United Kingdom Accreditation Service

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ASSESSMENT REPORT

Name & Address of Organisation	Aberdeen City Council Accounts Payable Section Aberdeen City Council Woodhill House Westburn Road Aberdeen AB16 5GB United Kingdom	**Type of Assessment**	Accreditation - Re-assessment
		UKAS Reference Number	5464 1325
		Date(s) of Assessment	19/02/2019- 20/02/2019
Assessment Location(s)	Aberdeen Scientific Services Laboratory Old Aberdeen House, Dunbar Street Aberdeen AB24 3UJ United Kingdom	**Project references**	212315-03-01
Assessment Standard / Criteria	ISO/IEC 17025:2005 - Testing Laboratory	**Schedule Issue No(s)**	039
Name & Role of UKAS Assessment Team	: (Lead Assessor), (Technical Assessor), echnical Assessor), Technical Assessor)	**Date(s) of Assessment Plan**	20th December 2018
		No. of (M) Findings: Action Mandatory	34
Name of Organisation Representative(s)		**No. of (M) Findings: Require Evidence to UKAS**	32
Report Issued By		**No. of (R) Findings: Action Recommended**	4
Report Issued Date	6th March 2019	**Method of Reviewing Evidence**	Remote
Report Acknowledged By		**Quote for Reviewing Evidence**	1.25 Days
Report Acknowledged Date	As email	**Agreed Action Completion Date**	29th March 2019
Report Acknowledged Method	email	Please return evidence to customerservices@ukas.com Quoting the UKAS Ref.No. in the subject field	

AREAS SAMPLED AT ASSESSMENT (*marked as 'X'*)			
ORGANISATION		**IMPARTIALITY & INTEGRITY**	
Legal Status	X	Independence, Impartiality & Integrity	X
Liability Cover (CB / IB only)	N/A	Confidentiality	X
Management of Finances (CB/ IB only)	N/A	**EVALUATION PROCESSES**	
Resources	X	Design & Development of Methods	X
Organisation Structure	X	Enquiries, Tenders, Contracts	X
Responsibility & Authority	X	Planning & Resource Allocation	X
MANAGEMENT		Testing	X
Management System Including Documented Policies & Procedures	X	Reports & Certificates	X
Roles & Responsibilities for Quality	X	Decisions/ Opinions	X
Control of Documents and Records	X	Certification & Maintenance of Certification (CB only)	N/A
Management of Sub Contractors and Purchases	X	**TECHNICAL COMPETENCE**	
Service to Clients (Test / Cal only)	X	Personnel	X
Handling of Complaints	X	Methods	X
Control of Non-Conforming Items Dealing with Corrective & Preventive Actions and Improvements	X	Facilities/Equipment/Environmental conditions	X
Internal Audit and Management Review	X	Assurance of Quality of test	X
Supervision & Monitoring of Staff	X	Witnessed Activities	X
Conditions for Granting & Maintaining Certification (CB only)	N/A		

Executive Summary and Recommendation

This was a Reassessment visit to assess the continuing conformity against the requirements of ISO/IEC 17025:2005 and DWTS requirements for the laboratory at Aberdeen Scientific Services.

The laboratory has not yet progressed to the transition to ISO/IEC 17025:2017 and this has been postponed until their visit in early 2020. The laboratory has been reminded of the importance that the transition to ISO/IEC 17025:2017 must take place alongside their next visit, otherwise an extra assessment will be required. Any delay in the process for the transition in 2020 may result in the laboratory losing their accreditation if the transition is not completed before the end of November 2020.

The laboratory has had a new Public Analyst appointed since the last assessment. This was discussed in detail at the visit in 2018 and the laboratory informed UKAS at the time the new Public Analyst was appointed. There was a short handover period between the outgoing Public Analyst and new appointment. The newly appointed Public Analyst also undertakes other work outside of the work for Aberdeen, this was agreed on appointment. The laboratory will need to ensure that it fully documents this and identify any risks that may arise and how it mitigate these risks, this is required as part of the transition to ISO/IEC 17025:2017.

The Quality System has in general been well maintained, audits have been conducted as planned and where findings have been raised these have been closed out promptly and effectively. Complaints and anomalies have been suitably investigated and corrective actions implemented. There has been some steps to reduce the amount of paperwork by using electronic systems for records, this appears to have been undertaken in a systematic manner, working through one aspect at a time, ensuring that the integrity of the systems is maintained. The generation of quotations requires some oversight, specifically where a quotation covers more than one discipline.

The analysts within the Water Chemistry section were found to be knowledgeable, conscientious and competent at performing the tests witnessed. Technical record keeping was being maintained to a high standard and both the internal quality control and external proficiency testing scheme results over the past 12 months or so were very good (>95% results being "satisfactory") giving a good confidence in the analytical results being produced.

Within the Microbiology Section, overall compliance with the requirements of ISO/IEC 17025:2005 is satisfactory. Laboratory PT testing meets TPS47 requirements and DWTS Lab 37. Staff demonstrated methods competently and had a very good understanding of the methods being performed. Finding raised were varied and most should be easily addressed. The assessor stressed the need to the laboratory ensure the Legionella method is under full control.

Technical competence within the Food Chemistry section was demonstrated throughout the visit, there were some challenges in witnessing all of the test methods due to the absence of a member of staff, however where tests could not be witnessed, review of IQC and EQA was undertaken. The performance in the internal Quality Assurance scheme and external proficiency scheme has been very good. PT failures have been fully investigated and documented.

Recommendation

The recommendation is that accreditation to ISO/IEC 17025:2005 is renewed for the current schedule of accreditation subject to those changes identified in this report and resulting from review of evidence and clearance of Mandatory Findings raised within the agreed timeframe. The renewal of Accreditation also covers the DWTS requirements for which the laboratory is accredited.

Schedule Changes

Please refer to the individual Technical Assessor reports regarding identified changes to the schedule.

Scope

Due to some staff absences on the day of the assessment not all of the food chemistry tests could be witnessed. The Technical Assessor was able to undertake a series of vertical audits and review AQC and PT data for those methods not witnessed.

Organisation

Legal Status

The laboratory is a department within Aberdeen City Council and as such is considered a legal entity.

Resources

The laboratory has had some recent changes in personnel, the previous Public Analyst retired in middle of 2018, a new Public Analyst was appointed to replace him, there was a period of hand over which enabled a certain amount of continuity. The new Public Analyst was formerly at West Yorkshire Public Analyst laboratory and has previous experience and knowledge of the type of role. He spends approximately 3 days a month on site working for Aberdeen City Council in the role of Public Analyst, with additional time allocated form his home address. This entails being on site in Aberdeen for this time, he is also able to undertake some work remotely. As well as the work for Aberdeen City Council, he also undertakes some other work under the banner of The Public Analyst Services Limited, which is a registered company. This involves some additional PA work for local authorities in West Yorkshire region where he was previously the Public Analyst. The laboratory will need to identify this as risk to impartiality under the changes required as part of the transition to ISO/IEC 17025:2017, which has been postponed until early 2020.

The laboratory is housed in a building which it shares with a school and the City Archives. Access to the laboratory side of the building is restricted. Entry is gained via a key pad entry system, visitors are required to report to the reception to sign in. The laboratory occupies the ground floor and the second floor, with some storage located on the first floor. The laboratories are generally well fitted out although there is a large number of older instruments, that continue to operate, although are perhaps no longer supported by the manufacturers.

The laboratory has recently been in discussion with the Scottish Environment Protection Agency (SEPA) about sharing facilities at Torry, this however appears to have stalled due to the potential costs involved in some structural work which would be required. They have identified another potential site at the James Hutton Institute and a feasibility study is being undertaken.

laboratory is reminded of the importance of keeping UKAS informed of progress with the project for the relocation.

The laboratory has taken on a number of new staff, including the new appointment of the Public Analyst. There are training records in place for these new staff, however it was noted that there was nothing recorded in the electronic training log for , who started in September 2018 (See Finding E01490-006).

There is a requirement that new starter should complete an induction. it was identified that these have not been fully completed for and (See Finding E01490-007).

Organisation Structure

The structure is detailed in Appendix 2 of the Control Manual. The organisation chart includes the job titles, the persons holding each position is further detailed in Appendix 2. The current issued version of the Control Manual includes the names of all current staff within the laboratory.

Responsibility & Authority

Roles and responsibilities are defined throughout the Control Manual. This includes the role of Food Examiner and Public Analysts, these are statutory positions which require specific qualifications and experience, both the current post holders hold the required qualifications and experience and maintain their CPD as required for their posts.

Management

Management System Including Documented Policies & Procedures

The Quality Management System is documented with a Control Manual (PA/POL/0001), there are supporting procedures which cover additional elements that are not covered in the Control Manual. The top-level documents are held as a single hard copy which is available in the Library. Controlled hard copies of test methods are all available in the laboratory locations. The Control Manual includes a series of Appendices which include some additional detail, it was noted that Appendix 6 which covers DWTS requirements includes references to the Private Water Supplies (Scotland) Regulations 2006, this has been superseded (See Finding E01490-001).

The records are held as a combination of hard copy and electronic, although the laboratory is gradually transitioning to electronics records for the majority of the records.

The Control Manual appears to capture the key requirements of ISO/IEC 17025:2005.

Roles & Responsibilities for Quality

the Quality Manager, this is a part time role as he is also the Principal Scientist for the Environmental Section. : has been in the post of Quality Manager for a number of years and is conversant with the Quality System in place.

The role of Technical Manager is undertaken by the Public Analyst, the current Public Analyst has only been in place within Aberdeen Scientific Services since July 2018, although he held the position of Public Analyst at another laboratory previously.

The deputies for these key roles are defined in the Control Manual. The Technical Manager deputises for the Quality Manager and vice versa.

Control of Documents and Records

The process for document control is detailed in procedure PA/IHP/0001. The master list of documents is held in the LIMS system.

All documents have a unique document number, issue date and issue/revision number. All controlled hardcopy methods and procedures include a signature of authorisation, which is completed in red ink. Amendments to methods and procedures may be issued as the whole document or by issuing individual pages. The current issue/revision number is identified in the document header.

The Quality Manager has overall responsibility for document control however, any Senior Member of staff can make a change to procedures. These are subject to approval before issuing. Staff are informed of changes as they happen.

The laboratory holds copies of all UKAS documents that apply. They also hold copies of other external documents that are relevant, including copies of British and Internal Standards, Legislation and Regulations that are relevant.

Management of Sub Contractors and Purchases

There is a list of approved suppliers and subcontractors, this is held in the LIMS system. There is a folder on the system which contains copies of Certificates including ISO 9001, ISO/IEC 17025:2005 testing and calibration, ISO 17034 and ISO/IEC 17043 as appropriate. The laboratory procedure specifies that organisation that are ISO 9001 certified are considered as approved, the procedure does not specifically state that there are other approvals which may be more suitable, however there are records to show that the laboratory does consider other approvals, e.g. Accreditation. This has been raised as a Recommended Finding (See Finding E01490-011)

The list of approved suppliers was noted to not include Trescal, who are used for calibration of reference thermometers. There were also no records/certificates in the folder (See Finding E01490-010).

The laboratory logs receipt of all chemicals and consumables and these are checked against what was ordered and against the grade required. The laboratory source their reference materials from ISO Guide 34/ISO 17034 accredited organisations where they are available.

The laboratory uses four Subcontract Laboratories, these are Eurofins, ALS Environmental, DETS, and Scottish Water. Scottish Water are used for DWTS testing where the laboratory itself does not have the capability to do the test. All of the subcontract abs are on the approved supplier list and are UKAS accredited. The laboratory has not had course in the last year to subcontract any work for which itself holds accreditation.

Service to Clients
The majority of the laboratory customers are Local Authority customers, Feedback is sought via the regular meetings that are held between the laboratory and the local authorities.

Feedback is actively sought and acted upon where there are instances of negative feedback. No negative feedback has been received in the last year.

Handling of Complaints, Control of Non-Conforming Items Dealing with Corrective & Preventive Actions and Improvements
Records for complaints, anomalies and non-conforming work are held electronically. In 2018 there were a total of 13 anomalies recorded, in 2019 to date there have been 5 so far.

A review of complaints logged noted that there were only 2, both being logged in 2019.
The first related to a query over test results, there were inconsistencies between the results provided by ASSL and another laboratory, who the customer was using. The investigation identified that the results generated by ASSL were correct and that the other labs results were incorrect. The investigation included a good level of detail. As this was found not to be justified, there was no root cause applicable to ASSL. The second issue was raised via customer feedback on the 19th February 2019, and related to turn around times, specifically relating to the lack of communication where results were going to be delayed. The laboratory has identified areas for improvement and are looking at implementing a system for notifying customers where results are going to be delayed beyond the agreed turnaround time.

It was noted that of those anomalies raised in 2018, the majority were raised in the Microbiology and Environmental Chemistry section with only one raised for Food Chemistry. The anomalies were all suitably investigated, and a root cause was identified, it was noted that the form used for recording anomalies does not include a prompt for the user to record the root cause. The inclusion of a prompt would ensure that users would need to consider identifying a root cause, this has been raised as a recommended finding (E 10490-004).

The complaints and anomalies raised were all closed out promptly.

Proficiency test failures are recorded on separate forms, these were reviewed by the Technical Assessors.

Internal Audit
The laboratory has an audit programme in place which covers system audits, method witness audits, vertical audits for DWTS work as well as an audit of the flexible scope process.

There is a procedure in place for Quality Audit and Management System Review (PA/IHP/005), this references PA/LOOG?1101 for a list of audit officers, on review of the list held it was noted that this appeared to be a historic document, the list of auditors is held elsewhere in the system, this reference is therefore incorrect and requires amending (See Finding E01490-002). There is a team of trained internal auditors who tend to audit their own area but may if required audit other activities.

The procedure details the process for how the audit is recorded using the forms in place. There is an audit checklist which details the activities audited, audit summary, which summarises the audit non-conformances and audit reports, which are used for recording the audit non-conformity and actions to be taken. Individual audit reports are generated for each audit finding raised. Section

4.4.2 of the procedure states that "on completion of the audit, the auditing officer must complete an audit report form" this is misleading as an audit report form is generated for each non-conformance raised (See Finding E01490-003).

The laboratory holds the audit records as electronic files and have started to use electronic signatures to reduce the amount of paperwork generated. The system appears to be appropriate. The audit records are being hyperlinked to the audit checklist, this enables easy retrieval of the individual audit findings.

The audit record reviewed provided good evidence of traceability with the use of objective evidence. Audits were completed as planned and closed out promptly.

Management Review
The laboratory held the annual review on the 30th January 2019. The meeting took place between the Laboratory/Quality Manager, J. and the Public Analyst/Technical Manager, (Although not in attendance the Principal Scientists provided data for the review.

The minutes of the review covered the key elements of ISO/IEC 17025:2005. The laboratory will need to carefully review the requirements of ISO/IEC 17025:2017 to ensure that for future Management Reviews that all of the necessary areas are covered.

The minutes provided good detail, and evidence of the discussions held, the minutes included a review of use of the Generic Protocol/Flexible Scope, this identified that it had been used once for analysis of nitrite and nitrate in meat products. The laboratory may wish to consider expanding the detail a little more e.g. to cover number of samples tested and outcome of the validation.

Impartiality & Integrity
Independence, Impartiality & Integrity
Staff were honest and open throughout the assessment enabling access to all records requested. The Quality Manager allowed the Lead Assessor full access to the Quality Management system, which allowed for unhindered access to all areas.

The laboratory undertakes testing on behalf of local authorities as well as for some private clients. Care is taken to ensure that any work undertaken on behalf of private clients does not conflict with work for local authorities, particularly for enforcement purposes.

The new Public Analyst, works part time for the laboratory, contracted to do 24 hours a week, this may be at the laboratory or remotely, he is required to attend the laboratory at least one week a month at the laboratory. In addition to the work he does for Aberdeen he owns The Public Analyst Service Limited and acts as Public Analyst for the 4 South Yorkshire Local Authorities. This may involve sending work to a number of laboratories, including Aberdeen City Council. Care is taken to ensure that this relationship does not impact on the impartiality and integrity of results. He also reports Veterinary Residue results for Fera, this is a continuation of work that he undertook in his previous role as Public Analyst at West Yorkshire. The laboratory will need to ensure that this is fully documented as part of the assessment of risks to impartiality, which is a new requirement in ISO/IEC 17025:2017, as well as consideration of risks associated with other members of staff, be they personal relationships or business relationships.

Confidentiality
The staff are required to sign a confidentiality agreement on commencement of employment. For the new members of staff, including the Public Analyst these were seen to have been signed.

Evaluation Processes
Enquiries, Tenders, Contracts
The laboratory meets regularly with the local authorities to discuss their needs and any specific projects that are due, these meetings are held quarterly. These meetings are minuted and copies of the minutes retained for reference. There are also Service Level Agreements in place between the laboratory and the local authority, these date back several years, however they have been subject to extensions.

The laboratory has been undertaking analysis as part of the Aberdeen Western Peripheral Route (AWPR). This project is not drawing to a close as the construction work has been completed, although there is some post construction testing due to take place, however no decision has yet been reached on how much and for how long. This has formed a large portion of work for the laboratory over the last few years.

Where the laboratory receives adhoc requests for testing, quotations are generated. The laboratory has a quotation template that includes the full colour version of the UKAS Testing Symbol and the laboratory testing number. The templates include disclaimers for accreditation status and where work is to be subcontracted.

A selection of quotations were reviewed and the following issues were noted.

Quote number ASSL072-18(2) for testing of dog biscuits, for chemistry and microbiology testing. The laboratory does not currently hold accreditation for microbiological testing of pet foods or animal feeds and this was not disclaimed as such on the quotation (See Finding E01490-009).

Quote number ASSL024-18 for testing of Draff a by-product whisky production that is used for animal feed, included microbiological testing, this was not disclaimed as not accredited (See Finding E01490-009).

Other quotes reviewed which included only Chemistry or Microbiology testing were noted to contain the correct information regarding accreditation status. It appears that only those quotes which included both types of testing did not correctly disclaim the microbiology testing on animal feeds/pet foods as outside the scope.

Quote number ASSL061-18 for chemical testing of homogenised herring fillets, included fat analysis, the laboratory is currently accredited for 4 fat methods on foods, the quote does not fully identify which test method was to be used (See Finding E01490-007).

Quotes Generated for testing of Potable Waters do not specify whether the testing is to be undertaken against the DWI/DWTS requirements (See Finding E01490-008).

Where the laboratory receives a new enquiry, it is sent to the Aberdeen Scientific Services Laboratory central email address, this is then forwarded to the most appropriate person to handle the enquiry. The person in receipt of the enquiry will then ascertain with the customer their requirements, this may be in the form of a telephone call or email. There was good evidence to show from emails of what is covered, this includes sampling, transportation and limitations which could impact on the testing, specifically regarding micro testing e.g. time from sampling to analysis for water samples must not exceed 24 hours.

Decisions/ Opinions
Where the laboratory reports include an opinions or interpretations these are correctly disclaimed.

Flexible Scope
There are two procedures in place for flexible scope, PA/IHP/0030 describe the use of the Generic Protocol/Flexible scope and details the process for managing any additions using the flexible scope and PA/IHT/3000 which details the process for how a method is developed under the flexible scope.

Procedure PA/IHP/0030, defines the bounds of the flexible scope and references to PA/IHT/3000. The techniques listed cover those for which they are accredited and appear on the laboratories fixed scope. The procedure defines the responsible persons and details where their competence is recorded.

There is a register in place, where each use of the generic protocol is recorded, each use is given a unique number. The forms to be used are included as appendices in the procedure. Records of the single instance were reviewed, and the laboratory has used the procedure as described and forms were completed as appropriate.

The laboratory enquired regarding using the flexible scope for GC-MS, as this does not appear within their procedure or on the schedule, the laboratory believed that this was an oversight, this was discussed during the assessment and it was identified that a GCMS technique (Acrylamide) had been assessed under the flexible scope back in 2015 at the last re-assessment visit. The outcome of that was that the validation and approach had been accepted by the Technical Assessor and Lead Assessor/Assessment Manager, see Technical Assessor report below under flexible scope for more details. It is therefore proposed that the schedule be updated to include GCMS under the techniques for which the flexible scope applies, see also Technical Assessors report below. The laboratory currently has one GCMS method on the fixed scope already.

Technical Competence - Food Chemistry

Changes to Schedule (Issue 039)

Materials /Products tested	Type of test	Equipment Techniques used
ANIMAL FEEDINGSTUFFS FOOD and FOOD PRODUCTS	Contaminants & Composition	Development and Modification of Methods for the analysis of foods using Generic In-House Procedure PA/IHT/3000 for the techniques GC, *GCMS*, HPLC, AAS, ICP-OES, UV/Visible Spectrophotometry, Microscopy and Classical Techniques
FOOD and FOOD PRODUCTS	Additives, Colourings, Preservatives and Related Contaminants & Composition	Development and Modification of Methods for the analysis of foods using Generic In-House Procedure PA/IHT/3000 for the techniques GC, *GCMS*, HPLC, AAS, ICP-OES, UV/Visible Spectrophotometry, Microscopy and Classical Techniques

Addition of GCMS to the Generic Protocol (Flexible Scope) for reasons as detailed below.

NOTE: There will be further changes regarding Schedule entries for fatty acids and sugars, but these are subject to satisfactory clearance of Mandatory Findings and will be covered on the IAAF.

Use of Generic Protocol – Review of Technical Records as applicable.
The procedure for Flexible Scope is detailed in PA/IHT/3000 and PA/IHP/0030. Procedure PA/IHT/3000 details the general policy and procedure for management of the process and includes the scope of the "Generic Protocol", the current scope is limited to development or modification of methods using GC, HPLC, AAS, ICP-OES, UV/Vis Spectroscopy and Microscopy in Foods and Foodstuffs.

The laboratory re-presented data from the 2015 UKAS Assessment Report. This concerned an exercise undertaken to have GCMS included in the range of techniques on the Generic Protocol. The laboratory has GCMS on their Fixed Scope (PA/IHT/2171, MCPD by GCMS). The example validation had concerned analysis of acrylamide in foodstuffs by GCMS. The conclusion drawn on the Assessment Report by the, then, Lead Assessor was that the laboratory had submitted a generally suitable validation package. This was expanded on by the, then, Food Chemistry Assessor's report. The Food Chemistry Assessor had raised one Mandatory Finding which was subsequently cleared by the laboratory. In discussion with the current Lead Assessor it was agreed that the GCMS could have been added to the UKAS Schedule following the 2015 report. The change to Schedule, detailed above, is effectively a catch-up exercise.

The laboratory has applied their Generic Protocol once in the past year. This application was associated with meeting a customer request for analysis of nitrate and nitrite in a batch of cured

meats. The application falls within the current boundaries of the Flexible Scope. Although 2 accredited methods (PA/VEM/0157 for nitrite and PA/IHT/2307 for Nitrate & Nitrite) were available, the laboratory considered that these were not appropriate in this case, mainly due to the presence of high concentrations of sodium chloride which may cause significant interference. Suitable selection of a procedure was undertaken, resulting in use of a R-Biopharm enzymatic colorimetric kit. The laboratory was able to demonstrate that the requirements, set out in PA/IHP/3030, for authorisation, identification of responsible analysts and approval of the proposed approach had been undertaken. Appropriate method performance criteria were set to ensure fitness for purpose of the method and compliance with any statutory limits. The member of staff selected to undertake the work had appropriate training. An appropriate method was developed based on the manufacturers' kit instructions. The laboratory was able to demonstrate that the target criteria set had been achieved. All records had been sufficiently detailed and retained in the allocated file allowing reconstruction of the work if required. The results had been appropriately approved and authorised before release to the customer. The report provided suitable information regarding the Generic Protocol status of the method used. In conclusion the example application of the Generic Protocol met all the requirements of the laboratory's accredited SOP.

Test Methods
The test methods are all available as controlled hard copy documents in the laboratory; they are readily available to the staff and were referred to by the staff demonstrating the procedures. The methods are clearly written and detailed with good associated procedures detailing the use and calibration of the equipment.

Frequency of use of the methods on the Visit Plan varies. Tests associated with nutritional components are received fairly regulatory but in other cases the frequency drops to a handful per year, and in some cases is restricted to participation in proficiency testing. The laboratory does have a documented Infrequent test method which requires escalation of the quality assurance of the method if it has not been undertaken for 24 months. Competence is maintained through participation in relevant proficiency testing, which is to a high standard.

The method for analysis of fatty acids, PA/IHT/2151, is described on the Schedule as being applicable to oils and fats and providing fatty acid profile. This implies that that it is mainly used to characterise and identify edible oils. In fact, the laboratory mainly uses it to provide information on the nutritional composition of foods. The method is based on an acceptable standard procedure for fatty acid analysis. Performance in proficiency testing for saturated, monounsaturated and poly-unsaturated fatty acids has been consistently good for several years. The laboratory has appropriate accredited methods for the extraction of fats from foodstuffs which would be used to reach the stage described in the current method where a sample of oil or fat is taken. In order to present this test more effectively on the Schedule the laboratory needs to redraft the SOP to address the calculation and reporting of saturates, mono-unsaturates and poly-unsaturates and to describe how the fat sample analysed is obtained from food samples (E00365-001). This change can then be reflected on the Schedule.

The method for analysis of sugars (PA/IHT/2318) is described on the Schedule as covering 5 individual mono- or disaccharides. In practice the laboratory may report Total Sugars. The method does not detail how these are calculated or reported and needs to be redrafted (E00365-002). This change can then be reflected on the Schedule. Proficiency testing over a number of years has been good and supports the fitness for purpose of this method, however the approach may benefit from consideration of how to address analysis of samples containing galactose.

Personnel and Training records
Methods were well demonstrated by very experienced staff who showed a good understanding of the procedures and principles of the equipment involved.

Training records are maintained electronically within the LIMS system, detailing the training that has been received in the analytical procedures. Three training records were viewed, L
1 and [redacted], these provided satisfactory evidence of competence and associated authorisation.

Accommodation and environment

Accommodation is fit for purpose with appropriate segregation of tests where required. The standard of housekeeping is good. Ambient laboratory temperature probably varies by more than the generally ideal acceptable limits across the Seasons, but there was no evidence of this having any significant detrimental effect.

Method Validation

Records associated with the original validation of methods are stored. Documentation for the more established methods are retained as hard copy and the laboratory was able to locate and demonstrate these for a selection of methods. Later methods data are stored electronically. The combination of assessment and review of Method Uncertainty, method audit and review, scheduled review of Quality Control charts, and maintenance of Proficiency Testing to a good standard have ensured that the laboratory has maintained the performance of their methods to an acceptable level since initial validation.

Equipment and calibration records & In-house calibrations

Balances are calibrated by an external UKAS accredited organisation on an annual basis, all balances seen were labelled with a current calibration status. The balances are monitored on a daily basis using appropriate weights and records maintained in logbooks. Laboratory autopipettes and dispensers are calibrated on a three-monthly basis using five aliquots at three points over the operating range.

Major items of equipment were uniquely identified and labelled appropriately with a calibration status label. The laboratory has succeeded in maintaining their gas-chromatographs in good working order for an exceptionally long time, calling on the experience and expertise of the chromatographer. It would be helpful if the records of this in-house maintenance were more comprehensive. Records associated with in-house maintenance of HPLC equipment are well maintained.

IQC and EQA including trend analysis

Internal Quality Control

Batch-wise IQC relies mainly on a combination of reference material (in-house or FAPAS) analysis supplemented by duplicate analysis of a sample within the batch. Typical batch sizes are quite small. In cases where results were found to be outside acceptance limits appropriate action is taken. Shewhart charts are set up in accordance with standard acceptance rules. The charts viewed reflected acceptable precision (see individual method reviews below). Charts are subject to periodic review in accordance with a documented procedure.

External Proficiency Testing

The laboratory participates in FAPAS Series 1,3,4,7,8,10,13,14,15,17,18,20,21,24,25,26,27,28,29 & 30; together with LGC QDCS 56 and QFCS 774. Participation in tests is scheduled to cover the UKAS Scope over a two-year period and adequately covers the accredited Schedule. Inspection of proficiency records dating back over several years confirmed consistent very good performance. Records for the past year showed participation in 21 Rounds comprising 71 tests. 97% of tests generated good z-scores (z-score<|2|) which is very good. Results are plotted and subject to trending.

In cases where z-score>|2| results are subject to documented investigations. There were two instances in the past year. The results for Total Volatile Basic Nitrogen (TVB-N) in fish gave a z-score of 2.9. Previous z-scores had all been good. The laboratory investigated this. Consideration of the FAPAS report indicated that the assigned mean had been calculated from a combination of the Fish TVB-N method and an alternative, Total Volatile Nitrogen in Flesh foods, (for which the laboratory also holds accreditation). The FAPAS sample was analysed using this alternative procedure, generating a lower (acceptable) z-score. Further investigation of the spread of results achieved across all the laboratories suggested a bimodal distribution. The laboratory has notified FAPAS of these observations but has not yet received a response. In conclusion the laboratory considered that they had used the correct EU Regulatory method and that their z-score had reflected a bias introduced by the, fairly widespread, use of an alternative method. I agree with this conclusion.

The second investigation concerned a z-score of 4.1 for nitrate in meat. The laboratory had undertaken an extensive re-testing of this sample by HPLC and colorimetry. They were unable to ascertain any definite root cause, but the report demonstrated a good approach to resolving quality failures. Previous z-scores had been good and the PT for this test is schedule for 2019.

Reference material/standards
All reference standards seen showed appropriate traceability to ISO Guide 034. All reference materials seen were within their expiry dates and appropriately stored.

Uncertainty of Measurement
Method Uncertainty is estimated using a spreadsheet which is common to a number of Public Analyst laboratories. This calculates uncertainty of measurement using a combination of precision from repeatability data and bias from proficiency test performance.

The laboratory has a schedule to review the Uncertainty budgets of its accredited tests. Less frequent tests are reviewed over a 5-year cycle, but the more common tests, e.g. nutrition analyses, are subject to annual review. The requirements of the schedule had been achieved with current uncertainty budgets available. As precision (normally the major MU component) has been good for all methods seen in the visit MU may be expected to be generally fit for purpose.

Records, worksheets and reports
The standard of record keeping at the laboratory is good, all requested records were readily available, and had been completed to a good standard.

Vertical audit
One vertical audit was undertaken. This involved analysis of a batch of unsmoked bacon from a Local Authority exercise (Laboratory identification 10189360). The laboratory was able to retrieve all documentation (Work sheets) and to demonstrate that AQC requirements and had been met and the samples had been analysed by a suitably trained analyst. The report met customer requirements and all data were accurately transferred.

Reporting of results
Reports viewed met the requirements of LAB 1 and BEIS publication, Accreditation Logo and Symbols, Conditions of Use.

Practical witnessing:
One of the senior analysts had called in sick on the day of the visit. There was insufficient time, or appropriately trained staff, for the laboratory to re-group to provide practical demonstrations of all the methods on the visit plan. Several methods were covered by review of performance, all these reviews were conducted with [redacted].

Witnessed Activity (test/ calibration/ inspection/ audit*)	Performed By	Technical Assessor	Comments
PA/IHT/2520: Arsenic and Selenium by Hydride Generation AAS	Document review		Throughput; approximately 5 samples per year. PT performance consistently good for both arsenic and selenium. Method developed in-house. *Arsenic.* IHRM is a FAPAS rice flour, laboratory mean is in good agreement with the consensus mean. Precision acceptance set at z-score $\pm$ 2 until such time as sufficient data points can be obtained to review and replace with in-house precision. Data indicate that routine precision is well within this, with a good $Horrat_R$ value of 0.4. Meeting the performance criteria set in COMMISSION REGULATION (EU) 2016/582 for arsenic in food.

			Duplicate data charts set at an appropriate level reflecting good control. Sensitivity. LOD set at 0.05mg/kg is fit for purpose for monitoring compliance with lowest MRL in Feeds Regulation 2015/186 (2 mg/kg). The method is also used for food analysis. COMMISSION REGULATION (EU) 2016/582 performance criteria require LOQ $\leq$ 2/5 MRL. The LOD of 0.05mg/kg; is assumed to be equivalent to a LOQ of 0.17mg/kg (i.e. x 10/3). As such the method would not be fit for purpose for monitoring compliance with the MRLs in COMMISSION REGULATION (EU) 2015/1006 for arsenic (inorganic) in rice. *Selenium.* IHRM is a FAPAS Dairy Ration, laboratory mean is in good agreement with the consensus mean. Precision acceptance set at z-score $\pm$ 2 until such time as sufficient data points can be obtained to review and replace with in-house precision. Insufficient data to form any robust assessment of precision but the values presented are within the FAPAS limits and reflect good routine performance. Similarly, there are few duplicate data points but they do not indicate any problems with the method. Sensitivity. LOD set at 0.05mg/kg. No regulatory MRLs for selenium.
PA/IHT/2062: Crude fibre using Fibretec system			Demonstrated by analysis of a batch of samples comprising the current IHRM and a repeat sample on the Fibretec. Method undertaken up to the stage when samples would be presented for ashing. Results not available before end of visit. Throughput; seasonal formal feed surveys plus several samples received from farmers. PT performance consistently good. Method based on Feed Regulations (Scotland) 2010, therefore suitable for analysis of formal samples. IHRM is an established in-house feed reflecting an appropriate mean crude fibre level. Precision is good (for an empirical method of this nature) with a $Horrat_R$ of 1.2 Duplicate data charts set at an appropriate level reflecting good quality control. These should reflect compliance with the repeatability criteria in Commission Regulation 152/2009 for the official control samples but there was insufficient time to go into this level of detail for the overall chart.
PA/IHT/0401: Alcoholic Strength of Spirits by	Document review		Throughput; several samples a year. PT performance consistently good.

Obscuration using a Pyknometer		Method referenced to BS ISO 3507:1999 & BS 3733: Part 2 1987 (both current) using a Sprengel Pyknometer as specified in BS 3733 Part 1. IHRM is an LGC CRM (certificate available). The laboratory has opted for a 15% alcohol strength CRM to better reflect samples rather than rely on a spirits (40%) CRM. The mean is set at the certified value with the LGC limits set as acceptance. The chart reflects good routine performance. Duplicate data charts set at an appropriate level reflecting good quality control. The calibration requirements set for the Pyknometer are met and records confirmed this.
PA/IHT/2201: Propionic and Sorbic Acids in Bread:	Document review	Throughput; no routine samples since 2016 PT performance for sorbic consistently good, no propionic schemes available. Method developed in-house. No appropriate IHRM, performance is monitored based on spiked recovery set at appropriate levels. Few data points to consider but the average spike recoveries (95.3%) reflect acceptable performance. This should probably be treated as an Infrequent Test.
PA/VEM/0131: Titratable Acidity of Milk		Demonstrated by analysis of a duplicate milk sample obtained from a local supermarket. Results from the duplicates met the SOP acceptance criterion and confirmed acceptable quality of the milk. Throughput; mainly complaint samples, a few per year. PT performance consistently good. Method based on BS 1741-10.1: 1989 (Current). Quality control based on precision criteria set to reflect BS performance criteria. Charts reflect good routine control.
PA/IHT/2171: 3-monochloropropane-1,2-diol in fish and fish products using GCMS	Document review	Throughput; recently only the PT samples. PT performance consistently good. Method based on the collaborative trial GCMS method provided by CSL and cited in CSL Report FD 97/95. Quality control based on use of the most recent FAPAS sample, acceptance criteria set at z-score $\pm$ 2. No recent data points other than samples analysed for PT. Performance should be assessed against the requirements in Commission Regulation 836/2011 for precision and recovery (75-110%). The relevant MCPD MRLs are in Commission Regulation 1881/2006, (20µg/kg). Regulation 836/2011 requires an LOQ of 10µg/kg on

		a dry matter basis. The laboratory Reporting Limit is 10µg/kg. Introduction of appropriate acceptance criteria into the SOP to ensure maintenance of routine sensitivity in compliance with the performance criteria given in Regulation 836/2011 is needed (E00365-003).
PA/VEM/0151: Fish Species Identification by Iso-Electric Focussing		Demonstration of the interpretation of the polyacrylamide gel associated with the most recent FAPAS Round. The analyst explained how the initial screening set was interpreted, homing in to repeat running of a gel with the unknowns (3 fish FAPAS fish samples) positioned adjacent to the most likely reference species. Finer tuning of the interpretation led to the correct identification of the 3 fish species. These were in line with the successful FAPAS Round. Note: Although this exercise had been undertaken with the analyst already aware of the correct answer it did serve as a valuable exercise in demonstrating the main factors influencing an experienced analyst. There also would have been insufficient time or resource to run this test completely on unknown samples. Throughput; mainly complaint samples (several a year), but a useful facility for Local Authority for surveys. PT performance consistently good. Method based application notes and JAPA method. Quality control. It is increasingly difficult to source reference fish species. The laboratory sources reference fish from the Senior Authorised Officer for Fish. Written authorisation of the identity of some recent fish species was presented as an example. The laboratory can call on a reference library covering 38 raw and 5 smoked species which meets current requirements. These are stored in a controlled deep freeze and appropriately labelled.
PA/IHT/0075: Diastase activity in Honey		Demonstration by duplicate analysis of a honey sample bought from a supermarket. The results obtained from manual plotting of the intercept absorbance against time plot were confirmed by Excel. The Diastase activity results of 18 and 17 met the acceptance criterion for duplicate analyses. This confirmed satisfactory quality of the honey sample meeting the EU Honey Directive (Council Directive 2001/110/EC) as Diastase Number not less than 8 Schade Units Throughput; recently one batch per year to meet Local Authority sampling PT performance consistently good.

		The method is referenced to Harmonised Methods of the European Honey Commission and is based on the Schade method. Quality control is based on duplicate analysis within a batch with an appropriate acceptance criterion (within 2 units) set. The laboratory considered using an ex-FAPAS sample as an IHRM but was concerned about stability.
PA/IHT/0076: Electrical conductivity of Honey EU reference method, Method 12		Demonstration by duplicate analysis the honey sample used for the Diastase activity method. Check on the calibration status of the conductivity meter. Analysis of the Control Solution (KCl) met the acceptance criterion. Duplicate results were identical (at 0.17mS/cm). This confirmed satisfactory quality of the honey which should be not more than 0.8 mS/cm (Council Directive 2001/110/EC). PT. The laboratory agreed at the visit to participate in the next FAPAS Round associated with electrical conductivity (2844, November 2019). The method is referenced to Harmonised methods of the European Honey Commission and The Honey (Scotland) Regulations. 2015. Quality control is based on duplicate analysis within a batch and analysis of a Control solution of potassium chloride which must give a result of 132.8±5 µS/cm.
PA/VEM/0092: L(-)Hydroxyproline in Meat and Meat Products:		Demonstration by duplicate analysis of a mince sample and analysis of the IHRM, (ex FAPAS 01122). The calibration achieved, R^2 0.9996, met the acceptance criterion. Results from the duplicate mince sample fell within the repeatability limit acceptance criterion. The IHRM results fell within acceptance limits. Throughput; regular batches as part of Local Authority testing. PT performance consistently good. The method is referenced to BS 44401:11. 1995 (Current). Quality control involves analysis of an IHRM, (currently FAPAS 01122). The laboratory mean value is in close agreement with the FAPAS consensus mean value. Limits were set at z-score ± 2 but have now been adjusted to reflect the laboratory's own (improved) precision as sufficient data points have been accumulated. Batch-wise precision is good with a $Horrat_R$ value of 0.9. Duplicate analysis sets an acceptance criterion in line with that in BS 4401 and

			inspection of records confirmed routine compliance.
PA/IHT/2151: Fatty Acid Profile by analysing fatty acids converted to fatty acid methyl esters using GC	Document review		Throughput; several samples per year. PT performance consistently good for saturates, mono-unsaturates and poly-unsaturates. The method is referenced to AOAC 16th Edition (1995). The method needs to provide a description of how to calculate the nutritional fatty acid components and how to extract the fat from the food sample (E00365-001). The example chromatograms provided indicated satisfactory chromatography. The method relies on a reference mixture which covers 25 fatty acid methyl esters. The laboratory was able to provide evidence of the certificates associated with the methyl ester mixes used. Evidence of consistent good PT performance supports this range of fatty acid standards, but it may be usefully expanded, particularly to include the fish oil acids DHA and EPA. Quality control is based on analysis of an ex FAPAS sample. This has recently been taken up as the FAPAS walnut oil sample, and there are few data points accumulated so far. However, inspection of historical quality control charts supports good routine performance.
PA/IHT/2101: n-Butyric Acid	.		Demonstration by duplicate analysis of an IHRM butter plus duplicate analyses of a butter sample intended as a replacement IHRM. Preparation of sample extract from one of the butter samples demonstrated. Presentation of the sample extracts to the gas chromatograph. Consideration of the chromatography and results from the analysis. Chromatographic performance met acceptance criteria. Calibration R^2 0.9999 met the acceptance criterion of >0.9985. The result obtained for the IHRM fell within the acceptance criteria (first of routine results within warning limit and action limit) and the duplicate (new IHRM) results met the repeatability criterion at 3.57 and 3.55g/100g. Throughput; several samples a year. PT performance consistently good. The method is referenced to the Philips & Sanders JAPA method. The n-butyric acid to milk fat conversion factor used is 3.42 rather than the 3.6 adopted by Philips & Sanders. However, the n-butyric acid content of milkfat is subject to natural variation, between 3.3 and 3.9%, and 3.42 has been adopted by Public Analysts. This

			is also in line with Codex recommendations. Quality control is based on analysis of the IHRM butter with an established n-butyric acid content of 3.7g/100g. Batch-wise precision is good with $Horrat_R$ =1.0. Inspection of the duplicate analysis chart confirmed good routine performance.

Technical Competence – Water Chemistry

Schedule Changes

The statement at the beginning of the WATERS section ***"Examination for the purpose of enforcement of..."*** needs to be replaced with "**Examination for the purpose of enforcement of The Private Water Supplies (Scotland) Regulation 2006, The Water Intended for Human Consumption (Private Supplies) (Scotland) Regulation 2017 and The Public Water Supplies (Scotland) Regulation 2014.**" as regulations have been updated.

Personnel

All analysts witnessed were familiar with the techniques and showed a good level of competency and knowledge when carrying out the tests.
Analysts were effectively "signed off" as competent in the AIS LIMS against competence data.
Senior staff and analysts involved in DWTS testing had appropriate CPDs in place.
On-going competence is monitored analysts running proficiency samples and recording the results by analyst on a spreadsheet.

Test Methods and Validation

Test method documentation was fit for purpose, detailed and easy to follow for the methods witnessed, with only minor amendments, required to ensure consistency of application.
It was noted that the suspended solids reporting limit is set at 10 mg/l but when smaller volumes than 1000 ml are taken the reporting limit does not change proportionately.

There was appropriate validation data in place for metals and IC anion parameters.
However, there was limited validation data or summaries available for BOD (AQC data, water matrix data and replicates) and for suspended solids (AQC, duplicate data, PT data) but again no overall performance summary.
The laboratory has not yet reprocessed previous DWTS validation data to show that performance meets the new Water Directive specification in terms of LoQ and UoM targets.

Equipment and Resources

All equipment witnessed was uniquely identified (e.g. ICPAES instrument PA1257 & Oven PA1366) and had next maintenance / service date or recalibration date labels.
Manufacturer service records were available for major piece of instrumentation. In-house instrument maintenance books are in place.
There were appropriate equipment records in place for the equipment checked.

The laboratory space available for preparation and testing and environmental conditions are suitable for the analysis taking place.

Working thermometers (e.g. PA0949) were found to be in-date and appropriately labelled with the next calibration check date. The suspended solids oven thermometer (PA0949) had been recently in-house calibration checked against an N-type thermocouple reference thermometer (PA0854) calibrated by Trescal in April 2016. The reference thermometer calibration certificate was readily available showing the N-type system had been calibrated up to 600°C.

However, it was found that there was no associated estimate of uncertainty and no procedure in place on how the overall uncertainty associated with a calibration check is to be estimated so that

such takes into account working thermometer readability, any offset and reference thermometer calibration certificate uncertainties.

Mechanical pipettes (e.g. PA1315 (0.1-1ml) & PA1362 (1-10ml)) are calibration checked quarterly with both precision and accuracy checked against defined targets across the range of volumes used. Electronic records were readily available for each pipette checked.

No volumetric equipment or timers were calibration checked during the visit.

All reagents checked had expiry dates and the calibration and quality control reagents and stock solutions were in separate cupboards and appropriately labelled.

All laboratory balances checked (e.g. 4-place Sartorius, PA0010) were on a stable balance bench and were calibrated by an appropriate external accredited company, Precisa UKAS No. 0428, in Jan 2019. There were appropriate daily check weights and records in place covering the typical mass range used. Balance calibration certificates were readily available and showed that the balances were fit for purpose.

The metal standards used for ICPAES and ETA-AAS instrument calibration are sourced from Inorganic Ventures via Esslab and were traceable to national standards being ISO 17034 or ISO Guide 34 accredited products.
The metal stock standards are clearly labelled for calibration or AQC use with product certificates readily available. pH calibration standards were supplied by Reagecon.

Records
Technical record keeping was good with preparation books being used to record stock standard Lot No used for the preparation of working calibration and control solutions giving good traceability.

Assuring the Quality of Test Results
All re-assessment test methods witnessed had appropriate instrument system suitability checks (e.g. ICPOES intensities across wavelength range, ETA-AAS absorbance value for a calibration standard and slope for pH determination) with appropriate acceptance thresholds in place.

The laboratory operates a comprehensive QC system via the AIS LIMS system with AQC (CCV) checks run at an appropriate level. AQC charts were available for all parameters witnessed and additionally instrument system suitability check data for many systems were also charted so that trends could be identified.

Test method parameter AQC control limits have are regularly reviewed every 60 points or on a 3-monthly basis by the Laboratory Manager. All control limits checked had been statistically set using an appropriate data set. The AQC precision performance for all DWTS parameters at PCV level met the specification except for Pb by ETA-AAS that was running at ~6% RSD (c.f. 5% target).

Proficiency scheme results were available for all accredited water chemistry methods with all parameters covered except for Ti, Tl & Sn by ICPAES. The overall performance for waters over the past year was good with >95% results being satisfactory. Any *"questionable"* (aluminium, antimony) or *"unsatisfactory"* (alkalinity, aluminium, BOD) results had been investigated and the root cause found where possible and changes made to prevent re-occurrence.

Measurement Uncertainty
Uncertainty of Measurement estimates are re-assessed annually from precision and duplicate data for all parameters checked and the values recorded in a spreadsheet so that trends can be identified. To date, the laboratory has not implemented the required change in how uncertainty estimates are calculated for DWTS parameters.

Reports
Test reports checked during the vertical audit of samples appeared to comply with 17025 requirements with appropriate use of the logo and any comments made clearly identified as outside accreditation scope.

Samples are stored in fridges set at 2 - 8°C if not analysed on the day of receipt. All samples are registered into the AIS LIMS on receipt and any required sub-samples are then taken.

All samples checked were clearly labelled with their AIS LIMS unique identity.

DWTS

Summary

The DWTS AQC performance over the past year for inorganic and metal analytes has been very good with all RSD performance data, except for lead by ETA-AAS, meeting DWTS requirements. The laboratory is aware of but has not re-evaluated DWTS performance data against the Water Directive specification changes and has not implemented the changes to how uncertainty estimates are to be calculated etc. to date.

There were appropriate training records and CPDs in place for senior staff and all analysts involved it potable water analyses.

Samples for total metals are digested with acid at 80°C overnight (or equivalent) as per DWI Guidance document.

For the DWTS parameters, the QC charts were all running with control limits well within the Bias and RSD targets for all parameters except for lead by ETA-AAS that is running with an RSD of ~6% that needs further investigation. In addition, to the 10ug/l Pb PCV AQC, a 1 ug/l Pb check standard is also run with appropriate acceptance tolerances in place further control low level lead determinations.

Proficiency scheme results were good over the past year or so for DWTS parameters with only aluminium generating a "questionable" and an "unsatisfactory" result. There was an appropriate non-conforming work investigation in place covering aluminium that appears to be linked to the aluminium level, being near their LOD.

Vertical audits were carried out on two private supply potable water samples for a selection of results including one that had breached a PCV threshold. The audit found that the laboratory record system was working well with the results traceable back to worksheets and instrument results via the AIS LIMS. Analysts had appropriate authorisations in the AIS LIMS with associated competence data. Analyst work sheets are scanned into the system so that original observation are recorded.

There was appropriate validation data in place for DWTS metals and IC anion parameters etc. However, the laboratory has not yet reprocessed previous DWTS validation data to show that performance meets the new Water Directive specification in terms of LoQ and UoM targets.

The laboratory has downloaded the SCA (MEWAM) Estimation of Uncertainty of Measurement for Chemical and Physico-chemical Determinands in Drinking Waters 2018 - Jan 2018 document and spreadsheets but have not yet assigned the bias component methodology for each DWTS parameter and no example of reprocessing validation data using the spreadsheets was available during the visit.

In addition, the in-house procedures for processing data to meet DWTS requirements have not been updated to take into account the new DWTS requirements for assessing performance, estimating uncertainty and LoQ.

Also, the current DWTS AQC (CCV) standard is spiked acidified DI water and not a "real" typical water sample spiked at appropriate levels to meet DWTS requirements.

Witnessed Activity (Test Methods)	Performed By	Technical Assessor	Comments
PA/IHT/4203 - pH of potable waters (Regulatory / DWTS)			Good competent demonstration of pH methodology by analyst. System suitability "Slope" check in place to show pH system was fit for purpose. AQC in place with control performance is well within DWTS requirements for pH. All proficiency test samples for pH satisfactory over past 12 months or so.
PA/IHT/4005 - Lead in potable waters by ETA-AAS (Regulatory / DWTS)			Good competent demonstration of ETA-AAS method by experienced analyst. Calibration standards traceable to national standards. Appropriate system suitability checks in place. AQC 10 ug/l Pb run and an additional check standard run with 1 ug/l Pb. The 10 ug/l Pb AQC is running with RSD ~6% outside DWTS requirement (5%). No significant bias in system. All proficiency test samples for Pb satisfactory over past year or so.
PA/IHT/4512 - Suspended Solids in surface & ground waters & landfill leachates **PA/IHT/4514** - Biochemical Oxygen Demand (BOD) in surface & ground waters & landfill leachates			Good competent, conscientious demonstration of test methods and system suitability checks by analyst. For both BOD and suspended solids, the AQC results were plotted and passed set criteria. BOD control chart running with RSD ~5-6% - very good with mean value ~210 mg/l.
PA/IHT/4524 - Metals (Sb, As, Ba, Be, B, Cd, Ca, Cr, Co, Cu, Fe, Pb, Mg, Mn, Hg, Mo, Ni, P, K, Se, Ag, Na, Tl, Sn, Ti, V, Zn) in surface & ground waters by ICPAES			Good competent, conscientious demonstration of ICPAES methodology. Calibration standards traceable to national standards. Appropriate instrument system suitability checks in place. Sample batch and AQC (CCV) controls during run and another CCV at end of run. AQC control charts in place for all elements and regularly reviewed. No proficiency cover in place for Ti, Tl & Sn.
Vertical Audit Samples (DWTS)			
(1) Lab No. 10182671 - potable private supply water - taken 3 May 2018, received 3 May 2018, reported 15 May 2018 for pH (10.6 PCV breach), colour, turbidity, nitrate,			Two PCV failure private water samples were selected from AIS LIMS system ~3 & 9 months ago. Test Reports printed and analytical results traced back to original values. All records found within AIS LIMS giving traceability of results back to original records.

copper, manganese, iron, nickel, zinc & lead (2) Lab No. 10189416 - potable private supply water - taken 7 Nov 2018, received 7 Nov 2018, reported 23 Nov 2018 for pH, conductivity, turbidity, nitrate (60 mg/l PCV breach), manganese, iron & lead			Analysts were signed off in AIS LIMS as competent with associated competence data. AQC sample results associated with analytical results had been plotted on control charts within AIS LIMS and passed. All results were fully traceable with the sampler or customer section being informed of PCV failure as per agreed procedure.

Technical Competence – Food and Water Microbiology (

Schedule

Proposed schedule changes:

- Enterobacteriaceae PA/IHT/6517 ISO 21528-1:2004 update to 2017
- Enterobacteriaceae PA/IHT/6505 ISO 21528-2:2004 update to 2017

The laboratory is to provide evidence to verify the updates.

- Bacillus cereus PA/IHT/6502 remove 'based on ISO7932:2004' as the laboratory uses chromogenic media, not that in the standard.

- Listeria monocytogenes detection PA/IHT/6513 ISO 11290-1:2017, add Listeria spp.

The laboratory currently reports both Listeria species and Listeria monocytogenes for the detection and enumeration methods. However, Listeria species are only included on the scope of accreditation for the enumeration method. The laboratory wishes to add Listeria species to the detection methods accreditation and is to provide supporting evidence including confirmation of LOD.

- Legionella spp. PA/IHT/7608 ISO 11731:1998 update to 2017.

The laboratory is to provide evidence to verify the update. The current method is closely aligned to procedures 8, 9 and 10 of the new standard.

- The Water Supply (Water Quality) (Scotland) Regulations 2001 update to The Public Water Supply (Scotland) Regulations 2014.

The laboratory reference the new standard when reporting results.

Test Methods

Methods are a combination of those referenced against BS/ISO standards, Drinking Water standards and documented in house methods. The methods include those required for DWTS water testing. Each method is well documented and includes cross references to supporting procedures.

The laboratory is reminded that when new versions of standards are issued, they should be reviewed, and changes implemented in as required. The amount of information UKAS will require, will vary from a simple comparison of versions, where minimal changes are required by the laboratory, to methods requiring an extension to scope and validation work. The laboratory should not report work as accredited based on the new version of the standard until is in included on their scope of accreditation. The laboratory has identified 2017 versions of both the Enterobacteriaceae and Legionella methods but has not yet completed the evaluation or transition, see finding.

The laboratory holds original validation data for the methods. On-going method validity is confirmed by the participation in EQA and a range of IQA testing and process controls. Methods are considered fit for purpose.

The laboratory has an audit program including method reviews and test witnessing. These are presently carried out a different time for each method, although the Principal Scientist is looking to do these at the same time. This approach has some logic as it incorporates all aspects of one method

in a single audit. It was suggested to the laboratory that more frequent audits could be performed on more complex methods, such as Legionella. Test witnessing audits appear to up to date. Those method audits reviewed contained sufficient detail. DWTS methods are witnessed on an annual basis.

Staff & Training

The laboratory has adequate staff and levels of supervision and experience for the work type and workload. As previously seen, methods were demonstrated with good technical competence and a good understanding of the activities been witnessed.

Two members of staff, KP & JP, are designated competent persons responsible for DWTS work. Training records including CPD were reviewed and show on-going training is maintained. Records were also available to show participation in EQA and IQA. For all members of staff performing water testing a Performance Audits are in place on a planned program.

There is one designated food examiner, KP, who oversees the testing of 'formal' food samples which are rarely received from the Environmental Health Offices. In the unlikely event that KP is absent when a formal sample was received, support is available from other accredited labs. Samples collected by the EHOs for surveillance purposes are put thought the 'formal' sample system, which demonstrates the system is working.

External Proficiency Testing

The laboratory uses a combination of PT schemes to cover all methods on the scope of accreditation, including DWTS. These schemes are provided by PHE and LGC and include a variety of matrices. PT testing meets UKAS requirements, with a suitable plan in place for 2019.

For 2018 PT testing, the results for most parameters have been very good. Anomalies during the year included:

- Incorrect reporting of Clostridium species x2 (Isolated but wrong ID). Incorrect gelatine result for the target organism, which is being investigated. This includes checking with the PT provider that the strain is not atypical.

- False negative for Campylobacter detection in June, not investigated at the time, see finding. Previous and subsequent PT results have been correct.

- Unacceptable result for November Legionella PT distribution. See notes in methods above.

- Legionella testing: Historically, Legionella PT testing performed by the laboratory has been very good. In November the laboratory received two PT samples, which both 'failed' with regards to isolating the target organisms. Repeat samples also gave unacceptable results. The laboratory is investigating this and currently processing further PT samples. During the assessment it was identified that the PT samples may have been made up with the wrong strength diluent, which may affect results. As the same diluent has been used for the current PT in progress, the assessor suggested ordering additional PT samples. In the short term it was agreed that a quantitative process control will be run with every batch of samples tested, to ensure adequate recovery is being achieved.

Internal Quality Control

The laboratory uses a variety of internal quality controls on a monthly basis and process controls with each batch of samples. During 2018 and to date this year, planned monthly IQA testing was maintained.

Trend, Bias, Uncertainty of Measurement (UoM) and Limits of Detection.

The laboratory has procedures in place for reviewing trend, bias and calculating UoM. Data is used from EQA and IQA. The laboratory is monitoring these graphs on an on-going basis. A negative bias has been identified for the Pseudomonas aeruginosa in water, which is now under investigation. Otherwise there was no trend or bias identified. UoM is calculated over three-year blocks and

compared every year, eg 2015-2017, 2016-2018. For 2016-2018 most UoMs values were 5-10% for food methods and all results were acceptable. For waters methods the laboratory historically uses 95% confidence level and results seen for all methods were acceptable. The laboratory has now also started to collate the water results for UoM.

Low level inoculum, including some of <10cfu/25g, have been used to confirm acceptable levels of detection, for all of the detection methods.

Sample handing
Samples are allocated a unique number within the laboratory, which is traceable throughout. There are appropriate storage conditions for samples. Good aseptic technique was observed during testing and sample integrity maintained.

Media and reagents
All reagents and media seen during method demonstrations were in date and appropriately stored. Batch numbers of the media and reagents used were recorded. However, the batch/lot numbers of the raw material used to make the reagents was not. The need for this was highlighted when investigating the failure of a VP test and it was not possible to check the KOH preparation. The test unexpectedly went turbid and therefore there was some doubt if the chemical was KOH. The laboratory uses a combination of in house prepared and commercially made culture media. These media are generally well controlled, with just a simple improvement required the QC enrichment broths. Media records were well maintained.

Reference standards
Most of the laboratory cultures are obtained from PHE as freeze-dried culture, which are traceable to NCTC. These cultures are then stored on cryobeads before being put in to use. Overall traceability of the strains was good, but the identification of specific lot numbers was only possible by linking delivery dates to culture certificates. Lot numbers need to be recorded and directly traceable from the culture held frozen, see finding. These reference cultures are appropriately stored, and newly prepared cultures are checked for purity and characteristics. Cultiloops are used for Legionella and Campylobacter as these have been found to be more consistent. There is good traceability for these.

pH buffers were NIST traceable.

Equipment
The laboratories are suitable equipment for the present work load and work type. External calibration records for autoclaves, reference thermometer and balances. All external calibrations were performed by UKAS accredited calibration companies, covered an appropriate range of calibration and had been reviewed by the laboratory. Equipment seen, except check weights, was uniquely identified and correctly labelled.

Intermediate checks such as daily balance checks, pipette calibrations and incubator monitoring are being maintained. Pipette calibrations and incubator mapping are carried out on a planned program, which is being maintained. Results reviewed were within acceptable tolerances. Evidence that the check weights are included in the quality system and have been verified is required, see finding. All equipment used, including for DWTS testing appeared clean and fully functional.

Records
Technical records relating to testing were of a very good standard. The need for improvements to records for some supporting activities was identified. eg reagent preparation.

Facilities and Environmental Conditions
Access to the laboratory is controlled by electronic keypad. The microbiology department comprises of several rooms, with a logical work flow in place. This segregation of work limits the potential for cross contamination. The laboratory was clean and tidy.

A monthly environmental monitoring program is in place, which has been well maintained. Environmental monitoring included; air plates (ACC &Y/M), contact plates (ACC) and swabs for

pathogens. Results were reviewed for the past four months and the results support a clean working environment is being maintained. Where action limits had been exceeded additional testing had been implemented but what remedial action had been implemented was not recorded. The laboratory also had issues with the air conditioning system and rightly implemented additional testing. Other than the results, there was nothing documented relating to the issue with the A/C. see finding.

Reports and Certificates

A selection of laboratory reports/certificates were reviewed, including all test methods listed on the visit plan. There was good compliance with the requirements of ISO 17025. For the Listeria detection method reports contain two results, one for Listeria monocytogenes and one for Listeria species. The scope of accreditation on lists list Listeria monocytogenes as accredited. The Listeria species results should be marked as non-accredited (see comment in methods). Otherwise there was correct use of the UKAS symbol and appropriate disclaimers present where relevant.

Vertical audits

Vertical audits were carried out on three samples, two mains and one private, taken for regulatory purposes. Sample numbers 10185652, 10183827, 10184023, which included high total counts and the presence of Coliforms, E. coli and Enterococci. The audit demonstrated comprehensive technical records are in place from sample receipt to reporting. There was good traceability for all stages of the tests with regards to staff, materials, equipment's and timings. It is noted that not all samples are received with sample submission forms but the information was taken from the detail on the container. It was suggested to the laboratory they should put a comment on reports when no submission form is received, for completeness of information provided, relating to the sample/s.

Witnessed Activity (test/ calibration/ inspection/ audit*)	Performed By	Technical Assessor	Comments
Enumeration			
PA/IHT/6510 L. monocytogenes and L. species.			All test methods demonstrated with good technical competency. All colony morphologies typical. With the exception of the initial VP test on Bacillus, confirmatory test gave expected results. A repeat VP test on the Bacillus using new KOH gave the intended result. See findings. Appropriate controls being used throughout. Additional Legionella controls are to be implemented for each batch of testing until the investigation into poor PT results is addressed.
PA/IHT/6502 Bacillus cereus			
PA/IHT/6403 E. coli			
Detection			
PA/IHT/6513 Listeria monocytogenes			
PA/IHT/6508 Salmonella			
Drinking Water (Regulatory/DWTS)			
PA/IHT/7604 Enterococci			

Next Step

Submission of evidence to address the mandatory findings raised within the agreed timescale. Objective evidence to demonstrate that the mandatory findings requiring close out action have been suitably addressed is to be submitted electronically by email to UKAS at customerservices@ukas.com both your UKAS reference number(s) and the project number within the subject field. You should receive notification from UKAS that this evidence has been received within three working days of submission. NB: If this notification is not received, please contact UKAS. In order to ensure reliable delivery we request that all emails to be kept below approximately 5MB, if a large amount of data is to be submitted we request that multiple emails are used marked 1 of x, 2 of x to x of x etc. Where no evidence has been requested please indicate the action taken on the Improvement Action Summary form (IASF). Please use a separate form for each assessor.

Note: the laboratory is advised that if corrective action evidence supplied does not clear the nonconformities raised within two submissions of evidence, a review will be carried out with the expectation that an extra visit will be necessary to review actions taken and their implementation with the organisation.

References (if applicable)

ISO/IEC 17025:2005
ISO Guide 34
Lab 1: Reference to Accreditation for Laboratories.
Lab 37: DWTS requirements
TPS 47
SCA (MEWAM) Estimation of Uncertainty of Measurement for Chemical and Physico-chemical Determinands in Drinking Waters 2018 - Jan 2018

Appendices (if applicable)

Improvement Action Report (Sent Separately)