a minimum academic qualification in an appropriate scientific subject [2] such as NVQ level 3 or equivalent, which will, as a minimum, permit them to seek and eventually obtain full membership of the relevant professional body, although the standard of academic achievement required for full membership status is normally greater than this. Competence should be fully demonstrated and recorded as set out in 3.4 and 3.5 below.

3.3 In certain circumstances extended relevant experience can be a suitable substitute for formal qualifications, provided competence can be fully demonstrated and recorded as set out in 3.4 and 3.5 below.

3.4 In addition to appropriate qualifications a competent person will be able to demonstrate appropriate relevant experience through their CPD record in respect of each of the nine professional development areas set out in 7.1 below. The portfolio should form a key part of the assessment, which should be carried out by the Technical Manager or nominated deputy and should be subject to audit by the Quality Manager or nominated deputy.

3.5 All competent persons should keep their own CPD record and portfolio up to date. It should be subject to formal review by the Technical Manager or nominated deputy every five years to ensure that competence has been maintained. Failure to maintain competence, unless addressed immediately, should result in loss of competent person status. It would be prudent for informal reviews to be carried out annually to allow early identification of development needs.

3.6 The above approach is in line with ISO 17025 accreditation, but also includes background knowledge and minimum technical qualifications. The following sections 4, 5 and 6 assume that the laboratory has a system of quality management in line with that required for ISO 17025 accreditation, but additionally sets out a standard of technical competence necessary to provide the high level supervision and management needed to ensure that all analysis is carried out by or under the supervision of a competent person in compliance with the other relevant requirements of regulation 16. Any alternative system adopted should be demonstrably equivalent.

4 COMPETENT QUALITY MANAGEMENT

4.1 Competent laboratory quality management including the Quality Manager and nominated deputies, should have chartered status in their chosen profession [3] , or be a chartered scientist, or be working towards chartered status. In addition to appropriate qualifications, a competent Quality Manager or deputy will be able to demonstrate appropriate relevant experience through their CPD record. In certain circumstances, extended experience can be a suitable substitute for formal qualifications. In all cases competence should be fully demonstrated and recorded as set out in 7.2 below.

4.2 A competent quality manager or deputy should be available for consultation to ensure that the quality system functions correctly and to discuss and resolve quality problems as they arise.

5 COMPETENT TECHNICAL MANAGEMENT

5.1 A competent Technical Manager, including nominated deputies, should have chartered status in his or her chosen profession[3] or be a chartered scientist. In addition to appropriate qualifications, a competent Technical Manager or deputy will be able to demonstrate appropriate relevant experience through their CPD record. In certain circumstances, extended experience can be a suitable substitute for formal qualifications. In all cases competence should be fully demonstrated and recorded as set out in 7.2 below.

6 OTHER MANAGEMENT ISSUES

6.1 The Technical Manager and Quality Manager roles should normally be separate and filled by different persons, except in the smallest of laboratories where there may be an insufficient number of appropriately qualified and competent persons for the roles to be

split. Furthermore it is required that the Quality Manager has a reporting line to more senior management which is independent of the laboratory's technical management.

6.2 Persons in other technical management or supervisory roles who manage or supervise analysis or related technical matters, or may be required to deputise for a competent person should be appropriately qualified and experienced to perform those duties.

6.3 It is essential that all competent persons remain up to date with respect to all matters pertaining to their work. This should be demonstrated by their CPD record, which they should keep up to date at all times.

7 CONTINUED PROFESSIONAL DEVELOPMENT

7.1 *Competent persons should be able to produce evidence that they possess the following skills: -*

1. **Make significant personal contributions to key tasks in their employment area and understand fully the chemistry/microbiology objectives of the work done and its relevance to the employer or others.**

2. **Demonstrate a high level of appropriate skills in the practice of chemistry/microbiology.**

3. **Develop their chemistry/microbiology and other skills as required for the work undertaken and career development.**

4. **Demonstrate an understanding and appreciation of Health, Safety and Environmental issues and adhere to the relevant requirements relating to their role.**

5. **Evaluate critically and draw conclusions from scientific and other data.**

6. **Demonstrate integrity and respect for confidentiality on work and personal issues, demonstrate other professional attributes such as thoroughness and reliability.**

7. **Plan and organise time systematically, demonstrate foresight in carrying out tasks, and offer suggestions for improvements to tasks/duties.**

8. **Demonstrate a commitment to continuing learning and development.**

9. **Demonstrate a high level of understanding of the principles and practice of analytical quality control.**

7.2 *Competent Technical Managers, Quality Managers, and those who deputise for these two roles should be able to produce evidence that they possess the following professional skills: -*

1. Make significant personal contributions to key tasks in their employment area and understand fully the chemistry/microbiology objectives of the work done and its relevance to the employer or others.

2. Demonstrate a high level of appropriate professional skills in the practice of chemistry/microbiology/water science.

3. Develop their chemistry/microbiology/water science and other professional skills as required for the work undertaken and career development.

4. Demonstrate an understanding and appreciation of Health, Safety and Environmental issues and adhere to the relevant requirements relating to their role.

5. Evaluate critically and draw conclusions from scientific and other data.

6. Demonstrate integrity and respect for confidentiality on work and personal issues, demonstrate other professional attributes such as thoroughness and reliability.

7. Plan and organise time systematically, demonstrate foresight in carrying out tasks, and offer suggestions for improvements to tasks/duties.

8. Demonstrate a commitment to continuing learning and development.

9. Demonstrate a high level of understanding of the principles and practice of analytical quality control.

10. Demonstrate an interest in broader developments in chemical/microbiological/water science and make a contribution to their profession outside their direct work environment.

11. Write clear, concise and orderly documents and give clear oral presentations.

12. Discuss work convincingly and objectively with colleagues, customers and others. Respond constructively to, and acknowledge the value of, alternative views and hypotheses.

13. Demonstrate the ability to work as part of a team and to implement and introduce change.

14. Exert effective influence.

15. Demonstrate competence in staff management and if relevant contract management.

16. Plan the operation and continuing maintenance of new systems and services.

Note: These competencies have been derived from those required of chartered members of the Royal Society of Chemistry, the Institute of Biology and the Chartered Institute of Water and Environmental Management..

8 IMPLEMENTATION

8.1 Water companies, their laboratories and contract laboratories will be expected to start demonstrating the competence of their analytical staff in line with this guidance from 1 January 2009, the various parts of the guidance being implemented to a phased programme as set out below.

8.2 By 31 December 2008, companies and their contract laboratories will be expected to have in place suitable systems for the implementation of the guidance. New appointees as Competent Persons will be expected to be appropriately qualified and have 50% of the final CPD requirement. All Competent Persons and Competent Managers (Competent Technical Managers, Quality Managers and their nominated deputies) should actively undertake CPD and maintain full records.

8.3 By 31 December 2011, all new appointees as Competent Persons should meet the requirements in full.

8.4 Also by 31 December 2011, Competent Technical Managers, Quality Managers and their deputies should be able to produce a CPD record as specified in 7.2. They will be expected to be able to demonstrate that they have 50% of the final CPD requirement. In addition new appointees should have membership of the relevant professional body or be of demonstrably equivalent status.

8.5 By 31 December 2012 new appointees as Competent Technical Managers, Quality Managers or their deputies should have chartered status or equivalent or be undergoing mentored development leading to chartered status. CPD requirements should be met in full.

8.6 By 31 December 2013 all requirements should be met in full.

8.7 Throughout this period, the requirements for appointing persons to other technical management or supervisory roles which have not been specifically defined within this guidance should develop in line with the requirements for specified roles.

9 ‘GRANDFATHER RIGHTS’

9.1 Persons in specifically defined and other technical, management and supervisory posts at 31 December 2008 and considered competent in that post at that date should remain competent, provided they can demonstrate a fit for purpose CPD record and portfolio. Such persons should be encouraged to seek suitable qualification, membership of professional body and/or chartered status as appropriate. Similar provisions apply for persons appointed or promoted during the implementation period of 1 January 2009 to 31 December 2013. All such persons will be expected to meet the CPD requirements in full from 31 December 2013.