# APPROVALS OF PRODUCTS FOR USE WITH DRINKING WATER

# TEST PROTOCOLS FOR DESIGNATED LABORATORIES

Leaching of substances from products used in contact with water intended for human consumption

# Protocol 0 Designated test laboratory requirements

#### **DOCUMENT CONTROL**

The only controlled version of this document can be accessed on the DWI Website – <a href="https://www.dwi.gov.uk/drinking-water-products/index.htm">www.dwi.gov.uk/drinking-water-products/index.htm</a>. Printed copies of this document, together with electronic copies held on local computers and other storage devices are uncontrolled.

#### INTRODUCTION

This test protocol, which is one of a series prepared by the Drinking Water Inspectorate, provides details of the requirements for designated test laboratories, covering:

- the initial assessment and designation of them
- on-going requirements

The following test protocols are currently available

#### Number Title

### 0 Designated test laboratory requirements

- Leaching of substances from products used in contact with water intended for human consumption: Reporting requirements
- 2 Leaching of substances from products used in contact with water intended for human consumption: General Method
- 3 Leaching of substances from products used in contact with water intended for human consumption: Admixtures for cementitious products
- 4 Leaching of substances from metallic products used in contact with water intended for human consumption: General method *provisional*
- 5 Leaching of substances from products used in contact with water intended for human consumption: Water treatment membranes
- 6 Leaching of substances from non-metallic products used in contact with water intended for human consumption: Filter media and ion exchange resins

# IMPACT OF EUROPEAN TECHNICAL REQUIREMENTS

Currently a series of test methods are being prepared within CEN in support of the approval of products used with water intended for human consumption. As these EN methods are published any conflicting national test protocols will have to be withdrawn.

It is currently anticipated that published EN standards will become available for most of the areas covered by these test protocols during the next few years.

#### **AVAILABILITY**

Copies of these test protocols, together with information requirements for applicants, can be freely downloaded from our website – <a href="http://www.dwi.gov.uk/drinking-water-products/advice-and-approval/index.htm">http://www.dwi.gov.uk/drinking-water-products/advice-and-approval/index.htm</a>

#### **CONTACT**

For further information or help please contact us – Regulation 31 Enquiries, Drinking Water Inspectorate,

Tel +44 (0)300 068 6400

E-mail: reg31.enquiries@defra.gov.uk

Revision notes:

Version 1.1 – addition of reporting requirement to Section 8

Version 2 – revisions to reflect new approval processes and requirements; v 2.1 – updating, including the Bibliography V2.3 change in Regulations in England and Wales V2.4 change in test methods V2.5 additional requirement for designation.

#### **CONTENTS**

0	Introduction	4
1	Requirements for Designation	4
2	Proficiency Testing	4
3	Confidentiality	4
4	Routine Analysis	5
5	Non-routine Analysis	5
6	Inter-laboratory Trials	5
7	Audit Visits	5
8	Testing and Reporting	5
9	European Standards	5
10	Sub-contracting	6
	Bibliography	6

#### **GENERAL DEFINITION** (for use with all Test Protocols)

# The relevant regulations (for public drinking water suppliers)

The following regulations apply to the approval of substances and products used in the provision of public water supplies within the United Kingdom:

- a) England Regulation 31 of The Water Supply (Water Quality) Regulations 2016 (Statutory Instruments 2016 No 614) - http://www.legislation.gov.uk/uksi/2016/614/contents/made
- b) Wales Regulation 31 of The Water Supply (Water Quality) Regulations 2010 (Welsh Statutory Instrument 2010 No 994 (W.99) http://www.legislation.gov.uk/wsi/2010/994/contents/made (and Amendment Regulations 2016 No. 410 (W. 128))
- c) Scotland Regulation 33 of The Public Water Supplies (Scotland) Regulations 2014 http://www.legislation.gov.uk/ssi/2014/364/contents/made
- d) Northern Ireland Regulation 33 of The Water Supply (Water Quality) (Amendment) Regulations (Northern Ireland) 2009 (Statutory Rules of Northern Ireland 2017) http://www.legislation.gov.uk/nisr/2017/212/contents/made

Where reference is required to specific regulatory requirements, these are given in footnotes.

# DESIGNATED TEST LABORATORY REQUIREMENTS

#### 0. INTRODUCTION

Analytical work specified by the Drinking Water Inspectorate (DWI) is implemented by, or under the supervision of, a designated test laboratory that has been subject to assessment and on-going audits to ensure its capability for undertaking this work. The basis for designation is set out below.

#### 1. REQUIREMENTS FOR DESIGNATION

Organisations seeking accreditation as designated test laboratories for preparing test leachates and undertaking analysis specified by DWI shall;

- a. be accredited by UKAS under BS:EN ISO/IEC 17025 for undertaking testing to BS 6920, parts 1 to 2 inclusive
- b. ensure that they maintain BS 6920 (parts 1 to 2) within their BS:EN ISO/IEC 17025 Schedule of Accreditation on an annual basis
- c. participate in relevant inter-laboratory trials
- d. be accredited in the BS:EN 12873 series of leaching standards and BS:EN 15768 if providing this testing
- e. participate in Aquacheck group 22 distributions (GC-MS general scan) see Section 2 below
- f. be subject to an initial audit assessment visit by an inspector appointed by the DWI
- g. provide a copy of the most recent UKAS report including closure of any corrective actions raised.

#### 2. PROFICIENCY TESTING

Organisations seeking accreditation as designated test laboratories offering GCMS analysis shall participate in current Aquacheck group 22 distributions (GC-MS general survey). Once accepted as a designated test laboratory, continuing satisfactory participation in Aquacheck group 22 is a requirement for retaining designation.

Designated test laboratories are required to submit their results from each distribution of Aquacheck Group 22 to the DWI, together with relevant comments in all cases where they have failed to achieve a score of 100. The results obtained by each test laboratory in each distribution are considered by the DWI and its advisers. Unsatisfactory performance that is not adequately explained and corrected will lead to removal of the designation

# 3. CONFIDENTIALITY

Organisations seeking accreditation as designated test laboratories shall put in place adequate documented processes to ensure that all information supplied to them by DWI is treated as strictly confidential and is not accessible to staff having no involvement in testing to the requirements of the DWI. As a minimum all product related documents shall be stored in security locked cabinets when not in use, or stored within an office which is always locked when staff involved in testing to the relevant regulations are not present.

Continuing compliance with these requirements will be assessed during subsequent audit inspection visits of the designated test laboratory.

# UNCONTROLLED IF PRINTED

#### 4. ROUTINE ANALYSIS

For routine analysis, e.g. total organic carbon, the test laboratories shall comply with the analytical performance requirements of ISO/TS 13530:2009 Ed 1 - Water quality — Guide to analytical quality control for water analysis. In addition, an estimate of the combined uncertainty (Eurachem / CITAC Guide: Quantifying Uncertainty in Analytical Measurement) should be calculated and reported, taking into account variances associated with the selection of the test piece, transportation and storage, leachate preparation, storage and analysis.

#### 5. NON-ROUTINE ANALYSIS

So far as possible, the same level of validation should be undertaken as for a routinely analysed determinand (see the previous section). A procedure detailing the minimum evaluation of a method will be required where full validation is an unreasonable burden. In general the DWI will need evidence that the method can detect the determinand, at a defined concentration, without undue interference from other components in the leachate/extract. Where the experimental data show that the accuracy of the method is poor, more reliance should be placed on estimating the combined uncertainty from first principles.

#### 6. INTER-LABORATORY TRIALS

Each designated test laboratory is required to participate in inter-laboratory trials organised by the Drinking Water Inspectorate.

#### 7. AUDIT VISITS

Each designated test laboratory shall agree to participate in any announced audit visits to their premises by an inspector appointed by the Drinking Water Inspectorate.

#### 8. TESTING AND REPORTING

This shall be undertaken in accordance with information and test procedures specified by the DWI at the time of notification of test requirements.

NOTE: The normal test requirements and test protocols are published on the DWI website - http://www.dwi.gov.uk/drinking-water-products/advice-and-approval/index.htm. Reports shall confirm with the requirements of Test Protocol 1, available from this website.

#### 9. EUROPEAN STANDARDS

European Standards (ENs) have been developed to replace existing national standards for assessing the effects of products and materials on water quality. The accepted standards for leachate preparation for GCMS and specific determinands from factory made products BS:EN 12873-1; site applied products BS:EN 12873-2; ion exchange resins BS:EN 12873-3; and water treatment membranes BS:EN 12873-4. The designated test laboratories shall use these ENs as the basis for preparing leachates for subsequent analysis, and ensure that these ENs are included within their Schedule of Accreditation under BS:EN ISO/IEC 17025. Where EN standards are to be adopted in the UK DWI will provide notification.

#### 10. SUB-CONTRACTING

Designated test laboratories shall only sub-contract testing work on the following basis -

- a. prior written agreement for the sub-contracting has been obtained from the DWI
- b. all sub-contracting is undertaken in accordance with the designated test laboratory's written procedures under their BS:EN ISO/IEC 17025 accreditation

Note – agreement for sub-contracting will normally be given only on the basis that the sub-contractor is another designated test laboratory.

# **BIBLIOGRAPHY**

BS EN 1484:1997	Water analysis – Guidelines for the determination of total organic carbon (TOC) and dissolved organic carbon (DOC)
BS 6920 Parts 1 to 2	Suitability of non-metallic products for use in contact with
[Current editions]	water intended for human consumption with regard to their effect on the quality of the water —
	Part 1: Specification
	Part 2: Methods of test
BS:EN 12873-1 to 4	Influence of materials on water intended for human
[Current editions]	consumption – Influence due to migration –
	Part 1: Test method for non-metallic and non-cementitious factory made products
	Part 2: Test method for non-metallic and non-cementitious site applied materials
	Part 3: Test method for ion exchange and adsorbent resins
	Part 4: Test method for water treatment membranes
BS:EN 15768	Influence of materials on water intended for human
[Current Edition]	consumption. GC-MS identification of water leachable organic substances
ISO/TS 13530:2009 Ed 2	Water quality — Guide to analytical quality control for water analysis
BS:EN ISO/IEC	General requirements for the competence of testing and
17025:2005	calibration laboratories
BS:EN ISO 9001:2008	Quality management systems. Requirements
Eurachem/CITAC – 2000	Quantifying uncertainty in analytical measurements (2 <sup>nd</sup> edition)