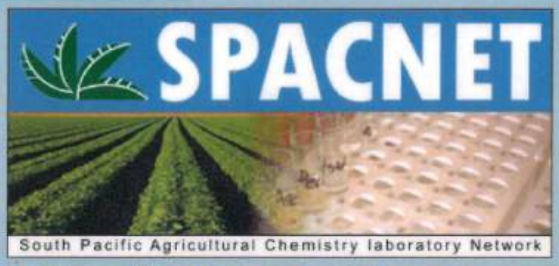
Generic Quality Manual for Soil and Plant Laboratories

compiled by Linda Hill and Brian Daly

South Pacific Agricultural Chemistry Network (SPACNET)
An NZODA Contestable Fund Project



August 2007

Landcare Research New Zealand Ltd
in association with
the Land Resources Division,
Secretariat of the Pacific Community (SPC)

South Pacific Agricultural Chemistry Laboratory Network (SPACNET)

Generic Quality Manual for Soil and Plant Laboratories

(Needs to be customised for an individual laboratory)

compiled by

Linda Hill & Brian Daly

Landcare Research New Zealand

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PREFACE

This manual is intended to be a resource for small Pacific Island laboratories that do not have the time or resources to write their own Quality Manual from the beginning. It is expected that considerable modification and additions will be made to this template manual to make it specific for each laboratory.

The first version of this manual was produced as part of the SPACNET (South Pacific Agricultural Chemistry laboratory Network) programme to improve quality assurance in member laboratories. An updated version was compiled to bring the manual in line with the requirements of the international standard ISO/IEC 17025:1999 "General requirements for the competence of testing and calibration laboratories." The standard has since undergone revision in order to align it with ISO 9001:2000, resulting in the publication, in May 2005, of ISO/IEC 17025:2005 General requirements for the competence of testing and calibration laboratories. Accordingly, this generic quality manual has been updated again to meet the requirements of the new standard.

The changes to the standard have been relatively minor, essentially affecting only the management system requirements with the technical system requirements effectively unchanged. Aside from generic changes in terminology ("customer" for "client", "management system" for "quality management system" and "non-conformity" for "non-compliance") the following is a summary of the key changes:

- Staff need to be made aware of how they contribute to meeting management objectives
- Internal communication mechanisms and their effectiveness need to be demonstrated, including communication about the effectiveness of the management system.
- Quality policies need to include the management commitment to continual improvement of the effectiveness of the management system, and evidence of the implementation of this needs to be demonstrated.
- The importance of meeting customer and regulatory requirements needs to be communicated to all levels of staff.
- Change management practices need to ensure continuity of system integrity during change.
- Laboratories are required to seek feedback (both positive and negative) from direct customers, to analyse this and to institute improvements.
- A new clause (Improvement) requires laboratories to continually improve the effectiveness of its management system through quality policies and objectives, audits, data analysis, corrective action, preventive action and management review.
- Preventive action is now also specifically tied into non-conformity and corrective action practices.
- The effectiveness of training of personnel now needs formal evaluation.
- Equipment checks are now recognised as a formal quality control activity.
- Quality control data now needs to be formally analysed and action taken (both corrective and preventive) when outside predefined limits, and to prevent results from being reported.

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1. INTRODUCTION

1.1 PURPOSE

The *XYZ Laboratory* operates to the international standard ISO/IEC 17025:2005 for the tests set out in Appendix 1 of this manual. This Quality Manual describes the quality assurance and quality control policies and procedures followed by the laboratory to ensure that the analytical results reported are reliable and of known quality. Documentation as a formal management system ensures that policies and procedures are communicated, available, understood and implemented.

1.2 SCOPE

The Quality Manual is designed to provide an overview of operations. Detailed methodologies and practices are written in individual method manuals and standard operating procedures; these are referenced where appropriate. The *XYZ Laboratory* is primarily responsible for only the analysis of samples; hence this manual does not address field sample collection activities.

1.3 REVISION

The Quality Manual will be reviewed annually and the review documented in the master review directory, even if no changes are required. The review will use the NATA Laboratory Assessment Worksheet to check compliance to ISO/IEC/17025. If any revisions are required, the necessary changes will be made under the authority of the Quality Manager. Laboratory personnel will be briefed as to the changes at the next laboratory meeting.

1.4 STATUS

The Quality Manual is a controlled document for internal use only. The electronic version represents the current documentation level. A single hard copy exists bound within a folder kept *state where* and is recorded in the master document control log that identifies the revision status and current distribution of controlled documents. Any other paper forms are not controlled and should be checked against the electronic version before use.

2. QUALITY POLICY STATEMENT

The *YYY* is *Country Name's* organisation serving ..... Our mission is "*{detail}*." The *XYZ Laboratory* contributes to the achievement of this mission by aiming to provide accurate and timely analytical services that meet or exceed the expectations of our customers. The laboratory is committed to good professional practice and to the quality of testing.

To achieve these goals, policies and procedures have been documented and implemented to form a management system that ensures services provided meet the quality requirements of customers. The management system is communicated to laboratory personnel as part of initial and ongoing training so that they are all familiar with the requirements. As well as being responsible for working in accordance with the management system, laboratory personnel are encouraged to be actively involved with management in the process of continuously improving the system in order to improve the services provided to the customer.

In addition to specific performance expectations agreed with our customers, quantifiable key performance indicators defining the laboratory's standard of service are set each year and achievement is assessed formally as part of the management review process.

Senior management have committed its full support to provide the necessary personnel, training, facilities, equipment, funding and procedures required by the management system. This quality policy statement is made under the authority of *the Permanent Secretary or equivalent position*, reflecting the high degree of commitment from management of the company to compliance with all the requirements of ISO/IEC 17025:2005 General requirements for the competence of testing and calibration laboratories.

Name
Position
Ministry/Company etc

3 ORGANISATION AND RESPONSIBILITY

3.1 INTRODUCTION

The *XYZ Laboratory* is part of the *XXX department* of the *YYY Ministry*. Its focus is on *ZZZ*. There are approximately # staff working directly in the laboratory.

The laboratory offers a range of services to both ministry and external clients, including:

- Chemical analyses of soils and plants for extension officers and farmers for soil fertility and plant nutrition purposes.
- Chemical analyses of soils and plants for researchers for agronomic and other purposes.
- Chemical analyses of soils for soil classification / soil survey purposes.
- Chemical analysis of water for decisions on suitability for irrigation.
- Limited interpretation service for advice on the need for fertilisers.

3.2 LABORATORY RESPONSIBILITIES

A staff organisation chart is given below in Figure 1.

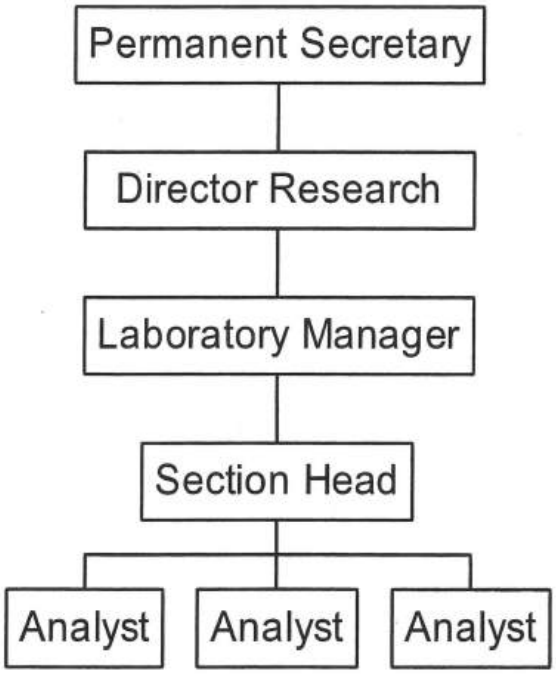

Figure 1. XYZ laboratory staff organisation chart

Job descriptions for the positions from Laboratory Manager down are contained in Appendix 2.

3.2.1 PERMANENT SECRETARY

The Permanent Secretary has overall responsibility for management and financial decisions covering the direction, safety and working environment of the Ministry. Decisions involving the hiring of staff and the purchase of equipment for the laboratory are made by or through the Permanent Secretary. The Permanent Secretary reports to the Minister.

3.2.2 TOP MANAGEMENT

The Director Research and the Laboratory Manager together comprise the top management team for the laboratory. Top management have the following responsibilities:

- To ensure laboratory personnel are aware of the importance of the relevance and importance of their activities and how they contribute to achievement of the objectives of the management system.
- To ensure that appropriate communication processes are established within the laboratory and that communication takes place regarding the effectiveness of the management system.
- To provide evidence of commitment to the development and implementation of the management system and continually improving its effectiveness.
- To communicate the importance of meeting customer as well as statutory and regulatory requirements.
- To ensure the integrity of the management system is maintained when changes to the management system are planned and implemented.

3.2.2.1 DIRECTOR, RESEARCH

The Director Research has overall responsibility for the safety and work of the XYZ Laboratory. The *XYZ* Laboratory Manager and staff report to the Director. The Director reports to the Permanent Secretary.

3.2.2.2 LABORATORY MANAGER

The Laboratory Manager is a principal technician who reports to the Director, Research. He has the overall responsibility and authority for technical operations and the provision of resources needed to ensure the required quality of laboratory operations. The Deputy Laboratory Manager, a senior technician, will take on these roles and responsibilities in his absence.

The Laboratory Manager:

- Serves as the primary contact for the laboratory - liaises with customers, reviews requests and contracts, accepts work for the laboratory.
- Has financial responsibility for the purchasing of laboratory supplies.
- Issues jobs to technicians, and monitors overall workload.
- Provides adequate supervision of laboratory personnel.

- Ensures suitable training is provided for new personnel or when new techniques and/or instrumentation are introduced.
- Is responsible for all data produced by the laboratory
- Is responsible for performing a final overview of each job and then reporting it to the customer.
- Provides leadership promoting a work culture that stresses the importance of safety, integrity, data quality and meeting customer requirements as well as statutory and regulatory requirements.

The Laboratory Manager is *A.B. Cdefg*. The deputy Laboratory Manager, who assumes the above responsibilities in the absence of the Laboratory Manager, is *H.I. Jklmnop*.

3.2.3 QUALITY MANAGER

The Quality Manager has responsibility and authority for ensuring that the management system related to quality is implemented and followed at all times. This involves fulfilling of quality assurance requirements and implementing good laboratory practice. He is responsible for ensuring compliance with ISO/IEC 17025. In this regard, the Quality Manager has direct access to the highest level of management at which decisions on laboratory policy or resources are made.

The Quality Manager:

- Ensures necessary calibration activities are carried out according to schedule.
- Reviews the results of proficiency programmes.
- Ensures appropriate actions are taken as a result of quality control indicators.
- Will identify and record any quality problems in testing work.
- Has the authority to restrict further testing work until deficiencies have been rectified.
- Has the authority and resources needed to identify and initiate actions to prevent or minimise departures from the management system and testing procedures.
- Ensures that personnel are aware of the importance and relevance of their activities and how they contribute to the achievement of the objectives of the management system.

The Quality Manager is *Q.R. Stuv*. The deputy Quality Manager, who assumes the above responsibilities in the absence of the Quality Manager, is *W.X. Yzabc*
Note: for small laboratories, the Laboratory Manager can also be the Quality Manager and the Deputy Laboratory Manager can also be the Deputy Quality Manager.

3.2.4 SECTION HEADS

Section heads are senior technicians who assume responsibility for a certain section of the laboratory's work in areas where they have specialist expertise, such as for a piece of equipment or package of laboratory analyses. They lead the development of operating procedures and practices within these areas and supervise and manage technicians in their section.

3.2.5 LABORATORY ANALYSTS

Laboratory analysts are technicians working in the *XYZ Laboratory*, carrying out analyses to good laboratory practice standards. Analysts have a responsibility to:

- Follow appropriate analytical methods and standard procedures.
- Ensure all appropriate Quality Control (QC) activities are performed as described by the method.
- Ensure the Laboratory Manager is notified when qc indicators do not meet the required criteria.
- Ensure all analytical and qc activities are properly documented.
- Show a commitment to compliance with ISO/IEC 17025.
- Contribute towards achievement of the laboratory's objectives each year as well as achieving their own individual objectives.
- Be mindful of opportunities for improvement in all aspects of the laboratory management system and communicate these to the Laboratory Manager.

The laboratory's work is spread over a wide range of sample types and analyses. Due to the small number of technicians and to maintain flexibility of staff placements, job descriptions define staff responsibilities so that specialisation is avoided. All technicians receive training to operate all instruments and carry out all methods. Tasks related to the management system, such as purchasing, equipment calibration and instrument maintenance are spread amongst the technicians and appropriate training for them given.

3.2.6 CONTRACTED PERSONNEL

Normally, laboratory technicians working in the *XYZ Laboratory* are permanent employees. It may however be necessary at times e.g. due to seasonal work influx, to hire outside additional personnel on short-term contracts. It is the Laboratory Manager's responsibility to ensure that such personnel are trained to do the tasks required, are supervised and that they work in accordance with the laboratory's management system.

3.3 KEY TECHNICAL PERSONNEL

3.3.1 POLICY

Key technical personnel (KTP) authorise the release of test results and issue formal test reports thus taking responsibility for the content of that report. The appointment of KTP is a formal internal process using documented criteria and position specifications, as described below, carried out by laboratory top management. They are supervisory staff who are competent and experienced in the technical areas that they sign for. They must be able to oversee operations and cope with any problems that arise in their work or that of other laboratory staff.

The laboratory maintains a list in Appendix 3 of its KTP which defines the areas of testing for which they hold responsibility; together with a cv-type summary of their qualifications and experience. The list is reviewed annually for currency.

3.3.2 PROCEDURE

The Laboratory Manager is responsible for assessing whether staff can be confirmed as key technical persons. This is done by comparing their summary CV of qualifications and experience, together with their lab training record, against the following position description:

Position Description:	Key Technical Person
Main function of Position:	To take responsibility for the validity of outputs from their particular testing area within the laboratory.

Person Specification:

- Relevant tertiary science qualification.
- The necessary scientific expertise and experience to be aware of and understand any limitations of the test procedures, and to fully understand the scientific basis of the procedures.
- A position in the staff structure which gives the authority to implement necessary changes in the laboratory operation to ensure the integrity of test results is maintained i.e. a minimum of senior technician/section head status.
- A position where they can maintain a working knowledge of the quality assurance and technical systems in operation in the laboratory on a day-to-day basis.
- A working knowledge of and commitment to the quality and technical management principles of ISO/IEC 17025.
- Sufficient experience in the *XYZ Laboratory* to address all of the above points.

Key Accountabilities:

- Management: Responsible for completion and reporting of assigned tasks on time, accurately and to agreed standards of quality. Will have the knowledge, responsibility and authority to identify and resolve problems.
- Strategy: Will have the knowledge, responsibility and authority to develop and implement new operational procedures.
- Leadership: Will have the knowledge, responsibility and authority to design quality control programmes, set action criteria and take action when these criteria are exceeded.
- Extent of Influence: Expected to be recognised by peers, some external as well as internal, as a source of advice or comment.
- Complexity of tasks: Need the ability to allocate and manage resources (staff and equipment.)

If the candidate's CV confirms their suitability for key personnel status, the Laboratory Manager will ask them a series of questions for each of the tests and associated quality control parameters. Another set of questions will be used to gauge understanding of the laboratory's quality system. These questions will not be a standard set in order to avoid candidates being able to "study" for the correct answers; rather they will be posed at the time using the Laboratory Manager's knowledge of the candidate. The questions used, together with the candidate's responses, will be recorded. A summary will be made of the assessment process, including a final decision on whether key technical personnel status is given. A certificate is issued to confirm key technical personnel status; copies are maintained in Appendix 3.

3.4 ADMINISTRATIVE AND SUPPORT PERSONNEL

3.4.1 HUMAN RESOURCES

The Human Resources (HR) section is responsible for maintaining records of the educational and professional qualifications, and training, skills and experience of all technical personnel. It is the responsibility of laboratory personnel to advise HR of any training completions and supply them with verification such as certificate copies so that records can be kept up to date.

3.4.2 FINANCE

Laboratory personnel interact with the Finance Team in a number of activities including purchasing, setting up job budgets, expense claims and invoicing. The Finance Team are responsible for the storage and retention of all documentation relating to purchasing, including original purchase orders, tax invoices and credit notes.

4. TRAINING

4.1 POLICY

The Laboratory Manager is responsible for ensuring the competence of all personnel who perform tests, operate equipment, evaluate results and sign test reports. To achieve this, all laboratory personnel must have education, experience and training commensurate with responsibilities. Detailed consistent training procedures are of the utmost importance in ensuring personnel are competent before performance of duties without direct supervision is allowed. Further, any personnel assigned new duties must receive appropriate training. Supervision will be provided as required throughout the training period. The Laboratory Manager is responsible for:

- Reviewing training records of laboratory staff annually for currency.
- Assessing training requirements for the coming year.
- Sourcing suitable training.
- Making budgetary provisions for staff training.
- Ensuring that laboratory staff register and attend all scheduled training.
- Ensuring training completions are recorded.

4.2 INITIAL TRAINING

New staff undergo an induction process that includes the following:

- General induction from Human Resources staff covering basic employment conditions.
- A briefing from the Laboratory Manager on the functions of the laboratory, its place in the overall organisation, the services it provides, the laboratory's structure staffing arrangements
- A tour of the laboratory and introduction to staff
- An introduction to the laboratory manuals and other laboratory documentation
- Instructions on the duties required, including a copy of the relevant job description
- Basic safety instructions and a description of safety policy and equipment available. The Safety Manual must be read and signed off.
- Training in the laboratory Quality System, including this manual and its relationship with ISO/IEC 17025.
- Training in the operation, maintenance and fault-finding for the range of instruments and equipment used in the laboratory.
- Graduated training in relevant analytical methods, data transfer to calculation spreadsheets, filing of results, etc.

4.3 ONGOING TRAINING

The *XXX department of YYY* recognises that the great majority of staff regard their work as a profession and want to progress by acquiring and enhancing their skills and expertise. This also benefits the company, as for long-term viability it is necessary that employees continually develop their skills in relevant areas.

Suitable training can include:

- Health and safety training in safe work practices (e.g. four wheel driving, first-aid.)
- Technical training such as for specific analytical techniques such as FIA and ICP.
- Attendance at workshops and conferences such as those run by the South Pacific Agricultural Chemistry Network (SPACNET) or the Australasian Soil & Plant Analysis Council (ASPAC.)
- Short courses and relevant university or technical institute courses.
- Communication e.g., presentation skills, scientific writing.
- Time and project management.
- Management and business skills such as accountancy or marketing.
- Leadership and interpersonal skills.
- Software packages such as Excel, Access and Systat.
- Expert witness training for those who may appear before tribunals or other courts as a professional witness.

4.4 EVALUATING TRAINING EFFECTIVENESS

Training in laboratory operations is verified and competency assessed by successful analysis of Quality Control (QC) samples under the laboratory's Analytical Quality Control (AQC) programme. Proficiency criteria have been established using levels of:

- Introduced - method, technique or instrument operation performed under direct supervision.
- Competent - minimal supervision is required.
- Key Technical Personnel (KTP, formerly Expert) – no supervision required. Considered competent to train others in that particular method, technique or instrument operation.

Details of this type of training are recorded *where*.

Other forms of training undertaken are reviewed at the annual performance appraisal to assess the effectiveness of the training with regard to why it was undertaken. This information is then used by the Laboratory Manager in making decisions on future training.

5 ENVIRONMENT

5.1 LOCATION

The *XYZ Laboratory* is located in the *Abc Building* in the town of *Qprst.* This Quality Manual covers the activities at this site. The physical location of the laboratory and address for courier deliveries is:

5.2 CONTACT DETAILS

The mail contact for the laboratory is:

Other contact details are:

Phone:
Fax:
Email:
Website:

The Laboratory Manager can be contacted for any after hours/emergency matters on:

5.3 ACCESS

5.3.1 VISITORS

Access to the *Abc Building* is controlled by Reception. Visitors must be signed in and issued with a Visitor pass tag. Visitors must be warned of any hazards they may be exposed to. An *XYZ Laboratory* lab staff member must take responsibility for their presence beyond Reception, and should accompany them at all times within the laboratory areas. Attention should be paid to protect customer information from being inadvertently observed by visitors. Casual visits to the laboratory area by other staff are discouraged.

5.3.2 AFTER HOURS

Laboratory areas are kept locked and alarmed outside normal working hours. Laboratory personnel are issued with keys and alarm pass codes to enable them access.

5.3.3 SERVICE PERSONNEL

Service personnel will not be permitted to enter laboratory areas to work on any utilities without prior approval from the Laboratory Manager to safeguard the inadvertent disruption to work in progress. Regular cleaners have unaccompanied access to laboratory areas only after undergoing health and safety induction. They need to be shown where to find after-hours contact information for laboratory management to be able to report any incidents or problems.

5.4 FACILITIES

A floor plan of the *Abc building* where the *XYZ Laboratory* is located is given in Appendix 4. Care must be taken to ensure that facilities and conditions do not compromise the quality of results. This includes environmental aspects such as lighting, ventilation, temperature and humidity as well as utility services such as electricity voltage and supply, compressed air, gases and water. Utility equipment is maintained using external service contracts to ensure systems perform reliably. The timing of service events is approved in advance by the Laboratory Manager to ensure testing work is not affected.

Tests with specific requirements in regard to such parameters have these documented as part of the methodology. Where specific conditions are required by a method, or where they may influence the quality of results, the level or status at the time of testing shall be checked and recorded. If conditions are outside allowed limits then the Laboratory Manager will investigate the problem and liaise with the Building Manager if necessary to get repairs underway. Certain testing activities may be stopped until the problem has been rectified. The procedure for non-conforming work will be followed in order to investigate whether any work in progress or recently completed has been affected. Further testing will not resume until corrective action has been taken.

5.4.1 LIGHTING

The building has been designed to utilise natural lighting as much as possible, complemented by fluorescent lighting where needed. To assist in meeting sustainability targets related to energy consumption, staff are encouraged to turn off unnecessary lights; however this must not compromise any aspects of the testing process or safety.

5.4.2 VENTILATION

Windows in laboratory areas are not opened except in extremely hot weather, in order to keep contamination from external sources to a minimum. The soil preparation room has a secondary extractor fan that operates to removes warm moist air from the room and speed the drying process when samples are being dried in the drying cabinets.

5.4.3 DUST EXTRACTION

Sample preparation and extraction areas need to be kept separate from analytical areas. This is to contain contamination and to eliminate potential contamination from specific areas that require low ambient background levels. Working directly with soil or plant material is restricted to designated preparation, grinding and weighing rooms. Incompatible activities, such as the grinding of soils and the grinding of plants, are carried out in separate rooms to prevent cross contamination. Preparation rooms are equipped with ventilation systems that operate to protect the health of personnel working in the rooms and to minimise the spread of dust to other work areas. Dust masks and hearing protection must be worn at all times when grinding is being done. At the end of use, grinding rooms and equipment should be cleaned by vacuuming and later wet-wiping.

5.4.4 FUME EXTRACTION

Extractor fans are in place above the flame atomic absorption spectrophotometer to remove fumes generated. They are turned on whenever the instrument is in use, and left on for a further 30 minutes after the run is finished to clear any residual fumes.

The fume cupboard is used for acid work and high temperature kjeldahl digestions. It is also turned on when the muffle furnace is in use to remove smoke and ensure a continuous airflow to aid combustion. A second fume cupboard is used for any work involving organic solvents, and medium temperature extractions using the water bath. Digestions for metals analyses are carried out in this fume cupboard to avoid any copper contamination from the catalyst used in kjeldahl digestions.

5.4.5 TEMPERATURE

Temperature is an important factor in methods involving extractions, often governing extraction efficiency, so rooms where shakers are located need to be temperature controlled. These room temperatures are monitored and recorded daily. Data is plotted onto pre-printed sheets kept beside the thermometer in each room. Allowable ranges are marked on the sheets with shading. Completed monitoring sheets are archived.

5.4.6 ELECTRICAL SUPPLY

Susceptible instruments are connected to an uninterruptible power supply (UPS) which maintains a continuous supply of electric power by supplying power from a battery when mains power is not available. As well as compensating for total loss of mains power the UPS can also ensure constant voltage, filtering out the effects of disruptions such as voltage spikes or under voltage which could potentially damage equipment or lead to data loss.

5.4.7 COMPRESSED AIR

Compressed air is supplied from a central compressor to instrumentation in several locations. Water traps are in place prior to the instrument connection, and there are operating procedures which remind users to check traps at the start of each run.

5.4.8 WATER

Reverse-osmosis (RO) grade water used for washing labware is supplied to all preparation areas from a central plant. Supply water from the main reticulation system is passed through a softener to remove the high levels of calcium and iron. The softened feed water then passes through two particulate filters and an activated charcoal cartridge before passing through the RO cartridge. The product water, which has a conductivity of less than 10 µS, is stored in a reservoir in the plant room. An alarm sounds when the reservoir get down to about the quarter full level.

Deionised (DI) water is used for the preparation of **all** reagents and standards, even though methods may have written just "water" rather than DI water specifically. DI water is reagent grade water with electrical resistivity of at least 10 megohm-cm (conductivity less than 2 µS) produced by a MilliQ ion-exchange system. The MilliQ unit processes RO feed water through an activated carbon cartridge which removes dissolved organic contaminants and residual chlorine, then two ion exchange cartridges which remove dissolved inorganic electrolytes, and finally a 0.22 μm filter to remove any particles or micro organisms. Because output from the unit is slow, small quantities of DI water are kept in 10-litre storage tanks. Note that some methods may specify the use of freshly generated DI water, especially for tests that may be affected by changes in pH or increased inorganic carbon levels due to dissolution of atmospheric gases upon standing.

The conductivity of both RO and MilliQ water is monitored and recorded daily with data plotted onto pre-printed sheets. Allowable ranges are marked on the sheets with shading. Completed monitoring sheets are archived. A trend of rising conductivity, even within the shaded area, indicates system maintenance is required. Laboratory personnel are responsible for maintenance of the systems, with the frequency and procedures specified in the RO and MilliQ water systems SOPs.

5.5 HOUSEKEEPING

Housekeeping must be of a high standard at all times, for reasons of safety as well as for quality of results. There is an SOP detailing cleaning procedures for various labware. Washing-up should be done as soon as possible after completion of a test to avoid residues becoming dried on, and to make equipment available for other users.

The facility is cleaned by after hours on a regular basis to ensure that environmental contamination is minimised. Cleaners will vacuum and polish floors and empty waste and recycling bins. Wiping of benches and window sills is to be done by lab personnel due to frequent work-in-progress on benches. Lab personnel jointly carry out a major clean of lab areas annually, usually just before the summer break. Tasks include dismantling of fume cupboard baffles for full cleaning, and emptying of the silt-traps beneath all sinks.

5.6 SUSTAINABILITY

5.6.1 POLICY

The *XXX department* of *YYY* is fundamentally committed to protecting and enhancing the environment. It is therefore important to have adequate checks and balances in place to ensure that our own activities do not adversely affect the environment in a significant manner and that we strive to continually improve our own in-house environmental performance. Accordingly, we have adopted a statement of environmental obligations and objectives that is included in our sustainability policy. Laboratory staff need to be familiar with the policies and SOPs in regard to regarding reducing our environmental effects in areas such as:

- Discharges to the sanitary sewer.
- Waste disposal.
- Air pollution.
- Hazardous substances.
- Energy and water consumption.

5.6.2 LIQUID WASTE DISPOSAL

The use of modern instrumental techniques ensures that the *XYZ Laboratory* generates only small quantities of liquid chemical waste. These are disposed of to the sanitary sewer in combination with water diluent. These discharges are in compliance with *Pqrst town council* regulations. Methodology has been reviewed to ensure such chemicals are generally of low toxicity in nature; anything regarded as significantly toxic is disposed of by a commercial firm. Organic liquids are not used in significant quantity in the laboratory, and any waste is disposed of via evaporation in a fumecupboard (see 5.6.4 below.)

5.6.3 SOLID WASTE DISPOSAL

Excess sample material and samples that have been analysed need careful disposal due to the biosecurity risks from the possible presence of pest organisms in soil or the ability of plant material to propagate. Such material is disposed of to landfill via the general rubbish skip. Samples with quarantine status must be incinerated or autoclaved prior to disposal.

5.6.4 AIRBORNE WASTE DISPOSAL

Hazardous fumes are discharged to the atmosphere via fumecupboards and extractor fans, in accordance with *Pqrst town council* regulations.

5.6.5 RECYCLING

The *XXX department* of *YYY* has a goal of achieving zero waste by 2010. The *XYZ Laboratory* contributes to this as follows:

- Using paperless systems wherever possible e.g. electronic data capture and transfer from instruments.
- Using the double-sided printing capability of printers and photocopiers.
- Placing paper waste in the paper recycling bins.
- Rinsing empty glass chemical containers and placing in the glass recycling wheelie bin.
- Placing plastic waste such as empty sample vials, rinsed chemical containers and pipettor tips in the plastics recycling bin.
- Sorting packaging waste (cardboard boxes, bubble wrap etc) to place in the appropriate recycling areas.

Large containers used to hold low toxicity chemicals e.g. 10-litre aluminium acetone drums, plastic ethanol jerrycans, are thoroughly rinsed and offered to staff for alternative uses such as storage of waste at field stations.

5.7 SAFETY

5.7.1 POLICY

The *XXX department* of *YYY* is committed to the provision of a healthy and safe work environment for its staff; to protecting its staff, visitors, contractors and the public from accidental injury or harm; and to developing an active programme to manage unscheduled leave through preventative health care.

To meet this commitment top management undertake to:

- Comply with all health and safety legislation and related regulations, codes of practice and standard operating procedures.
- Record and report all accidents, incidents and related information accurately.
- Provide resources to eliminate, isolate or minimise identified significant hazards.
- Provide training and proper equipment to ensure staff are competent and suitably equipped to carry out their jobs safely.
- Implement systems and procedures to document safe work policies and practices.
- Manage health and safety through groups including staff representatives which will encourage staff to contribute to and participate in the identification and management of workplace hazards.
- Continuously improve health and safety management and report annually on this.
- Conduct annual self-assessment audits of health and safety.
- Encourage the early reporting of work-related discomfort and pain and to manage these situations to avoid injury wherever possible.
- Manage timely social and vocational rehabilitation at work, of injured staff, in an open and consultative manner.

The policy requires that staff undertake to:

- Comply with all health and safety legislation and related regulations, codes of practice and standard operating procedures.
- Comply with all company health and safety procedures, practices and rules.
- Not engage in any workplace activities likely to endanger themselves or others.
- Always use protective equipment and safe work practices.
- Immediately report any new hazards observed in the work place.

5.7.2 PROCEDURES

The *XYZ Laboratory* has its own Laboratory Safety Manual which all personnel wishing to work in the laboratory must read and sign before commencing work. Generic safe methods of use (SMOU) for the various classes of chemicals are contained in an appendix to the manual and are displayed prominently in the laboratory. Other sections in the manual relate to task-specific procedures such as electrical safety, fieldwork, leptospirosis and manual handling. The Hazards Register section contains a list of hazards which have been identified and the SOPs, practices, personal protective equipment and training requirements put in place to isolate or minimise the risks involved. The section on workplace accidents deals with what to do if accidents do occur.

6 EQUIPMENT

6.1 POLICY

The *XYZ Laboratory* has all items of measurement and test equipment required for the correct performance of tests. Where the lab needs to use equipment outside its permanent control, it will ensure that all necessary requirements e.g. calibration and maintenance, for such equipment have been met. If such equipment needs to be borrowed on more than one occasion then the Laboratory Manager is responsible for investigating whether the laboratory needs to purchase that equipment for future use.

Equipment and its software must be capable of achieving the accuracy required and will comply with specifications relevant to the tests concerned. Calibration programmes have been established for key areas of instrumentation where these properties have a significant effect on the results.

6.2 INVENTORY

The laboratory maintains an equipment inventory for all equipment *in the form of an Access database*. Each item has the following records:

- Unique identifier of the form *XYZ###*.
- Equipment identity.
- Equipment type.
- Serial number.
- Current location.
- Purchase date.
- Purchase price.
- Supplier and/or service agent.
- Estimated working life.
- Tentative replacement date.
- Notes e.g. if the equipment is no longer in use.

6.3 EQUIPMENT PURCHASING

Equipment items costing less than $### may be purchased at any time using the laboratory budget under the financial delegation of the Laboratory Manager. Typically this covers items such as beakers, timers, thermometers etc. Items costing more than $### are categorised as capital expenditure (capex), and a case should be prepared containing the following information:

- Justification e.g. number of samples processed, improved detection limits, less maintenance, replacement of old or obsolete equipment, new methods, etc.
- Any health & safety/compliance/ environmental effects that will be improved by the purchase.
- Cost estimate, preferably at least two quotes from different suppliers.

6.4 COMMISSIONING OF NEW EQUIPMENT

Prior to being placed into service, equipment and associated software used for testing is fully evaluated by the laboratory staff to establish that it meets the specification requirements and complies with any relevant performance standards. Where necessary, equipment will be calibrated before first use. Results are stored in the appropriate method validation file.

6.5 AUTHORISATION

Specific authority is not required to operate any equipment. Technicians whose equipment training is at the "Introduced" level will use that equipment under supervision. Once a training record shows that the "Competent" level has been achieved then they are able to use that equipment unsupervised. Some areas of equipment software e.g. relating to operating parameters or calibrations may be password-protected to restrict access to personnel with both the training and authority to make changes in those areas.

6.6 OPERATING PROCEDURES

All equipment is usually supplied with operating instructions. These manuals are the primary source of information about operation, calibration and maintenance. Original manuals are stored in box files in the instrument room. However, because these manuals are usually too detailed and complicated for everyday use, standard operating instructions (SOPs) have been written up for most equipment. Hard copies are available beside each instrument. A number of SOPs will include pre-use checks and shut-down procedures as well as basic operating instructions. Shut-down procedures in particular are important in ensuring that equipment is clean after use and appropriate steps are taken to prevent deterioration such as algae growth which can block tubing.

6.7 CALIBRATION

Most instruments are either calibrated before use or have an existing calibration verified before use. Calibration requirements are detailed in the SOP for each equipment item. Traceability of calibrations is dealt with in section 7 of this manual. Results of calibrations are recorded in the equipment operating and maintenance log which is held in a combined folder with the SOP beside the equipment. Items requiring periodic rather than each-use calibration are labelled with a small yellow sticker indicating the date when recalibration is due. This includes pipettor, dispensers, timers and ovens. Ongoing checks on the operational efficiency of equipment are obtained through testing of Laboratory Check Samples (LCS) as described in section 12.4.

6.8 MAINTENANCE

Proper maintenance of laboratory equipment is a key ingredient to longetivity, reliability and performance. Maintenance procedures for major equipment items are described in the equipment SOPs. Any maintenance carried out is recorded in the equipment's operating

and maintenance log. A conservative inventory of critical spare parts is maintained for high-use instrumentation. Other parts are ordered as and when required. Scheduled maintenance and trouble-shooting of equipment is carried out by laboratory staff who have had specialised training in that area either by the equipment service agents or by other trained laboratory staff.

An external electrical company is contracted to carry out a bi-annual electrical safety check of all electrical equipment. All items tested have a sticker affixed to the power cord recording the details of the testing and date for retest. Items that fail this check are tagged and taken out of use until repaired.

Ongoing checks on the operational efficiency of equipment are provided through the laboratory's analytical quality control programme. Additional checks may be conducted if the performance of the instrument is suspect, or as part of a quality problem investigation as described in section 13 of this manual.

6.9 SERVICE AND REPAIR

Equipment that has been subject to overloading or mishandling gives suspect results or has been shown to be defective or outside specified limits will be taken out of service. If possible, it will be isolated, clearly tagged as being out of service and an explanation for this will be provided. After repair, the equipment will be tested and recalibrated if necessary before the tag is removed and the equipment placed back in service.

Similarly, if an equipment item is lent outside the laboratory it must be tagged and not returned to service until it has been tested and recalibrated if necessary. The effect of the defect or departure from specified limits on previous tests using that equipment will be examined using the quality problem investigation procedure described in section 13 of this manual.

Laboratory personnel who have had suitable training may carry out minor service jobs. This is normally done under instruction from the service agents. More complex jobs are done by the agents themselves. Any repairs involving mains or high voltage components are to be performed only by personnel holding current electrical registration

6.10 TRANSPORT AND STORAGE

Major equipment items, such as instruments, are not to be moved. If relocation is necessary, then the manufacturer's instructions should be consulted to secure the instrument so that no damage is incurred. After a move, the equipment shall be tested to check performance, and recalibrated if necessary.

The portable balance should be used where a balance must be carried around. If any other balance has to be moved, the technician responsible for balances should be consulted to ensure calibration checks are conducted before use both in the new location and on return.

If any equipment item is to be out of use for a significant length of time it should be prepared for storage according to the manufacturers instructions. Before use again, the proper flushing and/or conditioning steps need to be carried out before recalibration.

7 TRACEABILITY AND CALIBRATION

7.1 POLICY

All testing equipment having a significant effect on the accuracy of the result shall be calibrated using established procedures before use. Further, the calibration programme will be operated so that calibrations are traceable to the International System of Units (SI). Measurements are traceable when they can be related to recognised standard references through an unbroken chain of comparisons, each with stated uncertainties.

7.2 NATIONAL MEASUREMENT STANDARDS

The *XYZ Laboratory* uses the services of the *Measurements Standards Laboratory (MSL) of New Zealand*, who are responsible for maintaining the national standards for the basic and derived SI units under the authority of government legislation. Their calibrations are issued under the *Measurement Standards Act 1992 and the National Standards Regulations 1976 (Amendment No. 1, 1992)*, and by definition meet laboratory accreditation requirements. Traceability to national measurement standards can also be obtained via third party laboratories accredited for such measurements.

7.2.1 TIME

The time and frequency standard consists of *three commercial caesium atomic clocks that are maintained in continuous operation by MSL.* The time and frequency of these clocks is known from regular time transfers with the International Bureau of Weights and Measures (BIPM) in Paris. *MSL operates a talking clock derived from the caesium clock that is available to the public via the Telecom 0900 service.* The SOP for calibration of laboratory timers details how changes in time from two calls to the talking clock are used to enable traceable calibration.

or

Time signals are broadcast by *Radio New Zealand* on the *National Radio station*. These are derived from the *MSL caesium clocks* and are transmitted every hour. They consist of six "pips" of 1000 Hz tone, at one second intervals, the beginning of each pip marking the exact second. When a pip marks the exact hour, its length is doubled. The SOP for calibration of laboratory timers details how changes in time from two broadcasts of time pips are used to enable traceable calibration.

7.2.2 MASS

The SI unit of mass is the kilogram (kg), and it is equal to the mass of the International Prototype Kilogram (IPK). The IPK is a cylinder of Platinum Iridium alloy kept at the BIPM in France. *MSL hold New Zealand's primary standard of mass (called P1); a stainless steel weight, nominally of mass 1 kilogram. Every five years a kilogram weight is sent to BIPM for calibration, and when this returns it is weighed against P1, thus ensuring traceability of the mass of P1 to the IPK. The primary kilograms are used to establish a scale of mass from 1 milligram to 20 kg by a build-up and build-down process, in which a series of groups of reference weights are weighed. These reference weights are used for calibrating weights for trade, industry and analytical services.* The *XYZ Laboratory* holds

a set of weights calibrated by *MSL* which are used for used for balance calibration. Their use is described in the SOP on balance checking and calibration.

7.2.3 TEMPERATURE

The measurement community, through the SI system maintained by the General Conference of Weights and Measures (CGPM) in Paris, defines a temperature scale that is periodically updated. Instead of a true metric temperature scale the CGPM has defined a more practical scale based on defined temperatures for the melting, freezing and triple points of pure substances, and approved interpolating thermometers that define the temperature at intermediate temperatures. This scale, which is reproducible to about 1mK for temperatures below a few hundred degrees Celsius, is updated approximately every 20 years. The current version is called the International Temperature Scale of 1990, or ITS-90.

The *XYZ Laboratory* uses a third party accredited calibration laboratory (*Lmnop Laboratories*) for the calibration of the reference thermometer. Such calibration is traceable to the ITS-90 through an unbroken chain of measurements via *MSL*. A thermometer calibration SOP describes how working thermometers are calibrated against the reference thermometer.

7.3 CALIBRATION INTERVALS

IANZ lists guidelines on calibration requirements and recalibration intervals for specific equipment items in Appendix 3 of Specific Criteria for Accreditation Chemical Testing 2 (2004). The guidelines are maximum permitted recalibration intervals established by industry practice; however extended intervals may be accepted based on factors such as history of stability, accuracy required and ability of staff to perform regular checks. It is the responsibility of the laboratory to provide evidence that its calibration and maintenance systems will ensure that confidence in the equipment can be maintained.

In the *XYZ Laboratory*, all items of testing equipment are calibrated before being put into service, and further calibrated in accordance with the programme in Table 1 below. If any suspicion of overloading or mishandling occurs the equipment in question will be checked immediately and thereafter at frequent intervals until it can be shown that stability has not been impaired.

Equipment Type	Calibration Interval	Procedures
Burettes, dispensers, pipettors	Initial then 3-monthly	Accuracy & repeatability at volumes in use. Gravimetric check.
Balances	Initial calibration then 3-yearly recalibration	By an accredited calibration laboratory or alternatively, by formally trained staff using traceable certified masses.
	Each weighing	Zero check
	Monthly	One point check using known mass close to balance capacity
	Six monthly	Repeatability checks at upper & lower ends of the scale
Barometer (aneroid)	One year	Telephone comparison with nearest meteorology office.
Conductivity meter	Each use	Check using appropriate standards
Digestion block	Two years	Temperature variation check across working spaces using thermocouple.
Furnace	Each use	Monitor temperature with appropriate sensor.
	Six month	Accuracy check of sensor using melting point of known material.
	Two years	Temperature variation within working space sensor using melting point of known material.
Masses	Initial calibration	By accredited calibration laboratory
	Three years (first recalibration)	By accredited calibration laboratory
	Five years (subsequent recalibrations)	By accredited calibration laboratory
pH meter	Each use	Calibrate using at least 2 appropriate standard buffers.
Thermometer – reference	Five years	Complete calibration by an accredited calibration laboratory
	Six months	Ice point
Thermometers - working	Initial	Check against reference thermometer across working range
	Six months	Ice point and/or normal working temperature
Thermostatically controlled equipment (incubators, ovens, waterbaths)	Daily	Monitor temperature and record
	Two years	Temperature variation within working space.
Timers	One year	Comparison against radio time pips or talking clock.

Table 1. Recommended calibration intervals

Standard operating procedures are used for the calibration of these items. Every equipment item requiring scheduled calibration carries a yellow dot sticker indicating when recalibration is next due. Calibration data is stored in the Calibration subdirectory of the Quality Assurance directory.

7.4 TRACEABILTY OF CHEMICAL SUBSTANCES

Where parameters in a test are defined physical measurements such as temperature or mass, the traceability chains are well established. Often however the parameter is an instrument response (peak height/area, absorbance, etc) compared with a calibration from a known amount substance – a reference standard. Where traceability to SI units is not possible or relevant, traceability to other appropriate reference standards such as certified reference

materials is acceptable. Testing laboratories are expected to source their reference materials (RMs), including analytical standards, from the following sources (in decreasing order of preference) where availability permits:

- Certified reference materials (CRMs) from national measurement institutes e.g. NARL in Australia.
- CRMs from reference material producers accredited to ISO Guide 34.
- CRMs and RMs from well established and reputable reference material producers.
- Reputable chemical supply houses (particularly for pure analytical standards.)
- In-house produced reference standards.

Participation in Inter-Laboratory Comparison Programmes provides a means of maintaining confidence in reference materials and analytical standards. Poor performance may result in the calibration status of these materials being examined.

In addition, for empirical methods where the measurand is defined by the method of measurement used e.g. Olsen-extractable phosphorus, traceability relies on the laboratory complying in full with the method as published. The EC Lab uses published methods for all tests. Where there is deviation from the published method full validation against the primary reference method has been carried out to establish the relationship with results achieved by the reference method.

7.4.1 ANALYTICAL STANDARDS

Chemicals used for preparation of analytical standards need to be of the highest grade available. Suppliers must be able to provide certificates of analysis on request. The *XYZ Laboratory* uses chemicals only from reputable suppliers such as *APS, Biolab and Pure Science* who have in-house accredited QC laboratories performing analyses of materials in-process and as finished products to ensure that they comply with specifications to American Chemical Society (ACS) or International Organisation for Standardisation (ISO) requirements. Acceptable brands and grades are listed in Table 2 below.

Brand	Grade	Features
Ajax	UniVar	High purity analytical grade
BDH	AnalaR	High purity, extensive specifications, batch to batch reproducibility Specifications are maximum impurity levels rather than "typical batch" analyses
	Aristar	Exceptionally pure, tested for large number of potential impurities down to ppb levels
	ColourKey	Colour-coded pH buffers NIST traceable
	SpectrosoL	Specially purified & packaged standards for metals analyses Concentrations analysed against standards verified by SRMs traceable to NIST
Merck	GR	High purity, quality exceeds requirements of ACS and ISO
	CertiPUR	NIST certified standards for metals by AAS pH buffers traceable to primary standards from NIST
VWR/Prolabo	NormaPur	High purity analytical reagents complying with ISO specifications

Table 2. Brands of chemicals suitable for use as analytical standards

Details for preparation of working analytical standards, including special steps, such as pre-drying of chemicals, are contained in the Standards section of each individual analytical method.

All standards are labelled as to analyte, concentration and matrix if other than water e.g. 2M KCl. The top standard of a set should carry a yellow dot sticker indicating the expiry date, which can be obtained from the list affixed to the door of the standards fridge. Prepared standards are kept in this fridge when not in use.

Preparation of new stock standards is recorded in the Standards and Reagent log which is kept in the Balance Room. Details include:

- Date.
- Initials of person preparing the standard.
- Brand and grade of chemical used.
- Chemical batch number if possible.
- Weight taken.
- Special steps such as drying temperature and time.

Reagents and extractants also have their preparation details recorded in this log. As well as providing traceability these records are useful when carrying out investigations into non-conforming work, where it may be that the wrong chemical was inadvertently used, or the wrong weight taken.

Before the new standards can be used to generate results they must be verified by comparison against a separate standard (the check standard), preferably one prepared at a different time by a different technician using different source chemicals. This is fully described in the Laboratory AQC Programme SOP.

7.4.2 CERTIFIED REFERENCE MATERIALS

Several problems exist with the regard to the use of certified reference materials (CRM). The first is that for soils there often simply is no suitable CRM available. While there are a number of sediment CRMs, the United Kingdom accreditation body UKAS for example do not accept that a sediment matrix is suitable for validating a method to be used for the analysis of a terrestrial soil. Where soil CRMs do exist the certified values are often only for "total" determinands rather than extractable components determined using empirical methods, such as Olsen-extractable phosphorus. Finally the cost of CRMs is often prohibitive – VWR list a CRM loam soil, certified only for total elements, available for $1000 for a 70g bottle. The *XYZ Laboratory* holds the following CRM's:

7.4.3 SECONDARY REFERENCE MATERIALS

Secondary reference materials (SRMs) are often standards produced by chemical or equipment suppliers and calibrated against certified reference materials such as those from NIST. They are usually cheaper than CRM's. The *XYZ Laboratory* has the following secondary reference materials:

7.4.4 ILPP SAMPLES

The Australasian Soil and Plant Analysis Council (ASPAC) in conjunction with Proficiency Services Ltd operate a soil and plant tissue Inter-Laboratory Proficiency Programme (ILPP). Samples are analysed by participating laboratories throughout Australasia, SE Asia, and the South Pacific. One of the benefits of participation is that the laboratory acquires a set of soil and plant samples covering a wide range of measurand levels with summarised data from the ILPP. The EC Lab utilises these as laboratory control samples for tests where the in-house laboratory control sample does not have sufficient data available, and in method validation when setting up new test methods.

7.4.5 IN-HOUSE REFERENCE MATERIALS

In its routine analytical quality control (AQC) programme described in section 12 in this manual the *XYZ Laboratory* uses laboratory control samples. These in-house reference materials are soils and plants that have been analysed many times over a number of years, and have also been analysed by other laboratories as part of sample exchanges. Those currently in use are:

8 PURCHASING & SUPPLIES

8.1 POLICY

The *XXX department* of *YYY* policy on purchasing is designed to secure goods and services at the most economically favourable terms, while ensuring health and safety, environmental and quality requirements are being met. This section of the Quality Manual describes requirements relating to purchase, reception and storage of supplies and services that are required by the *XYZ Laboratory* in testing work.

8.2 APPROVED SUPPLIERS

A register of approved suppliers of critical consumables, supplies and services that affect the quality of the laboratory's testing work is kept in the form of an Access purchasing database. Consumables shall, whenever possible, be obtained from a supplier that has obtained a minimum of ISO 9001 accreditation, and such status will be recorded in the database. Performance of suppliers is monitored continually by the purchasing technician and any problems are brought to the immediate attention of the Laboratory Manager and dealt with via the Quality Problem Report system if necessary. A short summary of supplier performance will be made for the Management Review meeting.

8.3 DOCUMENTATION

The Internal Requisition for Supplies/Services form is filled in, giving the quantity and full description of supply or service, and the required supplier. The description should include type, class, grade, specification, quality required or quality system standard. The current code for laboratory operating costs must be used. Specific delivery instructions e.g. must be kept frozen, and required delivery dates can be noted. The completed requisition must be signed by the Laboratory Manager to indicate financial approval. The requisition is sent to the company purchasing officer who then draws up an official company purchase order and submits this to the requested supplier. A copy of the purchase order is sent to the laboratory's Purchasing Technician who checks it immediately for any errors, and then holds it to check compliance when goods arrive. Full details of the purchase are recorded in the purchasing database.

8.4 DELIVERY AND VERIFICATION

Purchased supplies and services that affect the quality of tests are not used until they have been inspected or otherwise verified as complying with requirements and specifications stated in the purchase order. If the goods or services do not meet the criteria then the supplier is contacted to make arrangements to replace or repair the item.

All inwards goods are delivered to Reception who then advise the laboratory Purchasing Technician that the goods have arrived. If the goods are described as dangerous then laboratory staff must endeavour to collect them as soon as possible.

The Purchasing Technician physically segregates the goods until they have been verified. Items requiring calibration before first use, such as volumetric glassware, remain segregated until calibration has been done and compliance indicated with a yellow dot sticker. The following verification procedure is used:

- Examine packaging for any signs of damage or leakage before opening.
- Check contents for signs of damage.
- Check off contents against packing slip and purchase order.
- Conduct any activities necessary for verification of compliance with specifications. This may be as simple as checking that the grade specified on the purchase order has been supplied. Record any actions taken on the purchase order.
- Initial and date packing slip and purchase order to indicate goods delivered meet specifications requested.

Documents such as packing slips and tax invoices are sent to the company Purchasing Officer for archiving. The signed-off purchase order copy is filed with the laboratory's purchasing records after using it to fill in the date received field in the purchasing database. When the final invoice or statement is received the company Purchasing Officer will send it to the Purchasing Technician for approval for payment. This signature constitutes formal acceptance of the goods and closure of the purchasing verification.

8.5 STORAGE

When verification of compliance has been completed, the goods can then be stored in their appropriate location in the laboratory. For most consumables, the date received is written on the container or packaging. This ensures, especially for chemicals, that the oldest stock can be used first. Limited storage facilities together with health and safety regulations mean that purchasing bulk quantities of chemicals is strongly discouraged. Note:

- Chemicals must be stored in the chemical pantry according to their hazard class.
- Flammable liquids are stored in the flammables cabinet.
- Alkalis are stored in basins *where*.
- Acids are stored in basins *where*.
- Consumables such as sample containers should be kept in their transport boxes to keep them free of dust.
- Instrument spares and consumables are stored *where*.

8.6 CONSUMABLES, REAGENTS AND SUPPLIES

8.6.1 GASES

Individual gas cylinders are used where required. Cylinder size and gas purity are specified on the purchase order when gases are ordered, and the certificate of analysis should be checked for conformance before connecting a new cylinder to an instrument. Gases are obtained from approved suppliers (currently *Qwerty*) who have been found to consistently supply gases of acceptable quality.

8.6.2 ACIDS, ALKAIS AND SOLVENTS

Where the quality of these chemicals can impact on the validity of results the highest grade available should be used. Grades of HPLC solvents such as BDH HiPerSolv and Merck LiChrosolv which have good optical transparency and low levels of organic impurities which could cause background interference and reduced detection limits are preferred. Acids used for sample digestion and/or preservation of standard solutions must have low levels of trace impurities, such as BDH AnalaR and Aristar and Merck SupraPur. Ammonia is available in a number of different strengths – that used in the soil CEC method is 25% NH_3, sp gr about 0.91. This must be specified on the purchase order and verified by label check before being put into use.

8.6.3 REAGENT CHEMICALS

Method validation may determine that less than top grade chemicals may be adequate for reagent preparation; however if there is little price difference then the best grade available is preferred. All chemicals are carefully assessed for suitability through examination of blanks and laboratory control sample results before being approved for use.

8.6.4 DRUM CHEMICALS

Drum grade chemicals are so named because they are supplied in large containers or drums of 10 to 20 litres capacity (and are thus considerably cheaper). They are normally technical grade but may be suitable for certain testing uses if the method is properly validated using them. The *XYZ Laboratory* uses drum ethanol for washing excess ammonium acetate from the sample in the soil CEC test method and drum acetone for sample washing in the plant lignin method.

8.6.5 LABORATORY WARE

Laboratory ware is normally obtained from approved suppliers such as *Asdfg and Zzxcvb*. This includes items such as filter paper, pipettor tips, plastic test tubes and sample vials. All labware is subject to the purchasing verification procedure described above in section 7.4. If a new brand or product is purchased the quality must be validated before being put into use. Items not having an effect on testing quality, such as batteries and spray bottles may be purchased from non-approved suppliers such as *Mnbv* and *Lkjhg*. If there are any concerns about possible impact on quality then method validation will be carried out.

Individual test methods may specify certain types or grade of labware. Only A-grade volumetric glassware is used in the *XYZ Laboratory* and it must pass initial calibration testing before acceptance into use. Glassware in general use is borosilicate unless otherwise specified by the method e.g. tests for boron must use plastic flasks. Plastic test tubes and water sample bottles are generally HDPE, with LDPE also acceptable for soil and plant sample containers. Test tubes and caps that will be autoclaved must be polypropylene. Glassware and water samples bottles are cleaned prior to first use by triple rinsing. Soil and plant sample containers and disposable test tubes have been found not to require pre-cleaning and are used as received.

9. SERVICE TO CUSTOMERS

9.1 INTRODUCTION

Successful relationships with customers are established through effective communication. This applies right throughout a job, from review of requests and tenders (such that testing work is defined in sufficient detail to ensure the customer's requirements are satisfied) through to reports of results which include all information required by the customer. Along the way, any problems and non-conforming work are identified, documented and resolved also with communication with the customer as necessary. Unnecessary or overly expensive testing should not be undertaken, as it serves neither the interest of the customer nor the laboratory. Each contract shall be acceptable to both the customer and the laboratory.

9.2 REVIEW OF REQUESTS, TENDERS AND CONTRACTS

This section details policies and procedures the laboratory has in place for review of requests, tenders and contracts. A contract may any written or oral agreement to provide a customer with testing services. The aim of the review is to ensure that:

- The requirements, including the methods to be used, are adequately defined, documented and understood.
- The laboratory has the capability and resources to meet the requirements.
- The appropriate test method is selected and is capable of meeting the customer's requirements.

Customers often require advice and guidance in technical matters, hence request, tender and contract reviews are conducted by the Laboratory Manager who has the necessary knowledge and experience to undertake this role. Given the defined range of analytical tests offered by the *XYZ Laboratory* the review usually takes a simplified form whereby both parties discuss issues such as:

- Type of sample to be tested e.g. plant, soil, water.
- Any sample preparation required e.g. drying and grinding.
- Other work necessary as part of the test e.g. moisture factor determination to convert soil results to an oven-dry basis.
- Test methods to be used.
- Detection limit or uncertainty requirements.
- Any work that will be subcontracted by the laboratory.
- Sample requirements – amount of sample, containers, preservation, and return of samples after testing.
- Biosecurity or quarantine requirements.
- An estimate of cost or written quote.
- Timeframe – when the samples will be received, date results are required by.

During the discussion the Laboratory Manager will consider whether the laboratory possesses the capability and resources (both equipment and personnel) to carry out the work requested and within the agreed timeframe. Records of reviews should be documented and filed in the job envelope. If the review was verbal, notes should be made of all discussion points. Records should show the date and identification of the person

conducting the review. In large jobs, communication with the customer should be maintained throughout the work with appropriate records being kept.

9.3 CHANGES TO CONTRACTS

The customer must be informed (and records made of this notification) if there are any changes made to what was originally agreed upon for the job. This includes any changes to tests used, or any delays or major deviations in the performance of tests. If a contract has to be amended after work has begun, the same review process set out above must be carried out. Differences between the request or tender and the contract are resolved before any work commences. When samples arrive at the laboratory without full instructions a review must be carried out with the customer, typically by phone or email, before any work commences.

9.4 SUBCONTRACTING OF TESTS

The laboratory does not normally subcontract work. If a request is made for tests the laboratory does not perform, the customer will be referred to other laboratories known to have this capability.

Due to the nature of the *XYZ Laboratory's* work, turnaround times are not normally affected by short-term delays caused by equipment breakdown and such. However, if an unusually long delay occurs, the laboratory will look at subcontracting affected tests. In this case, the customer will first be consulted for agreement about use of a subcontractor, and approval for such will be obtained in writing. Preference will be given to using an accredited laboratory wherever possible.

Tests performed by subcontractors will be clearly identified on the test report. The report will contain the endorsement "Tests marked "**" have been performed by a subcontracted laboratory which is/is not accredited", and the relevant tests will be marked accordingly in the body of the report. The *XYZ Laboratory* remains responsible to the customer for the subcontractor's work.

The laboratory will maintain records in the Access purchasing database of all subcontractors it uses for testing work, including details of the subcontractors' accreditation status and/or competency. These records will be part of the Approved Suppliers Register.

9.5 FEEDBACK

The laboratory actively seeks feedback, both positive and negative, from its customers. Such feedback is used and analysed to improve the management system, testing activities and customer service. The most common form of feedback is in the form of informal discussions between customers and the Laboratory Manager, usually phone calls and emails that occur when negotiating new work contracts or reviewing completed work. Notes are kept of discussions together with copies of emails in the Customer Feedback folder. The Laboratory Manager compiles a feedback summary for the annual Management Review to ensure the laboratory is performing satisfactorily and to identify what could be done to

improve both our service and our management system. Complaints from customers are taken seriously. The policy and procedures for resolution of complaints is described fully in section 13 Nonconforming work and corrective action in this manual.

9.6 CODE OF ETHICS

9.6.1 POLICY

The *XYZ Laboratory* is committed to acting in an ethical manner in all aspects of the conduct of its business. This code of ethics serves to provide guidance on the ethical responsibilities to the *YYY Ministry*, other staff, our customers and the community. Often ethical questions arise over issues which are not clearly prescribed. The code is designed to help individuals understand and implement their responsibilities themselves and test the ethics of their actions. If in a particular instance the correct course of action appears to be unclear the issue should be raised with management.

9.6.2 BEST INTERESTS OF THE LABORATORY

Staff must act honestly and in good faith in what they believe to be the best interests of the *XYZ Laboratory*. They must act in a manner consistent with the good reputation of the laboratory and refrain from any conduct that might bring discredit to the laboratory, or bring harm to their colleagues.

9.6.3 LAWFUL CONDUCT

XYZ Laboratory staff must carry out their duties in a lawful manner and use reasonable endeavours to ensure that the laboratory conducts its business in accordance with the law and with a high standard of commercial morality.

9.6.4 CONFLICTS OF INTEREST

XYZ Laboratory staff must avoid conflicts of interest as far as possible. Where a conflict or a potential conflict arises they must adhere scrupulously to procedures provided by law and by the policies of the *YYY Ministry* for dealing with conflicts. Staff are considered to have a conflict of interest if they engage in any activity, investment or commitment which may adversely prejudice the ability of staff to carry out their responsibilities toward the *YYY Ministry*; may put staff in competition with the *YYY Ministry*, or may benefit others who are in competition with the *YYY Ministry*. The structure of the *XYZ Laboratory* within the *YYY Ministry* hierarchy is such that laboratory management and personnel are free from any undue internal or external commercial, financial or other pressures and influences that may adversely affect the quality of work.

9.6.5 DILIGENCE

XYZ Laboratory staff must perform their duties diligently and observe and maintain a high level of competence. They must follow the *XYZ Laboratory's* policies, rules and procedures, avoid unauthorised absenteeism and maintain accurate timekeeping.

9.6.6 CONFIDENTIALITY

XYZ Laboratory staff must observe the confidentiality of non-public information acquired by them during their involvement with the *XYZ Laboratory*. They must not discuss such information with other persons or firms nor make use of it for their own benefit or the benefit of others during or after their employment with the *XYZ Laboratory*, unless with the *XYZ Laboratory's* permission. In practical terms, this means all results should be treated as confidential unless the customer specifically indicates that this is not necessary. Once paid for, results for private customers remain the property of those customers. Access to the laboratory's computer network server is restricted to laboratory personnel to prevent other *XXX department or YYY Ministry* staff accessing confidential customer results.

To maintain customer confidentiality with electronic transmission of reports and results all emails are appended with the following footer:

> WARNING: This email and any attachments may be confidential and/or privileged. They are intended for the addressee only and are not to be read, used, copied or disseminated by anyone receiving them in error. If you are not the intended recipient, please notify the sender by return email and delete this message and any attachments.

Faxes have the following statement in the header:

> This information is CONFIDENTIAL and may be LEGALLY PRIVILEGED. Any unauthorised use of this document is strictly prohibited. If you are not the addressee please telephone us immediately and destroy this document.

9.6.7 INTELLECTUAL PROPERTY

If *XYZ Laboratory* staff, during the performance of their duties, make any invention or make or develop any design or copyright work then such intellectual property rights belong to the *XYZ Laboratory*. Staff must ensure that such rights remain with the *XYZ Laboratory*.

9.6.8 SCIENTIFIC HONESTY

XYZ Laboratory staff must act in an intellectually honest manner. They must not knowingly falsify or misrepresent results, or allow or commit plagiarism. They must ensure due acknowledgment of the intellectual, material and practical contribution of colleagues to their work. In particular it is our policy to generate accurate and reliable data and not to engage in any conduct which would diminish confidence in the laboratory's impartiality.

Dishonest actions can include activities such as:

- forging of names, signatures or initials
- making up data for an analysis that wasn't performed or creating information that isn't true
- knowingly altering data entries without acceptable justification
- performing multiple calibrations until acceptance criteria is met rather than taking corrective action
- falsifying QC data to meet run criteria

9.6.9 DUE RESPECT

At all times the customer must be given due respect, which means that unnecessary delays or sloppiness in sample analysis or report preparation cannot be excused. Wherever possible, the *XYZ Laboratory* staff will be willing to co-operate with customers or their representatives in clarifying the customer's request and in monitoring the laboratory's performance in relation to the work performed. This may be in the form of visits to the lab for witnessing of tests. To maintain confidentiality for other customers, visiting customers shall be accompanied at all times by the Laboratory Manager.

9.6.10 FAIRNESS IN RELATIONSHIPS

XYZ Laboratory staff must act in their relationships with all other persons in a fair and open manner, consistent with any requirements for confidentiality. They must refrain from any form of harassment and always act without discrimination on the basis of gender, ethnicity or sexual orientation.

9.6.11 PRIVACY

XYZ Laboratory staff must, when carrying out research or other professional duties, respect the privacy, welfare and dignity of all individuals. Legislative requirements and accepted scientific standards must be complied with when carrying out research involving people.

9.6.12 ENVIRONMENTAL SUSTAINABILITY

XYZ Laboratory staff must use practices that as far as practicable minimise impacts on the environment by performing work for customers in the most efficient manner possible, avoiding wastage of resources. In practical terms this means that the Laboratory Manager will assign work to technicians that may involve batching of work from multiple customers, and taking into consideration the availability of equipment and resources and the time and ability of personnel.

9.6.13 PRIVATE SUBMISSIONS/STATEMENTS

It is recognised that *XYZ Laboratory* staff will on occasions wish to make submissions or statements to public bodies or processes as private individuals on matters which may have an impact on the business or interests of the *XXX department or YYY Ministry*. When making submissions or statements, staff must understand that such submissions or statements could deprive the debate of expert testimony, could have an adverse effect on the *XXX department or YYY Ministry*, the relationship between the *XXX department or YYY Ministry* and its customers, and the employment prospects of themselves or their colleagues.

Where a staff member proposes to make a public submission or statement which relates to matters relating to the core business of the *XXX department or YYY Ministry*, the staff member is required to consult the *XYZ Laboratory Manager* in the first instance before making such a statement. If, in the opinion of the *Laboratory Manager*, the proposed statement is likely to have any adverse effects the staff member will be discouraged from making the statement public. The *Laboratory Manager* must clearly explain the reasons for the advice and inform *the Director Research* of the circumstances under which the advice has been given.

The staff member must ensure that it is clear any statement is being made by a private individual, and not being made by an employee of the *XYZ Laboratory, XXX department or YYY Ministry*. Where it can be readily inferred that a private statement is from an employee of the *XYZ Laboratory, XXX department or YYY Ministry*, a clear disclaimer that the views expressed are the employees own must be included in the statement. This disclaimer will normally be written as part of a written statement. On occasions when an oral statement is being made an oral disclaimer will be appropriate.

9.6.14 MEDIA

Because of the realities of greater accountability, communicating with customer and stakeholder groups as well as the public is an important staff responsibility. The *XXX department of the YYY Ministry* encourages a positive, proactive attitude to the media to establish a high profile as a source of authoritative scientific information. All media contact must be recorded. Details of coverage and publication clippings or broadcast tapes should be sent to the *VVV department of the YYY Ministry* as soon as possible after publication or broadcast.

The *Laboratory Manager* is the official spokesperson for the *XYZ Laboratory* to present the laboratory view on an issue if required. Although encouraged to speak out on areas of research and expertise, he should not comment on policies - financial, human resources, or otherwise - or matters of business that *the YYY Ministry* would ordinarily consider proprietary. On occasion, a "hot" (extremely controversial) issue may be identified by the *YYY Ministry*. In this case, no one may address that issue, including scientific information, without explicit authorisation from the *YYY Ministry*.

9.6.15 PROTECTED DISCLOSURES

A protected disclosure is one made by an employee about serious wrongdoing in the laboratory, where the employee reasonably believes it likely to be true, they want it to be investigated and want to be protected. *XYZ Laboratory* staff who are aware or suspicious of any case of data manipulation or falsification, fraud or any other unethical practices within the laboratory should notify the Laboratory Manager under the company's protected disclosure policy. If the Laboratory Manager is involved in the alleged wrongdoing or closely associated to someone who is, the disclosure can be made to the *Director Research*.

9.6.16 DISCIPLINARY ACTION

XYZ Laboratory staff who participate in unethical conduct are subject to disciplinary action. A progressive procedure is used to provide employees with every reasonable opportunity to explain poor work performance or unacceptable behaviour and be assisted to correct it. All disciplinary situations will be approached with the objective of gaining a win-win outcome whereby the employee is able to improve their work performance or behaviour to ensure continued employment and the employer benefits from having a productive contributing employee. Punitive actions will be taken as the last resort. In certain situations, such as serious misconduct, it will be appropriate to accelerate the process or to begin disciplinary action at the final written warning stage, or to instantly dismiss the employee.

10 HANDLING OF TEST ITEMS

10.1 INTRODUCTION

This section describes the procedures for the transportation, receipt, handling, protection, storage, retention and/or disposal of test items. It includes provisions necessary to protect the integrity of the test item and to protect the interests of the laboratory and the customer.

10.2 SAMPLING

The laboratory does not carry out sampling for customers; however, information sheets on appropriate sampling methods are available to customers on request.

10.3 SAMPLE TRANSPORT

Most soil samples received by the *XYZ Laboratory* are transported in *cardboard boxes/sacks* delivered by commercial carrier (heavier consignments or multiple boxes) or courier (consignments < 5kg.) Due to their small size and weight, plant samples are usually transported in file boxes or plastic envelopes by standard post or by courier. Water samples are transported in chillybins or polyboxes, and as they are usually heavy, come by courier or commercial carrier. Requirements for deliveries to be signed off as received vary according to delivery mode and the particular carrier.

10.4 SAMPLE RECEIPT

Reception is open from *8.30 am till 5.00 pm Monday to Friday* for receipt of samples. This needs to be taken into consideration when discussing sending of samples with customers to avoid having samples waiting around in transit under uncontrolled environmental conditions.

Consignments to the *XYZ Laboratory* are taken by the driver to *Reception,* who then advises the Laboratory Manager that samples are there to be collected. The Laboratory Manager assigns a technician to collect the samples and transfer them to the *Wet Preparation room*, where they are unpacked and laid out in order on the bench. The following information will be recorded and given to the Laboratory Manager along with any associated documentation:

Date of receipt.

- Customer details.
- Sample id details.

Any discrepancies between sample identification on accompanying documents and on actual samples. The most common include apparent duplication of sample id, missing samples and extra samples.

- Condition of samples if anything unusual noted e.g. cracked bottle, ripped bag, partially thawed waters, cross threaded lid causing leakage of sample etc.

Normally all samples received are analysed regardless of their condition and the report footer states "Results apply to samples as received and…." If, however, any unusual

features were noted on the documentation when the samples were received, the customer should be contacted and advised prior to commencing work on those samples. The results may not be meaningful because of deterioration or contamination occurring between sampling and receipt at the laboratory. The customer shall be given the option of whether or not the affected samples should be analysed. The customer's decision should be recorded and filed in the job envelope. If a customer does wish to go ahead with the analysis of such a sample, then the sample condition as recorded on receipt should be noted on the final report.

10.5 SAMPLE STORAGE AND SECURITY

Sample security is maintained by Reception who restrict access to laboratory areas to authorised personnel only. Following receipt, samples are stored appropriately. Fresh plant material and field-moist soils for chemical analyses are stored refrigerated until they can be transferred to soil air-drying cabinets or plant drying oven. This should be done within 2 days. Field-moist soils for biochemical analyses are stored refrigerated and analysed as soon as possible. Air-dry soils and dry plant material require no special storage conditions. They are transferred to appropriate containers if necessary e.g. from plastic bags to vials and placed on trays in *the Balance Room*.

Water sample storage and preservation requirements vary according to analyses to be performed, and are dealt with in detail in the water sampling and preservation SOP. In general though, the following conditions apply:

- Samples for pH and EC need to be analysed within 48 hours.
- Samples for metals analysis need to be acidified to pH <2, refrigerated and analysed within 6 months.
- Samples for solids need to be refrigerated and analysed within 7 days.
- Samples for anions need to be refrigerated and analysed within 30 days.
- Samples for soluble nutrients and/or carbon analyses need to be field-filtered, frozen and analysed within 30 days (48 hours for nitrite-N.)
- Samples for total nutrients and/or total carbon analyses should be unfiltered, frozen and analysed within 30 days.

10.6 SAMPLE REGISTRATION

Each separate batch of samples (i.e. job) coming into the laboratory is given a unique job number, and each sample within a job is given a unique sample number. The job number is of the form LJ#######, where LJ stands for Lab Job, the first two digits refer to the current financial year and the remaining digits increment sequentially for each new job. For example, LJ06025 is the twenty-fifth lab job registered in the 2005/2006 financial year. The sample number is of the form M#/#### where M#/ stands for the current financial year and the following four digits are the number assigned to the sample e.g. M6/0256 is the 256th sample registered in the 2005/2006 financial year.

The recording of these numbers is done electronically in a sample registration Access database, with job number as the relational field. The advantages of a database system are speed of entry and the convenience of being able to search and sort data to rapidly produce information for annual reports and other uses. As the database is on the company computer

network, a full tape back-up service is provided. A hardcopy printout of the job and sample registers is also maintained. The registration process is described fully in the Job Registration SOP.

Two hard copies are printed of the samples report from the registration database. These are headed with the job number and list the laboratory-assigned unique sample numbers, client identification for each sample and analyses requested. One copy accompanies the samples while the other is placed in the job envelope. Sample identification labels carrying the job number, client identifications and the laboratory sample number are printed also. These go with the samples report and samples and get affixed to the samples as part of the sample preparation process.

10.7 JOB TRACKING

The Laboratory Manager maintains an electronic list entitled "Analyses Progress" of jobs currently on hand in the laboratory, with a hard copy kept on a clipboard in his office. This list details the registration number of each job, the job name, sample type, number of samples and analyses required. The list is used by the Laboratory Manager to assign analyses to individual technicians, and allows ready batching of jobs with samples requiring the same tests. When a particular test is assigned it is marked with a single diagonal mark on a hard copy of the list kept on a clipboard in the Laboratory manager's office. When the test has been completed, with QC checks meeting criteria and data entered, the test is then marked off as complete with a second diagonal across the other direction.

10.8 HANDLING OF HAZARDOUS SAMPLES

Soils, particularly those treated with effluent, can contain potentially hazardous organisms. The Laboratory Manager is responsible for advising the technicians assigned to work with such samples of their hazardous status. Appropriate precautions to be taken will also be discussed. Generally both gloves and dust masks need to be worn when working with hazardous samples. Soils can often contain sharp stones, roots or foreign material such as glass, so technicians need to be vigilant when preparing or wet sieving samples, as gloves will only provide limited protection against cuts.

10.9 HANDLING OF QUARANTINE SAMPLES

10.9.1 MAF CERTIFICATION OF FACILITY

The *XYZ Laboratory* is approved by *MAF* as a *Transitional Facility - facility number 2478, under MAF Biosecurity Authority Standard 152.04.03F Requirements for holding and processing facilities (Class: transitional facilities)* for uncleared risk goods. The laboratory holds an importation permit from *MAF* to import multiple consignments of soil and healthy plant tissue for chemical analyses, from all countries. The permit is renewed annually. The Laboratory Manager is responsible for operation of the facility in accordance with *MAF* requirements, regular internal auditing of compliance with *MAF* regulations, maintaining complete and up-to-date laboratory-related records as required by *MAF*, and reporting

immediately, and remedying, any instances of non-compliance with standard facility procedures or *MAF* regulations.

10.9.2 DOCUMENTATION FOR QUARANTINED SAMPLES

Samples from outside the country are subject to quarantine requirements under the *Biosecurity Act 1993*. When arranging a job involving overseas samples, a copy of the import permit is sent to the customer. This must accompany the samples during transportation to the laboratory. The samples will be inspected by *MAF* upon entry to the country and a Biosecurity Authority/Clearance Certificate issued. If samples are received by the laboratory without *MAF* clearance, *MAF's local Biosecurity Officer* will be advised, and clearance sought before analysis of samples. The certificate details are entered in the Quarantine Register, which is maintained as an Access database, once the samples arrive.

10.9.3 ANALYSIS OF QUARANTINED SAMPLES

The Laboratory Manager is responsible for advising the technicians assigned to work with such samples of their quarantined status. Red dot stickers are placed on the sample containers as an additional reminder. Quarantine samples are processed in the same manner as other samples except that all residues are retained and autoclaved before disposal. This includes materials such as filter papers and gloves that have been used in the processing of the samples.

10.9.4 DISPOSAL OF QUARANTINED SAMPLES

Once quarantined samples have been analysed the sample containers are placed in a plastic bag labelled with the job number and their quarantined status. The bags are then stored on the quarantine-labelled shelf in the *Dry Preparation Room*. At the end of the sample retention period quarantined samples are disposed of by *handing to the local MAF inspector on the next inspection visit. The MAF inspector then takes responsibility for ensuring that the samples are destroyed by incineration.* Once the samples have been destroyed the Quarantine Register will be updated accordingly.

10.10 OTHER SAMPLE DISPOSAL

Soil and plant samples remain in the *Balance Room* for a month after the job has been reported, in case any queries result in a need for re-analysis. After this period they are transferred to *the shelves in the Wet Preparation room* for long-term storage. After 2 years samples from here will be disposed of *in the skip*.

Water samples are held in the *walk-in fridge* for 1 month after the job has been reported, then disposed of *in the skip*. If the samples are in *XYZ Laboratory* sample bottles then they are disposed of down the sink and the bottles washed up for re-use. As a number of tests have a tight timeframe during which measurement must be made (e.g. pH, nitrite-N) repeat analysis outside of the documented time limit can be indicative only, and will be flagged as such on the report to the customer.

If a customer has requested that the analysed samples be returned to them then this will be done one week after the test report has been sent to them, again in case any queries result in a need for re-analysis. The final whereabouts of samples, either returned to client or disposal, is recorded in the sample registration Access database.

11 TEST METHODS

11.1 POLICY

Tests carried out in this laboratory will be validated test methods and procedures set out in the Method Manuals and will be the most up-to-date versions of methods. Where appropriate, an estimation of the measurement uncertainty will be made. All analytical methods used in the *XYZ Laboratory* are drawn from reliable published sources, and any modifications have undergone extensive validation processes.

The methods selected and used will meet the customer's needs, and will be appropriate for the test. In particular, the relevance to the customer's needs of the range and accuracy of the values (e.g., uncertainty of results, detection limit, selectivity, matrix interferences) obtained will be considered. The customer will be informed of the method chosen if it is not the method specified, and the laboratory will also inform the customer when the method proposed by them is considered to be inappropriate or out of date. Deviation from test methods shall only occur if the deviation has been documented, technically justified, authorised, and accepted by the customer.

11.2 AVAILABILITY

Two hard copies exist of each of the Soil Test Methods Manual and the Plant and Water Test Methods Manual. One copy of each manual is kept in the Laboratory Manager's office and one copy of each is used as a working reference in the *Main Laboratory*. Each page in the folder is kept inside a document sleeve for protection during use at the bench. The folder copies of method manuals are controlled documents. Electronic read-only versions of the method manuals can be accessed via the Manuals subdirectory of the Quality Assurance directory. Any other paper forms are not controlled and not recommended for working use. Method manuals are for internal use only and as such are not available to the customer. Method descriptions suitable for use in publications, together with relevant references, are available to customers via the *XYZ Laboratory* website.

11.3 REVISION

Test methods are under constant review in that changes can be and are made at any time where a valid case is made to the Laboratory Manager. Changes may be made where errors are found in the procedure, or where new equipment is used, for example. In addition, at least one soil, plant and water method will be reviewed annually to ensure that what is described is actually being done and the review documented in the master review directory, even if no changes are required. If any revisions are required, the necessary changes will be made under the authority of the Laboratory Manager. The manual update sheet in the front of each manual will be appended with a brief outline of the changes and laboratory personnel will be briefed at the next laboratory meeting.

11.4 NEW METHOD DEVELOPMENT

At times it may be necessary to introduce new test methods, e.g., as a result of customer demand for such a test. The introduction of such methods shall be a planned activity carried out by qualified personnel with adequate resources. Plans will be updated as development proceeds, and communicated to laboratory staff at the regular laboratory meetings. Staff will receive training in the how to perform the new methods, and such training will be recorded in their individual training records.

It is preferable that methods have been published either in international, regional or national standards, or by reputable organisations, or in relevant scientific texts or journals, or as specified by equipment manufacturers. When the methods used are not standard methods then the purpose of the test must be identified, the method validated before use, and customer agreement must be obtained and must include specifications of customer requirements.

11.5 INITIAL DEMONSTRATION OF PERFORMANCE (VALIDATION)

Validation is the confirmation by examination, and provision of objective evidence, that the particular requirements for a specific intended use are met. New equipment and associated software used in data calculation e.g. converting peak heights or voltages into concentrations using calibration curves constructed from analysis of standards, are validated in the same way as test methods. A full validation SOP based on US EPA recommendations has been prepared. The following parameters are determined:

- Linear calibration range (LCR.)
- Laboratory Control Sample (LCS) or Standard Reference Material (SRM.)
- Laboratory Fortified Matrix (LFM.) The LFM (or spike) is a sample aliquot to which a known quantity of analyte is added. Its purpose is to ascertain whether the sample matrix contributes bias to the results.
- Instrument detection limit (IDL) The IDL for an analyte is established using a sample extract with known low levels of the analyte in question, preferably at a concentration of two to three times the estimated detection limit. 10 replicate samples are taken through the instrumental part of the method and the IDL calculated statistically using student t-values.
- Method detection limit (MDL.) The MDL differs from the IDL in that samples themselves are processed through the complete analytical method i.e. extraction/digestion as well as instrumental determination. It is more practical than the IDL as it includes the results from different analysts over different days. Method detection limits will be reviewed annually by inclusion of a set of 10 MDL samples as part of a normal analytical run. Detection limits will be adjusted by the Laboratory Manager if the resultant data supports such a change.
- Recovery. The initial recovery is determined by taking 10 replicate samples of a mid-range standard through the entire method.
- Precision. The initial precision is taken as the standard deviation of the 10 replicate aliquots of mid-range standard in the recovery determination above.
- Uncertainty. This is described in the estimation of uncertainty SOP.

Other techniques used in validation include comparison of results achieved with other methods, and inter-laboratory comparisons. The validation procedure is fully documented and records include the procedure used, the results obtained, and a statement that the method is fit for its intended use. Validation data is stored *where*.

11.6 TEST METHOD FORMAT

All analytical test methods should be written according to the format adopted in the Test Methods Manuals, and should include the following sections:

- Identification (title and method number.)
- Introduction – explaining the relevance of the test, the scope, the type of material being tested and typical or comparative values.
- Preparation of reagents.
- Preparation of standards.
- Apparatus – special equipment requirements, including technical performance requirements.
- Procedure – a step-by-step description of the procedure, including:
  - Environmental conditions required.
  - Handling, transporting, storing and preparation of test items.
  - Checks that equipment is working properly and, where required, calibration and adjustment of equipment before use.
  - The method of recording observations and results.
  - Any safety precautions.
- Calculations – full description of calculations and accuracy required for results.
- The uncertainty.
- References – the source of the method or other information.

11.7 CARRYING OUT TESTS

The Laboratory Manager will assign either an entire job or certain analyses within a job to an individual technician. He will advise where the samples are located, which will be dependent on what stage of preparation they are at. Methods to be used are specified on the samples report printout which accompanies the samples. Technicians should not rely on memory in performing tests. The appropriate method manual and equipment SOP should always be referred to, as methods and procedures are continually being updated and improved. The amendment record sheet in the front of each manual provides a quick indication of which methods have been changed recently and in what way.

The first task is to lay out the samples in order according to the samples report printout, at the same time checking that this information is correct. Once sample ids have been confirmed, sample identification labels are affixed to each sample container. If the sample is yet to be prepared (dried and/or ground) the labelled sample container accompanies the sample as a further check on id. Sample preparation for plant and soils needs to be started promptly as no testing is possible until prepared material is available.

The order in which tests are performed needs to be prioritised, in discussion with the Laboratory Manager if necessary. This is to ensure that the tests with the shortest maximum holding times are performed first. If limited amounts of sample are available then the

amounts taken may need to be scaled down; again this is done jointly with the Laboratory Manager. Waters may be able to be diluted to give enough sample for tests; however this and the implications of doing so must be discussed with the customer first and their approval obtained. Insufficient sample may also prevent all Analytical Quality Control (AQC) procedures, particularly duplicates, from being performed. This is permitted at the discretion of the Laboratory Manager, who may place tighter limits on other AQC procedures for that test.

The laboratory's AQC programme is followed as part of the testing procedure. It serves to provide an ongoing demonstration of method performance. The programme includes the running of blanks, laboratory control samples, the use of sample duplicates and the use of spikes to check for matrix effects and recovery where appropriate.

Equipment logs are to be filled in at the completion of each run. These include details of system parameters such as baseline voltages and lamp currents, which indicate whether equipment is performing correctly, and calibration parameters such as values of residuals which are part of the AQC system. Instrument run results are saved prefixed with the job number and test e.g. 135_TKN with suffixes such as .csv or .dat depending on the software.

11.8 DATA INPUT

The *XYZ Laboratory* uses a system of template Excel spreadsheets for data input, calculations and reporting. A separate spreadsheet page is used for each test, with the final results copying to the report on the front-page. Each test is identified by the tab at the bottom of the page and by a heading that gives the method name and method number, date and analyst's initials. The spreadsheets interface with the sample registration Access database to allow client and laboratory-assigned sample id's to be copied into the working spreadsheet, and when the job is completed the results page can be copied to Word and saved as a .pdf file for reporting. The template spreadsheets are read-only, so each job spreadsheet is set up from the templates using a "save as" procedure to prevent templates from being altered or corrupted in any way.

All instruments are linked to networked computers so very little manual data transcription is necessary. Volumes used for suspended solids measurements are one exception. This avoids transcription errors where a value may be read incorrectly from an instrument, written down in a notebook or worksheet incorrectly or typed incorrectly into a spreadsheet. Weights can be captured directly from the balances directly into spreadsheets as well.

The instrument calibration and results are copied from the instrument run file and pasted directly onto the appropriate test page of the job spreadsheet. They should be positioned out to the right of the final calculation cells, preferably with each result in line with its sample id on the left of the page. It may be necessary to shift reslope and recalibration data to achieve this. The raw calibration and result data must remain here i.e. not be cut and pasted elsewhere, to enable the Laboratory Manager to check the data input step. The cells in a spreadsheet where an analyst is required to input data (date, initials and results) are coloured green. Results are copied and pasted into the correct green cells. All calculations are set up in the template spreadsheets so that final calculated results will appeared in columns further to the right of the input raw data.

Because the actions of spreadsheets and the formulae they use are mostly hidden, and are not immune to accidental corruption, a system is required to ensure that spreadsheets give the required and correct results in the first place, and continue to do so in the longer term. The steps in place (read-only templates and data input into green- coloured cells only) serve to provide this protection. In addition, the first sample in every spreadsheet is either the laboratory control sample, or check standard. If the result calculation formula has been corrupted in any way this would immediately show up in an unusual and probably out-of-control result for this sample. Investigation of the formula is the first step in investigation of non-conforming results.

Hard copy instrument printouts should be made where possible, and these are stored in the job envelope. If an instrument run covers more than one job then either take photocopies of the print-out for each job or write a cross-reference on the job envelope as to where the hard copy data has been filed.

11.9 DATA REVIEW

The technician carrying out the test is responsible for reviewing the results before checking the test off as completed. The first area of review is any tests that are part of the AQC programme, such as laboratory control sample, check standard and duplicates. If any items do not meet the criteria then the Laboratory Manager must be advised, so that the SOP for non-conforming work can be followed.

If all AQC tests pass then all customer sample results need to be scanned for obvious outliers. This requires some degree of experience with that particular test, so newer technicians will do this alongside a senior technician or the Laboratory Manager until they are comfortable with what the normal or expected ranges are. Once this has been completed the test may be marked off as completed on the Analyses Progress sheet on the clipboard in the Laboratory Manager's office. If all the tests on the sheet are marked off then "Report" should be written in beside the job name and the Laboratory Manager advised that the job is ready for reporting.

11.10 CLEAN UP

Extracts and digests should be retained until data has been input and reviewed in case there is a need to re-analyse a sample. Once the review has been completed though washing up should be done promptly so that labware and equipment is available to other users. If any consumables have been used up or are running low then the Purchasing Technician must be advised.

12 ANALYTICAL QUALITY CONTROL PROGRAMME

12.1 POLICY

The *XYZ Laboratory* is committed to achieving a high standard of analytical work. To achieve this objective, the laboratory has in place an Analytical Quality Control programme (AQC) for monitoring the validity of tests undertaken. AQC data is analysed following every test run, and where pre-defined criteria is not met then planned action is taken to correct the problem and to prevent incorrect results from being reported.

Records that define the AQC data quality are kept so that trends are detectable, and statistical reviewing of the results is carried out. The overall performance of the AQC programme is reviewed annually as part of the management review process.

12.2 PROCEDURE

The AQC programme consists of an initial demonstration of capability followed by regular analysis of a range of samples or solutions as a continuing check on performance. The initial performance demonstration, also known as method validation, is used to characterise equipment and test method performance before routine introduction of the method.

Continuing checks of performance are made using the following techniques:
Calibration standards.
Check Standard (CS), also known as Initial Calibration Verification Standard.
Laboratory Reagent Blank.
Laboratory Control Sample (LCS.)
Digested Standard.
Drift Standard, also known as Continuing Calibration Verification Standard.
Laboratory Duplicates.
Proficiency programmes.

The use of these techniques for ongoing monitoring of performance is outlined below and described in detail in the Laboratory AQC Programme SOP.

12.3 CONTINUING PERFORMANCE CHECKS

12.3.1 CALIBRATION STANDARDS

Working calibration standards are prepared by dilution from a concentrated primary standard, as described in the Preparation of Standards and Reagents SOP. Calibration standards are used to calibrate the instrument response with respect to analyte concentration. Also included in this set is the calibration blank, or zero standard, which is an aliquot of reagent water fortified with the same matrix as the calibration standards but without the target analyte. Section 7.4.1 of this manual describes how traceability of these standards is established.

12.3.2 CHECK STANDARD (INITIAL & FINAL CALIBRATION VERIFICATION STANDARD)

The check standard is a standard additional to those used to prepare the instrument calibration. It is prepared in an identical manner to the calibration standards but preferably from a separate stock solution and by a different analyst. It is analysed immediately following calibration to demonstrate that the calibration is valid and that the instrument is capable of acceptable performance. It is analysed again at the end of the run to demonstrate that the initial calibration has remained valid throughout the course of the run. Criteria have been set for each instrument. The check standard also provides confirmation that new analytical standards have been prepared correctly.

12.3.3 LABORATORY REAGENT BLANK

This is a volume of deionised water or other matrix that is treated exactly as a sample including exposure to all labware, equipment, filter paper and reagents that are used with other samples. The blank, as it is known, is used to determine if method analytes are present.

12.3.4 LABORATORY CONTROL SAMPLE (LCS)

12.3.4.1 USE

A laboratory control sample is a sample containing a known concentration of the analyte being tested for which is analysed exactly like an unknown sample. All plant and soil analytical runs include an LCS sample. As described in section 7.4 of this manual, these would ideally be Certified Reference Materials (CRM) from a reputable supplier; however these are very expensive, and are not readily available for soils. This laboratory uses Secondary Reference Materials (SRMs) that are in-house samples, which have been calibrated against CRMs where possible, and have also been analysed by other trusted laboratories.

The current soil LCS is *what* called *Efghi*, and the current plant LCS is a *what* called *Jklmn*. Details of preparation of a new LCS, and subsequent setting of target values are described in the SOPs for Soil LCS Preparation and Plant LCS Preparation. The frequency of LCS inclusion is usually specified in each method; however as a general rule one LCS sample is included for every 40 samples.

Where there is insufficient data on the LCS sample, as with tests that are not performed very often, then a sample that has been analysed as part of an ASPAC soil or plant ILCP, and for which statistical data is available, will be analysed as the LCS.

Laboratory control samples for water tests are not always available, mainly due to problems with storage and deterioration over time. This is particularly so for parameters such as suspended solids and dissolved nutrients.

12.3.4.2 MONITORING THE LCS WITH CONTROL CHARTS

Once the target value (mean) and upper and lower limits have been established, the values obtained for each run by every analyst are recorded directly into the appropriate quality control spreadsheet. The result, date and the analyst's initials are entered on the page for that test. The latest result is automatically plotted on the control chart and must be inspected in light of the criteria in 12.3.4.3 below. The Laboratory Manager is notified immediately if any criteria fail, and is responsible for setting up a Quality Problem Report (see section 13 of this manual.)

12.3.4.3 CRITERIA FOR REJECTING DATA

- LCS result outside upper or lower warning limit: Data require careful inspection but may be acceptable.
- LCS result outside upper or lower control limit: Data are rejected and analyses are repeated.
- Two successive results beyond the same warning limit: Data are rejected and reason for bias is investigated.
- 10 successive LCS results on the same side of the mean: Data are rejected and reason for bias is investigated.

12.3.4.4 CONTROL CHART REVIEWING

The Laboratory Manager will monitor the control charts regularly as part of checking data when reporting jobs. This will include looking for any trend in results caused by biases not large enough to put the result out of range. Such biases are revealed by most or all the values lying above or below the mean, rather than being evenly distributed about the mean. The reasons for any bias may be investigated by use of the Quality Problem Report system, and it may be an outcome that the mean and warning limits are to be recalculated based on current data points. A set of red initials will be placed beside the last data set checked on the appropriate LCS spreadsheet page. Any statistical recalculations will also be similarly marked.

12.3.5 DRIFT STANDARD (CONTINUING CALIBRATION VERIFICATION STANDARD)

The drift standard is a mid-range calibration standard that is re-analysed at regular intervals to verify the accuracy of the existing calibration. The instrument may adjust the calibration based on the drift standard result (resloping in atomic absorption spectroscopy) or else criteria can be set so that if the drift standard value falls outside a certain range then recalibration will occur (as in flow injection analysis).

12.3.6 LABORATORY DUPLICATES

Laboratory duplicates are two aliquots of the same sample taken in the laboratory and analysed separately with identical procedures. They are distinct from field duplicates, which are two separate samples collected at the same place and time in the field. Laboratory duplicates indicate precision associated with the laboratory procedures only,

whereas field duplicates indicate the precision associated with sample collection, preservation and storage as well as with laboratory procedures. One in every ten or twenty samples (depending on the test) are analysed in duplicate. Criteria are set so that if the difference between the duplicates is outside a certain value then the run should be repeated.

12.3.7 PROFICIENCY PROGRAMMES

The aim of proficiency programmes (also known as Inter-Laboratory Comparison Programmes, ILCP) is to provide laboratories with objective assessments of the accuracy and reliability of their test results. Proficiency testing also provides the opportunity for laboratories to benchmark their performance within a pooled industry group, nationally or internationally. Measurement of performance in comparison with other laboratories provides confidence that:

- Test methods are being followed.
- Test results are accurate.
- Technician training has been appropriate.
- Systematic errors are identified before the cost of correction escalates.
- Results issued from another lab are unlikely to be significantly different.

The *XYZ Laboratory* participates in the following external quality assurance programmes:

- Australasian Soil and Plant Analysis Council (ASPAC) soil and plant proficiency programmes that involve over 40 laboratories in Australasia and issue certificates for laboratories that achieve certain standards.
- Water Test proficiency programme, used by over 60 laboratories in 7 countries.

The External QC programmes SOP describes how the results of these programmes are reviewed and what actions are taken when pre-defined criteria are not met.

12.4 MEASUREMENT UNCERTAINTY

12.4.1 POLICY

It is the policy of the *XYZ Laboratory* to estimate the uncertainty of measurement for all testing work. Typically the nature of the test methods used precludes the use of the rigorous metrological approaches to calculation of uncertainty; hence the alternative approach using available precision data, such as method validation data, repeat analyses of laboratory control samples, and interlaboratory comparison programmes as outlined in the Eurachem/CITAC Guide *Quantifying Uncertainty in Analytical Measurement* has been used.

12.4.2 PROCEDURE

The procedures used to calculate measurement uncertainty are described in the Estimation of Uncertainty SOP. For soil and plant analyses, accumulated control sample data is used, whereas for soil biochemical tests and water analyses, where stable control samples are not available, use is made of duplicate data.

12.5 DETECTION LIMITS

12.5.1 POLICY

At low concentrations, there is the possibility that noise and analyte signal may become indistinguishable. As the analyte concentration drops, the relative uncertainty associated with the result tends to increase, first to a substantial fraction of the result and finally to a point where the uncertainty interval includes zero. This is the region of the practical limit of detection for a given method. Detection limits can be calculated in a number of different ways, resulting in very differing detection limits being derived from the same set of data. It is the policy of the *XYZ Laboratory* to calculate detection limits for all test methods.

12.5.2 PROCEDURE

The procedure used to calculate detection limits is described in the Detection Limits SOP. It is based on the method detection limit (MDL) approach of the US Environmental Protection Agency (USEPA) whereby the standard deviation of (n =)10 measured concentrations is multiplied by student's t value at n-1 degrees of freedom and 1-α (= 99%) confidence level.

13 NONCONFORMING WORK AND CORRECTIVE ACTION

13.1 INTRODUCTION

Quality control is primarily aimed at the prevention of errors. However, despite all efforts it remains inevitable that errors are made; therefore the control system must have checks to detect them. The occurrence of sub-standard testing and complaints is a sign of quality breakdown in the laboratory, and must be urgently addressed. Sub-standard work may not necessarily relate to the correctness of analytical data, e.g., results may be delivered late, they may not be adequate for the customer's purpose, there may be a potential safety problem in the laboratory, performance in a sample exchange programme may be poor, calibration activities may be overdue, etc. Sub-standard work may be due to inaccuracies in calculations, incomplete checking, use of the wrong techniques, standards, components, or some form of equipment failure. These are most likely to be picked up by the report signatory, but could be missed and result in a complaint by the client.

13.2 POLICY

All complaints received from customers and all instances of sub-standard work will be investigated and resolved as soon as is practical. Relevant test reports/testing work will be reviewed and, if inaccurate, will be recalled.

The Laboratory Manager is responsible for non-conforming work from the laboratory, and has the authority to manage the resolution of nonconforming situations, and to carry out actions to:

- Halt work and withhold reports where necessary
- Evaluate the significance of the nonconforming work
- Take immediate corrective action and decide on the acceptability of the nonconforming work
- Notify the client, if necessary, to recall work
- Define the requirements for the resumption of work.

Where the evaluation indicates that the nonconforming work could recur or there is doubt about the compliance of the laboratory's operations with its own policies and procedures then corrective action will be taken.

13.3 PROCEDURE

When errors are suspected or discovered, the following questions must be asked:

- What error was made?
- Where was it made?
- When was it made?
- Who made it?
- Why was it made?

The Quality Problem Report is a system designed to answer these questions in order to take proper action to correct the error, and prevent the same error being made again. As soon as a Quality Problem is found or suspected it is reported to the Laboratory Manager. The Laboratory Manager or person delegated by him will make a full evaluation of the nonconforming work as soon as practical by initiating a Quality Problem Report (QPR). This is described fully in the Quality Problem Reports SOP.

The QPR begins with a description of the problem and is followed by an investigation. Firstly, the job spreadsheet is checked for transcription and/or calculation errors, and the analytical quality control (AQC) programme results are re-examined to make sure criteria was met for that batch. If everything appears correct then re-analysis is the next step. This may not be possible in some cases due to insufficient sample material being available.

13.4 CORRECTIVE ACTION

When the investigation determines that a significant problem has occurred then the following corrective action must be taken immediately:

- The Laboratory Manager will immediately contact the affected client and arrange for recall of the test report in question.
- The Laboratory Manager will discuss the problem with the client and advise them of action being taken. This may include arranging for another sample to be analysed.
- The Laboratory Manager will review all other results in the affected batch, and preceding batches, to see if other samples are similarly affected. This may in turn mean further clients to be contacted/reports recalled.
- The Laboratory Manager will stop all analyses of the type in question until it can be determined that the analysis is producing valid results.
- Corrective actions identified in the Quality Problem Report shall be implemented immediately. These may include:
    - Instrument/equipment servicing or recalibration.
    - Preparation/purchase of new standards or reagents.
    - Replacement of faulty consumables.
    - Application of another analysis method.
    - Modification of the current analysis method.
    - Staff training.

The Laboratory Manager will issue an amended report if appropriate. The investigation may however determine that no significant problem has occurred. It may be that there is no problem with the laboratory's work and the problem has occurred prior to the samples being received, e.g. the investigation may find that the results are correct and indicate that a topsoil and subsoil have had their labels transposed during sampling by the client. The client must still be contacted and fully informed of the QPR findings.

The Laboratory Manager is responsible for authorising the resumption of work once the corrective action has been taken and it has been established that the corrective action has been successful in eliminating the problem. All further testing will be monitored closely by the Laboratory Manager to ensure that the corrective actions have been successful and there is no recurrence of the problem. Affected areas should be fully audited if the non-conformance indicates the laboratory is not complying with its own quality system.

13.5 RECORDS

Document the investigation fully, including discussions with clients and staff. The report is not confined to the boxes and questions on the QPR form. Records of the complaint or sub-standard work and the corrective action taken will be kept in the Quality Problem (QP) folder in the Laboratory Manager's office. This will record all details, including dates, client, job and laboratory numbers, discussions with the client and staff, trace back of spreadsheets and QC results, courses of action and the clearance of the problem. A register in the front of the QP folder with clearance dates recorded serves as a reminder to ensure all reports are cleared.

13.6 REVIEW

The quality of the testing and reporting process is monitored by the QPR documentation. A summary of the QPR file will be presented as a component of the Management Review process. Key performance objectives may be set for the laboratory pertaining to the number of QPR incidents logged, the nature of the incidents and the timeframe in which the incidents were closed off.

13.7 PREVENTIVE ACTION

In the evaluation of nonconforming work, and in the Quality Problem procedure, consideration should be given to what might be done to prevent a recurrence of the problem. The QPR forms contain a section in which the preventive actions may be described.

Preventive action is a pro-active process to identify opportunities for improvement, rather than simply a reaction to the identification of problems or complaints. Staff are encouraged to keep an open mind about such opportunities in their work, and to contribute to discussion on such matters at the weekly laboratory team meeting. Preventive action could include:

- Further staff training
- Changes to instrument operating procedures
- Improvements to methods e.g. use of a larger sample weight
- Use of different consumables e.g. more durable sample labels.

13.8 IMPROVEMENT

The *XYZ Laboratory* is committed to continually improving the effectiveness of its management system through the use of quality policy, quality objectives, audit results, analysis of data and management review and corrective actions. In addition, the QPR system can be a useful tool in achieving improvement by utilising preventive actions as opportunities for improvement.

14 TEST REPORTING

14.1 POLICY

Results of tests carried out by the laboratory shall be reported accurately, clearly, unambiguously and objectively, and in accordance with any specific instructions in the test methods. Results will be reported in the form of a test report which includes all the information requested by the customer and necessary for the interpretation of the test results and all information required by the method used. Only key technical personnel are authorised to issue test reports.

14.2 CHECKING TEST RESULTS

As described in section 11.9 of this manual, the technician carrying out testing work is responsible for reviewing the results before checking the test off as completed. Before the results can be reported to the customer, the Laboratory Manager or, in his absence, another key technical person, must make a separate verification check. The checking procedure is described fully in the SOP Checking analytical data, and basically involves:

- Checking all data input by hand (usually total suspended solids volumes) with the manual worksheet for transcription errors.
- Checking raw results columns with the data imported from instrument result files. This is normally done by checking a random number of result rows rather than every row.
- Checking template spreadsheet formulae have not be altered or corrupted.
- Checking all AQC tests have been performed.
- Checking all AQC criteria have been met, and if not, that appropriate corrective action has been taken.
- Ensuring the correct number of significant figures is reported for each test and result
- Visually examining the suite of data for any abnormalities, such as obvious mistakes in transfer of data, results that do not "tie-in" with the general trend of results, an abnormally high result amongst a series of low results, poor correlation across a set of results, etc.

The checker will place a red set of initials beside the initials of the technician who performed the test to indicate that the entire test page has been checked and approved. Additionally, where individual data results have been checked a set of red initials will be placed in that data row. The final checked spreadsheet is saved with the job number as the title.

14.3 REPORTING TEST RESULTS

14.3.1 PROCEDURE

The format of analytical reports has been preset in the template spreadsheet whereby individual test results automatically copy through to a front Report page. All the results are highlighted, copied then pasted back into their original position as values. The individual test pages can then be deleted without loss of the test results. The reporting date is filled in

and the line of AQC data in the first row deleted. This spreadsheet is then saved with the Results_Job number as the title. Customers requiring test results in spreadsheet form e.g. to allow statistical manipulation of data, have this spreadsheet emailed to them as an attachment. The format of the spreadsheet report page allows the results to be used but prevents them from being presented or misrepresented as an official test report.

To produce an official test report, the final report page is copied into either of the Word files "Analysis Report_Portrait.doc" or "Analysis Report_Landscape.doc". These file templates contain preset headers and footers. The table size may be changed to accommodate differing numbers of test and/or samples. When complete the document is saved as a .pdf file which is then emailed to the customer. This format prevents the test report from fraudulent electronic alteration. A hard copy of the test report is stored in the job envelope.

At least twice a year the Laboratory Manager will contact both an internal and an external customer and request that they fax or post back to the laboratory a copy of the test report that was sent to them electronically. This serves to provide a check on the integrity of the electronic transmission system.

14.3.2 REPORT FORMAT

All test reports will include at least the following information:

- A title, normally Soil or Plant or Water Analysis Results.
- The name and address of the laboratory.
- Unique identification of the test report in the form of the unique "LJ" job number.
- On each page an identification in the form of "Page # of ##" to ensure that each page is recognised as part of the rest report and that the end of the report is clearly identified.
- The name and address of the customer.
- Identification of the test methods used.
- Date of receipt of the test items.
- Date of issue of the test report.
- Test results with appropriate units of measurement.
- Name, signature and position of the key technical person authorising the test report.

Any tests carried out by a subcontractor must be clearly identified as such, usually by means of an endorsement that "Tests marked "**" have been performed by a subcontracted laboratory ", and the relevant tests will be marked accordingly in the body of the report.

For soil and plant analyses the following footer is appended:

> Results apply to the samples received and are expressed on an oven-dry (105°C) basis. This report may not be reproduced, except in full, without the consent of the signatory.

For water analyses the footer is:

> Results apply to the samples as received. This report may not be reproduced, except in full, without the consent of the signatory.

If a test report needs to be re-issued for any reason, the re-issued report will be bear the same job number as the form LJ#####, but with a clear "Amended Report" title. The Laboratory Manager will ask the affected customer to either destroy the original report of return it to the laboratory.

14.4 INTERPRETATION

The laboratory does not provide interpretations or recommendations on test reports; however customers often request opinions based on results. Informal discussions may take place with customers, notes of which should be taken and placed in the job envelope.

15 TEST RECORDS AND DOCUMENT CONTROL

15.1 INTRODUCTION

Laboratory documents and records define the operation of the laboratory and chronicle the activities associated with the analytical process. The management and control of these documents and records are necessary to ensure that laboratory data are of known quality, retrievable, reproducible and, if necessary, legally defensible. These procedures define how the laboratory controls the preparation, approval, distribution and revision of procedures and contains policies relating to the retention, retrieval and disposal of data. Management system documentation is communicated and made available to all laboratory personnel so that they are fully able to implement the system requirements.

15.2 POLICY

The *XYZ Laboratory* has in place procedures for the identification, collection, indexing, access, filing, storage, maintenance and disposal of management system, quality and technical records. All records shall be legible and shall be stored and retained in such a way that they are readily retrievable in facilities that provide a suitable environment to prevent damage or deterioration and to prevent loss. All records will be held secure and in confidence. Procedures are in place to protect and back-up records stored electronically, and to prevent unauthorised access to or amendment of these records. All management system, quality and technical records will be kept for as long as storage facilities allow and for a minimum of 7 years. Retention times of records will be kept.

15.3 SCOPE

Records and documents that must be maintained or controlled include:

- Sample receipt records.
- Equipment analysis records.
- Other analysis data records e.g. weights, volumes, dilutions.
- Instrument and equipment logs and maintenance records.
- Quality assurance data including qc data and proficiency programme results.
- Method manuals.
- Safety manual.
- Laboratory standard operating procedures.
- Method validation data.
- Reports from internal audits.
- Reports from management review.
- Quality problem reports including corrective and preventive actions.
- All other records affecting data quality.
- Test reports

15.4 TECHNICAL RECORDS

15.4.1 DEFINITION

Technical records are accumulations of data and information which result from carrying out tests and which indicate whether specified quality or process parameters are achieved. They may include forms, contracts, worksheets, control graphs, test reports, customers' notes, papers and feedback

15.4.2 POLICY

Records will be retained of original observations, derived data and sufficient information to establish an audit trail, calibration records, staff records and a copy of each test report issued. The records for each test will contain sufficient information to facilitate if possible identification of factors affecting the uncertainty and to enable the test to be repeated under conditions as close as possible to the original. Records will include the identity of personnel responsible for carrying out each test and checking test results.

Observations, data and calculations will be recorded at the time they are made and will be identifiable to the specific task. Technicians do not use personal workbooks as this precludes records being stored with the particular job they are applicable to. All written data will be recorded in ink rather than pencil. Where mistakes occur in records, each mistake will be crossed out (not erased, made illegible, whited-out or deleted) and the correct value entered alongside. All such alterations will be initialled by the person making the change. In the case of alteration to electronic data, the mistake will be crossed out by means of strikethrough and red font. Where a test is repeated e.g. where a value is over range and the test must be repeated with a diluted sample the original entry should be left where it was but marked with a red strike-through and the new value pasted to a cell in a column further to the right.

15.4.3 HARDCOPY JOB FILE

The hardcopy job file is the primary job management and documentation tool. It consists of a foolscap envelope that contains all information relating to every individual job e.g.

- The job quotation.
- Notes of phone calls discussing the job.
- Any correspondence, including hard copies of e-mails from or to the customer.
- All primary records from analyses including worksheets and hard copy printouts from instruments.
- Any observations and derived data.
- The analysis report.
- A copy of the budget and invoice request form.

The hardcopy job file is kept *where* which provides safe secure storage and prevents unauthorised access. At the end of each financial year, the hard copy job files are transferred into a file box, labelled for contents, and the year covered. The boxes are stored *where*.

15.4.4 ELECTRONIC JOB FILE

The electronic component is a subdirectory for each job on the laboratory's computer system. It contains the primary spreadsheet and result data files from instruments. The spreadsheet has the form of a pre-formatted report on the front page where the final calculated results are copied from worksheets on other pages. Access to the computer system is restricted by the requirement for formal authorisation by the Laboratory Manager. At the end of the financial year all the electronic job spreadsheets are moved to one directory (LJ_completed) and kept forever. Electronic files are backed up *nightly, weekly and monthly* by *whom*. The electronic tape back-ups are stored in the fireproof safe, with the monthly tapes being kept in perpetuity.

15.5 MANAGEMENT SYSTEM RECORDS

15.5.1 AUTHORISATION AND SECURITY

The Laboratory Manager is responsible for all aspects of the management system documentation. All management system documents are reviewed, approved and authorised by the Laboratory Manager prior to issue. The Laboratory manager maintains a master document control log that identifies the revision status and current distribution of documents. Electronic versions of management system documents are read-only. The Laboratory Manager is the only person authorised to change this status.

15.5.2 DISTRIBUTION

Hard copy versions of documents are used for practical reasons e.g. for method manuals used at the bench. These are controlled documents and updated copies are printed after revision but the electronic copy is the master document and represents the current version of all management system documents. Hard copies of manuals are held *where* and most documents are also available as read-only documents on the laboratory's computer system.

15.5.3 IDENTIFICATION

All management system documents are uniquely identified using standard headers and footers on each page. The header includes the laboratory name, the manual in which the document belongs, and the document name. The footer contains the document revision status, issue date, pagination in the form "page … of…", the name of the document's author and the name of the person authorising the issue.

15.5.4 REVIEW

All documents in the Quality System are reviewed annually to ensure continuing suitability and compliance with requirements, and changes made where required. Obsolete or invalid documents will be promptly removed from all points of use.

15.5.5 CHANGES

Changes can become necessary to management system documents as a result of review, or at any other time where it is determined that they do not reflect current policy or procedures. All changes must be justified to and approved by the Laboratory Manager. If the Laboratory Manager feels the changes as justified then he will ensure the affected documents are changed and formally re-issued.

Handwritten amendments to management system documentation may not be made. The recommended procedure is to photocopy the section in question, write on the proposed changes and submit it to the Laboratory Manager. Once changes are approved the Laboratory manager will ensure that the master electronic copy is changed and any necessary hard copy reprints produced. The master document control log is used to ensure all copies in circulation are updated.

Each hard copy document is accompanied with an amendment record sheet which records the date of change, the unique document name, the revision status, and a brief outline of the change. A verbal explanation will be given at the next laboratory meeting if the change is considered significant.

15.5.6 REMOVAL

The Laboratory Manager must approve the decision that a controlled document is to become obsolete. This is recorded in the master document control log, together with the date and reason for obsolescence. The master log is then used to ensure all copies of the obsolete document are removed from circulation. A hard copy set of obsolete methods will be retained for knowledge preservation purposes, and will be marked "Copy for historical purposes only." The obsolete electronic copy will be transferred to the appropriate Historical subdirectory.

16. AUDITS

16.1 MANAGEMENT SYSTEM AUDIT

16.1.1 POLICY

The *XYZ Laboratory* will conduct an annual management system audit after the end of each financial year. The purpose of this audit is to verify that laboratory operations continue to comply both with all aspects of the management system and with the requirements of ISO/IEC 17025. This audit is intended to be fact finding not fault finding; i.e. should be viewed constructively as seeking opportunities for improvement.

Specifically the audits are intended to determine:

- Whether procedures described in the management system are being followed.
- Whether objectives (as defined in the management system) are being achieved.
- Whether designated duties are being carried out satisfactorily.
- If there are opportunities for improvement.

The Laboratory Manager is responsible for planning, organising and ensuring this audit is carried out. Due to the small size of the laboratory it is not possible to have an independent auditor; therefore the Laboratory Manager will nominate a senior technician with suitable training and knowledge of the management system to conduct the audit.

16.1.2 PROCEDURE

The audit will be carried out using a pre-prepared checklist as shown in Appendix 5. It will include a review of the previous audit to ensure all findings were addressed and the audit formally closed off. The completed checklist will be used to compile an audit summary detailing all nonconformities and any recommendations the auditor may have for improving the quality system. A maximum timeframe of approximately 3 months will be given for addressing the summary findings. The areas of activity audited, the audit findings and the corrective actions that arise from them will be fully recorded.

The audit summary will be submitted to the Laboratory Manager for comment, including setting timeframes for any corrective actions. He will be responsible for registering any major nonconformities as Quality Problem Reports to be dealt with through the QPR system. He will also ensure that minor nonconformities and recommendations will be dealt with as soon as practical. When the audit findings cast doubt on the effectiveness of the operations or on the correctness or validity of the laboratory's test results, the laboratory will urgently carry out corrective action, and will advise customers in writing if investigations show results may have been affected. The auditor will follow-up the progress in addressing the summary findings on a monthly basis and will verify and record the implementation and effectiveness of corrective actions taken.

The Management Review will review the audit summary, the Laboratory Manager's response and verify that the audit has been formally received and maximum timeframes set for the audit non-compliances and recommendations to be corrected/implemented.

16.2 EXTERNAL SURVEILLANCE

Wherever possible the laboratory will seek to have surveillances carried out by non-laboratory personnel, such as the SPACNET co-ordinator. These visits provide an external check that technical and management systems are operating effectively and meeting the criteria laid out in this manual. Any changes (both non-compliances and recommendations) from such visits will be dealt with in the same manner as the internal audit findings described in section 16.1.2 above.

16.3 METHOD AUDIT

As discussed in section 11.3 of this manual, test methods are under constant review in that changes can be and are made at any time where a valid case is made to the Laboratory Manager. In addition, the Laboratory Manager is responsible for ensuring that a formal method audit will be carried out annually. At least 3 methods will be chosen (1 soil, 1 plant and 1 water) and the full analysis procedure audited to detect any deviation from the method as documented in the manual. Analytical quality control data performance and trends will be examined as part of the process. Opportunities for improvements to methods will also be examined. Reviews will be documented in the Review subdirectory of the Quality Assurance directory.

16.4 SAFETY AUDITS

The purpose of safety audits is to identify any hazards or unsafe practices that may exist. The Laboratory Manager will appoint a technician to carry out a concise safety check on a monthly. The aim is to identify any potential hazards requiring urgent attention, as well as ensure safety equipment such as eyewashes and showers are functional. A pre-prepared safety checklist in Appendix 6 is used to document findings. The Laboratory Manager will ensure that minor issues will be dealt with immediately before signing off. More serious nonconformities will be registered as Quality Problems and actioned through the QPR system.

A more comprehensive annual safety audit will be carried out using the annual safety review checklist in Appendix 7. This audit will review previous monthly non-compliances as well as the previous annual audit findings. The completed checklist will be used to compile an audit summary that will be submitted for comment to the Laboratory Manager and presented at the Management Review meeting.

17 MANAGEMENT REVIEW

17.1 INTRODUCTION

The management system can be summarised as follows:

- Objectives are established (quality policy.)
- A plan to achieve these objectives is formulated (quality procedures.)
- Performance is regularly monitored (internal audits.)
- Action is taken if the procedures are not being met (corrective actions.)
- The procedures are adjusted, if necessary (manual review.)
- The final outcome is reviewed (management review.)

This section describes the Management Review process in detail.

17.2 POLICY

The laboratory's top management will conduct an annual review of the laboratory's management system and testing activities after the end of each financial year. The purpose of this review is to ensure their continuing suitability and effectiveness, and to introduce necessary changes or improvements. The review will take account of the following:

- Matters arising from the previous Management Review.
- Achievement of the objectives set after the previous Management Review.
- Any third-party (e.g. SPACNET) assessments, findings and corrective action.
- Customer feedback and any complaints from customers.
- Internal safety audits & third party HSNO audits.
- Environmental and sustainability concerns.
- Quality problem reports, corrective and preventive actions.
- Opportunities for improvement.
- Equipment performance and maintenance.
- Future plans and projections for staff, training, equipment.
- Supplier performance.
- Results of internal audits, findings and corrective actions.
- Results of participation in proficiency testing.
- Performance of in-house AQC programme.
- Changes in the volume and the type of work.
- Report from Laboratory Manager.

Objectives for the coming year will be set, ensuring at the time that they are SMART:

- **S**pecific to the laboratory's role.
- **M**easurable, in an objective way, so that at the end of the year it is clear whether the objective has been achieved or not.
- **A**chievable, within the expected ability (not unreasonable) of the laboratory team.
- **R**elevant to strategy both re the laboratory's development and to the company's goals.
- **T**imed, so that review can take place on an ongoing basis through the year.

17.3 RESPONSIBILITY

The Laboratory Manager is responsible for seeing that the management review is carried out. This includes advising the review team, gathering information on performance, and setting out an agenda of items to be covered. Top management i.e. the Director Research and the Laboratory Manager, are the review team.

17.4 DOCUMENTATION

The management review process will be recorded by minutes taken by a nominated secretary such as the Deputy Laboratory Manager. Documentation and records from the Review are located in the Review subdirectory of the Quality Assurance directory.

17.5 FOLLOW-UP

The management review should result in a number of action points being decided, much like with the internal audit. The secretary responsible for recording the review meeting minutes will also ensure that the action points and their associated deadlines are recorded. At the end of each month following the review the secretary will send out an email to review team members with the outstanding action points highlighted to serve as a reminder, until such time as all points have been actioned and the review can be formally closed off.

APPENDIX 1: Scope Of Tests Carried Out

CONFORMANCE STANDARD
ISO/IEC 17025:2005
General requirements for the competence of testing and calibration laboratories

Classes of test:
AGRICULTURAL PRODUCTS AND AGRICULTURAL MATERIALS
In accordance with In-house test methods

(g) Soils
Acid oxalate extractable iron, aluminium & silicon
Anaerobic mineralisable nitrogen
Available boron
Bray-2 soluble phosphorus
Calcium carbonate
Bulk density
Cation exchange capacity
Dithionite-citrate extractable iron & aluminium
DTPA-extractable Fe, Mn, Cu, Zn
Electrical conductivity
Exchangeable aluminium & ECEC
Exchangeable bases
Microbial biomass carbon
Mineral nitrogen
Moisture factor
Olsen-available phosphorus
Organic phosphorus
Particle size (whole soil & fine earth)
pH
pH in H_2O_2
Phosphate-extractable sulphate
Phosphate retention
Pyrophosphate-extractable iron & aluminium
0.5M H H_2SO_4-soluble phosphorus
Total carbon and nitrogen (LECO)
Total Kjeldahl nitrogen
Total Kjeldahl phosphorus

(h) Plants

Acid-detergent lignin
Ca, Cu, Fe, Mg, Mn, Na, Zn (ashing)
Nitrogen, carbon (LECO)
Ca, Mg, nitrogen, phosphorus & potassium (Kjeldahl)

WATERS

In accordance with APHA"Standard Methods for the Examination of Waters and Wastewater" (21st ed) 2005

(a) Potable waters
(b) Non-potable waters

Ca, Mg, Na, K 3111 B
Hardness by calculation 2340 B
Electrical conductivity & dissolved solids 2510 B
Total suspended solids 2540 D
Total dissolved solids 2540 C (dried at 105° deg)
Total dissolved solids by calculation 2510 A
Acid-extractable metals 3030 E
Cd,Co,Cr,Cu,Fe,Mn,Ni,Pb,Zn by FAAS 3111 B
Aluminium 3111 D
Silicon 3111 D
Inorganic ions by IC 4110 B
pH 4500-H
Ammonia, nitrate, nitrite, phosphorus by FIA Method 4500-NH_3 H, Method 4500-NO_3 I, 4500-PG
Total organic carbon 5310 B
Total nitrogen & phosphorus by persulphate digestion Inter.J.Environmental studies 1986 vol27, p26775

APPENDIX 2 Job Descriptions

Position Title: Laboratory Manager
Reports To: Director, Research
Direct Reports: Section Heads, Laboratory Analysts
Main function of Position: Manage operations and laboratory staff at the *XYZ laboratory*.

Person Specification:

- Relevant tertiary science qualification.
- Significant experience of laboratory operations management, especially chemical analysis.
- Successful staff supervision, development, and team leadership skills
- Financial management skills including budget preparation, and management to budgets.
- Strong client relationship skills.
- Strong safety and quality experience
- Strong process innovation and improvement orientation
- Knowledge of developments in analytical technology and methods and equipment
- Experience of working in a scientific research environment.

Key Accountabilities:

- Manage the laboratory staff at the *XYZ laboratory* ensuring effective workload planning, personnel training and development, and performance management.
- Manage the day-to-day operations of the *XYZ laboratory* ensuring effective interaction with internal and external clients, work scheduling, equipment maintenance, financial management and the safe and structured use of the laboratories for other laboratory users and visitors.
- Manage standards of laboratory performance including quality and health and safety.
- Ensure that the laboratory maintains:
    - an appropriate skill base among the laboratory staff;
    - an appropriate suite of equipment with effective maintenance fit for purpose and work volumes;
    - the ability to handle fluctuating analytical workloads
- Develop and maintain a business plan for the *XYZ laboratory* which covers the purpose, scope, resources, staffing, quality, revenue and workload aspects.
- With support from HR, ensure personal development plans are developed for laboratory staff and providing coaching and mentoring as needed.

Position Title:	Section Head
Reports To:	Laboratory Manager
Direct Reports:	Laboratory Analysts
Main function of Position:	To take responsibility for a certain section of the *XYZ laboratory's* work in areas where they have specialist expertise.

Person Specification:

- Relevant tertiary science qualification
- Considerable relevant practical experience.
- Well skilled in a number of areas or very high degree of skill in a specialised area.
- Initiative and originality in relation to application of skills.
- Good communication skills generally.
- Able to obtain co-operation of others in complying with technical and other requirements of their tasks.
- Ability to think interdependently and plan own work schedule
- Good computer skills.
- Ability to function as part of a team.
- Ability to work substantially unsupervised.

Key Accountabilities:

- Expected to lead the development of operating procedures and practices in areas where they have specialist expertise.
- Expected to manage equipment or an integrated package of laboratory but with no delegated financial authority.
- Expected to lead a group of staff in the performance laboratory tasks in accordance with company standards, health & safety regulations and science excellence.
- Expected to supervise and manage performance of up to three technical staff.
- Responsible for completion and reporting of assigned tasks on time, accurately and to agreed standards of quality.
- Must be able to draft related standard operating procedures or health and safety guidelines.
- Expected to suggest improvements to procedures within area of work.
- Expected to communicate results of assignments in such a manner that may include co-authorship of a scientific paper or significant contract or technical report.
- Tasks use established methodologies, and are often repetitive in nature, but involve a team of people and more than one stage. Some modifications are expected to be required to methodologies in consultation with Laboratory Manager, and hence original thought in a specialist area is required.

Position Title:	Laboratory Analyst
Reports To:	Laboratory Manager (overall responsibility) Section Head responsible for work area
Direct Reports:	Occasionally will need to supervise a technical assistant
Main function of Position:	To carry out analytical testing work in the *XYZ laboratory*

Person Specification:

- Relevant tertiary qualification (e.g. diploma or certificate) or equivalent background knowledge and exposure to techniques
- Sufficient work experience to demonstrate ability to perform technical duties independently
- Ability to collate and report data/findings accurately
- Reasonable communication ability.
- Ability to think independently and plan own work schedule
- Reasonable computer skills
- Ability to function as part of a team.

Key Accountabilities:

- Responsible for completion and reporting of assigned tasks on time, accurately and to agreed standards of quality.
- Expected to supervise performance of technical assistants occasionally, when assigned to own work area.
- Expected to initiate communication in advising and reporting on tasks assigned to them, or in relation to their work area.
- Tasks will be short to medium term, using established methodologies, with minimal supervision. Regularly supervised with new tasks. Tasks will often be complex in that they involve more than one stage and may involve the use of complex equipment.
- Some independent, original thinking is required, with minor modifications to processes expected on occasion. Problem-solving will usually involve the supervisor.

APPENDIX 3 Key Technical Personnel

The following staff have been assessed and designated as the *XYZ laboratory's* Key Technical Personnel for the tests specified.

A.B. Cdefg	*Soils, plants, waters*
H.I. Jklmnop	*Soils, plants*
Q.R. Stuv	*Waters*

Curriculum vitae for these KTP:

Curriculum Vitae

Full name:

Present position:

Present employer:

Academic qualifications:

Years as a practising analyst:

Professional positions held:

Number of refereed publications:

Number of significant publications not included in the above:

Certificate of appointment as KTP:

XYZ Laboratory

Certificate of Key Technical Personnel Status

This is to certify that

A.B. Cdefg

Having been assessed against the criteria outlined in the Laboratory Quality Manual and found to meet the defined professional and technical standards is hereby designated

Key Technical Person

in the field of ***Chemical Testing***

for the following classes of test ***Plants, soils, waters***

as described in the Laboratory Methods Manual

and is approved to sign reports issued by the XYZ Laboratory

Date

APPENDIX 4 Floor Plan Of Laboratory

APPENDIX 5 Management System Audit Checklist

XYZ LABORATORY
INTERNAL QUALITY AUDIT CHECKLIST

1. DOCUMENT CONTROL

Locate the Document Control file in the Laboratory Manager's office.
Choose 1 soil manual, 1 plant & water manual, 1 equipment operating manual.
Are the manuals located where stated?
Are the manual amendment sheets up to date?
Do the manuals contain the current versions of documents?
Are manuals (except Lab Manager's) free of hand-written amendments?
Has the Quality Manual review been completed to date?
Have any Method Manual reviews been completed to date – soil/plant/water?

---

2 STAFF/TRAINING

Are staff resource levels adequate for the current workload?
Is there sufficient time for quality system activities?
Do lab training files show all current personnel?
Are non-current files removed to the historical section?
For at least 2 lab staff - are staff training records up to date?
Check with Team Leader whether staff training needs being identified and addressed?
Is the list of key technical personnel in Appendix of the Quality Manual current?

---

3 ENVIRONMENT

Are temperature records up to date?
Are temperatures in controlled rooms within limits?
If not, has action been taken?
Are RO & MilliQ water records up to date?
Are RO & MilliQ water conductivities within limits?
If not, has action been taken?
Are grinding room dust extraction systems functioning?
Are grinding rooms being used for correct samples?
Plant drying oven not being used for sample storage?
Grinding rooms and equipment being cleaned after use?
Grinding room logs being used?
Overall housekeeping standard high?

---

4 EQUIPMENT

Do all equipment items have an inventory no?
Are records of new instrument commissioning in Equipment & Calibration file?
Does every instrument have an operation/service/maintenance log?
Are instrument logs being used to record use?
Are all required log details being filled in?
Is instrument servicing being recorded in logs?
Is instrument maintenance being carried out?
Is instrument maintenance recorded in logs?
Is calibration reminder wall planner in place in Instrument Room?
Is calibration schedule being adhered to:

- Pipettors 6 monthly?
- Dispensers 6 monthly?
- Timers annually?
- Thermometers 6 monthly?
- Balances monthly, 6 monthly, 3 yearly full calibration?
- Ovens spatial variation 2 yearly?
- Muffle furnace single point 6 monthly, spatial variation 2 yearly?
- New volumetric glassware calibration checked before put into service?

Do all items requiring calibration bear a current yellow dot calibration due sticker?
Are calibration records (in Equipment Maintenance & Calibration file) up to date?
Are stock standards stored appropriately?
Are there no standards past their expiry date being used?
Are there no reagents/eluents past their expiry date being used?
Is the Analytical Standards Prep log being used by all staff?
Are fresh analytical standards being compared against old?
Are standards & reagents/eluents being appropriately labelled?
Do all standards & reagents/eluents carry a yellow dot expiry date sticker?
Is the Reagent Preparation log being used by all?
Are suitable reference materials being used?
Are template spreadsheets validation records up to date?

---

5 SUPPLIERS

Are all suppliers' details recorded in the approved suppliers register?
Have there been no problems with any suppliers?
If there were problems, have these been subject to a Quality Problem report?
Was the Quality Problem Report concluded satisfactorily?
Do purchase order requisitions contain details of quality standards required?
Are copies of the purchase order sent out to suppliers received and checked by the purchasing officer?
Is purchasing verification being carried out?

---

6 SAMPLE HANDLING

Walk round the balance room, Main Lab, prep rooms. Look in fridges, freezers and cold room.
Are samples stored in the appropriate locations?
Are sample identified with unique lab numbers?
Can the job the samples belong to be identified?
Is sample disposal up to date?
Are sample disposal records up to date?
Are quarantine records up to date?
Can 3 sets of samples currently under analysis be located?
Can 3 sets of samples completed within the last 3 months be located?
Do records indicate where to find 3 sets of samples analysed a year ago?
Is sample storage in good consecutive order?

---

7 TEST METHODS

Choose 1 soil manual, 1 plant & water manual, 1 equipment operating manual.
Are lab copies of method manuals in good condition?
Do lab copies of method manuals contain hand-written amendments?
Are there any new methods? If so, can validation data be found?
Are method uncertainties documented?

---

8 TEST RECORDS (JOB ENVELOPE)

Take a selection of 4 job envelopes at random.
Are sample receipt details present?
Are client discussion records present?
Are instrument printouts present?
Do manual worksheets have the date and analysts initials on?
Are manual worksheets free from use of pencil or Twink?
Is the test report present?

---

9 TEST RECORDS (ELECTRONIC)

Take a selection of another 4 jobs at random and open their electronic records.
Has the date and analyst initials been filled out for each test?
Is the imported instrument data available to the right of the spreadsheet?
Has the data been checked?

---

10 ANALYTICAL QUALITY CONTROL PROGRAMME

Are LCS results being entered in the appropriate spreadsheet?
Is there evidence of the control charts being regularly checked?
Are appropriate actions being taken & recorded due to LCS results?
Are control charts functioning and up to date?
Are proficiency programme results available?
Are proficiency programme results summarised?
Is action taken as a result of proficiency programme results?

---

11 TEST REPORTS

Take a selection of 4 job envelopes at random and check the test reports.
Are client identification details present?
Is the job identification number present?
Is the sample receipt date noted?
Are the reports laid out in an easy to read manner?
Are the laboratory contact details present?
IANZ endorsed reports:
Does an approved signatory sign the report?
Is the footer statement present?
Are methods referenced?
Are methods and uncertainties available?

---

12 NONCONFORMING WORK

Locate the Quality Problem Report file and Client Feedback file in the Laboratory Manager's office
Have any QPRs been recorded in the last year?
Have all QPRs been signed off?
What is the spread of times elapsed between logging and closing off?
Have all action items/recommendations been carried out?
Have any feedback items from clients been filed?
Is client feedback being actively solicited?

---

13 SAFETY/SUSTAINABILITY

Are monthly audits being conducted according to schedule?
Has an annual safety audit being carried out?
Are non-compliance items from these audits being actioned?
Has compliance with appropriate HSNO legislation been assessed?
Are there any HSNO non-compliances?
Are actions being taken to ensure these non-compliances are rectified?

Have there been any laboratory accidents recorded in the Site Accident Register?
Does the laboratory have a sustainability policy?
Are recycling activities clearly described to staff?

---

14 INTERNAL AUDIT

Was the audit carried out according to schedule last year?
Have all items raised from the last audit been actioned?

---

15 MANAGEMENT REVIEW

Has a review been carried out since the last audit?
Have all items raised been actioned?
Did the review set clear objective targets for the lab?
Have lab staff been advised of the outcomes of the Review?

APPENDIX 6 Monthly Safety Audit Checklist

Monthly Safety and Housekeeping Audit

Item	Yes/No	Details of Non-compliance	Lab Manager's Comments & Clearance
All items cleared from previous audit?			
Benches cleared promptly after use?			
Aisles free of boxes and clutter?			
Chemicals being returned to correct storage locations?			
Glassware being returned to cupboards from oven and drying racks?			
Fumehoods free of clutter and functioning?			
Eyewash stations functioning?			
Safety showers functioning and access clear?			
Adequate supplies of hot & nitrile gloves?			
Adequate supplies of dust masks?			
Fire extinguishers present and checks current?			
Fire Blankets in place and checks current?			
Balances and benches free of spills?			
Broken glass bucket being emptied?			
Wastes bucket being emptied?			
Prep & grinding rooms and equipment clean?			
Rubbish and recycling being placed in correct locations?			
All gas cylinders secured?			
No new hazards or unsafe practices identified?			

Auditor: _____ **Date:** _____

APPENDIX 7 ANNUAL SAFETY AUDIT CHECKLIST

INTERNAL SAFETY AUDIT ANNUAL CHECKLIST

Date: _____

Auditor: _____

1. LABORATORY WORK PRACTICES

	Yes	No
Is there a designated laboratory manager?	❒	❒
Is a monthly safety check carried out?	❒	❒
Are the monthly checks displayed prominently?	❒	❒
Has action been taken on items raised from the monthly checks?	❒	❒
Is the safety manual available?	❒	❒
Is food & drink not stored in lab containers and areas?	❒	❒
Are visitors informed of lab hazards?	❒	❒
Are pipetting aids available and used?	❒	❒
Are work surfaces cleaned after use?	❒	❒
Are used needles & broken glass disposed of in suitable containers?	❒	❒

Comments:

---

2. HOUSEKEEPING

	Yes	No
Are lab and storage areas uncluttered and tidy?	❒	❒
Are aisles and exits free from obstruction?	❒	❒
Are the tops of cabinets free from stored items?	❒	❒
Are heavy items confined to lower shelves?	❒	❒
Is glassware free from cracks/ sharp edges?	❒	❒
Is glassware stored to prevent fall from shelves in an earthquake?	❒	❒
Are fumehoods free from clutter/stored items?	❒	❒
Are fumehoods tested regularly?	❒	❒
Do fumehood sashes function correctly?	❒	❒
Is cleaning scheduled out of work hours?	❒	❒

Comments:

---

3. PERSONAL PROTECTIVE EQUIPMENT

	Yes	No
Do staff wear lab coats when working in the laboratory?	❒	❒
Do staff remove their lab coats in non-lab areas e.g. common room?	❒	❒
Are dirty lab coats stored in a bag until removed for laundering?	❒	❒
Is suitable eye protection available and used?	❒	❒
Are protective gloves available?	❒	❒
Is there a selection of gloves available according to hazard type?	❒	❒
Are dust masks available and used?	❒	❒
Is suitable hearing protection available and used?	❒	❒

Comments:

---

4. HAZARD COMMUNICATION AND LABELLING

	Yes	No
Is the correct signage present at the building entrance?	❒	❒
Is the correct signage present at the entrance to the lab?	❒	❒
Is a glove suitability chart posted in the lab?	❒	❒
Is there a table of incompatible chemicals posted in the lab?	❒	❒
Do storage areas have signs consistent with the hazards within?	❒	❒
Are all chemical containers labeled as to contents?	❒	❒
Are MSDS sheets available for all chemicals used?	❒	❒
Do the staff know the location of MSDS sheets?	❒	❒

Comments:

---

5. ELECTRICAL SAFETY

	Yes	No
Is electrical equipment tested for safety regularly?	❒	❒
Are electrical cords in good condition?	❒	❒
Is equipment in good repair?	❒	❒
Are cords tidy?	❒	❒
Are power points and multiboards not overloaded?	❒	❒

Comments:

---

6. CHEMICAL STORAGE AND SAFETY

	Yes	No
Is there a register of chemicals held and their quantity?	❒	❒
Are chemicals dated on arrival?	❒	❒
Are unnecessary chemicals removed back to the store?	❒	❒
Are toxic chemicals stored in a locked cupboard when not in use?	❒	❒
Are organic acids stored away from inorganic acids?	❒	❒
Are acids stored away from alkalis?	❒	❒
Are other incompatible chemicals segregated?	❒	❒
Are corrosives and flammables stored below eye level?	❒	❒
Are hazardous materials limited to small quantities?	❒	❒
Are safety carriers available and used?	❒	❒

Comments:

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7. FLAMMABLE LIQUIDS STORAGE

	Yes	No
Are flammable liquids stored in an approved cabinet?	❒	❒
Are flammable liquids used away from ignition sources?	❒	❒
Is the quantity of flammables stored in the cabinet within limits?	❒	❒
Is the flammable liquids cabinet appropriately labelled?	❒	❒
Does the flammable liquids cabinet door close properly?	❒	❒
Is there less than 15 l of flammable liquid out on benches?	❒	❒

Comments:

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8. COMPRESSED GAS CYLINDERS

	Yes	No
Are gas cylinders securely chained?	❒	❒
Are gas cylinders transported on a suitable trolley?	❒	❒
Are gas cylinders not attached to an instrument stored externally?	❒	❒
Are empty gas cylinders labeled as empty?	❒	❒
Are supply valves turned off when not in use?	❒	❒
Are hoses, tubing and regulators in good condition?	❒	❒

Are acetylene cylinders fitted with flashback arrestors?	❒	❒

Comments:

---

9. TRAINING

	Yes	No
Do staff receive training in use of fire fighting equipment?	❒	❒
Do fire wardens receive training?	❒	❒
Is first aid training available to all staff?	❒	❒
Is there a trained first aider on every level?	❒	❒
Is there a list of trained first aiders displayed prominently?	❒	❒

Comments:

---

10. FIRE SAFETY

	Yes	No
Are exits clearly marked?	❒	❒
Is there an emergency lighting system?	❒	❒
Are exits free from obstruction?	❒	❒
Are fire doors either self closing or kept closed?	❒	❒
Are fire alarms tested regularly?	❒	❒
Are telephones labelled with emergency numbers?	❒	❒
Is an evacuation procedure available?	❒	❒
Are staff familiar with evacuation procedures?	❒	❒
Are regular fire drills held?	❒	❒
Do staff have training in use of fire fighting equipment?	❒	❒

Comments:

---

11. WASTES

	Yes	No
Are hazardous wastes not accumulated?	❒	❒
Is there a waste disposal procedure?	❒	❒

Comments:

---

12. SAFETY EQUIPMENT

	Yes	No
Are safety showers present?	❒	❒
Are eye wash stations present?	❒	❒
Are showers and eye wash stations free from obstruction?	❒	❒
Are showers and eye wash stations in good condition?	❒	❒
Are showers and eye wash stations tested regularly?	❒	❒
Are fire extinguishers available?	❒	❒
Are fire extinguishers appropriate to the hazard types?	❒	❒
Are hose reels available?	❒	❒
Are fire extinguishers checked regularly?	❒	❒
Are fire detection devices present?	❒	❒
Are first aid supplies available and visible?	❒	❒
Are first aid supplies checked and maintained?	❒	❒
Are spill kits available?	❒	❒
Do staff know the location of spill kits?	❒	❒

Comments:

---

13. PREVIOUS AUDITS

	Yes	No
Have all items from previous audits (monthly & annual) been cleared?	❒	❒

ANNUAL SAFETY AUDIT SUMMARY

Date: _____

Auditor: _____

Summary:

Laboratory Manager's comments:

Signed: _____ **Date:** _____

Team Leader's comments:

Signed: _____ **Date:** _____

AUDIT IMPROVEMENTS & RECOMMENDATIONS

Non-compliance/Recommendation No.

Description:

QPR No.

Action Taken:

Signed: _____ **Date:** _____