



# Drinking Water Quality Regulator Risk Management Guidance

Version 2.0

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## 1.0 Introduction

Regulation 30 of the Public Water Supplies (Scotland) Regulations 2014 (as amended) (“the Regulations”) requires Scottish Water to carry out risk assessments, often referred to as Drinking Water Safety Plans (DWSP), for each of its water treatment works and connected supply systems. These risk assessments must be carried out in accordance with a method which is approved by the Drinking Water Quality Regulator (DWQR), and must be based on the general principles of risk assessment set out in relation to international standards including BS EN 15975-2:2013. This guidance sets out the minimum requirements that Scottish Water must meet in order to gain approval from the DWQR.

Approval of risk assessment methodology is confirmation that the DWQR has determined that Scottish Water has established the systems, procedures and competencies needed to demonstrate consistent water safety planning. An essential feature of this is the assurance that procedures and practices against which approval has been awarded are consistently applied and maintained by Scottish Water. This assurance is achieved throughout the accreditation period through the implementation of a surveillance visit programme.

Scottish Water is required to engage an Independent Assessment Body which is approved by the DWQR to determine compliance against BS EN 15975. The Independent Assessment Body will report findings and recommendations to the DWQR, and the DWQR will have responsibility for the approval of Scottish Water’s risk assessment process. When the Independent Assessment Body reports to the DWQR that it is satisfied that Scottish Water complies with BS EN 15975, this shall result in approval being given by DWQR.

## 2.0 Purpose of Accreditation

DWQR’s expectation is that accreditation to the Standard provides an assurance of the:

- Execution of a methodology which supports the production of full and accurate Regulation 30 risk assessments and Regulation 31 compliant risk assessment reports;
- Implementation of a comprehensive risk management process;
- Competence of the participating specialists involved in the risk management process;
- Span of the risk management process encompassing all potential hazards from catchment to tap;
- Robustness of the risk management process to identify and mitigate hazards ensuring public health is protected;
- Consistent standards that are achieved and maintained across all of Scottish Water’s drinking water supplies;
- Reliability of information collated and reported for regulatory purposes;
- Benchmarking of risk assessment standards which promotes and raises the professional reputation of Scottish Water and its staff.

### 3.0 Responsibilities

#### **DWQR**

Responsible for developing and maintaining regulatory inspections and serving as the approval body for the methodology of risk assessments.

#### **Independent Assessment Body**

Assesses Scottish Water's risk assessment methodology and inspects it as being commensurate with the relevant standards and specifications and meeting regulatory requirements.

Assesses content and presentation of reporting as compliant with requirements.

The Independent Assessment Body shall:

- Conduct evaluations against the scheme requirements in a technically competent and objective manner;
- Adopt a pragmatic but consistent approach to the evaluation of scheme standards as defined by BS EN 15975-2:2013 and this document in order to validate the water safety planning methodology;
- Establish conformity to scheme requirements through evidence based evaluation, comprising procedural review and effective implementation thereof determined through observation and demonstration as applicable;
- Endeavour to respect Scottish Water's business constraints;
- Ensure any information determined in respect of Scottish Water's commercial business interests are treated in confidence and not passed to any third party with the exception of the DWQR;

#### **Scottish Water**

Achieves accreditation status with BS EN 15975-2:2013 through an approved Independent Assessment Body, and thereafter maintains that status on an ongoing basis.

Develops and maintains a risk management process conforming to the following:

- The principles of the WHO DWSP process (WHO Guidelines for Drinking Water Quality, fourth edition) and requirements of BS EN 15975-2:2013;
- Spans catchment, abstraction, treatment, storage, distribution and domestic distribution systems to consumers' taps;
- Risks are assessed for each hazard/hazardous event using a scoring system based upon likelihood and consequence criteria;
- Risks are assessed both pre and post mitigation measures, incorporating the residual risk analysis and determination if additional control measures are required;
- Inclusion of any monitoring carried out under article 7(i) and article 8 of the Water Framework Directive;

- Inclusion of risks to meeting defined water quality standards to consumers;
- Inclusion of the multiple barrier approach and, where practicable, control measures identified for all stages in the supply system to mitigate risk to water quality;
- Maintenance of a continuous review process of the risk assessment for each supply system, incorporating new information, changes to risk scores and mechanisms for feeding into company processes for agreeing and prioritising actions;
- The development and maintenance of a competency matrix for all risk assessors detailing training, experience and qualifications to support their participation in the process. The competency matrix shall be supported by a training programme to demonstrate the process by which competency gaps may be closed out;
- Evidence of interdisciplinary participation in the development of risk identification, analysis and applicability of control measures;
- Fully integrated into a Scottish Water Quality Management System;
- Identify a link between risk assessment and investment processes;
- Periodic review and sign off by a designated authority.

#### 4.0 Scottish Water Risk Assessment Interdisciplinary Team Competence

Risk Assessment team personnel should:

- Have a good understanding of the underpinning theory of Water Safety Plans and be familiar and knowledgeable with the key publications; BS EN 15975-2:2013 and chapter four of the WHO Guidelines for Drinking Water Quality, fourth edition;
- Be able to demonstrate an understanding of compliance with the requirements of the Regulations;
- Be from a range of backgrounds and disciplines and/or be able to input knowledge about a variety of aspects of the water supply chain (source to tap). This may include experience of catchments, treatment, storage or consumers, or other aspects such as validation and data evaluation or laboratory experience;
- Demonstrate an ability to provide credible and relevant input into the water safety planning process;
- Be able to demonstrate ready access to specialist support within Scottish Water and from third parties who are able to input into the water safety planning process. This will always include senior managers as it is a requirement for the assessments to be signed off at a senior level;
- Be able to show that they have access to and have given consideration to external inputs from other stakeholders who would be considered relevant to the task and its outputs. For example this could include the Scottish Environment Protection Agency (SEPA). The competency of other stakeholders is not considered in this document;
- Senior Personnel within Scottish Water signing off drinking water safety planning methodology documents and risk assessment reports shall be designated by the

company as being able to sign off risk assessment reports, and their competence will be pre-determined by the company for their role;

- External Auditors of water safety planning methodologies are designated by the Independent Assessment Body organisation and their competency is pre-determined for their given role by that organisation. This is outside the scope of this document.

## 5.0 Water Safety Plan Methodology

This section describes the prerequisites for a DWSP methodology.

The DWSP methodology shall be commensurate with the requirements of all aspects of BS EN 15975-2:2013 and shall be based on the principles of the World Health Organisation's guidance on Water Safety Planning<sup>1</sup>.

Provision is made for Scottish Water to outsource some aspects of water safety planning due to the availability of expertise, however responsibility for the DWSP methodology remains with Scottish Water, and Scottish Water remains responsible for any findings, improvements and subsequent notices applied by the DWQR and/or the Independent Assessment Body.

For all documents and risk assessment outputs, there should be the following elements and considerations:

- There shall be documented evidence of procedures describing how to implement DWSP hazard identification and risk assessment;
- There shall be documented and defined roles and responsibilities for the tasks and descriptions or diagrams of team structure;
- The entire supply system will be considered, and where there is an inability or other reason for excluding any aspect this should be documented;
- There shall be a defined mechanism with triggers for the review and update of the methodology document and related procedures and protocols;
- Scottish Water should be able show evidence of internal audit or verification exercise to assure of the quality and compliance of the process to the company's own internal procedures/guidance;

The outputs of the application of the methodology will be the regulation 30 risk assessment reports. It is not intended that these outputs will form a significant part of the methodology audit, but these reports may be examined during the audit to verify details contained within the methodology. The Regulations describe the requirements for regulation 31 risk assessment reports. The DWQR performs regular and routine assessment of the risk assessment reports - this is a separate activity outside the scope of this document.

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<sup>1</sup> Chapter 4, World Health Organisation's Guidelines for Drinking Water Quality, Fourth edition

## 6.0 Variation from Regulatory Sampling Programme

If Scottish Water wishes to apply for a variation from the regulatory sampling programme using Part C of the Regulations, it is required to apply separately to DWQR for approval.

## 7.0 Gap Analysis

The compulsory gap analysis represents an interview and discussion based process which serves as a cost effective means of establishing a high level overview of Scottish Water's drinking water safety planning processes and highlighting any areas of perceived weakness, the early closure of which will support early arrangements for the subsequent audit. A gap analysis agenda will be issued to Scottish Water a minimum of seven working days prior to the due date.

Gap analysis feedback is provided both verbally, at the close out of the day, and also by way of a report which details the findings log and categorises the findings in terms of major non conformity, minor non conformity etc. as defined in section 13 of this Guidance. If major non-conformities have been identified, then Scottish Water will be required to confirm their closure prior to arrangements being made for the formal audit process. If no significant non-conformities are identified then arrangements for the formal audit may be agreed with the assessor at the gap analysis close out meeting.

## 8.0 Formal Audit

Upon receiving confirmation of the closure of any major non conformities identified during the gap analysis from Scottish Water, the Independent Assessment Body will agree a date for the commencement of the formal audit of drinking water safety planning.

An agenda, the outline of which will be confirmed at the gap analysis stage, will define specific areas to be covered as well as potential sites to be visited, and will be issued to Scottish Water a minimum of seven calendar days before the agreed commencement date, following discussion and input from the DWQR as necessary. Site visits shall form part of the standard audit programme unless extenuating circumstances prevail, as determined by the DWQR. The DWQR will be represented at the audit. The DWQR's role will be to support the Independent Assessment Body assessor.

The audit will be evidence based and will verify that drinking water safety planning and associated processes, as described by Scottish Water during the gap analysis, have been effectively implemented and are in full conformity with the requirements and this guidance.

The close-out will follow a similar format to the gap analysis with verbal feedback as to findings, followed by a report with an update of the findings log produced following the gap analysis, and a recommendation to the DWQR as to conformity.

The report will be issued by the Independent Assessment Body within 20 working days of the completion of the audit, and it will be the responsibility of the DWQR to confirm

approval within the same timeframe to Scottish Water and to the Independent Assessment Body.

## 9.0 Surveillance Programme

Following approval by the DWQR, the Independent Assessment Body will institute a surveillance programme to ensure that water safety planning and associated processes are maintained to the same standard as that against which conformity against the requirements of BS EN 15975 and this guidance were initially verified.

The frequency of visits under the surveillance programme will depend upon a number of variables and will be agreed with the DWQR and the Independent Assessment Body at the accreditation stage, but would typically represent three visits within the term of accreditation. For example, this could consist of the first surveillance visit at, or before, six months, the second surveillance visit at, or before, 18 months, and the third visit at, or before, 30 months from the date of certification.

Accreditation will be valid for three years, at which point a formal audit will be required to renew the accreditation.

A commercial contract will be established by Scottish Water with the Independent Assessment Body for the surveillance programme. Surveillance visit reporting will comprise the updating of the findings log developed during the gap analysis and the audit and will provide an ongoing auditable trail of Scottish Water's water safety planning performance.

An agenda will be issued by the Independent Assessment Body to Scottish Water a minimum of seven calendar days prior to the surveillance visit due date.

In the event that the DWQR find issues through its own audit programme then it would reserve the right to request the Independent Assessment Body to arrange a supplementary visit, which would be additional to the agreed surveillance programme and for which Scottish Water would be charged at the standard rates as detailed within the surveillance contract. An example of such an instance may be the issue of a notice set out in Regulation 30(7) of the Regulations by the DWQR.

## 10.0 Cancellation or Amendment of Approval

Approval of risk assessment methodology shall be subject to cancellation or amendment by the DWQR if Scottish Water:

- Is found to have made false claims within the application for accreditation which are considered to impact on the integrity of Scottish Water's operations; or
- Does not implement within 28 days remedial actions needed to rectify a major or series of minor non-conformances to the satisfaction of the Independent Assessment Body and the DWQR; or

- Implements corrective action which is subsequently found to have been inadequate to prevent a reoccurrence (at any location) of recently identified non-conformances; or
- which caused to be overlooked systemic failure to implement or implement effectively, risk mitigation measures; or
- which caused to be overlooked cultural concerns that have arisen from the audit or the DWQR's findings through a regulatory activity; or
- Undertakes work below the standard required and demonstrates a lack of commitment to achieve the required standard, or is unable to continue to comply with the criteria set out in the scheme requirements.

The DWQR shall notify Scottish Water in writing of the intention to cancel approval, fully detailing the reasons for such action. Normally, unless the nature of the non-conformance merits immediate action or is a reoccurrence of a recently closed non-conformance, the process will comprise two stages;

- Firstly Scottish Water will be notified that their approval is at risk from cancellation, and will be given a limited time to address the non-conformance giving rise to the potential loss of approval. If the non-conformance is not satisfactorily addressed during the allotted time period, and steps are not taken to prevent a reoccurrence, approval will then be cancelled.
- Once approval has been cancelled, re-establishing approval will be subject to a full re-assessment of Scottish Water.

### 11.0 Appeals, Complaints and Disputes

If Scottish Water wishes to object to action taken, including withdrawal of approval by the DWQR, it shall, within twenty-one days of the issue of the notification to them, give notice in writing to the DWQR of its objections, setting out clearly the grounds for an appeal. Any such appeal will be assessed by DWQR staff independent of those members of the DWQR's team and Independent Assessment Body associated with the original withdrawal action.

The results of the review will be communicated to Scottish Water in writing, detailing clearly the basis for the decision.

In the event that the appeals process finds the approval withdrawal to be the correct course of action, then re-instatement of Scottish Water would entail a re-run of the formal audit, with the surveillance visit cycle being reset.

### 12.0 Scheme Management Review

The DWQR and the Independent Assessment Body will hold a meeting or a teleconference initially at three monthly intervals following Scottish Water gaining approval for its risk assessment methodology, to discuss issues arising and lessons learned from the initial



scheme assessments with a view to providing continuous improvement of the process and coordination of scheme delivery and roll out. The frequency of the review will be subject to review at each meeting or teleconference.

## 13.0 Definitions

### 13.1 Mandatory/non-mandatory terms

The following terms have the stated meanings:

Shall:	Indicates a mandatory requirement;
Should:	Indicates a strong preference and is used to denote best practice or where a new requirement is being introduced;
May:	Indicates an option which is not mandatory.

### 13.2 Major and Minor Non conformities

Major Non-Conformities occur where there is:-

- Objective evidence which demonstrates that a required element for approval has not been documented, implemented or maintained;
- Evidence of repetitive failures (product quality or systems) or multiple minor non conformities in a single category;
- Evidence of significant numbers of minor non conformities;
- Evidence of action not taken to close previously identified minor non conformities within agreed timescales or to meet the milestone goals set at the time of approval;

Minor Non-Conformities occur where there is:-

- Objective evidence that there is a weak element within the management system, procedure or control for the effective implementation and maintenance of the Scheme requirements;
- Evidence of isolated cases of non-conformance to procedures.

### 13.3 Additional Findings classifications

The Independent Assessment Body may have additional findings classifications, which will be defined by the Independent Assessment Body.