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Water safety plan review, approval and audit

An appropriate body, usually the regulator or their designated agents, should review and approve water safety plans prepared by suppliers or Government agencies. This process is designed to ensure that the water safety plans developed are consistent with the water safety requirements articulated within the health-based targets. The review process is essential in the overall implementation and links to ongoing audit by providing the basis from which future assessments can be based.

14.1 INTRODUCTION

Undertaking a systematic technical review of the water safety plan is based on the assessor using a range of materials. In particular the review team will be expected to review the documents provided by the supplier, to undertake field investigations, to interview and question the water safety plan team and to review material from similar supplies and best-practice guidance.

The review process should come to one of the following conclusions:

- Water safety plan is approved in full and is ready for implementation. This approval would be time-bound and a date for the next review would be set at this time (usually 2-5 years from the initial review);
- Water safety plan receives provisional approval and can be implemented subject to ensuring identified information gaps are filled. In this situation the water safety plan would be likely to adequately cover most areas of concern in delivery of safe drinking-water, but may have some gaps in knowledge, for instance because there remains a lack of research. Provisional approval allows implementation, but should set time limits for the resolution of identified problems.
- Water safety plan is rejected as inadequate and the supplier is required to go back and develop a new water safety plan. This situation would only occur when the supplier had failed to cover the major issues for which knowledge is adequate to establish a water safety plan or has failed to employ sufficient staff to implement the water safety plan. Failure should be linked to a requirement for a re-submission or, if there is repeated failure, for the imposition of a water safety plan by the review team.

14.2 IMPLEMENTATION, HUMAN RESOURCES AND DOCUMENTATION

The first stage of the review should be to evaluate whether an appropriate water safety plan team has been established, with allocation of responsibility for specific tasks and an overall water safety manager who is responsible for the delivery and implementation of the water safety plan. In addition, the full water safety plan should be appropriately documented, with supporting materials available that provide justification for decisions and which provide an outline of the work undertaken and the work proposed. It is very important that this material is available for review and if any documentation is lacking, the assessor should ensure that the supplier provides this before the water safety plan is approved.

The documentation should typically contain:

- A system assessment that provides an indication of whether the health-based targets can be met.

- The detailed water safety plan, including identified hazardous events and their location within the system, proposed control measures with associated monitoring and critical limits and details of corrective actions.
- Monitoring plans should be provided as an annex to the water safety plan and provide justification for the selection of parameters (including where available the relationship between the parameter and issues of health concern) and the frequency of monitoring.
- A verification plan for the water safety plan showing sampling programmes, parameters selected and justification of the selection of verification approaches in relation to demonstrating that the water safety plan will comply with the health-based targets.

14.3 EVALUATING THE SYSTEM ASSESSMENT

During the system assessment stage, the water supplier is expected to review the source water quality, the protection measures put in place, treatment process applied and distribution management in order to evaluate whether the health-based targets can be achieved. Most typically, it would be expected that for all processes of drinking-water production the expected reductions in pathogen or chemical concentration that are achievable will be documented and that for processes of distribution an evaluation made of whether risks will increase due to ingress of contaminated water. In reviewing the system assessment, therefore, a judgment is made as to whether the expected performance of the production processes and distribution maintenance processes are realistic.

This may be carried out at different levels of reliability and accuracy and this is important to consider when undertaking the review. The optimal system assessment is one where the water supplier has collected data on pathogen occurrence within the source waters and has made systematic evaluations of the reductions of organisms through source protection or treatment processes using either pathogens or accepted indicator organisms. This data will then have been used in a risk assessment to define whether the performance targets achieved result in a level of risk that is tolerable. This may be carried out following the more comprehensive approach outlined by Havelaar and Melse (2003) or the simplified approach outlined in the third edition of the *Guidelines for Drinking-water Quality*, (see also Chapter 12). The supplier should have also undertaken an assessment of the quality of water within the distribution system and made a risk assessment based on available data. By preference, this will be based on data collected on pathogens or indicator organisms from within the distribution system.

All the risk assessments, with any limiting assumptions that were made, should be presented as part of the documentation dealing with the system assessment. It is important that the supplier demonstrate at least some understanding of the public health consequences of poor system design and operation. The review of a quantified risk assessment should only be undertaken by an assessor with knowledge of such approaches. The review should assess whether the data presented is of sufficient depth and breadth to support the conclusions drawn, whether appropriate quality assurance and control procedures were followed and whether seasonal or other influences were taken into account in the survey design. For the risk assessment calculations, the source of information on aspects such as dose-response and population exposed should be documented and the assessor must assess whether these are reliable or whether there are local circumstances that may alter any of the assumptions made. Where data has been generated locally through public health assessments the study design should be evaluated and the data presented should be reviewed in order to satisfy the assessor that appropriate conclusions were drawn. This may involve review of data from other sources as a mean to compare locally generated data.

In some cases there may be a lack of quantified data on the system concerned. In this case, a more theoretical approach can be adopted, although the level of limiting assumptions will reduce the confidence that can be placed in the results. Theoretical approaches include the allocation of log-reduction credits to treatment processes, an approach that has been employed in a number of countries and which is based on research literature outlining the expected removal of pathogens or chemicals (see Chapter 12 and LeChevalier and Au 2004). Such approaches are valid in that they still attempt to provide an indication of the expected removal and can therefore be used as a planning tool to determine whether additional investment is required to upgrade the system. However, there are significant limitations on this approach because the allocation of credits may not take into account operational weaknesses that lead to lower than expected reductions. If theoretical approaches are adopted, it is worth considering making at least qualitative estimates of failures both within production and distribution facilities as a means of capturing likely operational failure (Westrell *et al.* 2003).

The review of a theoretical system assessment should focus on a number of issues, namely:

- are the expected source water concentrations reasonable assumptions;
- are the allocated log-reduction credits reasonable assumptions; and
- are the sources of these assumptions provided?

This is important, as such approaches rely heavily on the use of credible and valid scientific research. By preference, source material should be drawn from the peer-reviewed domain to provide some additional confidence in the results. If data is drawn from non peer-reviewed sources, then additional caution should be taken in signing off the system assessment. In this case, the assessor may demand that the supplier undertake a systematic review of the literature and repeat the system assessment using this as the basis.

14.4 HAZARDOUS EVENTS

The review of hazardous events requires two critical questions to be asked:

- are the hazardous events described credible within the system under consideration;
- are there any hazardous events that have been omitted that should have been included?

In order to answer these questions, the assessor should look at all the material presented on the nature of the system and the environment that surrounds it and decide whether the hazardous events appear reasonable or whether any may have been overlooked. The assessor should use experience from other systems within the country or documented in the literature to evaluate the hazardous events presented. It is also important to undertake at least some field work to visit parts of the system and request that the water safety plan team describe how the hazardous events they propose could occur. This may also provide the team with an opportunity to explain why particular severity or frequency categories have been allocated to hazardous events and to explain why, in their opinion, some hazardous events could not occur in their system. In the latter case, it is not acceptable for the team to use good operation as a justification, as this would logically appear within the water safety plan as a control measure. Rather, exclusion should be on the basis that either the source of hazard does not exist, that no pathway to the water source could occur or that it would be impossible for the hazard to gain entry.

Where the assessor identifies either a lack of credible evidence for identified hazardous events to occur or that credible hazardous events have been omitted, there should be a requirement placed upon the water supplier to address these within a specified time frame. In usual circumstances, the supplier will either be expected to remove or add the hazardous events identified or provide convincing evidence that there should be no change. Approval during the review process should be dependent on the water safety plan providing a full and comprehensive list of credible hazardous events that could affect the supply. If

this cannot be demonstrated then the water safety plan should not be approved until such time as the hazardous events are revised.

14.5 EVALUATING CONTROL MEASURES

The evaluation of control measures lies at the heart of an effective water safety plan and is critical to ensuring that the water safety plan developed can be approved as adequate. If no control measure is proposed to control a hazardous event, the water safety plan cannot be approved and the supplier must be required to develop proposed control measures for the event. If control will require a significant upgrade, then interim controls that will help reduce the impact of the hazardous event should be identified, while a longer-term plan is being developed to provide control.

The control measure put forward to deal with identified hazardous events must be credible and supported by evidence from the supplier. This may take the form of scientific research undertaken or commissioned by the supplier on the water supply or similar supplies that they manage or may be taken from the scientific literature. If evidence is not presented by the supplier, then the assessor may require that this be found before the water safety plan is formally approved. This may therefore result in the water safety plan being only provisional in the first instance with an agreed process by which the evidence will be obtained and presented.

When evaluating control measures, the important question to answer is whether the proposed measure would prevent the hazardous event from occurring. To do this, the assessor must be satisfied that the control measure will do one (or sometimes more) of the following:

- remove the source of hazards from the environment within an area that could feasibly affect the water supply (an example is the prohibition of sanitation facilities or animal feedlots within specified distances of water sources);
- act to reduce the concentration of hazards to acceptable levels (examples being treatment processes);
- prevent hazards from leaving the hazard source and entering the water supply (an example would be the use of a cut-off wall between a sewer and a water supply main that effectively prevents direct movement between the two); and
- prevent entry into the water supply (examples being wellhead completion or pipes with no leaks).

If the water safety plan does not provide adequate evidence regarding the control measure or if the assessor considers the control measure to be inadequate to provide protection of water safety, then the water safety plan cannot be fully approved and the supplier must be required to revise or develop new control measures. Much of the evidence presented should be derived from validation exercises. Where information is lacking (which may occur in many situations) the water safety plan should identify this and refer to a plan of validation and research.

14.6 MONITORING AND ESTABLISHED LIMITS

The review should also assess whether the proposed means of monitoring for each control measure is appropriate, whether the established limits (operational and critical) are appropriate and whether the monitoring plan is adequate to ensure that sufficient data will be collected to demonstrate that the control measure is in compliance.

The water safety plan team should present evidence to support why the means of monitoring is appropriate for the control measure. This need not be a lengthy discussion, but the team should provide a basic short description. This may be drawn on experience or the literature. The monitoring plan should also be reviewed to assess whether the proposed frequency of data collection is sufficient. This relies on an assessment of how rapidly it can be expected for the control measure to change and the severity of the resulting risk. Any control measure that would result in major or catastrophic results should have frequent and preferably on-line monitoring.

Reviewing monitoring relies heavily on expert judgement in relation to the specific control measures. In general terms, however, control measures that relate to *processes* (e.g. treatment) will tend to have monitoring that is more frequent and often on-line, whereas as those that relate to *measures* (e.g. source protection) will probably be less frequent and often be inspection based.

Equally, there should also be some justification of why the operational and critical limits have been set and evidence presented regarding whether these will provide adequate protection. The limits should be established such that remedial action can be taken to ensure the control measure is in compliance before a major health risk results. Evidence should be presented based on research undertaken by the supplier or from the scientific literature and the assessor should evaluate whether these sources are reliable and the results valid.

For some control measures and monitoring, there is ongoing work to define more precisely that relationship between monitoring parameters and likely pathogen concentrations, which will provide an improved basis for establishing

critical limits. Where the supplier have undertaken such research themselves, this should be documented.

14.7 CORRECTIVE ACTIONS

The corrective actions provided for within the water safety plan should ensure that the control measure will be brought back into compliance and the review should therefore critically appraise each suggested action to see whether this would ensure control was re-established. The review should also assess whether the proposed action is the most efficient and effective.

In addition to measures that directly bring the control measure back into compliance, corrective actions may also be proposed that will avoid the delivery of unsafe drinking-water. An example being switching to an alternative source during the period of non-compliance. This will provide the operator with an opportunity to bring the supply back into compliance. If switching to an alternative source is included within the water safety plan, an approved water safety plan is also required for the alternative source. The absence of such a plan should lead the assessor to reject the corrective action.

The review should evaluate the evidence presented by the water safety plan team that the corrective actions conform to best practice by drawing on examples of water safety plans from other similar situations. If a corrective action is defined that is not part of best practice, the assessor should expect the water safety plan team to present evidence as to why the corrective action is appropriate, drawing on experience within the supply or the scientific literature as appropriate.

14.8 DOCUMENTATION AND REPORTING

The review should assess whether the supplier has put in place systems for documenting the activities in implementing the water safety plan, including results of monitoring and verification exercises. Clear lines of reporting should also be outlined and it should be clear from the water safety plan which staff within the water supply organisation will receive what information at what frequency and also what other organisations will receive information and when. A plan for appropriate documentation and reporting must be provided in order for the water safety plan to be approved. This is particularly important as implementation of the water safety plan should be audited and this therefore provides the basis for undertaking this activity.

14.9 VALIDATION AND RESEARCH

Some evidence should be presented in terms of validation within the control measures section. However, it is likely that there will need to be a process of ongoing research or validation to support decisions made to improve or maintain water safety. The review should take care to assess proposed validation/research plans. If none are provided, the assessor may bring this to the supplier's attention and request that such a plan be developed. Given the overall limited data on efficacy under operational conditions of many potential control measures, it is likely that some programme of information generation will be required and this should be considered as important as routine implementation.

14.10 VERIFICATION PLAN

The review will need to assess the verification plan for the supply to check whether appropriate tools and approaches are identified and that the frequency of verification exercises are suitable. The assessor will need a good understanding of the role and potential benefits of commonly used indicator organisms and operational audit tools in order to evaluate whether the verification plan will provide a reliable overview of the performance of the water safety plan.

Where the water safety plan team propose new methods of verification that do not match standard practice, there should be documented evidence to demonstrate that this approach is valid. Such documentation could, for instance, be based on the scientific literature or on research undertaken by the supplier. Where the means of verification has not been widely accepted (for instance because it applies a new method or an organism not commonly used) then the assessor may insist that the 'new' verification should be operated in parallel to the usual practice in order to have confidence in its use. Such a period of parallel implementation may last for several months or even years to ensure sufficient data is available.

14.11 AUDIT

Following review and subsequent implementation of the water safety plan, periodic audit of the plan is required. The frequency and timing of the audit procedure will vary according to circumstances and local regulations, but it should be conducted:

- at intervals (the frequency of routine audits will be dependent on factors such as the size of population served, and the quality of source water/treatment facilities);
- following substantial changes to the source, the distribution or storage system or treatment process; and
- following significant incidents.

Periodic audit should include the following, in addition to review of the water safety plan:

- examination of the records to ensure that system management is being carried out as described in the water safety plan
- ensuring that operational parameters are kept within specification and that compliance is being maintained;
- ensuring that verification programmes are operated by the water supplier (either through in-house expertise, or through a third-party arrangement) assessment of implementation programmes and development of strategies for improvement and updating the water safety plan; and
- in some circumstances, sanitary inspection, which may cover the whole of the water-supply system including sources, transmission infrastructure, treatment plants, storage reservoirs, and distribution systems.

In response to reports of significant incident, it is necessary to ensure the:

- the event is investigated promptly and appropriately;
- the cause of the event is determined and corrected;
- the incident and corrective action is documented and reported to appropriate authorities; and
- the water safety plan is reassessed to avoid a similar situation recurring.

The implementation of an audit-based approach places responsibility on the water supplier to provide the surveillance agency information regarding system performance against agreed indicators. In addition, a programme of announced and unannounced visits should be made by auditors to water suppliers to review documentation and records of operational practice to ensure data submitted is reliable. The surveillance agency will normally retain the authority to undertake some analysis of drinking-water quality to verify performance or enter into a third-party arrangement for such analysis.