

Technical Audit of Severn Trent Laboratories Limited* under Section 86 of The Water Industry Act 1991

**Final Report of the site visit on 1 -3 September 2010 and subsequent
Investigation**

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1.Executive Summary

- 1.1. This report sets out the findings of the Drinking Water Inspectorate's (DWI) audit and subsequent investigation relating to the Bridgend laboratory of Severn Trent Services Analytical Services
- 1.2. The role of the DWI is to carry out independent checks within the framework of drinking water regulation to ensure that testing of samples is carried out to the required high standard of quality control and thus maintains public confidence that the robustness and integrity of water company results is beyond question.
- 1.3. The Inspectorate visited STS AS' laboratory on 1st - 3rd September 2010 to carry out an audit which was prompted by a change in the Inspectorate's assessment of risk to very high. The Inspectorate attended site with eight inspectors who carried out a systematic audit of records and informally interviewed staff in order to establish if there was a sound basis on which the perceived assessment was made. At the time of the visit the Inspectorate removed records from site for further investigation.
- 1.4. Following this audit and during the subsequent investigation the Inspectorate collected further data, records and personal statements.
- 1.5. Inspectors found significant evidence of fabricated results for one test parameter, logs and records completed retrospectively, and serious deficiencies in archived records. These deficiencies hampered the audit process. Analytical quality control records were found which did not fit statistical expectations indicating preferential selection in the course of analysis for a number of parameters. Inspectors also noted significant number of complaints from the water companies who were the customers of the laboratory, some of which lacked a robust and timely response.

- 1.6. Inspectors noted that whilst the general systems of control (operating procedures and quality manual) were of a good standard and the majority of the laboratory was operating appropriately, albeit under significant pressure of high workload, the situation in relation to the inorganic chemistry laboratory was unacceptable.
- 1.7. The inorganic chemistry laboratory was operating under significant pressure as evidenced by staff absence due to holiday or long-term sick leave with no allowance for this in the incoming work load, determined by a management model designed for another purpose. The management, and senior management, were aware of these staffing issues and the consequential irregularities through their own internal reporting systems but appeared not to have acted to resolve the situation. This inaction led directly to further pressures whereby important tasks were being deemed unnecessary and put to one side, for example worksheets, logs and analysis not within the scope of accreditation or considered non-regulatory.
- 1.8. Inspectors found breaches of the Water Supply Regulations 2010 (England), and the Water Supply (Water Quality) Regulations 2010 (England and Wales), specifically Regulations 16 and 34. Recommendations are made in the body of this report which water companies are required to act upon. Further recommendations are made in respect of improvement of the practices within the laboratory.
- 1.9. STS AS responded rapidly to the immediate feedback provided by inspectors and the evolving circumstances of the subsequent investigation by the Inspectorate. STS AS commissioned their own investigation and acted on the findings, putting in place a recovery process covering short and medium-term objectives.
- 1.10. The Inspectorate considers the findings identified by this audit a serious matter. Circumstances led to breaches of the Regulations, which had not previously been seen by the Inspectorate. The Water Industry Act imposes duties upon the water undertaker or the combined licensee in the provision of data. Additionally the provision of information extends to any person or company in that it must not be false. The Inspectorate did not

consider that the information gathered, in particular the evidence of complicity and the action of the company following the investigation provided sufficient grounds to take forward a prosecution in the public interest.

- 1.11. The Inspectorate makes this report available more widely for the benefit of the water industry for the purpose of learning and to prevent any recurrence.

2. Recommendations and Suggestions

2.1. Recommendations made under The Regulations¹ and The Act²

- 2.1.1. We recommend that the water undertaker or the combined licensee ensures that samples are analysed as soon as may be after they have been taken, observing IL 12/2005, and by or under the supervision of a person who is competent to perform that task and provide supporting evidence to verify this. Furthermore, analysis must be carried out with the use of equipment that is suitable for the purpose commensurate with Regulation 16(2)(d) of The Regulations
- 2.1.2. We recommend that the water undertaker or the combined licensee maintain sufficient records to enable it to establish, for samples taken for the purposes of the Regulations, that the appropriate requirements as are applicable to that sample have been satisfied commensurate with Regulation 16(4) of The Regulations
- 2.1.3. We recommend that the water undertaker or the combined licensee maintain those details acquired in 2.1.2, in order to establish 16(4), and this must be for at least five years as a requirement of 34(4)(b) for other particulars specified in 34(1)(g) and 34(1A)(d)
- 2.1.4. We recommend that the water undertaker or the combined licensee must put in place measures and verify, if necessary by audit trail, that all information provided to the DWI does not constitute knowingly an offence under sections 207 and 210 of The Act.
- 2.1.5. We recommend that the water undertaker or the combined licensee ensures that where there is a failure of a parameter to meet the requirements of the regulations that a robust investigation under

regulations 17 and 18 in England, and 18 and 19 in Wales, includes checks of analytical records held by the laboratory. Furthermore the water undertaker or the combined licensee should have a system in place to identify anomalous results which may require a proactive investigation.

- 2.1.6. We recommend that the water undertaker or the combined licensee ensures that where a parameter fails to meet any of the specifications, that the expediency of the analysis is commensurate with the ability to carry out an investigation under Regulations 17 and 18 in England, and 18 and 19 in Wales.
- 2.1.7. We recommend that the water undertaker or the combined licensee ensures that any data obtained from a laboratory must comply with the requirements of Regulation 16. Companies are reminded that this is not solely exclusive to Schedule 1 parameters but should include any data produced to comply with Regulations 4, 15, 16A or to inform, assess or verify a risk assessment under Regulations 26 - 28, (27 - 29 in Wales).
- 2.1.8. We recommend that water undertaker or the combined licensee either individually or as part of a syndicate demonstrate compliance with the recommendations stated within this section by no later 30 September 2011. Furthermore that all recommendations and suggestions from section 2.2 and 2.3 are completed by 31 January 2012. Both these requirements must be by written report and the provision of evidence.
- 2.1.9. We remind the water undertaker or the combined licensee that it is an offence on summary conviction not to provide all such assistance to a warranted Inspector acting under Section 86 of the Water Industry Act 1991.

2.2. Recommendations for avoidance of breaches of The Regulations¹ and The Act²

2.2.1. We recommend that water undertakers or combined licensees ensure that:

2.2.1..1. the laboratory implements the management requirements of ISO 17025:2005 section 4.1 including a quality hierarchy independent of operational objectives and business targets and is able to report its findings through quality systems to Director/Senior level independent of local management.

2.2.1..2. the laboratory implements and maintains a system of operational management that is committed to good professional practice and quality orientated testing commensurate with ISO 17025:2005 section 4.2 and should include the service to its customers specified in 17025:2005 section 4.7 and their regulatory duties and that this is clearly owned by a Director/Senior Management

2.2.1..3. the laboratory implements and maintains a system of operational management such that management or personnel are free from pressure that may affect the quality of work as specified in 17025:2005 section 4.1.5(b), allocating resources based upon appropriate management information which must be available to Director/Senior Management

2.2.1..4. the laboratory implements and maintains a mechanism of measuring the response to quality findings including robust and timely corrective actions from internal audits and other sources

as specified in 17025:2005 section 4.11 and such information is available to Director/Senior Management.

- 2.2.1..5. the laboratory implements and maintains a thorough management review including robust corrective actions from all laboratory activities, internal and external, as specified in 17025:2005 section 4.15 and this review includes Director/Senior Management level.
- 2.2.1..6. the laboratory implements and maintains a mechanism of measuring the robust and timely response to, and resolution of, concerns from the water undertaker or the combined licensee relating to analytical quality and other irregularities as specified in 17025:2005 section 4.8. This information must available to Director/Senior Management.
- 2.2.1..7. the laboratory is furnished with equipment that meets and is operated according to 17025:2005 section 5.5. In particular the capabilities, capacity, downtime and operational limits must not be exceeded. Reporting to senior management must occur if these factors are exceeded to avoid overloading, mishandling or the inability to produce assured results.
- 2.2.1..8. the laboratory operates management of personnel commensurate with ISO 17025:2005 section 5.2. In particular that competency and training is recorded, accurate, current and reviewed regularly and that proactive recruitment, training and information sharing across sites addresses highlighted gaps in capability. This should be endorsed by Director/Senior Management and acted upon by operational management.
- 2.2.1..9. the laboratory implements and maintains a system of analytical control that prevents exclusion of data and that data is monitored for statistical irregularities. Limit changes are required to be counter signed through operational and quality management.

- 2.2.1..10. the laboratory implements and maintains a system of robust investigation in relation to statistical irregularities such that action is both timely and effective and that outcomes are available to operational and quality management.
- 2.2.1..11. the laboratory implements and maintains a system to identify irregular patterns in analysis that may be considered unusual for that parameter e.g. excessive low blank results, and that outcomes are available to operational and quality management.
- 2.2.1..12. the laboratory implements and maintains a system to control nonconforming work as specified in ISO 17025:2005 section 4.9 including those areas specified in sections 2.2.1.. 9 to ..11
- 2.2.1..13. the laboratory implements and maintains a system of AQC tracking from its production, transport and use that is identifiable and traceable throughout and can be associated confidently with the analysis .
- 2.2.1..14. the laboratory implements and maintains a system for technical records as specified in ISO 17025:2005 section 4.13.2 that ensures observations, data and calculations are completed at the time of observation.
- 2.2.1..15. the laboratory maintains a robust control of records commensurate with ISO 17025:2005 section 4,13 for a period of time deemed by the licensed undertaker or the combined licensee to fulfil their regulatory duties including the management of worksheets in their provision, traceability, completion of data, signing and counter signing and retention in a manner which permits retrieval and that this is verified through audit . The information is required to be available to Director/Senior Management as part of the internal audit reporting systems.

- 2.2.1..16. that no part of these recommendations permit avoidance of any other part specified in ISO 17025:2005
- 2.2.1..17. the laboratory shares all learning through all practical routes across all sites using comparative data.
- 2.2.1..18. the laboratory produces and provides to the water undertaker or the combined licensee (or syndicate) a full report on the completion of all recommendations and suggestions to meet the requirements of the recommendation made in 2.1.8 and they in turn subsequently provide this to the Inspectorate as part of their own report.

2.3. Suggestions of Best Practice

- 2.3.1. We suggest that internal audits are not pre-warned where possible.
- 2.3.2. We suggest that staff within the laboratories are informed through a structured training program of wider matters relating to drinking water monitoring, regulation and analysis which will add perspective to the purpose and objectives of analysis
- 2.3.3. We suggest that analysts treat internal and external quality control samples in the same way as client samples
- 2.3.4. We suggest the laboratory considers the robustness of its recording of staff activity.
- 2.3.5. We suggest that the laboratory considers the effect of leave and sickness on its capacity to carry out analysis in agreed timescales.
- 2.3.6. We suggest that, where possible, concerns raised by analysts within the laboratory should be reported through team meetings or other means to enable matters to be considered in a transparent way by management.
- 2.3.7. We suggest that managers, supervisors and analysts are provided with a working environment where they can act at all times with quality in mind and are empowered to resist the desire to cut corners to help prevent a recurrence of the behaviours identified during the audit.

3. Investigation Framework

3.1. Introduction

3.1.1. The Drinking Water Inspectorate operates a risk-based audit process based upon the principles of Better Regulation. An audit is not carried out without due reason unless it falls within the very small percentage of those randomly selected for method verification purposes.

3.1.2. Prior to the audit of Severn Trent Laboratories, (STL), the DWI had, in the first instance, received a complaint from another Regulator on the matter of a) the expediency of analysis b). the validity of data received (both in robustness of the analysis due to the delays), and c) the usefulness of that data in applying it to the duties of the water supplier who received that data. This complaint came at a time when the Inspectorate was aware of non-specific wider concerns about the quality of drinking water sample analysis by STS AS. Further to this and at a later date, the DWI received specific information from a solicitor about a number of practices at the Bridgend laboratory site and more specifically the inorganic section.

3.1.3. The first notification heightened the priority for audit but the combination of both these occurrences led to a reappraisal of risk to the monitoring and records of water quality testing by water companies in pursuit of their duty to ensure that water supplied is wholesome. The revised risk of non-compliance of the duty under Section 69 of the WIA 1991 was considered to be very high.

3.1.4. The Inspectorate scheduled an audit under its duties set out in Section 86(2). The DWI considered there was a risk in requesting information (taking into account the nature of the notification) and decided under Schedule 6 Part II, 6(2) of the WIA 1991 to give the minimum twenty-four hours notice as required under section 86(4) to the laboratory.

- 3.1.5. It is the duty of the licensed water supplier to meet the requirements of sections 67 – 69 of the WIA 1991 and therefore the Inspectorate would normally give notice to the water supplier who themselves would notify the laboratory whether this be a contracting laboratory or otherwise. However the complexity of the commercial activities of STL are such that they carry out work for many water companies. The evidence available to the DWI was not detailed in a way so as to identify those customers who may be most affected by the concerns. Therefore if the usual procedure had been followed it would have required notifying all water companies who in turn would all have needed to inform the laboratory and potentially all would have sought to attend the audit. This would have resulted in an unworkable situation potentially detrimental to the business in the event of a satisfactory audit outcome. The approach adopted therefore was for the audit to be notified directly to the laboratory by the Inspectorate and for the audit work to be assigned to eight inspectors.
- 3.1.6. On 31 August 2010, the Bridgend Site Manager of STL was sent notification of the DWI's intent to audit the laboratory.
- 3.1.7. Inspectors attended site and the audit took place over 1,2 and 3 September 2010.
- 3.1.8. A team from Eversheds solicitors arrived on site at Bridgend on 2 September 2010 both to advise STL, to assist in the provision of information, and to provide assistance to the DWI to enable it to complete its initial audit.

3.2. Audit Objectives

3.2.1. To verify that the duties of the Water Supplier had been carried out with specific reference to Regulation 16 of the Regulations¹ and specifically:

- Samples were analysed as soon as maybe after having been taken by, or under the supervision of, a person competent to perform that task, with the use of equipment suitable for that purpose.
- That records were both maintained and sufficient to establish that the appropriate requirements of that sample were met. That is competency, equipment and a system of analytical control which was itself subjected to checking, (and therefore capable of being checked), by a person not under the control of the laboratory.
- The monitoring of water as supplied for the purposes of wholesomeness, as defined by Regulation 4 of the Regulations¹ including any data produced to comply with Regulations 16A or to inform, assess or verify a risk assessment under Regulations 26 - 28, (27 - 29 in Wales).
- Records were kept and information provided as required under Regulations 34 and 35 of the Regulations¹
- The reliability, veracity and intent in the provision of information to Water Companies in order to dispense their duties and to the Secretary of State through the submission of that information.

3.3. Audit Structure, Team and responsibilities

3.3.1. The audit team comprised eight Inspectors, namely:

- Investigating Inspector, Samantha Vince.
Responsible for leading the audit and subsequent investigation.
- Supervising Inspector, Marcus Rink
Responsible for overseeing the investigation and strategic liaison.
- Supervising Chemist, Malcolm Morgan
Responsible for supervising the interpretation of analytical quality data
- Investigating Chemist, Sarah Roberts
Responsible for detailed analysis of chemistry data
- Investigating Administrator, Suzanne Calmels
Responsible for assessing office management and administration
- Audit Inspectors; Dr Kevin White, Shaun Jones and Jane Allen
Responsible for general audit inspection

3.3.2. The initial audit plan was for a two day audit to cover the following areas but was not intended include method audits:

- Alkalinity by automated titration
- Total and Free Cyanide by continuous flow and spectrophotometric detection
- Anionic Detergents
- Manual colours
- pH, Turbidity, Conductivity by robotic Aqualyser
- Total Dissolved Solids, (T.D.S)
- Parameters analysed by the Konelab
- Records of analysis

3.3.2..1. Worksheets

3.3.2..2. Achieve and retention of data

- 3.3.2..3. Equipment records
- 3.3.2..4. Training records
- 3.3.2..5. Records of quality control

3.4. Staff.

- 3.4.1. Staff are considered to be a critical resource within any laboratory to enable high quality, robust and efficient analysis. Working practices within the laboratory, the management structure, team and the quality framework provides the basis of generated data which is trusted, assured and expedient to meet both the requirements of the clients and the Regulator.
- 3.4.2. As part of the investigation, staff were informally interviewed at an early stage to provide an opportunity to discuss any matters or concerns. This opportunity was provided not only to avoid any unnecessary inspection, but to allow evaluation of the audit risk assessment.
- 3.4.3. Finally staff activity and leave records were examined to provide a picture of not just general management but to identify any pressures that might challenge data validity.

3.5. Post Audit Investigation

- 3.5.1. The complexity of the audit required key paperwork to be removed from site. To enable this a records system of official tags was maintained.
- 3.5.2. During September 2010, the information retrieved from the laboratory required extensive examination to determine what, if any, further information was required to confirm initial findings.
- 3.5.3. Following this, requests were made to water companies who had commissioned and used the data to identify if they had processes in place to determine anomalous results since evidence indicated some customers had complained to the laboratory. Inspectors received the majority of this information during October 2010 but were disappointed that not all

companies responded. This observation has informed the Inspectorate's ongoing process of risk assessment of water companies in relation to the duty to ensure all samples are representative of water in supply.

- 3.5.4. Inspectors were delayed in being able to speak to one particular individual who eventually provided a statement in November 2010.
- 3.5.5. Inspectors were provided with a short investigation report on 29 November by Severn Trent Plc. The investigation involved a team drawn from both Eversheds and Ernst & Young and was based upon feedback and information provided by inspectors at the time of the audit and in meetings thereafter.
- 3.5.6. Inspectors were given access to a Severn Trent Plc investigation report on 16 December.
- 3.5.7. There were subsequent meetings 20 December and 7 January 2011 and an initial draft report from the laboratory was made available on 11 February 2011 with the final first stage report available on 25 March 2011.
- 3.5.8. The Inspectorate had received all the information it considered necessary in a usable format by the week of 4th April 2011.

4. Audit Findings

4.1. Records

- 4.1.1. In any audit, both the auditor and the audited must be able to demonstrate compliance with the requirements of the laboratory's own system, ISO 17025, The Regulations and The Act . All specify the keeping of accurate records .
- 4.1.2. There must be retention of sufficient information (original observations, derived data) for sufficient time to establish an audit trail. This should include calibration records, staff records, equipment records and the names of personnel responsible. Furthermore, observations, data and calculations must be recorded at the time that they are made and links established to the specific tasks and analysts. This can be either in a written or electronic format provided that these criteria are met and there is avoidance of loss or change of data.
- 4.1.3. The laboratory employs a system of unique numbers for each sample, batched by a job number and printed onto worksheets which themselves have a unique number assigned, a date of printing and if more than one page, page numbers. An audit trail can therefore be formed by any of these numbers and their associations. Each test type has a unique test or "determinand" code and this may represent the final reported result or associated (unreported) data. This code is printed on the worksheet if a paper system is used or may be retrieved from the Laboratory Information Management System, (LIMS), if data is automatically captured. In the case of a multiple stage analysis, critical data used to derive the final result must be retained to prove a robust analysis. Worksheets must be signed by the analyst and countersigned for verification. In the case of electronic capture, it must be possible to identify the analyst who made the record.

4.1.4. The Laboratory retains worksheets within an archive system with a list intended to identify each box and their contents. The audit sought to retrieve worksheets from the archive and the Inspectors make the following comments:

- The archive was incomplete with three boxes missing from the list at the time of the audit.
- An Inspector who located an archive box found within the laboratory was initially impeded when trying to retrieve it.
- There were multiple examples where worksheets either could not be found within archive boxes or parts of worksheets were missing. Information could not be easily or readily retrieved. The company's own investigation found 18% of worksheets to be incomplete.
- There were multiple examples where worksheets were not signed as required.
- In the specific case of analysis of Total Dissolved Solids, (TDS), which requires multiple steps including weight measurements to determine the final result, there were no workings to arrive at the result therefore no proof existed as to how the result was determined in many instances.
- In multiple instances, again in respect of TDS, only a conductivity result existed. The total dissolved solids concentration can be related to the conductivity of the water and is often used as a validity check. The relationship is not a constant and some variance outside of the range would be expected occasionally if non-ionic substances were present in a sample. There were no instances found where this happened. Without a record of raw data it was not possible to verify either the data or the validity of the conductivity check, if it was used in this way.
- In one instance, again with TDS, it was found that data entered onto the LIMS preceded the written worksheet record by forty days. The only conclusion that could be drawn in this instance was that the data recorded onto the sheet was not contemporaneous which

would mean that, at best, the data would have to have been recorded elsewhere which does not conform with either the laboratory quality system or ISO 17025:2005.

4.1.5. To form an audit trail there must be certainty between the data and the permanent record. The establishment of the audit trail was difficult and sometimes impossible because of reliance on the analyst to handwrite sample number sequences onto printouts from analysers (such as the aqualysers and alkalinities) with subsequent transposition onto worksheets. The method for ensuring the correct sample matches the correct result must be robust and is a requirement of ISO 17025:2005. Data gathered following the inspection showed there to be a number of instances where reported data was outside expected statistical limits This resulted in challenges by a company commissioning the analysis due to the high number of change requests; a circumstance that arises when data may not be valid for one reason or another, e.g. transcription errors. The approach of this commissioning company is to be commended since it shows awareness of, and independent action on, data quality. Another company that submitted fewer samples to the laboratory and therefore was not in the position of being able to challenge data on a statistical basis, was found to be in a position of having to accept a result for conductivity some 200 times lower than expected despite the improbability of such a value being correct.

4.2. Equipment.

4.2.1. A laboratory must use equipment that is suitable for the purpose and performs to the correct standard for the test for which it is used. Equipment should be able to achieve the accuracy required or be operating within key criteria established when commissioned and calibrated, a requirement of ISO 17025:2005. This includes key equipment such as ovens, pipettes and balances which require daily or before use measurement of temperature,

volume and weight and the appropriate records kept. The inspectors made the following comments:

- A number of records were noted over prolonged periods of time, (weeks), to be written in the same handwriting, pen and signed by the same analyst for ovens, pipettes and balances. In the case of one oven, not only was the above true but the temperature and time of recording was exactly the same over a period of months. In the experience of the Inspectorate it would be normal to see some variation in the records over time.
- Inspectors further observed during the audit that an oven thermometer reading was different to the log, supporting the hypothesis of incorrect completion of logs.
- The auditors examined electronic clocking records. Analysts are required to 'clock in' using an electronic system which calculates hours worked. Also the laboratory kept a written record of site attendance which analysts signed to indicate when they were on site. This is particularly relevant for weekends where it was/is normal not to 'clock in' electronically.
- The audit identified multiple dates when the analyst who had signed records on ovens, pipettes and balances had not 'clocked in' on that day. It is possible that the analyst may have forgotten to 'clock in' electronically. This was cross referenced with the written record and this corroborated, particularly for the oven records, that the signatory was not on site. Again the analyst may not have signed in. A cross-check was made with annual leave records and it was also found that there were multiple instances where the annual leave record indicated the staff member was actually on leave when readings were taken and signed in their name. The analyst in this instance claimed that they came in on their leave days to carry out work on multiple occasions. If correct this points to serious staffing shortfalls if a staff member needs to come into work on leave days.

- The pattern of records which were similar or exactly the same over a prolonged time together with the absence of the staff member identified as having made the records (on three separate occasions) presents very strong evidence of inappropriate retrospective completion of records and a serious breach of ISO 17025:2005 and the Regulations. Alternatively the findings point to serious management irregularities where staffing records do not reflect staff attendance, itself a serious concern of management control. Subsequently, both of these conclusions were corroborated within a witness statement provided to the Inspectors.
- Inspectors examined the internal quality audit records. These noted non-conformities in that the Analytical Quality Controls were not plotted at the time of analysis and that gaps existed in the daily pipette checks. The company's own investigation following interviews with staff support the conclusions that calibration records had been filled in retrospectively.
- Further observations made at the time of audit were that the water bath used for the analysis of TDS was not working. There were significant concerns surrounding this particular analysis at the time of audit. Records were found by Inspectors to show that sixty-one samples for TDS were recorded as having been analysed on one day. There was insufficient equipment available to achieve this number of analyses. Whilst the audit found this example, the company, in their own, investigation found another example where seventy-five samples were purported to have been analysed on one day.

4.3. Staff

4.3.1. The Bridgend site employs approximately 54 analysts, 4 team leaders and is run by a Site Manager and Assistant Site Manager. The site has its own Quality Manager and Assistant Quality Manager. The Quality Manager reports to the STL Group Quality Director. The Bridgend site mostly carries

out drinking water testing for Inorganic and Organic Chemistry, Metals and Microbiology.

- 4.3.2. The generalised position of the inorganic team can be seen within the overall structure of the organisation in Appendix I (fig 1).
- 4.3.3. The audit concentrated on the inorganic chemistry section as this was the high risk area previously identified.
- 4.3.4. The inorganic chemistry team consisted of nine analysts and a team leader. The team members worked varying hours with two staff being part-time. This equated to 7.2 FTE's (Full Time Equivalents).
- 4.3.5. During the investigation a statement made by a member of the staff from the inorganic team indicated that over two years prior to the audit the team experienced a heavy workload with inexperienced staff, absence and lack of availability of staff to complete work. Reasons given for this were diversion of staff to another site/ project, (specifically within the inorganic team but also the Laboratory Manager), sickness and generally too few staff to carry out the routine tasks.
- 4.3.6. The investigation examined staff numbers, allocated leave and the sickness records of the inorganic section over a two year period and found nearly four hundred days in sick leave of which approximately three hundred of these days were due to just three analysts, (this excludes any analyst who may have been on long term sick leave during this period). Taking into account available working days, sickness approximately equated to 13% of the available FTEs and was almost equal to the time taken in annual leave, (approximately 14% of FTEs). At any one time, on average, more than one-quarter of the allocated resource was unavailable and this equated to more than 2 FTEs in this team.
- 4.3.7. The audit did not specifically review overtime but the company investigation stated that from the review of electronic records there were high levels of overtime worked concurrent with absenteeism due to sickness in the Bridgend inorganics team.
- 4.3.8. Inspectors noted that the Team Leader was performing a significant amount of bench work based on records carrying their signature (including

worksheets, equipment records and logs, and statements). Part of a team leader's role is to supervise adherence to procedures whether this be quality, safety, or more generally, and to communicate as necessary any matters beyond their remit. As the team leader was performing a number of tasks as an analyst, including one complete analytical stream of work, It is the opinion of the Inspectorate that these responsibilities could not be met in full by one person.

- 4.3.9. The company concurred with this observation stating that the team leader had been identified as failing to perform team leader functions properly, which had led to that team leader being put on an improvement programme previously.
- 4.3.10. Inspectors became aware during the audit of the use of a "Capacity Model". This was not specifically audited since the means by which a company manages the business is beyond the scope of regulation. However, the Inspectorate is critical that this model may have been used to determine workload and resources without regard to quality requirements. During the audit staff referred to this model in respect of equipment and other staff requests.
- 4.3.11. The Annual Management Review in September 2009, (p20), identified that no additional staff were recruited following the award of a significant new contract. Whilst this in itself is not necessarily of concern, evidence indicates that the additional work came at a time when the team were suffering from considerable pressures of work as described above. In addition, the Inspectorate has become aware of significant consequential issues involving a delay in reporting results to clients. This is supported by evidence of complaints from another drinking water regulator and clients and is recorded in statements made by staff to the Inspectorate.
- 4.3.12. The company, in their investigation, demonstrated use of the 'Capacity Model and identified the inorganic chemistry operation at Bridgend had fewer staff than required. The company investigation noted that, in the period from June 2008 to November 2009, the total number of staff

required was greater than the total number of staff employed in 4 of those 18 months.

4.3.13. The company investigation noted further that team leaders requests to recruit new staff were repeatedly refused on the basis that the 'Capacity Model' suggested staff numbers were sufficient, despite the fact that evidence suggests the teams were struggling with the workload.

4.3.14. Inspectors noted that analysts made statements reporting heavy workloads and additionally internal audits pointed to this as a cause of errors. It was also noted that performance targets were set governing the turnaround and priority of analysis and the emphasis put on meeting the targets and pressure to meet these was made evident in staff statements to the Inspectorate

4.3.15. The Inspectorate would not normally comment on matters of staff, resources and management, this being a matter for the business, however, where circumstances may result in the data generated being useless for a company to act as required by Regulation 17 and 18, (18 and 19 in Wales) then conclusions, recommendations and criticisms are unavoidable. This is not only a serious failure of the requirements of ISO 17025:2005 but also a breach of regulations;

4.4. Analysis

4.4.1. To produce robust quality assured data, analysis undertaken by a laboratory must be by competent persons using an appropriate method, suitable equipment and using a system of analytical quality control which is subject to checking by a person who is not under the control of the laboratory. The laboratory was visited by UKAS, (United Kingdom Accreditation Service), on 9/10 September 2009. The following comments were made in their report of the visit in relation to the inorganic section:

- 'All staff demonstrated their methods with competence. An understanding of their role in maintaining and developing the quality system was self-evident. Methods are well documented and

frequently updated. A controlled hard copy is available at all stations where it is needed. Methods were seen to be comprehensive and accurate. Equipment records for all the methods witnessed are comprehensive, detailed and regularly updated. They include and inventory listing, service engineers' reports, operator maintenance and preventative maintenance records.'

4.4.2. Neither the findings nor expertise of UKAS are in dispute. The information provided by UKAS before the Inspectorate's audit was both useful and informative. The intention was therefore not to duplicate or verify these findings. The DWI's own observations support the fact that the quality system was self-evident, records for methods and equipment were well documented and with all supporting evidence. The audit instead focused on establishing whether there were deviations from the prescribed methodology.

4.4.3. However, once the Inspectorate identified irregularities with the TDS analysis, and with associated equipment and records, the Inspectorate concluded that it was possible further deviations from prescribed methodology may exist elsewhere.

4.4.4. The analysis of samples must be competently carried out with integrity and trust. It is impossible to prove retrospectively, one way or the other, in the case of some of the analysis specified in section 3.3.2 whether the data was produced with integrity. There is implicit reliance on analysts for the appropriate use of standards, blanks, quality control samples, calibrations as well as the appropriate setting of instrument controls such as sensitivity and gain and where there is manual recording of data, the correct readings noted. To look at individual methods in isolation, whilst having merit, cannot provide a full overview of behaviours.

4.4.5. Since inspectors had become aware that there were irregularities with records, equipment, staff and at least one specific analytical method, they went on to examine records for analytical quality control, (AQC), internal audits and trends within analytical data.

- The audit team reviewed three years of AQC charts. AQC charts within the laboratory are based upon the Shewhart system. The purpose of the control chart is to allow detection of events that may be out of control based upon statistically objective criteria of change. Where this happens the laboratory should investigate and remediate any cause. Under normal conditions of control there is approximately a 0.27% probability of a point exceeding the 3 standard deviation (SD) control limits. This statistically should occur on average once every $1/0.0027$ or 370.4 observations.
- It is therefore a balance; the laboratory seeks to maintain analytical control whilst acting on those results which flag as being outside of control whether this be bias as in nine points on one side of the mean or in a singularly increasing or decreasing trend or two consecutive points outside 2SD or single points outside 3SD to signal where this is not happening. Because this is a statistical analysis it is expected that some will occur normally and some will be false alarms. However a typical laboratory in the experience of inspectors, should take action on a 3SD failure.
- The audit team reviewed the analysis for ammonia, chloride, silicate, TOC, free and total cyanide. For these procedures, not a single 3SD failure was noted for each of three years and one for nitrite and alkalinity. For alkalinity this equated to in excess of 4000 AQC results. The inspectors could not trace the AQC's from raw data to worksheets and onto the LIMS system for TOC, and nutrients and therefore could not determine the true picture of AQC failures in these analysis. This is a serious breach of ISO 17025:2005.
- The Inspectors were aware of an alleged malpractice of inserting a new QC within the run for alkalinity should the first fail. The company investigation noted the finding of two consecutive AQC failures, the first being crossed out and the second accepted, on thirteen separate occasions. All of the crossed out AQC's exceeded the 3SD limit. The company investigation noted on one occasion, three

further AQC's were inserted following the initial fail until the final one passed and the data accepted. Inserting additional AQC's until one passes defeats the statistical basis of the system quality control.

This highlights that there was either a problem with the standards or the running of the equipment and there was a clear failure to resolve the underlying issue.

- The audit team reviewed data for the blanks at the start of the run for Alkalinity. The blank is taken from the laboratory supply of reverse osmosis water which should provide low alkalinity water. The criteria for passing a blank is that it should read less than or equal to 1.6mg/l. Inspectors noted at the time of the audit an unusual proportion of blanks that were reading zero. Whilst it is not impossible to register a zero reading, and is expected on occasions, it is generally not a routine finding. The inspectors during their review of internal audits became aware that the quality section had passed into the analysis system, dummy samples of R.O. water which were registered as if they were client samples. The auditing Inspector had noted that two of these samples were reading different results to the blank on the same run. Follow up investigations noted an example where the dummy sample was reading 4.7 mg/l CaCO_3 on the same run as a blank with a zero reading. Whilst the result for the dummy sample was still low and not within the range for drinking water, it exceeded the limit set for the acceptability of a blank. In all respects these two samples, the blank and the dummy result, were from the same source water and on the same run. Whilst this is not impossible within statistical variation, the likelihood of this occurring on more than one occasion considering the number of blanks reading zero noted at the time of audit is extremely low.
- The company investigation noted that there were 221 out of 336 blank results which read zero compared to 5 out of 150 at another laboratory. This difference was considered significant by the Inspectorate.

- The auditors were in possession of a statement which stated that there was deliberate alteration of blanks in order for them to meet the required standard to permit the instrument to run successfully. It is impossible to prove this retrospectively. The statistical difference between the two sites in the number of blanks, would, however support the statement. Alternatively it could indicate the titration instrument was reading low enough to produce an unusual number of zero blanks in Bridgend or it could be a chance occurrence. However this would not explain why the dummy sample then did not agree with the blank in the same run. A further consideration in this analysis in particular was the insertion of AQC's as the statement also discussed this. There were no 3SD fails recorded in 4000 AQC's and the probability of a fail exceeding 3SD is 0.27%. The chance of this not happening on >4000 occasions is <0.002%. Whilst not impossible this is improbable. If it was true that failing AQC's were avoided by de-selection or alteration, were the instrument to actually be out of control, then the very system to highlight this was not being used. Taken together, the statement suggesting AQC's, blanks and the drive to ensure runs on this machine met delivery targets under pressure of workload, appeared a probable explanation.

4.4.6. TDS analysis have been discussed earlier in this report. The statement available to inspectors described concerns surrounding the testing of TDS. This method places a 100ml sample of pre-filtered water into a previously weighed and named platinum crucible. The sample is evaporated in a water bath before being transferred to an oven before being reweighed. This takes a minimum time of four hours for a sample but more likely longer considering additional time taken for filtration, weighing and worksheet writing. The crucible has then to be carefully washed to remove all residue (normally in a washing machine). Arguably, two sets of analysis could be done in a working day if the working day was longer than eight hours. However to carry out the 75 tests on 12th Dec 2007 would have

needed 38 crucibles or spaces available in the water baths. There were in fact 24 spaces in the water baths and fewer crucibles. If all the spaces were utilised as far as possible even assuming sufficient crucibles were available to fill the spaces and no time allocated to any other task whatsoever, this number of analysis could not be completed in 12 hours. The statement described the use of conductivity to calculate the TDS result with the formula $TDS/Cond = 0.55 - 0.8$. The inspectors found evidence of conductivity records on worksheets, no weights, impossible numbers, inoperable water baths and no AQC 3SD fails ever. Therefore the evidence found by the Inspectorate supported the statement made to the DWI.

4.4.7. In respect of manual colours, this method utilised a spectrophotometer with a manual probe. This instrument was described as unreliable and the standing instruction was to shake the probe vigorously until QC's and controls provided the appropriate reading. This was said to occur during 2007 causing a rise in laboratory client complaints. This method was phased out in 2008 therefore the previous practice could not be inspected because the laboratory did not retain its' records beyond three years. However, the company investigation stated that "an analyst confirmed in interview that the instrument was unreliable and, as a result, the probe and/or sample had to be shaken until an acceptable AQC result was achieved". The analyst stated that this practice was necessary because it was known that the AQC was correct and it was the instrument that was faulty. The practice of forcing a result for an AQC or blank is not acceptable practice. The instrument was clearly unsuitable for the analysis and the data was likely to be affected and this was reflected in client complaints.

4.4.8. The company uses Robotic Analysers known as Aqualyser I & II for the determination of pH, Turbidity and Conductivity. Information provided to inspectors concerned alteration of standards as a matter of routine on these instruments and substitution of the designated AQC with one made up fresh. Inspectors were unable to locate the papers noting the methods to alter standards and therefore could not reach a conclusion about the

analytical practices employed. Inspectors were also unable to trace the origin of the AQC's through audit trail, from the point of production at Coventry, to the record on the printout. This is a serious failing of a quality system. At the time of the audit, staff were unable to calibrate one of the instruments and concerns existed regarding its operability at the time.

4.4.9. Anionic detergents are analysed using a methylene blue extraction followed by spectrophotometric detection. The statement indicated that the absorbance readings for the blanks and AQC were observed and as necessary compensated by alteration of the sensitivity on the instrument. It is not possible for an auditor to verify this because it would be unlikely for an analyst to do this in front of the auditor. A similar comment in the statement was also made in respect of the substitution of standard 2, (used to produce the standard or calibration curve of absorbance against concentration and which is normally the same concentration as the AQC in this method), for the AQC sample sent from the QC lab in Coventry. The auditors interviewed the Quality Assistant whose job it was to collect the AQC sample from sample reception and take them to the various work areas. She stated that her sole responsibility was to move the bottle from reception to the bench and there was no further record. Analysts interviewed did not confirm this practice. Inspectors therefore could not verify if substitution occurred. Finally, evidence provided to the Inspectorate suggested that a result in March/April 2009 was falsified as it could not be analysed. An absence of quality information on that day would verify this statement. The company in its' investigation of test results submitted to customers identified one instance in February 2009 where only one result was submitted on a particular day. The result reported was at the minimum level, consistent with the concern raised. From a review of AQC data, the company was unable to identify an AQC result from a test performed on the same day.

4.4.10. Testing for Free and Total Cyanide is undertaken on a continuous flow instrument combined with spectrophotometric detection. Similar to the anionic detergents, it was stated that the sensitivity of the instrument was

altered in order to achieve acceptable AQC and Blank values; and that the Calibration Standard 2 solution was used in place of the AQC solution supplied from Coventry. For the same reasons given in the anionic detergent section, Inspectors could not confirm this.

4.4.11. The laboratory uses a Konelab 60b for the analysis of sulphate, nitrate, ammoniacal nitrogen, chloride, total oxidised nitrogen, silicate, ammonia and phosphate. Inspectors were aware that this was an area with resource issues and minimal staff, an interview with a member of staff from this area confirmed this to be the case. Additionally, it was also determined that it was normal practice to remove the analysis following an AQC failure which stopped the upload of data to the LIMs system. In effect this would prevent any data from being sent that was out of specification. This is not considered poor practice. However, in doing so there is a de-selection of AQC data preventing an understanding of the performance of the analysis. The inspectors did not pursue this because the risk to analysis is small. The company, in their investigation, reviewed the AQC charts for four of the parameters tested for on the Konelab: Ammoniacal nitrogen; chloride; total oxidised nitrogen; and silicate. They found that there were no breaches outside of the 3SD limits over a three year period. In addition, the AQC chart for nitrite only showed one breach outside of the 3SD limit over the same period. Furthermore the company identified that documentation relating to the Konelab had not been kept up to date, in particular, the Drift check. The effect of an overworked and under resourced area means that such problems will be missed.

4.5. Quality Assurance/Control

4.5.1. Quality assurance within a laboratory can be simply defined as a planned and systematic pattern of all actions necessary to provide adequate confidence that the data produced meets the requirements of clients and the appropriate regulations.

- 4.5.2. The UKAS audit of 9-10th Sept 2009 concluded that, with the exception of the improvement actions, the laboratory complied with the requirements of ISO 17025 and DWTS.
- 4.5.3. The Inspectorate does not dispute this finding. In fact the quality manual and supporting documents were well maintained and up-to-date. Audit plans existed and were comprised of system audits for managerial and technical aspects of the management system and method witness audits in all areas including inorganic chemistry. Methods were up to date and reviewed and had appropriate detail. Audits were carried out and corrective actions were assigned. The audit programme and process were performing well and highlighted failures of the type that would be expected in a laboratory.
- 4.5.4. Overall, inspectors did not have concerns with the quality control systems instead concerns related to the application, independence and effectiveness of the system.
- 4.5.5. It is worth pointing out that auditing this laboratory was difficult. Access to information in respect of records particularly the archived records was difficult or impossible. Records were not in an order for easy retrieval, or they were completely absent. Equally, access to basic but detailed organisational information such as staff organograms were not available. Specific information about where each analyst worked and their reporting lines was absent. This made it very difficult to draw a picture of responsibilities, team numbers, relevant temporal training records such as who did what analysis, when, and their competence for the task. Inspectors derived this from a hand drawn diagram provided by the site management at the time of the audit. This was critically important because there were gaps in training records and circumstantial evidence indicated there were instances where analysis had been carried out by an untrained analyst with no evidence to show they were supervised at the time. This was compounded by the absence of information from worksheets.
- 4.5.6. Incomplete evidence has been mentioned as a common problem, in relation to analysis, worksheets, training records and archives. Inability to

audit a system is of itself a failure to meet the core requirements of quality assurance as it prevents the carrying out of vertical audits for compliance with the regulations.

4.5.7. The hierarchical arrangement of quality management should be such that those who are responsible for quality are managerially independent. The structure within the laboratory organisation permits this to be the case. However, the inspectors became quickly aware that there was erosion of independence and lack of empowerment of the quality department within Bridgend. For instance, the responsibility for the review of AQC charts was that of the site manager who initially reviewed these weekly. After April 2009 the review by the site manager or their deputy occurred monthly and the team leaders became responsible for the weekly checks. The review gives the appearance of a cursory one, or one where understanding was lacking because it did not cover obvious statistical anomalies discussed previously. There were no annotations and no evidence of critical evaluation by the manager or otherwise, only a simple initial with dates showing that a number of reviews were done at the same time. The quality section would have reviewed these on a quarterly basis but at this stage there was also no identification of statistical anomalies or appropriateness of limits. The F and T test calculations that should be carried out monthly on each analysis were incomplete. Both the team leader of the inorganic chemistry section and the quality team failed, on many occasions, to investigate significant ongoing deterioration in the SD of the AQC charts (F test) or significant bias from the mean (t-test). The root cause of this failure is unclear but under a quality system there should be the time, motivation and empowerment to drive response and/or investigation to irregularities. It was the understanding of the inspectors at the time of the audit that the responsibility was ultimately that of the manager and this finding was supported by the company's own investigation through interviews.

4.5.8. The company had a schedule of planned internal audits and, largely, these were carried out. These audits highlighted a number of issues that were occurring within the laboratory. The purpose of internal audits is to

identify issues and therefore it is not uncommon to find a number of comments on non-conforming areas. Following the identification of deviations from the quality system the objective is to respond appropriately with a robust action to prevent a recurrence. This is imperative to maintain an in-control system, however the Inspectorate found internal audits were repeatedly finding the same failing. For instance, the AQC was not plotted at the time, AQC reviews were not occurring on multiple and prolonged occasions, daily pipette checks were being missed regularly, and there were incomplete training records. The inspectors were able to verify all these observations at the time of the audit including incomplete training records which make it impossible to determine who is competent to carry out analysis at the time, a core requirement of ISO 17025 and the Regulations. There were multiple other repeating examples highlighted on the audit reports but one of the most concerning examples was the expansion of the warning and action AQC limits for conductivity because the limits were stated as being “too tight”. No investigation or determination of the root cause was carried out. Yet there was clear evidence of de-selection of failing AQC results and the net outcome of this would, of course be limits, which tighten. The responsibility for this was understood by inspectors to rest with the site manager. It was clear to inspectors that independent and robust follow up was lacking otherwise this pattern would not have been recurring.

4.5.9. Generally internal audit reports would be pre-planned at a frequency of one per month in the inorganic chemistry section covering various areas such as calibration or training. These were carried out generally on time but there were some occasions where this did not happen, (e.g. AQC audit B/572). This is not exceptional as varying demands of a laboratory may require some flexibility. However, the planned nature of these audits would, and could, permit the preparation of records or the retention of records showing anomalies in analysis and equipment. Information available to the inspectors before the audit indicated that this was occurring and was witnessed first-hand by one of the inspectors. During the audit an inspector

was searching for specific records in the archive room and noted the presence of a plastic bound document with a black spine that made it distinctive in an archive box. The Inspector requested to review the contents of the box back in the office and after a moments distraction by the accompanying analyst noted the document had been removed. The inspector searched in the vicinity and found the plastic bound document in a place where it had been put out of view behind boxes in the archive room and returned to retrieve it. In the opinion of inspectors this was a deliberate attempt to hide a key piece of information by the analyst. The company is reminded that it is an offence on summary conviction not to provide all such assistance to a warranted Inspector acting under Section 86 of the Water Industry Act 1991.

4.6. Customers

- 4.6.1. Water companies are required to take samples of water intended for consumption and test for specified parameters at specified frequencies. Additionally companies must carry out risk assessment of their supply systems which may additionally require the taking of samples from source to tap to establish, validate and verify any source, treatment and distribution that section 68(1) of the WIA 1991 is met.
- 4.6.2. To enable this, companies must take and analyse samples and maintain records specified in regulation 34 and provide that information to the Secretary of State as specified in regulation 35. It is therefore the duty of the water undertaker or licensed supplier to secure these requirements. Additionally, ISO 17025 clearly sets out the requirements of laboratories in respect of complaints and providing service to their clients
- 4.6.3. As part of the investigation, inspectors noted in records that water companies in some cases, had a reporting system for anomalous or unexpected results and that records had indicated that there was an increase in complaints. Inspectors were keen to understand where these concerns arose, why a result was thought to be anomalous, if any

investigation was undertaken, and the reason for any subsequent outcome such as a change of result. This information was requested from companies by e-mail in September 2010 and all but one responded.

- 4.6.4. The extent of the data analysis and controls generally followed the number of samples submitted to the laboratory. So for a company with a small number of samples the return consisted of identification of a few anomalies by the person responsible and for the largest company the analysis consisted of detailed statistical outliers.
- 4.6.5. There were clear themes within the data. Fluoride, turbidity, pH and conductivity were highlighted as being reported as low, (particularly fluoride mentioned by three separate companies), although there were unusually high results. Other parameters such as nitrite, nitrate, phosphate, colour, cadmium, chromium and nickel all were noted as requiring changes. Many of the errors were related to manual data entry errors (primarily with pH, turbidity and Conductivity). Equally there were a number of errors associated with sample aliquots incorrectly taken from the wrong bottle.
- 4.6.6. Highlighted particularly were the long timescales taken to complete investigations. Inspectors noted an outstanding request for an investigation into anomalous results for turbidity which was carried over four months. The observation about prolonged investigation was made by two companies.
- 4.6.7. One company commented that the quality management did not have the empowerment to progress investigations or drive resolution of outstanding queries.
- 4.6.8. Two companies (South Staffordshire and Severn Trent Water) are to be commended on their close observation of data. Severn Trent Water has adopted a statistical variation from the normal using standard deviations much the same as control charts and this is used to produce lower and upper trigger action limits. The company then uses a decision tree mechanism to initiate an investigation into the reason for the anomaly.
- 4.6.9. Regulations 17 and 18, (18 and 19 in Wales), require an investigation where a parameter fails to satisfy the requirements. This investigation

should not only include water supply activities but also that of the laboratory. Analysis of anomaly data indicates that investigations have resulted in about 0.33 – 2% necessary requests for changes. This equates to hundreds of requests over a year. Whilst there will always be the need for changes occasionally the extent of changes observed was very unusual, on such a small section of the laboratory.

4.7. Management

- 4.7.1. It is the responsibility of the laboratory to carry out testing and calibration to meet the requirements of both the regulators and the clients. ISO 17025 clearly sets out the management requirements to cover work carried out in the laboratory's facilities. Management and technical personnel require the authority and resources needed to carry out their duties. Duties include the responsibility of planning, organizing, staffing, leading or directing, and controlling. They are also required to identify the occurrence of departures from the management system or procedures and to be empowered to initiate action to prevent or minimise such departures.
- 4.7.2. The systems in place to highlight deviations include review of the control charts, internal audits, internal communications and management review. We have described the availability of the control charts and the quality reports to team leaders, the deputy manager and the manager highlighting a number of deviations. By design, the system is doing what it is intended to do by highlighting these issues.
- 4.7.3. The manager stated that there was a daily resources meeting which would fulfil the system requirement for internal communications to management. A statement by the team leader from inorganic chemistry indicated that he raised the matter of workload, inexperienced staff, sickness, equipment insufficiencies. The manager agreed that there were attendance issues in this team including periods of sick leave and that the team leader raised a query regarding resources, in the latter part of 2008.

As a result there was pressure on the team. By design, the system is doing what it is intended to do by highlighting these issues.

- 4.7.4. The company had a number of management tools, incentives and controls in place including KPI's, a Capacity Model, Staff Appraisal, Time Management and IT systems in support. This is not an exhaustive list. Systems available indicate when sample turn-around times were approaching or out of limits. The capacity model which was introduced three years ago indicated a predicted capacity taking into account methodology, analyst and instrument time and downtime for maintenance. Staff appraisals and time management tools enabled staff management. All these were available to the manager. By design, these systems were doing what they were intended to do by highlighting problems in these issues.
- 4.7.5. The company had in place an annual review to discuss matters of management up to senior level and minutes are available each year recording deviations. By design, this system was doing what it was intended to do by highlighting these issues.
- 4.7.6. Inspectors made the following observations: There were a number of departures from good practice in operating equipment, calibration, analysis, quality control and in the non-contemporaneous recording and review of records along with failure to retain an appropriate archive. A number of these observations were recorded on internal audits and in UKAS reports. The capacity model has been referred to in determining work capacity including its use in the tendering for two significant contracts, yet it would appear that work pressure figured highly in staff minds and no adjustment was apparently made in resources at Bridgend when one of the contracts was awarded. A number of statements point to the pressures of the workload, and staff resource issues in the inorganic section. Statements to the Inspectorate describe pressures of work, performance issues with specific staff and complaints not being pursued. There were some serious delays in sample analysis and inspectors discovered irregularities with time keeping. The annual review highlighted an increase

in customer complaints and non-conforming work reports. All of these indicators were available to managers and senior managers. Individually, any one of these observations is not unusual in a working laboratory but together, and with indications that problems were recurring, these are a cause for concern and require action from management. In this instance, the evidence shows that some tests were not actually carried out. Accordingly inspectors were highly critical of the laboratory management for failing to act appropriately in response to numerous indicators, a core principle of ISO 17025.

4.8. Accreditation.

4.8.1. The laboratory is accredited to ISO/IEC 17025: 2005 and the drinking water testing specification (DWTS) and receives an annual visit by UKAS as a matter of surveillance. The regulatory requirement for the collection and analysis of samples, is for the laboratory to have a system of analytical control that is subject to checking from time to time by a person who is neither under the control of the laboratory, the water undertaker or combined licensee and is approved by the Secretary of State, in practice DWI. The water companies and the laboratory complied with this requirement. UKAS visited the laboratory on 9-10th September 2009 and carried out a surveillance visit. The executive summary by UKAS of this visit stated “Throughout this laboratory methods are well written and good records are being maintained. Staff demonstrating methods are all well trained and performed analysis to a high standard, highlighting good staff competence.”

4.8.2. To put this in perspective, the laboratory at Bridgend uses in excess of 40 different methods covering over 250 measurements, (for compounds, elements, metals, pesticides, organisms) which produce over a million regulatory drinking water results for its' water company customers alone. This does not include operational data or non water company related data. UKAS visited the laboratory over two days of a pre-announced audit.

Within this audit about nineteen methods were observed for a single analyte either as a run, re-run or dummy run. Areas covered include registration documents, analysis required, worksheets, calibration data, system suitability checks, reagent and standard records, equipment records, sample storage conditions, AQC results, training records, final results reported to customer. In total the auditors carried out 4 vertical audits covering two customers.

- 4.8.3. The purpose of this visit therefore was to determine compliance with the general requirement for competence of testing and calibration to show systems are in place that support the principles set within ISO17025. It did not cover all tests and it did not cover all results, nor would this be the objective of such an audit. The audit carried out by UKAS achieved its objective and inspectors agree with the findings.
- 4.8.4. It is worth emphasising that the most serious discrepancies found by the Inspectorate's audit related to TDS. This test is outside the scope of UKAS accreditation. This lack of scrutiny was known and may have made this method more vulnerable to evasion of appropriate practice.
- 4.8.5. It is also worth pointing out that the percentage sample for vertical audits by UKAS is approximately 0.0004%. The purpose of such an audit therefore is not to verify the robustness of the data but to check that the principles and system in place is suitable for vertical audit.
- 4.8.6. The Inspectorate recognises the significant improvement in systems, practices and consistency in the application of these principles through the strategy adopted by UKAS in the implementation of ISO17025. Accordingly, the Inspectorate informs its risk assessment and is more likely to direct resource where there is an absence of accreditation.
- 4.8.7. As the objective of the UKAS audit is to check principles and systems, it is important to realise that such surveillance audits are not a means of assurance of data for customers.
- 4.8.8. In sections 4.6 and 4.7 the auditors discuss the importance of the role of management and customers in ensuring systems are adhered to and

that this is verified by robust internal checking and client surveillance to highlight anomalies.

5. Actions by the Laboratory following the Audit.

5.1. Response

5.1.1. In response to the Inspectorate's site visit the company took a number of rapid and decisive actions by 16th September 2010 which included the following:

- Severn Trent Plc executive board were informed
- The legal firm Eversheds was instructed to lead an investigation on behalf of both STS AS and Severn Trent Plc.
- Initial feedback and meetings were held between the Chief Inspector of Drinking Water and Directors of Severn Trent Plc.
- The decision to move inorganic testing from Bridgend to Wakefield whilst the investigation was undertaken with necessary recruitment of analysts; customer communications; internal and external communications and subcontracting to other laboratories to provide capacity whilst equipment was performance tested. Additional QC checks were implemented across all STS AS' laboratories.
- Staff suspensions to avoid conflict of interest during the investigation. Interim MD and interim Bridgend Site Manager appointed and other staff on paid leave of absence.
- Meetings with customers and the Inspectorate to provide briefing on progress with the recovery of the Bridgend Laboratory.

5.1.2. The Inspectorate commends the rapid response to its initial feedback on audit findings.

5.1.3. Subsequent actions have included production of a written short investigation report on 29 November and a wider report on 16 December 2010 commissioned by Severn Trent Plc.

5.1.4. Further meetings were held between the Inspectorate and Severn Trent Analytical Services on 20 December, and 7 January 2011.

5.1.5. An initial draft progress report from the interim managing director of the laboratory on 11 February 2011 with the final first stage progress report available on 25 March 2011 (Dated 23 March 2011).

5.1.6. The Inspectorate notes the progress made in delivering the actions set out in these reports across the analytical business.

5.1.7. The Inspectorate notes the reinstatement of inorganic chemistry methods assessed by UKAS on 10-13 January 2011 which was followed by an unannounced audit on 10th March 2011 with the following conclusion by UKAS:

- “ Overall the re-instatement of the equipment and methods can be deemed a success with the staffing levels being appropriate for the workload. The inorganic laboratory is now fully functioning and there were no apparent backlogs of work. The new staff have coped well with operating in the “live environment” and the last external PT scheme and on-going internal quality control results were satisfactory. The two main challenges for the laboratory is to sustain this performance in the face of further changes such as the introduction of more automated equipment and the implementation of the step change action plan.”

5.1.8. The Inspectorate welcomes the actions of Severn Trent Analytical Services in the providing a Progress Report on current and future actions.

5.1.9. The following objectives, extracted from the Progress Report have been noted:

- To set out improvements achieved, relating in particular to:
 - Stabilising and Improving the Business
 - Bridgend Recovery Plan
 - Strengthen Quality Control Plan
- To demonstrate rigour in acting on all of the independent investigation findings, recommendations developed from these findings, and other relevant inputs and insights
- To outline the STS AS Change Plan for the next 12 months

- To define Critical Success Factors / measures and set out future review points
- The Inspectorate notes and welcomes the actions by the company to strengthen quality control applying appropriate actions across all laboratories

5.1.10. The Inspectorate notes and welcomes the Business Change Plan covering the following areas:

- An improved managed system for archiving records
- Developing behaviour and culture in adherence to the Quality Management System
- Assessing Capacity & Resources for normal operation of the Bridgend Inorganics team.
- Ensuring analysts are competent with training needs identified from the appraisal process.
- Assessing feedback from clients on failures
- Reviewing current inventory of instrumentation
- Identification of systemic failures in the business processes by learning from audits
- A capability assessment of responsibilities and accountabilities
- Identification of operational synergy for standardisation and disaster recovery
- Prioritisation and assessment of initiatives for systems and management Information

5.1.11. The Inspectorate notes and welcomes the introduction of measurable critical success factors governing the Business Change Plan objectives

6. Conclusion.

- 6.1.1. The law requires that drinking water must be wholesome at the time of supply. The Drinking Water Directive (DWD), 98/83/EC, the Water Industry Act 1991, The Water Act 2003 and the Water Supply (Water Quality) Regulations in England and Wales set out these obligations. Both the DWD and the Regulations sets quality standards for drinking water quality at the tap. The DWD focuses on those parameters of importance to health as well as those that control water treatment process and the aesthetic quality of drinking water. The Regulations expand these principle to include monitoring of raw water and risk assessment.
- 6.1.2. Water companies are under a duty to collect samples to satisfy the requirements of the Regulations and that these results are available to customers as part of public reassurance and confidence.
- 6.1.3. To comply with these duties water companies must use a laboratory within their control, either directly or otherwise, which must have a system of analytical quality control that is subject to checking by an independent person and approved by the Secretary of State, (in effect the DWI), and by accreditation.
- 6.1.4. The role of the DWI is to carry out independent checks to verify that this testing is being performed to a high standard of quality control in order to maintain public confidence that the robustness and integrity of water company results is beyond question.
- 6.1.5. The Inspectorate applies the principles of Better Regulation and operates a risk based approach. In principle, the Inspectorate will not carry out an audit or investigation without a reason, with the exception of a small number of random audits. Therefore a laboratory without external accreditation is more likely to be visited as part of the verification process. However, where specific information indicates a risk, and this maybe through unusual patterns of failures, unusual patterns of statistical analysis

or specific other information, indicating that regulatory duties are not being met, the Inspectorate will carry out an audit or investigation. The Inspectorate received two separate indicators of risk in relation to the Bridgend Laboratory and acted accordingly to initiate an investigation. The resource allocation for this specific audit and investigation was significant.

6.1.6. The specific information received by the Inspectorate was extensive and detailed. The findings of the audit and investigation did not and could not verify all the information. However sufficient deficiencies were subsequently found to provide considerable confidence in the accuracy of the information received. In particular, the Inspectorate found clear evidence of the fabrication of data which included analytical data.

Accordingly the Inspectorate makes the following conclusions:

6.1.7. There is evidence to support that the undertakers and licensed water suppliers have failed to meet Regulation 16(4) by failing to maintain such record as are sufficient to enable it to establish, in relation to each sample taken, that such of the appropriate requirements as are applicable to that sample have been satisfied.

6.1.8. In failing to meet Regulation 16(4) undertakers and licensed water suppliers have thereby failed to meet Regulation 34(1) since the validity of particulars of the result of analysis of samples taken in accordance with Part IV of the Regulations or any of regulations 12 to 14, 17 and 28, (29 in Wales) is in doubt since records of the analysis were either unobtainable, could not be traced or uncertainty exists in the result itself.

6.1.9. Furthermore undertakers and licensed water suppliers have thereby failed to meet Regulation 34(4)(b) since the companies did not require other particulars to be retained for a reasonable period of time to permit verification of recent analytical data in order to establish the requirements of Regulation 16(4). Furthermore, this impeded the inspectors in determining how long the problem existed. Regulation 34(4) provides two time frames for retention of information, not less than 30 years and not less than 5 years. Regulation 34(4)(a) specifies 30 years for Part IV, 12 to 14, 16A and 28 of the Regulations which encompasses all the parameters, raw

water sample results and results of any other analysis carried out as necessary for risk assessment. It would be excessive to apply this retention period to analytical raw data but it is reasonable to require analytical raw data on which results are based, and available to anyone who requests it under regulation 35, to be kept at least five years. The laboratory practice was only to retain records for three years.

6.1.10. There is evidence to support that the undertakers and licensed water suppliers have failed to meet Regulation 16(2)(d) the sample is analysed as soon as may be after it has been taken—

- by or under the supervision of a person who is competent to perform that task; and
- with the use of such equipment as is suitable for the purpose in so far as failure to maintain such records as are sufficient to enable it to establish, in relation to each sample taken, that such of the appropriate requirements as are applicable to that sample have been satisfied.

The Inspectorate found evidence of the fabrication of results by a member of staff responsible for a team. Whilst this was not a Schedule I or II parameter it was nevertheless a parameter requested by water undertakers in the pursuit of their business and regulatory obligations. Furthermore, there is evidence to show retrospective completion of records for equipment intended to show control of those instruments (for several parameters) and doubt on the result of a Schedule I parameter. Any individual whether in charge of analysis or otherwise who knowingly fabricates, data and records cannot be deemed competent in the context of this regulation because doing so demonstrates a lack of understanding as to the consequence and meaning in relation to the regulations.

6.1.11. Regulation 16(2)(e) requires that any laboratory at which samples are analysed has a system of analytical quality control that is subjected from time to time to checking by a person who is—

- not under the control of the laboratory, the water undertaker or the combined licensee; and
- approved by the Secretary of State or Welsh Ministers as appropriate for that purpose

The Inspectorate considers that the laboratory was appropriately accredited with an appropriate scope by UKAS and therefore the water undertakers or the combined licensee's complied with this regulation. The Inspectorate accepts the comments of UKAS and agrees that systems were in place. The Inspectorate notes that accreditation was in place at the time of the audit, that the company withdrew this accreditation voluntarily to remediate matters and successfully reinstated it and received a favourable report following a subsequent unannounced UKAS audit. However, the Inspectorate is critical in one respect: whilst the laboratory Quality Manual, Group Procedures and systems were in place and of a good standard; the laboratory management arrangements, including critical process indicators, capacity models and commercial objectives had the effect of making these procedures, manuals and systems in some instances ineffective and circumvented. The Inspectorate therefore concludes that there was a failure of management commitment and control in relation to maintaining the necessary high standards of professional practice and the quality of testing and calibration such that serious deviations in good analytical practice were not identified and rectified and this led to a client requirements and regulatory duties not being met.

6.1.12. The WIA Section 70(1) describes offences of supplying water unfit to human consumption where supplied by a water undertaker or the combined licensee. This offence is decided in a court of law and is based upon the duty of the water undertaker or the combined licensee to provide drinking water which is wholesome. There was no evidence to suggest that any sample analysed where the data was fabricated would have resulted in

a substantive risk in regard to these duties. However, the Inspectorate is critical that this risk was not recognised.

6.1.13. The WIA Section 210 makes it an offence for an organisation or any director, manager, secretary or other similar officer to knowingly provide data which conceals the true state of the water. The Inspectorate considers that there is insufficient evidence to show any consent or connivance in relation to the provision of false information in the form of false data or assessments to the Inspectorate due to the specific type of data that was falsified. This is because data was not the type that was directly sent to the Inspectorate but instead to water undertakers or the combined licensee's who will have used it as part of their duties unknowingly.

Instead the Inspectorate considers that the laboratory management were unwilling to act, did not understand or were poorly advised on indicators of malpractice which was clear to some analysts who did not feel able to or could not reveal the true circumstances. This is therefore is a contractual matter for the clients of the laboratory to act upon.

6.1.14. The WIA Section 207 states *"that if any person, in furnishing any information or making any application under or for the purposes of any provision of this Act, makes any statement which he knows to be false in a material particular, or recklessly makes any statement which is false in a material particular, he shall be guilty of an offence"*. The Inspectorate found evidence that there was falsification of data which was submitted to the water undertaker or the combined licensee. This data was not specifically sent by the water undertaker or the combined licensee to the DWI and in effect the Secretary of State or Welsh Ministers but it would have been used for operational purposes by the water undertaker or the combined licensee. The Inspectorate has noted the actions taken by the company to prevent a recurrence and will expect measures to remain in place. Furthermore, the Inspectorate concludes that there is insufficient evidence and it would not be in the public interest to recommend a prosecution to the Director of Public Prosecutions on this occasion.

6.1.15. The Inspectorate is very critical of the laboratory management and senior management:

- in failing to identify, maintain, or restore an eroded quality system in which the manuals, procedures and systems were in place and identifying deviations.
- in their failure to respond to staff reports of irregularities and rectify matters at an early stage
- for choosing to ignore information raised through management systems highlighting deviations from normal practice.
- for their failure to respond expeditiously and adequately to client concerns.

None of the problems identified were insurmountable in a working laboratory and therefore should not have been a challenge to resolve in a timely and prompt manner. It is a matter of choice whether these matters are ignored rather than appropriately managed.

6.2. The auditors are critical of water undertakers and combined licensees for failing to meet their obligations under the Regulations and in particular regulations 16 and 34. It is the duty of the water undertaker or the combined licensee to ensure they are compliant and this duty cannot be deferred to a third party, in this case a laboratory, whose objectives are the provision of a service. Where this service is intended to comply with regulatory duties then the requirements must be clearly specified and there must be appropriate checks in place to secure that the service is meeting these requirements at all times.

Appendix I

Severn Trent Laboratories

- 6.3. Severn Trent Services Analytical Services is a provider of analytical services in water, land and waste analysis throughout the UK as well as range of support services including sampling and monitoring.
- 6.4. The organisation consists of five environmental analysis laboratories and two service centres throughout UK and Ireland.
- 6.5. Analysis for potable drinking water is carried out at Bridgend, Coventry, Wakefield and Runcorn for organic, inorganic and microbiological parameters.
- 6.6. The Bridgend laboratory predominantly carries out analysis on potable water for the broad categories of inorganic, organic, metals and microbiological analysis.
- 6.7. Potable water is analysed for a number of water companies and the data produced goes towards the requirement of these companies to fulfil their duties under the Water Quality Regulations. As part of this the company is audited on a regular basis by the United Kingdom Accreditation Service, (UKAS), for compliance with Regulation 16(2)(e)(i) of The Regulations
- 6.8. A generalised organisation structure can be seen in fig 1 below.

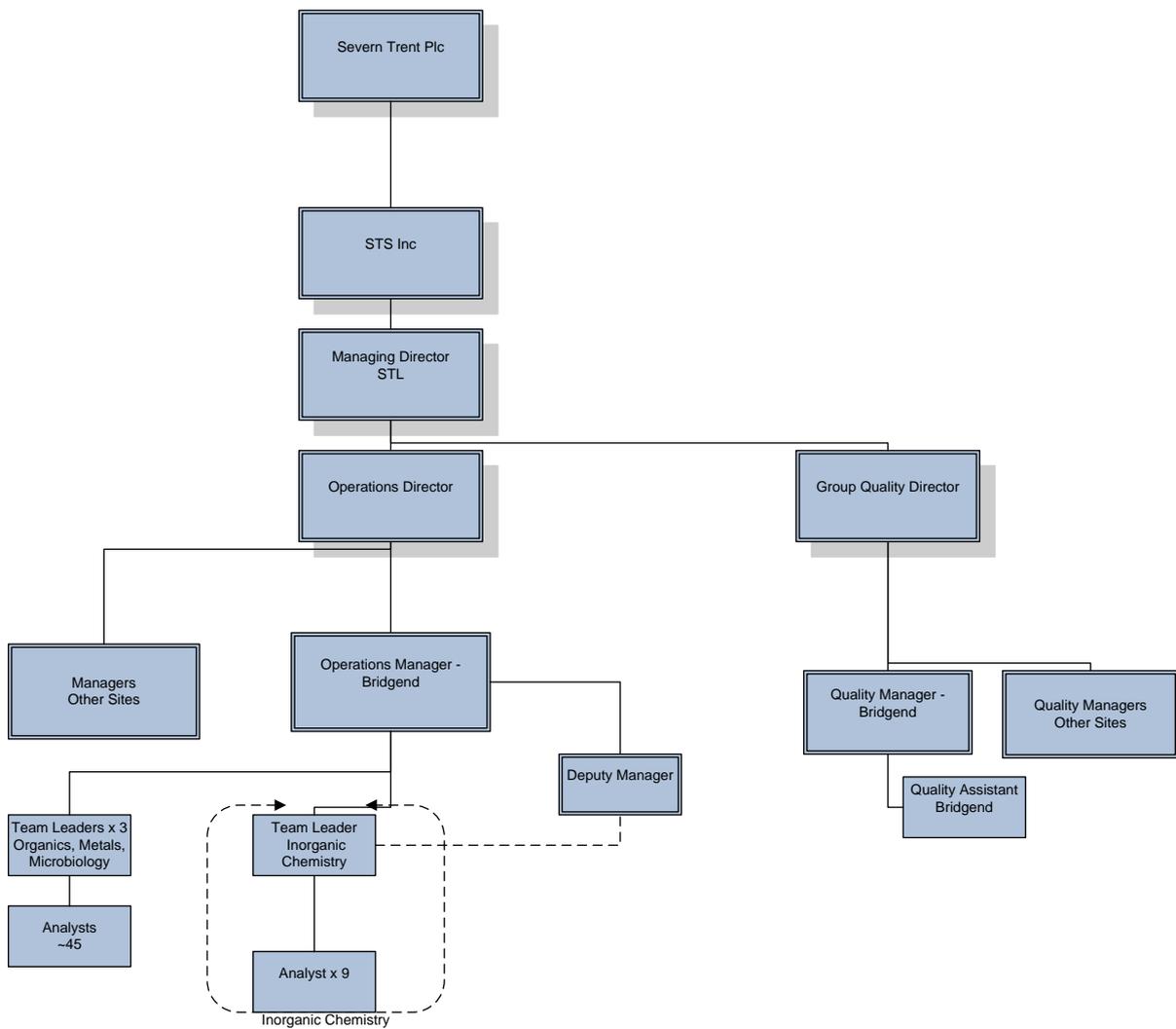


Fig 1: Generalised structure of Severn Trent Laboratories from Severn Trent Plc to team level structure.

Appendix II

Reference Legislation

- 1: The Water Supply (Water Quality) (England and Wales) Regulations 2000 SI No.3184 and Amendments
- 2: The Water Industry Act and Amendments