

The Drinking Water Inspectorate Risk Management Approval Scheme

Guidance document

Version 01
July 2019

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1.0 Introduction and Purpose

The purpose of this document is to provide details of the requirements needing to be satisfied for approval under the Drinking Water Inspectorate's Risk Management Approval Scheme (DWIRMAS).

The Scheme has been jointly developed by the Inspectorate, Lloyd's Register and in consultation with water companies who participated in the pilot process.

Approval under the Scheme facilitates the variation of sampling frequencies associated with the regulatory sampling programme which was introduced by regulation 9 of the Water Supply (Water Quality) (Amendment) Regulations 2018.

This document sets out the basic requirements a water company must meet in order to be deemed as conforming and achieve 'approved' status under the Scheme. It also details the route to approved status from application through the audit stages, to approval, and the subsequent surveillance programme.

The purpose of the Scheme is to verify that the risk based drinking water safety plan process (WSP), as advocated by the World Health Organisation, has been implemented, and is consistent with the requirements of the Water Industry Specification document (WIS) (WIS 04-01-04), together with the BSI standard for Security of Drinking Water Supply – Guidelines for Risk and Crisis Management – BS EN 1975-2, and this guidance document.

1.1 Definitions – Explanation of Terminology

Term	Explanation
Approval	See section 1.9 for details of the approval process and the arrangements covering the granting of approval
Approval Body	The organisation which approves water companies under the Drinking Water Inspectorate Risk Management Approval Scheme (DWIRMAS) based upon the assessment reports produced by the Independent Assessment Body and feedback from attendant Drinking Water Inspectorate Inspectors. In this instance the Approval Body is the Inspectorate.
Approval Certificate	A certificate awarded to the assessed water company by the Approval Body following verification of conformity to the Drinking Water Inspectorate Risk Management Approval Scheme Guidance document (the Scheme)
Approved Period	DWIRMAS approval is valid for a term of three years from the date the company is listed as approved on the Lloyd's Register website.
Approved Water Company	Any water company which has been assessed in accordance with the Scheme, as conforming and has been issued with a valid and current Approval Certificate.
Assessment	Objective and detailed evaluation of a Water Company to determine their conformity with the scheme criteria.
Independent Assessment Body	The body assigned by the Approval Body to assess applicant Water Companies for conformity to the Scheme. The Independent Assessment Body (IAB) is currently Lloyd's Register (LR)
Inspectorate	The Drinking Water Inspectorate
Milestones	Schedules agreed for the closure of gaps identified during an assessment, or the achievement of targets agreed at the audit stage, to demonstrate continuous improvement throughout the approval validity period.
Non-conformity	The identified absence of, or a failure to implement or maintain one or more of the minimum criteria against which approval may be granted. The non-conformity will be classified as either a major or minor non-conformity as defined in 1.3.

Scheme	The general requirements of the Scheme as defined in this document
WSP	Water Safety Plan

Uncontrolled

1.2 Mandatory/non- mandatory terms

In this document 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.

1.3 Definitions of Major and Minor Non conformities

Major Non-Conformities occur where there is:-

- Objective evidence which demonstrates that an element from the Scheme requirements has not been documented or implemented or maintained;
- Repetitive failures (product quality or systems) or multiple minor non conformities in a single category;
- Significant numbers of minor non conformities;
- 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;
- Isolated cases of non-conformance to procedures.

1.4 Additional Findings classifications are:

- 'Requires Correction' are raised when:
 - The assessment identifies a single incident which needs correction but does not imply a threat to process integrity.
- 'Scopes for Improvement' are raised when:
 - The assessment identifies an aspect of the water company's operation where, whilst scheme compliant, there is potential for improvement.
- 'LR Prompts' are observations made when:
 - The assessment identifies a potential weakness which the IAB may wish to fully examine at their next assessment visit.

1.5. Abbreviations

IAB	Independent Assessment Body
DWI	Drinking Water Inspectorate
DWIRMAS	Drinking Water Risk Management Approval Scheme
WHO	World Health Organisation
WIS	Water Industry Specification

1.6. Scheme Description

The Scheme comprises:

- A compulsory gap analysis
- An implementation audit
- Post approved status surveillance programme (audit)

Approval under the Scheme provides an assurance of the:

- Execution of a methodology which supports the production of full and accurate regulation 27 risk assessments and regulation 28 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 source to tap;
- Robustness of the WSP to identify and mitigate hazards ensuring public health is protected;
- Consistent standards that are achieved and maintained across all participating water companies;
- Reliability of information collated and reported for regulatory purposes;
- Benchmarking of WSP standards which promotes and raises the professional reputation of participating water companies and their staff.

The Scheme is operated by Lloyd's Register acting as the independent assessment body. However the Scheme, associated guidance and defined audit process is owned by the Inspectorate who also serve as the approval body. The relationship between the parties is defined in the Memorandum of Understanding which is illustrated in figure 1 below:

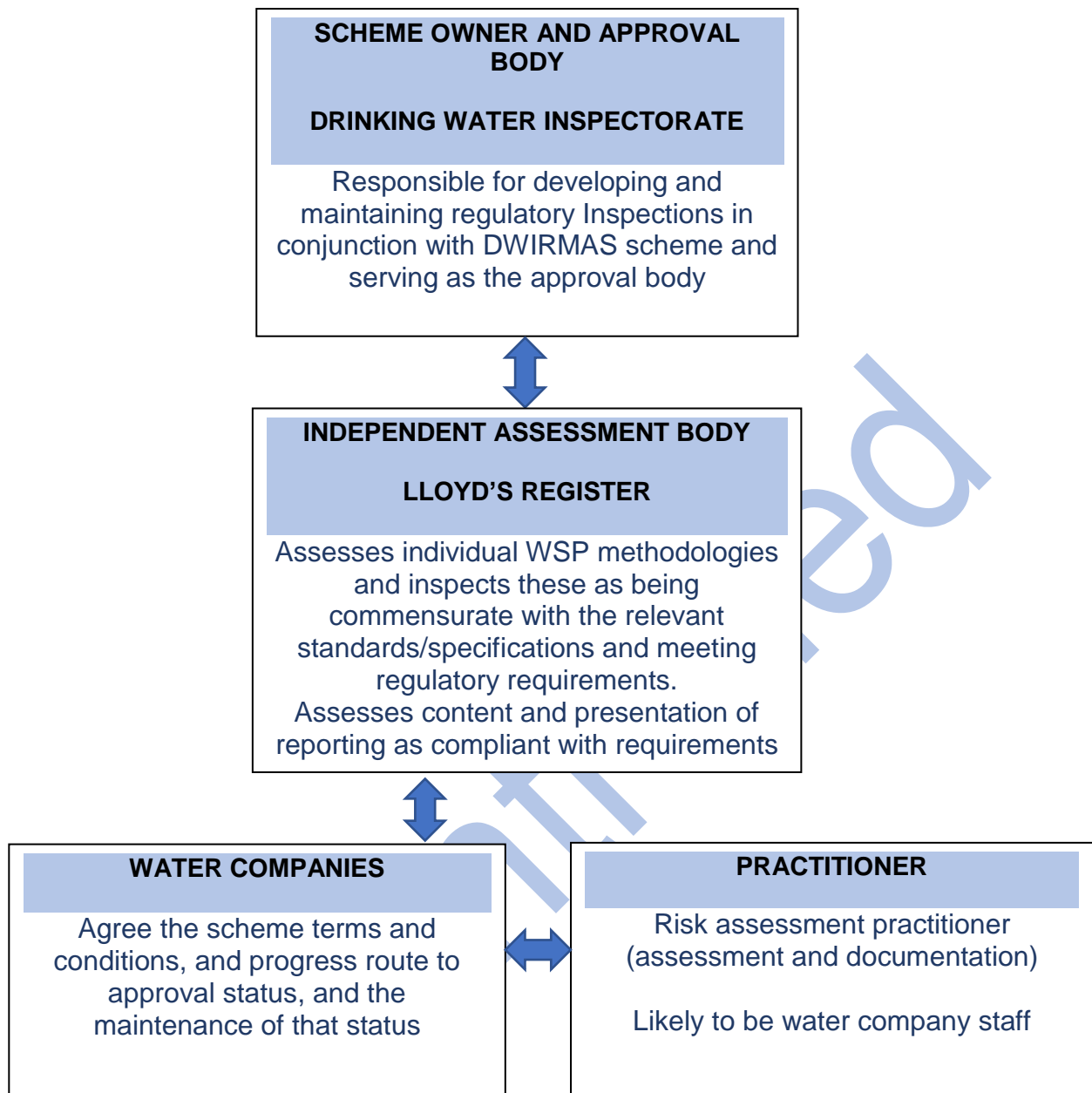


Figure 1 Defines the relationship between the Scheme Stakeholders

Note:

The practitioner category may be most relevant where a company has delegated the responsibility of the development or the administration of water safety planning to a third party or elements thereof which may be related to bulk supply arrangements or inset appointments.

1.7. Responsibilities

Approval under the scheme is a demonstration that a water company has established the systems, procedures and competencies needed for the consistent development of conforming water safety planning.

An essential feature of the approval process is the assurance that procedures and practices, against which approval has been awarded, are consistently applied and maintained by the water company. This is achieved, throughout the approval period, through the implementation of a surveillance visit programme.

To support and maintain the approval process, water companies and the Independent Assessor are required to work in the ways outlined below.

Independent Assessor:

In operating the scheme the IAB 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: WIS 04-01-04, 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 water companies' business constraints;
- Ensure any information determined in respect of the water companies' commercial business interests are treated in confidence and not passed to any third party with the exception of the scheme owner;
- Maintain a publicly available register of approved water companies.

Water Company:

Develop and maintain Water Safety Planning and management programmes conforming to the following:

- The principles of the WHO WSP process (WHO Guidelines for Drinking Water Quality, fourth edition) and requirements of BS EN 15975-2:2013 and the Water Industry Specification Document (WIS 04-01-04);
- Span catchment, abstraction, treatment, storage, distribution and within building plumbing systems to the consumers tap;

- Risks assessed for each hazard/hazardous event using a scoring system based upon likelihood and consequence criteria;
- Risks assessed both pre and post mitigation measures, incorporating the residual risk analysis and determination if additional control measures are required;
- The maintenance of a documented process with the provision of a summary report to the Inspectorate as detailed in the Water Industry (Suppliers' Information) Direction 2019 and IL 2/2019;
- 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 with regards to wholesomeness of water 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 WSPs, 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 the water company Quality Management System;
- Identify a link between water safety planning and investment processes:
- Periodic review and sign off by a designated authority.

WSP Interdisciplinary Team Competence

Drinking Water Safety Planning team personnel should:

- Have a good understanding of the underpinning theory of Water Safety Plans and be familiar and knowledgeable with the key publications;
- Be cognisant to the requirements of the Water Industry Specification Document (WIS 04-01-04), 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 water quality regulations¹;

¹ The Water Supply (Water Quality) Regulations 2016 (as amended)
The Water Supply (Water Quality) Regulations (Wales) 2018

- 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 consumer, 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 the water company and third parties who are able to input into the water safety planning process and risk assessments. This will always include senior managers as it is a requirement for the assessments to be signed off at a senior level. This may include personnel such as treatment works managers, maintenance or treatment operatives, planners, engineers, network controllers, resource planners etc.;
- 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 the Environment Agency (Take into account any monitoring carried out under Article 7(i) and Article 8 of the Water Framework Directive²), Natural England etc. The competency of these other stakeholders is not considered in this document and is outside the scope of this scheme.

Senior Personnel signing off drinking water safety planning methodology documents and risk assessment reports will 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. This is outside the scope of the Scheme and this document.

External Auditors of water safety planning methodologies are designated by Lloyd's Register and their competency is pre-determined for their given role by Lloyd's register. This is outside the scope of the Scheme and this document.

1.8. Water Safety Plan Methodology

This section describes the prerequisites for a WSP methodology.

The WSP methodology shall be commensurate with the requirements of all aspects of the Water Industry Specification Document (WIS 04-01-04), and hence BS EN 15975-2:2013 and be based on the principles of the World Health Organisation's guidance on Water Safety Planning³.

Provision is made for water supply licensees and small companies who may wish to outsource some aspects of water safety planning due to the

² Directive 2000/60/EC of the European Parliament and of the Council of 23 October 2000 establishing a framework for Community action in the field of water policy

³ Chapter 4, World Health Organisation's Guidelines for Drinking Water Quality, Fourth edition

availability of expertise, however the originator of the WSP methodology would remain with the owner, and would be responsible for any findings, improvements and subsequent notices applied by the Inspectorate and or the IAB.

The methodology may take different forms across companies. Expression of risk may differ (for example financial expression of risks or standard 5x5 risk matrix scores), however for all documents and risks assessment outputs, there should be the following elements and considerations:

- There shall be documented evidence of procedures describing how to implement WSP 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 (i.e.: in-development or site access issues, water supply licensees will not have catchments or treatment works etc.);
- There shall be a defined mechanism with triggers for the review and update of the methodology document and related procedures and protocols;
- The company 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 intended for the Inspectorate will be the regulation 28 risk assessment reports. It is not intended that these outputs will form a significant part of the methodology audit –these reports may be examined during the audit to verify details contained within the methodology. The Regulations and IL 2/2019 describe the requirements for regulation 28 risk assessment reports.

Note- The Inspectorate performs regular and routine assessment of the risk assessment reports. This is a separate activity outside the scope of this scheme.

1.9. Scheme Process

Water companies wishing to apply for a variation from the regulatory sampling programme are required to apply for independent confirmation of conformity of their water safety planning, with the IAB. A commercial contract will be established between the water company and IAB.

Once the contract between the applicant and the IAB has been established, the applicant will be contacted by the appointed IAB Assessor to arrange a date for the gap analysis which represents the first stage of the Scheme.

Gap Analysis

The compulsory gap analysis represents an informal interview and discussion based process which serves as a cost effective means of establishing a high level overview of the company's 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 the water company a minimum of seven working days prior to the due date.

The gap analysis is usually limited to one day and 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 1.3.

If major non-conformities have been identified, then the water company 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. As the gap analysis is not an evidence based process, unlike the subsequent formal audit, the DWI will not participate in this stage of the assessment.

Formal Audit

Upon receiving confirmation of the closure of major non conformities identified during the gap analysis from the water company, the IAB assessor will agree a date for the commencement of the formal audit of water safety planning against the requirements, as set out in this guidance document.

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 the water company a minimum of seven working days before the agreed commencement date, following discussion and input from the Inspectorate as necessary. Site visits shall form part of the standard audit programme unless extenuating circumstances prevail as determined by the Inspectorate. The Inspectorate will be represented at the audit, usually by the water company's liaison inspector. The inspector's role will be to support the LR assessor. The Inspectorate's costs will be recovered through the usual route.

The audit will be evidence based and will verify that water safety planning and associated processes, as described by the water company during the gap analysis, have been effectively implemented and is in full conformity with this the requirements and 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 Inspectorate as to conformity.

The report will be issued by the Inspectorate within 20 working days of the completion of the audit, and it will be the responsibility of the Inspectorate to confirm approval within the same timeframe to the water company and to LR.

Once confirmation is received from the Inspectorate, LR will update the DWIRMAS section on its website to identify the approval status of the water company.

The approval status will afford the approved water company the ability to adopt a flexible approach to their monitoring programmes.

Achieving approval under the scheme will also contribute to the move towards a risk based approach to water supply and management.

Surveillance Programme

Following approval by the Inspectorate, the IAB 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 the WIS, BS:EN 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 Inspectorate and the IAB at the approval stage, but would typically represent three visits within the term of approval.

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

A separate commercial contract will be established with Lloyd's Register 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 the water company's water safety planning performance.

An agenda will be issued by the IAB to the water company a minimum of seven working days prior to the surveillance visit due date.

In the event that the Inspectorate find issues through its own audit programme then it would reserve the right to request the IAB to arrange a supplementary visit, which would be additional to the agreed surveillance programme and for which the water company 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 regulation 27 notice, by the Inspectorate.

2. Suspension and Re- approval

Approval shall be subject to cancellation or amendment by the Inspectorate if a water company:

Is found to have made false claims within the application for approval which are considered to impact on the integrity of the water company's operations; and

- Does not implement within 28 days remedial actions needed to rectify a major or series of minor non-conformances to the satisfaction of the IAB and the Inspectorate
- Implements corrective action which is subsequently found to have been inadequate to prevent a reoccurrence (at any location) of recently identified non-conformances;
- Systemic failure to implement or implement effectively, risk mitigation measures. Cultural concerns that have arisen from the audit or the Inspectorate's findings through a regulatory, or other activity (such as a transformation programme);
- 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;
- Notifies the Inspectorate that they no longer wish to be approved under the scheme

The Inspectorate shall notify a water company 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 the water company will be notified that their approval is being suspended and given a limited time to address the non-conformances giving rise to the suspension. If the non-conformances are not satisfactorily addressed during the allotted time period and steps are not taken to prevent a reoccurrence approval will then be cancelled and monitoring variations will be revoked.
- Once approval has been cancelled re-establishing approval will be subject to a full re-assessment of the water company.

2.1 Appeals, Complaints and Disputes concerning Approval

If a water company wishes to object to action taken, including withdrawal of approval by the Inspectorate, they shall, within twenty-one days of the issue of the notification to them, give notice in writing to the Inspectorate of their objections setting out clearly the grounds for an appeal.

Any such appeal will be assessed by a panel within the Inspectorate, independent of those members of the Inspectorate and IAB associated with the original withdrawal action.

The results of the review will be communicated to the water company 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 the water company would entail a re-run of the formal audit.

2.2 Scheme Management review

The Inspectorate and the IAB will hold a meeting or a teleconference at three monthly intervals following the scheme launch, 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 first 360 degree feedback session incorporating all water companies involved in the scheme to date, will be held within the first year following scheme launch. The purpose of which will be to refine this guidance document as may be necessary and put suggestions for refinement of the WIS to Water UK.

Companies who are not listed on the Lloyd's Register website as conforming, must fulfil the standard monitoring frequency for all parameters as specified in the Regulations.

Examples

The following example describes a scenario whereby a company holding approval against the Scheme, may have their approval suspended or cancelled, as a result of an Inspectorate investigation.

1. The company is visited by the Inspectorate as part of the routine risk based technical audit programme.
2. It is found that a generic list of hazards and hazardous events has been used to produce a desk based risk assessment for all of the company's ground water sites. No site specific hazards have been included in the risk assessment.
3. Upon visiting three ground water sites during the audit, it is found that the sources of hazards and possible hazardous events in close proximity to the site, are easily identifiable. Many of these do not feature on the risk assessment or the regulation 28 report for the sites.

4. Conclusion : The hazard analysis has not been completed in a way that satisfied the WHO guidelines or the WIS. It applies to all the company's ground water sites.
5. The Inspectorate notifies the company and LR.
6. A major non-conformity is raised by LR, and the Inspectorate serves a regulation 27 notice.
7. The company has 28 days to close-out the Major non conformity. The major non-conformity will feature as one of the first steps of the regulation 27 notice. In this case it would most likely be for the procedure and process to be reviewed within the 28 day period. If this is achieved, the approval would not be suspended. Application of the new process to all ground water sites would then be covered by the remainder of the regulation 27 notice.
8. If the company fails to close-out the major non conformity, approval would be suspended which would trigger a review of the company's monitoring variations, review of the regulation 27 notice, and possibly further enforcement action. Compliance with notices would be monitored with on-compliance potentially leading to the cancellation of any monitoring variations.