QUALITY AND QUALITY CONTROL SYSTEMS
This section explains what is meant by Quality and Quality Management System and how this will impact on and improve working in a laboratory.

What does Quality mean?
Quality is not easy to define but it needs to be defined by an accredited laboratory. It can mean different things to different people. However, in all aspects of business ‘Quality’ has become very important. Whether it is a manufacturing or a multi-disciplinary organisation, all successful organisations want to be associated with the word ‘Quality’.

So what is Quality? A textbook definition is: Quality is fitness for purpose.
The International Standards Organisation (ISO) has produced a document entitled ‘Quality Management Systems – Fundamentals and Vocabulary’, in which the word ‘Quality’ is defined as: Degree to which a set of inherent characteristics fulfils requirements.

This clearly indicates that achieving quality means fulfilling requirements. The requirements may come from customers and in some cases from regulatory authorities.

How can Quality be achieved?
Quality is everyone’s responsibility; it must be built in at every stage of the process, from identifying the customer’s needs, through planning and implementation right up to the point of reporting analytical results.

In some cases, quality needs to be checked even beyond delivery to the customer since customer satisfaction can have an enormous impact on quality as perceived by them.

Making it happen!
It must be understood that quality does not occur by accident. The starting point is identifying the customer’s needs and from that a plan must be considered for the processes and resources and application of monitoring controls. The analyst needs to be continually assessing his/her performance against his/her own objectives and standards to strive for improvement. Since quality does not occur by accident there is a need to establish an effective Quality Management System in order to ensure that requirements are fulfilled efficiently and effectively. This manual is a start to achieving this.

Quality Management System
A Quality Management System directs and controls an organisation with regard to quality by putting in place standard operating procedures (SOPs) to which everyone operates in a
consistent manner. This, in combination with regular internal checks (audits), a system of investigating problems (anomalies) and constantly identifying opportunities for improvement will reduce the occurrence of unreliable results.

**Why implement a Quality Management System?**

Having a documented system results in all staff operating to a common standard and provides assurance to customers of test reliability and consistency of service. A Quality Management System that complies with an international standard will be recognised around the world and will demonstrate conformity in international markets.

**What a laboratory analyst is expected to do to comply?**

On commencing employment, all new staff should be issued with a copy of this manual. Staff are expected to read it and understand its contents (where appropriate). Staff should also be issued with a Training File in which they can demonstrate their experience and competency in following the standard, the Quality Management System and their proficiency in nutritional analysis procedures.

**Training File**

The training file should demonstrate experience and competency to perform the job the individual holds. This file should be held by the individual and updated as training is provided, in liaison with their supervisor. The Training File should contain a job description, an organisational chart, a CV (resume) and evidence of relevant training and education received to date. As new training is received, evidence verified by a line manager, should be included describing the training. Ongoing competency should also be demonstrated by documenting participation in EQA (External Quality Assurance) and IQA (Internal Quality Assurance) programmes managed by the laboratory.

**QUALITY ASSURANCE PURPOSE AND GUIDELINES**

Laboratory quality programs are a critical part of improving the agricultural laboratories in developing countries. The Laboratory Quality Manual is the essential source for communicating to the laboratory staff the manner in which laboratory testing is to be conducted. Adherence to the quality manual by laboratory staff is necessary to ensure both quality and consistency. Recognizing the Laboratory Manual may not cover all situations and variables arising from the laboratory setting, any significant departures must have the approval of management and must be appropriately documented.

The management within the laboratory is responsible for the quality and integrity of all data generated in the laboratory. The management, collectively, assures this quality through adherence to the laboratory manual, quality assurance plan, and through the development and adherence to standard operating procedures.

The flowchart in Figure 1 provides a simplified representation of the Quality Management System described in this manual and is not a substitute for the procedures contained within.
LABORATORY ORGANIZATION AND RESPONSIBILITIES

Each member of the laboratory should have clearly identified and documented responsibilities (Job Description). An organizational chart should be included in the laboratory quality document and made available in staff training records.

Laboratory Manager/Director has ultimate responsibility for implementing the quality system.

Quality Manager reports directly to the Laboratory Manager/Director and is responsible for maintaining and developing the quality procedures used in the laboratory.
Laboratory analysts responsible for following all quality procedures and identifying opportunities for improvement.

PERSONNEL TRAINING AND QUALIFICATION
Qualified and trained personnel are essential for producing analytical results of acceptable quality. Laboratory management ensures that laboratory personnel have the knowledge, skills and abilities to perform their duties. Competence is based on education, experience, demonstrated skills and training. Staff training files contain the documentation of personal education, experience, skills and training for the position held.

Analysts undergo a training program in accordance with the laboratory’s training procedure. The analyst must demonstrate and document proficiency in an analytical method before reporting results to the laboratory’s customers. The first step for qualifying in a new analysis is to read the standard operating procedure (SOP). A copy of this document can be obtained from the Laboratory Manager/Director. The method should be reviewed with the analyst by someone familiar with the procedure and then the analyst should run a specified number of known samples or standards. The training should be documented in the individuals training file. To assure the safety of everyone, the trainee must read the Material Safety Data Sheet (MSDS) for information concerning each chemical used in the analysis. The toxicity levels and method of waste disposal should be clearly understood before beginning any analysis. The number of samples and standards analysed should be specified by the supervisor. The results should be compared to previously obtained results using a paired t-test. If there is no significant difference at the 95% confidence level the new analyst can be considered qualified. On-going competency should be demonstrated by participation in Internal Quality Assurance (IQA) or ring trials at regular intervals.

ANALYTICAL PROCEDURES – SELECTION AND VERIFICATION
When the customer does not specify the method to be used, a recognised (ISO, CEN, AOAC, FDA etc.) standard method is preferred. If a standard method is not found the laboratory may use either a non-standard method or modify a method for use with the concurrence of the customer. The laboratory informs the customer when the method proposed by the customer is considered to be inappropriate for the intended purpose. The standard and non-standard or modified method must be sufficiently validated by the laboratory before being used to report data.

When the laboratory develops methods for its own use, the laboratory has a procedure for its introduction.

Non-standard methods are those methods not taken from authoritative, validated sources. A non-standard method has not undergone validation, such as a collaborative study or process to evaluate the method’s performance capabilities.

Non-standard methods are selected for use when a customer request cannot be addressed with the use of a standard method. Such methods are subject to agreement with the customer and are validated.

Validation is the confirmation by examination and the provision of objective evidence that the particular specifications for an intended use are fulfilled.
The laboratory validates standard methods, non-standard methods, laboratory developed methods and modified standard methods, including use outside the intended scope and applications. Validation is conducted to confirm that the methods are fit for the intended use. The performance of all methods is verified before being used to generate reportable data.

The validation process addresses the needs of the given application. The attributes and data quality objectives include but are not limited to:
- Accuracy
- Precision
- Limit of detection (LOD)
- Limit of quantification (LOQ)
- Linearity

Accuracy and precision target limits can be taken from AOAC (Horwitz). Precision or repeatability is calculated as the relative standard deviation (coefficient of variability) and accuracy is calculated as percentage recovery (Table 1).

**STANDARD OPERATING PROCEDURES (SOPs)**

SOPs are specific to the point of use for which they are written. The approval of a SOP is the commitment of a specific area to an action or behaviour. SOPs may be written by a competent employee within the laboratory. The SOP is then reviewed for content and authorised by the supervisor or manager in the area in which the SOP will be used. Once the SOP has been reviewed and found to be acceptable by the supervisor or manager, the SOP is given to the Quality Manager for approval and issue.

The format used for writing SOPs should contain the following when appropriate:
- Principle
- Scope
- Responsibilities
- Equipment
- Reagents
- Procedure
- Quality Control
- Calculations
- Troubleshooting
- Remarks
- References
- Appendix (Flow Charts, Tables, References, etc.)

SOPs are controlled documents and must include an issue (or effective) date, the name of the author(s) and person(s) authorising the SOP, a review date and version number. When a new version of an SOP is issued a ‘Log of Updates’ will summarize changes made at the start of the document. When a new version of an SOP is issued all previous controlled versions must be withdrawn.

It is advisable to forbid uncontrolled versions of SOPs.
EQUIPMENT MAINTENANCE AND SERVICE

The procedures to determine, maintain, and monitor instrument performance are an integral part of a quality control program as they promote a high degree of confidence in analytical results. Each procedure is described in the respective equipment SOP. All essential testing equipment has its own SOP and maintenance records that document operation, calibration and routine maintenance. Staff using essential equipment must have appropriate training documented in their training file.

Maintenance. Complete and accurate installation instructions, operating manuals, parts manuals, service manuals and written guarantees or contracts are kept with each instrument to assure proper functioning. The implementation of a preventive maintenance program which includes the testing of equipment against specifications and procedures for frequent calibration, checking and cleaning, is essential. The performance of instruments and equipment is evaluated on a regular basis to ensure that the equipment or instrument continues to function properly and has the appropriate historical records to properly audit and to evaluate. Routine maintenance tasks such as cleaning, adjusting, replacing of parts or lubricating are performed on each instrument by the responsible officer according to instructions provided in the operating manual of the instrument or as identified by past experience.

All maintenance tasks and repairs performed by the analyst or the service representative are recorded on the current instrument log sheet for each instrument. Analysts must report all malfunctions immediately to the responsible person for the instrument and clearly indicate that it is “OUT OF ORDER” when a malfunction occurs.

When available, service contracts which include semi-annual/annual maintenance of certain pieces of equipment should be obtained.

Calibration. The validity of the analytical results produced is strongly related to the performance level of the instrumentation used for analysis. It is therefore essential that for each instrument and each method, proper calibration procedures be established and that calibration results be recorded and used as a basis for continuous assessment of the instrument performance. The method calibration requirements are included as part of the method. Equipment/instrument calibration and traceability to national standards should be documented. Certified weights and thermometers are available and should be used and the documentation maintained in the laboratory.

Inventory. A permanent inventory record of all equipment is kept by the Laboratory Manager/Director. This record includes the equipment’s name, model number, serial number, manufacturer, date of acquisition, original cost and present location and any unique identifier assigned locally.

Parts and Supplies. The analyst must maintain a list of spare parts kept that are critical to keep the instrument operating and must review this list at least annually. This list is to be kept in the Instrument Log Book.
Responsible Officer. A responsible officer is assigned to the essential equipment. This person is normally the principal user of the system. In the case of shared equipment the responsible officer carries out performance checks and maintenance while the operators verify the calibration, run standards, operate the instrument in the correct manner, record data as required and informs the responsible officer of any anomalies or malfunctions.

The duties of the responsible officer are as follows:
1) To become thoroughly familiar, through training and experience, with the operation, maintenance and applications of the instrument.
2) To instruct and assist others in the use of the instrument.
3) To carry out regular performance checks on the instrument as outlined in the instrument and laboratory manuals.
4) To perform routine maintenance tasks according to the instrument manual.
5) To ensure the instrument log sheet or log book is filled out with each use.
6) To ensure that the instrument manuals are readily available and updated as required.
7) To establish a list of spare parts critical to keep the instrument operating and to ensure that there is an adequate supply of these parts. Alternatively a service and maintenance contract may be set up with a suitable sub-contractor.

A nominated deputy should be identified to perform these tasks in the absence of the Responsible Officer.

Instrument Log Book. The main purpose of the instrument log book is to provide a permanent record of instrument performance and to be used as a basis for validating data and projecting repair and replacement needs, or new acquisitions. If applicable, the service contract number is recorded in the log book.

Each time the instrument is used, the analyst must enter the information requested in the Log Book which will provide the laboratory with a record of use of the instrument, its performance and also any maintenance and repairs.

REPORTING ANALYTICAL DATA
Each procedure must specify the applicable range of the analyte to which it may be applied with some realistic significance (test limitation). The Laboratory Analyst is obligated to report numerical values which include only those numbers that are certain plus one digit that is estimated. This group of numbers is referred to as a significant figure. If more than one uncertain number is reported, a reader might be misled concerning the precision to which a measurement or set of measurements was made. To standardise the reporting of laboratory data, two conventions should be used. One deals with the rounding of numbers and the other with the reporting of significant figures. When it is necessary to round off data, round the number to the next higher value if the digit to its right is ≥ 5. If the last number discarded is < 5, leave the last retained digit unchanged. If the number to the right is 5, followed by zeroes only, round to the nearest even number.

The definition offered for significant figures is that they include all numbers in a result known with certainty plus one uncertain value. The position of the decimal point is
irrelevant. When data are reported, use the following rules to determine the number of significant figures:

1) Report only as many significant figures as are found in the least accurate measurement; and
2) Give the reader the best estimation of the errors in the measurement.

Some examples: If the zero is bounded on both the left and right by another number, it is always significant, 306 has three significant figures. If the zero is used to fix the decimal point it is never significant, 0.0024 has two significant figures, 0.00240 has three significant figures.

ACCURACY AND REFERENCE SAMPLES
To assure the accuracy of the procedure a reference sample (working standard) with known and stable values should be run with each batch and evaluated by means of a control chart (see section on control charts).

The reference material can be a pure substance Reference Material (RM) and the recovery of the analyte will be a measure of the accuracy of the method.

For most feed analyses however, Certified Reference Material (CRM) or a home-made feed reference sample (HRM) is used.

The CRM can be obtained from organisations for proficiency tests of animal feeds (Table 4) where the reference values are determined by several laboratories applying several independent validated test methods. A lab can also make its own reference sample. A feed material should be chosen which is representative for the bulk of feed samples analysed in the lab. This sample should be analysed in duplicate, at least in 6 different runs, spread over several days/weeks. In these runs preferably a CRM is analysed and only when the values of the CRM are within the control limits, the results of the HRM may be taken into account. Before calculating the mean and SD clearly deviating results should be eliminated. From the HRM a sufficient amount should be portioned; a portion should be sufficient for at least six months and the remaining portions should be preserved in the freezer. The control chart should be regularly evaluated for trends, which may be indicative of the deterioration of the quality of the portion. The same HRM may be used for several methods in the lab.

PRECISION AND BLIND DOUBLE SAMPLES
To increase the precision of the results (reduce the scatter), all analyses are preferably carried out in duplicate. As this is not always feasible because of financial reasons or sample amount, it is suggested that a minimum 10% of the samples in a batch be run in duplicate. The duplicated sample(s) should be preferably unknown for the analyst (double blind), so ensuring the precision of the samples analysed in singular. The acceptable range of the duplicate results varies depending on the method, the customer requirements and the sample matrix. The relative range or relative percent difference can be calculated as:

\[
\text{Relative Percent Difference} = \left( \frac{X_1 - X_2}{\text{mean of replicate values}} \right) \times 100\\
\text{where},\\
X_1 = \text{the largest replicate value}\\
X_2 = \text{the smallest replicate value}
\]
For guidelines to the analytical variation that can be expected from analysing a sample twice (Table 1). The analytical variation in this case is two times the coefficient of variation or relative standard deviation:

**TABLE 1**

Analytical Variations (AV) in [%]; \(x = \text{analyte concentration}\)

<table>
<thead>
<tr>
<th>Analyte</th>
<th>AV (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Moisture (Dry Mass)</td>
<td>12</td>
</tr>
<tr>
<td>Protein</td>
<td>(20x + 2)</td>
</tr>
<tr>
<td>Fat</td>
<td>10</td>
</tr>
<tr>
<td>Crude Fibre</td>
<td>(30x + 6)</td>
</tr>
<tr>
<td>Ash</td>
<td>(45x + 3)</td>
</tr>
<tr>
<td>Total sugars as invert</td>
<td>12</td>
</tr>
<tr>
<td>Calcium</td>
<td>10</td>
</tr>
<tr>
<td>Phosphorus</td>
<td>(3x + 8)</td>
</tr>
<tr>
<td>Salt</td>
<td>(7x + 5)</td>
</tr>
<tr>
<td>Vitamin A</td>
<td>30</td>
</tr>
</tbody>
</table>


For guidelines regarding the accuracy or percent recovery of quality control samples one can use the AOAC “International Guidelines for Single Laboratory Validation of Chemical Methods” (Table 2).

**TABLE 2**

Acceptable Recovery Limits

<table>
<thead>
<tr>
<th>Concentration</th>
<th>Recovery Limits (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>100%</td>
<td>98 - 101</td>
</tr>
<tr>
<td>10%</td>
<td>95 - 102</td>
</tr>
<tr>
<td>1%</td>
<td>92 - 105</td>
</tr>
<tr>
<td>0.1%</td>
<td>90 - 108</td>
</tr>
<tr>
<td>0.01%</td>
<td>85 - 110</td>
</tr>
<tr>
<td>10 μg/g (ppm)</td>
<td>80 - 115</td>
</tr>
<tr>
<td>1 μg/g (ppm)</td>
<td>75 - 120</td>
</tr>
<tr>
<td>10 μg/kg (ppb)</td>
<td>70 - 125</td>
</tr>
</tbody>
</table>

To calculate the percent recovery from a reference material:

\[
\text{Percent recovery} \% = \left( \frac{X_r}{X_k} \right) \times 100
\]

where,

\(X_r\) = observed value of reference material

\(X_k\) = certified or true value of reference material
TRACEABILITY OF RESULTS
Since all measurements made by the laboratory must be traceable to the International System of Units (SI), contracting metrologists should provide evidence of measurement traceability of its own measurement standards and measuring instrument to the SI. Further, they should provide documentation demonstrating measurement capability and competence to perform the calibration services requested by the laboratory. The calibration certificates for laboratory instruments (balances, pipettes, etc.) should include the measurement results along with the measurement uncertainty and a statement of conformance with an identified metrological specification. Purchased standards should be accompanied by certificates of analysis.

PROFICIENCY TESTING (EXTERNAL QUALITY ASSURANCE)
Participating in proficiency sample test programs allows for the assessment of the laboratory’s accuracy and precision. Where possible, the program’s matrices and tests should match that of the laboratories. In order to evaluate the laboratory’s performance a “Z” value is calculated. Any Z value ≤ 2 is satisfactory, values between 2 and 3 are questionable and any value ≥ 3 is unsatisfactory, requiring an investigation and corrective action. The Z value is calculated by taking the difference between the laboratory’s result and the program’s reported result and dividing that difference by the program’s reported standard deviation. In other words, the Z value is how many standard deviations the laboratory’s result is from the consensus value. The Association of American Feed Control Officials (AAFCO), the American Association of Cereal Chemists (AACC), the American Oil Chemists’ Society (AOCS) all provide such programs. The European PT Information System (EPTIS) maintains a current list of available proficiency programs. The laboratory should have a documented schedule for participation in proficiency schemes (Table 3).

### Table 3
Organisations providing proficiency testing and reference samples of animal feed

<table>
<thead>
<tr>
<th>Organisation</th>
<th>Address</th>
<th>Telephone</th>
<th>Email</th>
<th>Website</th>
</tr>
</thead>
<tbody>
<tr>
<td>AAFCO (Association of American Feed Control Officials)</td>
<td>175 S. University Street IN47907-2063 West Lafayette Indiana USA</td>
<td>+1 7654941565</td>
<td><a href="mailto:vsiegel@purdue.edu">vsiegel@purdue.edu</a></td>
<td><a href="http://www.aafco.org">www.aafco.org</a></td>
</tr>
<tr>
<td>IAG – Feedingstuffs (International Analytical Group, section feedingstuffs)</td>
<td>191 Spargelfeldstrasse 1220 Vienna Austria</td>
<td>+43 5055532700</td>
<td><a href="mailto:Renate.oeschmueller@ages.at">Renate.oeschmueller@ages.at</a></td>
<td><a href="http://www.ages.at">www.ages.at</a></td>
</tr>
<tr>
<td>BPEA (Bureau InterProfessionnel d’Étude Analytique)</td>
<td>6-14 av. Louis Roche F-92230 Gennevilliers France</td>
<td>+33 147335460</td>
<td><a href="mailto:Contact@bipea.org">Contact@bipea.org</a></td>
<td><a href="http://www.bipea.org">www.bipea.org</a></td>
</tr>
<tr>
<td>FAPAS (Food Analysis Performance Assessment Scheme)</td>
<td>Sand Hutton YO41 1 LZ York UK</td>
<td>+44 1904462100</td>
<td><a href="mailto:info@fapas.com">info@fapas.com</a></td>
<td><a href="http://www.fapas.com">www.fapas.com</a></td>
</tr>
<tr>
<td>LGC (Laboratory of the Government Chemist)</td>
<td>1 Chamberhall Business Park BL9 6AP Lancashire UK</td>
<td>+44 1617622500</td>
<td><a href="mailto:customerservices@lgcpt.com">customerservices@lgcpt.com</a></td>
<td><a href="http://www.lgc.co.uk">www.lgc.co.uk</a></td>
</tr>
<tr>
<td>WEPAL (Wageningen Evaluating Programmes for Analytical Laboratories)</td>
<td>P.O. box 8005 NL-6700 EC Wageningen The Netherlands</td>
<td>+31 317482337</td>
<td><a href="mailto:Info.wepal@wur.nl">Info.wepal@wur.nl</a></td>
<td><a href="http://www.wepal.nl">www.wepal.nl</a></td>
</tr>
</tbody>
</table>
CONTROLS CHARTS – STATISTICAL PROCESS CONTROL

To ensure that the laboratory methods are in statistical control, laboratory performance should be evaluated using control charts. Mean or X-bar charts are designed to point out changes in the value of the long term average for a sample analysed by a specific method. Range, or R-bar, charts are designed to point out changes in the repeatability of a procedure. If a statistics software program is not available, the data may be plotted using the following procedures:

Construct the basic charts by calculating the long term or grand average mean and grand average range by averaging at least 6 sets of duplicates obtained over 3 days. Make the X bar chart by drawing a solid horizontal line across the centre of the page, label it “0”, draw dashed lines at ± 1.25 (these represent the warning limits at 95% confidence. Draw two more lines at ± 1.88. These represent the control limits at 99% confidence. Label the y-axis with these values and what they represent, i.e. 1.88 is the upper control limit and -1.88 is the lower control limit. Average the two results of the control samples. Calculate and plot the Z values along the Y axis with the corresponding date along the X axis. Z value = (average of two controls minus grand mean) divided by the grand average range. Construct the R-bar chart by a drawing solid horizontal line across the bottom of the page, labelling it “0”. Draw dashed lines one at ± 2.51 which represents the warning level at 95% confidence and the second at ± 3.27 which represents the control limit at 99% confidence. Divide the difference of the two control samples by the grand average of the range of the controls and plot this on the chart along the Y axis with the date along the X axis.

Control charts should be evaluated after each group of samples is analysed and checked to ensure they are within specifications before the results are reported to the customer.

The process is in control if:

1) All points on the X bar and R bar charts are within the control limits (subject to limitations listed below).
2) One and only one mean value in the last 20 is outside the control limits and the range value is not.
3) One and only one range value in the last 20 is outside the control limits and the value of the mean is not.
4) Specific cause for an apparent out of control point has been identified and eliminated.

The process is out of control with respect to the mean (X bar chart) if:

1) More than one mean point in the last 20 has exceeded the upper or lower control limits but the range is within control.
2) Both individual values of the mean for a given control are outside the warning limits even if the mean is not.
3) Seven consecutive means are all on one side of the “0” line.
4) Seven consecutive means fall in a consistent upward or downward pattern.
5) There is a run of four means between the upper warning limit and the upper control limit or between the lower warning limit and lower control limit.
The process is out of control with respect to the range (R bar chart) if:
1) More than one point in the last twenty has exceeded the control limit and both
   values of x are outside the warning limits on the X chart.
2) The points on both the X bar and R bar charts are outside the control limits.
3) Seven consecutive points fall in a consistent upward or downward pattern in the
   points.
4) There is a run of four points between the warning limit and the control limit.

A method is not out of control if the analyst knows that he/she did something different
or some difficulty was experienced with the procedure or equipment on a given set. This
should be recorded on the appropriate worksheet. The control charts only allow for deter-
mining whether or not the variation observed can be described by random variation. The
acceptable variation or limits are determined by the laboratory customer.

See Figure 2 and Figure 3 for example Mean and Range control charts.

DOCUMENTATION AND CONTROL OF DOCUMENTS

Quality documents that form the management system must be controlled. Laboratory
document control procedures describe the process for controlling those quality documents
required for the generation of laboratory data. These documents include those published
by the laboratory and those published externally. Documents of external origin include
regulations, standards, test methods, instructions and manuals.

Documents issued to personnel in the laboratory as part of the management system are
reviewed and approved for use prior to issue in accordance with the laboratory’s document
control and management procedure. The laboratory’s master list of procedures identifies
the current revision status and distribution of documents. Through the use of the master
list, quality documents are issued to personnel to preclude the use of obsolete documents.

The laboratory’s master list and document control and record management procedure
provide for the following:

- Authorised management system documents and external documents are held at
  point of use.
- Documents are reviewed according to a schedule and revised to ensure continuing
  suitability and conformance with the management system, an appropriate revision
  date will be given to each document.
- Invalid or obsolete documents are promptly removed from all points of issue or use
  to assure against unintended use.
- Obsolete documents retained for either legal or knowledge preservation purposes are
  marked as archived or obsolete.
- To avoid the potential of different procedures being in use at the same time at dif-
  ferent locations hand amendments or uncontrolled copies should not be permitted.
- A document control header, as described in the laboratory’s document control and
  management procedure, uniquely identifies management system documents gener-
  ated by the laboratory. Such identification includes the date of revision, identification
  number, issuing authority and pagination.
- Proposed changes to documents are reviewed and approved in accordance with
Part I – Setting up a quality laboratory system

FIGURE 2
X-Bar chart for Acid Detergent Fibre (UCL, Upper control limit; LCL, lower control limit)

FIGURE 3
Range chart for Acid Detergent Fibre (UCL, Upper control limit; LCL, lower control limit)

the laboratory’s document control and management procedure. Unless designated otherwise, this procedure is followed by the same personnel as in the original review or approval.

- The altered or new text is identified either in the document, on a cover page, or in the attachments. A Log of updates, included in the first page of a new document, simplifies identification of any changes.
The laboratory’s document control and management procedure addresses the control of electronic management system documents.

LABORATORY SAFETY
As an employee you have a responsibility to do your job well and safely. A priority of the laboratory is to offer you a workplace free from recognizable and avoidable hazards to your health and safety.

Safety, however, cannot be mandated, nor is it something that can be given to an employee. Rather, you must make a conscious effort to help ensure safe conditions for yourself and for other workers in the area. This requires an understanding of potential hazards on the job and knowledge of the policies and regulations in dealing with those hazards.

There are unavoidable sources of risk in any work environment, particularly in a laboratory. To keep the hazards from causing injuries, each individual must know how to use the tools and equipment safely and be informed of what to do in case of a fire, injury or other emergency. However, information is not enough. Safety on the job is an attitude as much as it is knowledge. It means recognizing that accidents are not limited to those people who do not know how to prevent them. It is often the seasoned veteran, the person who “knows better,” who becomes a victim by allowing familiarity to dull the edge of caution.

You should maintain constant awareness. It involves your personal commitment to do every job safely.

Other workers must be alerted to danger if they are not following the safety procedures, these incidences must be documented.

Supervisors and Safety officers should be identified. These personnel should be notified immediately of defective emergency equipment or other potential dangers.

By participating on safety committees, assisting in making safety inspections and assuring that all safety practices are carried out every time you can ensure all work is done in a safe manner.

No work is so important that there is not time to do it safely and correctly!

For further information on Health & Safety in the laboratory see ‘Laboratory Safety’ (see page 61).

AUDITS/CORRECTIVE ACTIONS/MANAGEMENT REVIEWS
Internal audits are conducted as needed (minimum of annually). The internal audits are conducted to verify that operations continue to conform to the requirements of the quality management system.

The internal audit schedule addresses all elements of the management system, including analytical activities. The Laboratory Quality Assurance Manager is responsible for the coordination of internal audits in addition to any additional audits requested by management or identified through anomalies.

Trained and qualified personnel are responsible for conducting internal audits. Auditors may audit in their own area but must not audit their own work.

When audit findings cast doubt on the effectiveness of the operations or on the cor-
rectness or validity of the laboratory’s analytical results, the laboratory’s corrective action procedure is initiated.

The customer is notified if investigations show that non-conformances related to audit results have affected work performed for the customer. This notification is documented and an impact assessment carried out to identify possible anomalous results issued prior to identification of the finding.

The area of activity audited, the audit findings, and corrective and preventive actions (CAPA) that arise from them are recorded according to the laboratory’s audit procedure.

Follow-up audit activities are conducted to verify and record implementation and effectiveness of the corrective action taken. This follow-up is included as part of the management review process.

The laboratory’s management review procedure includes the schedule for conducting management reviews. This review is conducted by the laboratory’s executive management to ensure continuing fitness for use and effectiveness of the management system and to introduce needed changes and identify opportunities for improvements.

The management review addresses the elements of the management system and includes but is not limited to the following elements:

- Suitability of policies and procedures;
- Reports from managerial and supervisory personnel;
- Outcome of recent internal audits;
- Corrective and preventive actions;
- Assessments by external bodies;
- Results of inter-laboratory comparisons (proficiency tests);
- Changes in the volume and type of work;
- Customer feedback;
- Complaints; and
- Other factors, such as quality control activities, resources and staff training.

The findings and the actions that arise from the review are recorded according to the laboratory’s management review procedure. Each action includes a target date for resolution.