QUALITY ASSUARENCE IN THE FOOD CONTROL LABORATORIES

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OBJECTIVES & CONCEPTS

1. General principle

- The food control laboratory exists to provide information about the safety and composition of food
- The quality of that information is judged by whether it is appropriate standard, is available on time and is produced at acceptable cost

The criterion for “an appropriate standard” is whether or not the data is fit to be used for the intended purpose.

Quality assurance is the system which provides confidence that;

- The standard is adequate
- Failure to meet that standard will be detected
- The cause of the failure can be identified corrected

2 General principle

- The QA programme will cover all aspects of the laboratory's work which can affect the quality of its output.
- There is no "universal " QA programme , suitable for all food control laboratories. The emphasis given to each aspect of QA will reflect the laboratory's work & objectives.
- If staff are to be expected to implement a QA programme , they should be able to be involved in devising it.

Why do we need QA

- Importance of analytical science
- Demonstrate Validity of results
- Demonstrate Traceability
- Mutual Acceptance of Test Data

Importance of Analytical Science

- Underpins economic & social activities
- One billion measurements a year in UK
- High costs:
  - Of measurements
  - Of correction
  - Implication of errors

US clinical chemical analysis

- 3,000,000,000 analysis per annum
- Average cost $3 per test
- 1 in 10 repeated
- Cost of repeats $900,000,000 per annum

Total System Control

1. To avoid unforced errors
2. Protect laboratory and staff

Quality defined

- Deming : The difficulty in defining quality is to translate future needs of the user into measurable characteristics, so that a product can be designed and turned out to give satisfaction at a price that the user can afford
- Crosby : Conformance to requirements
- Juran : Fitness for purpose
- The totality of characteristics of an entity that bear on its ability to satisfy stated and implied needs (*as defined in ISO 8402;1994, Vocabulary)*

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Quality can also be expressed by the simple formula

$$Q = P/E$$

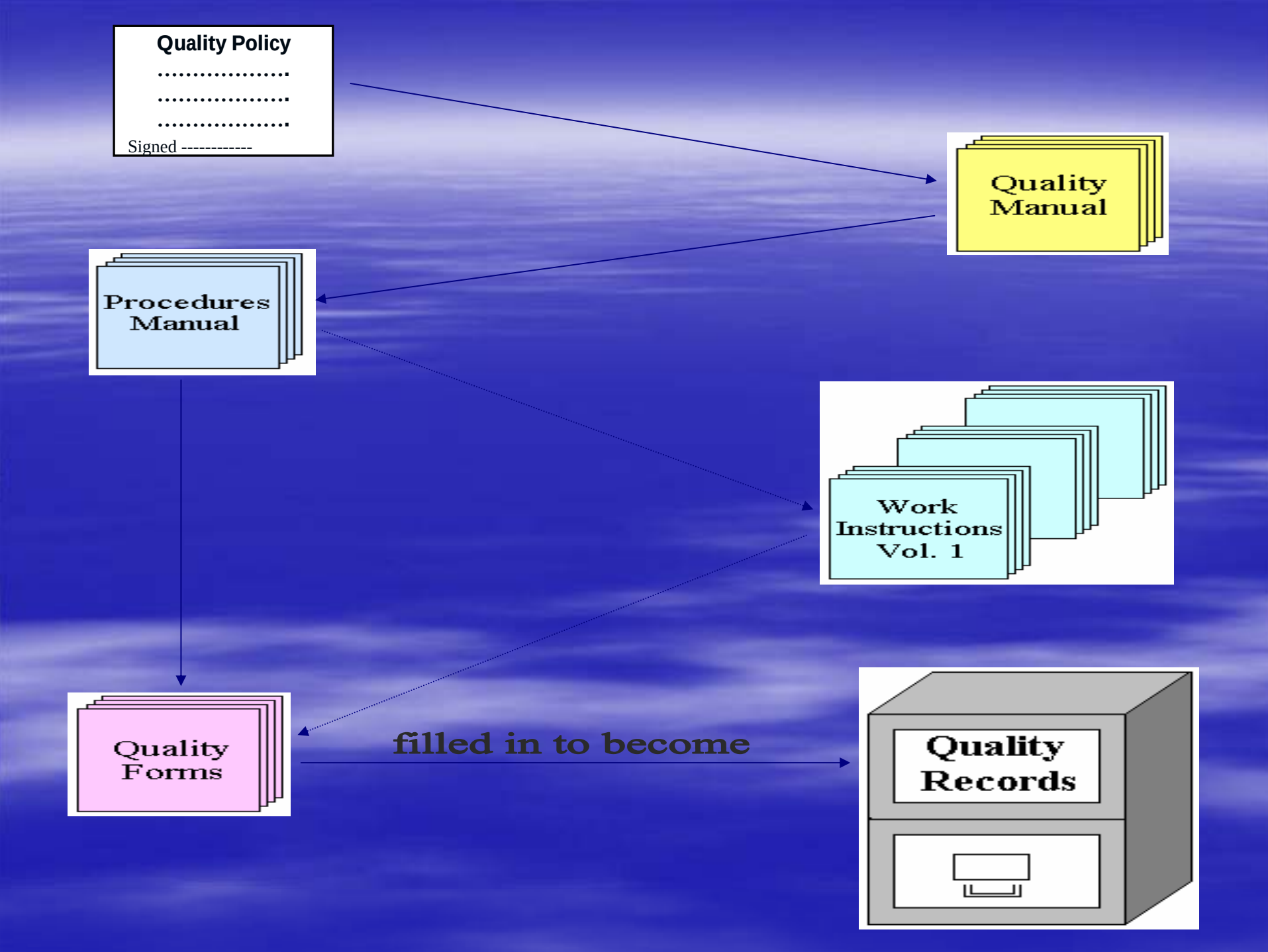
Where P= Performance or result

E= Customer's expectations

When Q=1, the customer's expectations are complied with and full customer satisfaction is attained. This is the ideal situation.

Quality

- Fitness for purpose
- Delivered on Time
- Acceptable Cost


Quality Policy
.....
.....
.....
Signed ----------
Quality Manual
Procedures Manual
Work Instructions Vol. 1
Quality Forms
filled in to become
Quality Records

Definitions

- Quality Control

  A planned system of activities designed to provide a quality product

- Quality Assurance

  A planned system of activities designed to ensure that the quality control programme is effective

Quality Control

"It costs less to prevent a problem than it does to correct it"

Quality control procedures:

- blanks
- standards
- QC samples
- control charts
- blind samples
- duplicate analysis

Ensure QC measures are satisfactory before analysing samples.

Quality Assurance

- Quality system
- Suitable environment
- Suitable caliber of staff
- Training procedures and competence records
- Suitable equipment appropriately maintained
- Suitable reagents and standards
- Documented validated methods
- Use of certified reference materials
- Calibration (traceable to National standards)
- Use of In-house internal QC samples (IHRM)
- Checking and reporting procedures
- Complaints procedures
- Quality audit and review
- External assessment
- Inter-comparisons and proficiency testing schemes

What will it costs

- Cost of measurement
- Cost of correction
  - re-sampling
  - reanalysis
  - scrapped data
  - trouble shooting
  - etc
- Cost of mistakes
  - replacement of goods
  - loss of business
  - health and safety
- Cost of quality
- Cost of QA
  - initial and running costs
- Cost of not having QA

Costs

- Prevention:

  - stop unacceptable data being generated

- Appraisal:

  - maintenance of performance level by formal audits of performance

- Correction:

  - for unacceptable results and consequences

Mutual recognition of analytical data

- The data must stand comparison over time so that trends can be followed
- Measurements made in different laboratories and in different countries need to agree

Benefits of Quality Assurance

- Valid measurements
- Traceability
- Laboratory status
- Laboratory performance
- Competitive edge
- Mutual acceptance of test data

Who does what in QA

Management:

- Decision to introduce QA
- Commit resources
- Designate a leader (QA Manager)
- Approve plan
- Carry out review

Leader

- Develop a plan
- Manage implementation
- Carry out quality audit

Staff

- provide technical expertise
- Develop and operate parts of quality assurance systems

Personal management

- Director - Overall responsibility for management of all programmes and resources
  - Attitude to QA critical
- Supervisors – Control work of group on day-t0-day basis
  - Allocate resources to jobs
  - Monitor progress
  - Advise on methodology
  - Oversee QA plan for group
- Operators - Responsible for carrying out specific tasks in line with agreed programme to meet customer demands
  - Participate actively in QA
- Support staff - Non-professionals working under direct supervision

Organisation structure

- Indicate clearly relationships of all staff

Job Description

- Responsibilities defined
- Leads to appropriate qualifications, experience, training required to fulfill position
- Duties
- Reporting route

QA System

1. QA Standard
2. Science
   - Methods
   - Calibration
   - Proficiency Testing
3. Organisation
   - Sample handling
   - Documentation
4. Personnel
   - Training
   - Management
5. Audit

Training

- Training of new staff.
- Retraining of existing staff on Procedures and use of Equipment.

Form T1 (G)TRAINING: STANDARD OPERATING PROCEDURES (GENERAL) Training protocol for SOP

- Training protocol for SOP.....Title.....
- 1. Trainee will be assigned to a supervisor by the .....
- 2. Supervisor will ensure the trainee has read the SOP, appreciates the principles involved and has understood the procedure (and any related hazards) sufficiently to allow practical training to commence
- 3. The trainee will observe the supervisor carrying out the SOP for a minimum of ..... times and (if longer) until the supervisor is satisfied the trainee appreciates the practical details of the procedure (and any related hazards) sufficient to allow the trainee to carry out the procedure themselves.
- 4. The trainee will conduct the procedure under a direct supervision of the supervisor a minimum of ..... times and (if longer) until the supervisor is satisfied that the skills/experience necessary to effective and safe conduct of the SOP have been achieved.
- 5. The trainee will perform the SOP a minimum of .....times preferably on a material analyzed by a competent number of staff and (if longer) until the supervisor is satisfied that the trainee is producing results which are consistent with normal standards.
- 6. Competence will be monitored by ....., who will also make a formal review after ..... months/years
- Approved by :
- Head Section Quality Manager
- A copy of this Training Protocol will be held by the line manager normally responsible for tests using this SOP and by the Quality Manager.

T1 (I)

Training Protocol for Instrumentation

- Date:
- 1.Trainee will be assigned to a supervisor by the Head of Unit.
- 2.Supervisor will ensure the trainee understands the principles on which the instrumentation operates and has read the relevant manuals and SOP's sufficiently to understand the working of the instrumentation (and any related hazards) sufficiently to allow practical training to commence.
- 3.The trainee will observe the supervisor using the instrumentation for a minimum of --- times and (if longer) until the supervisor is satisfied that the trainee appreciates the practical details of its use, control and day-today operation use and routine maintenance.
- 4.The trainee will use the instrumentation under the direct supervision of the supervisor a minimum of ---- times and (if longer) until the supervisor is satisfied that the skills/experience necessary to the safe and effective day-today use and maintenance of the instrumentation have been achieved.
- 5.The trainee will operate the instrumentation a minimum of ---- times, preferably on materials previously examined by a competent user of the instrumentation, and (if longer) until the supervisor is satisfied that the trainee is obtaining the expected performance from the instrumentation and can satisfactory carry out relevant system performance checks.
- 6.Both trainee and supervisor will sign and date the competence certificate.
- 7.Competence will be monitored by the line manager who will also make a formal review after ---- months/years.
- 8.Competence will be reviewed whenever there is any significant change in the instrumentation, any necessary refresher training must be completed before competence is re-validated.
- Approved by: Head of Section --------- Quality Manager --------

Form T1 (L)TRAINING: STANDARD OPERATING PROCEDURES (LABORATORY)

Training protocol for SOP.....Title.....

1. Trainee will be assigned to a supervisor by the.....
2. Supervisor will ensure the trainee has read the SOP, appreciates the principles involved and has understood the procedure (and any related hazards) sufficiently to allow practical training to commence
3. The trainee will observe the supervisor carrying out the SOP for a minimum of ..... times and (if longer) until the supervisor is satisfied the trainee appreciates the practical details of the procedure (and any related hazards) sufficient to allow the trainee to carry out the procedure themselves.
4. The trainee will conduct the procedure under a direct supervision of the supervisor a minimum of ..... times and (if longer) until the supervisor is satisfied that the skills/experience necessary to effective and safe conduct of the SOP have been achieved.
5. The trainee will perform the SOP a minimum of .....times preferably on a material analyzed by a competent number of staff and (if longer) until the supervisor is satisfied that the trainee is producing results which are within the acceptance criteria for the test.
6. Competence will be monitored by ....., who will also make a formal review after ..... months/years

Approved by : Head Laboratories Quality Manager

A copy of this Training Protocol will be held by the line manager normally responsible for tests using this SOP and by the Quality Manager.

Form T2

COMPETENCE CERTIFICATE (Training)

- SOP Title
- Review Frequency Months/Years *
- Trainee: Supervisor
- Training has been carried out under my supervision according to the Training Protocol dated and I am satisfied that the trainee has the skills and understanding of the SOP needed to conduct it safely and to the specified standard without direct supervision.

- Name: Signature: Date:

- I acknowledge that I have received training according to the Training Protocol dated ---- and I am content that subject to the availability when necessary, of advice from an experienced colleague I can conduct it safely and effectively.

- Name: Signature Date:

- To: Quality Manager (2) for SOP file/Training File
- Copies for information : Trainee
- Head of Section

- * delete as appropriate.

T3 (I) COMPETENCE CERTIFICATE (Experience)

Instrumentation:

Equipment Items:

On the basis of experience and performance with this instrument I am satisfied that [.....] is safe and competent in its use.

Signed -------- Head of Section -------- Date --------

I am satisfied that on the basis of experience and performance I can reasonably claim to be able to use this instrumentation safely and competently.

Name --------- Signed ---------- Date ----------

To: Quality Manager for Instrument file/Training
Copies for information: Quality Manager/Training or equipment files
Head of Section

Form T4
COMPETENCE CERTIFICATE (Re-validation)

- SOP Title
- Name
- Review Frequency Months/Years *

- I have reviewed the evidence for extending/re-establishing * the certificate of competence in respect of this SOP and I am satisfied that on the basis of current performance/refresher training * the certificate of competence for the above named should be re-validated for a further period.

- Signed Head of Section Date

- I am satisfied that on the basis of current performance/refresher training * with this SOP I can reasonably claim to be safe and competent in its use.

- Name Signature Date
- To: Quality Manager (2) for SOP/Training
- File Copies: Head of Section
  Member of Staff

* Delete as appropriate

Internal Audits

- Planned Program.
- Horizontal or Vertical
- Details of the audit report.
- Findings to be reported to the next Management Review Meeting of the Quality System.

Horizontal Audit

- In horizontal audits the following documents have to be checked:-
- Staff & Training Records.
- Equipment Records Sheets.
- Authorization Sheets.
- Observation/Documentation of methods.
- Tests Reports.
- Calibration Records.
- Sample Handling.
- Quality Manuals.
- Proficiency Testing Results.
- Analytical Standards.
- Lab Book.
- General Laboratory Environment.
- Complaints & Anomalies.
- Support Services & Supplies.

Activity / aspect audited Section Audit Officer		Report No : Date :
Details of activities, documents, methods procedures ، records ، results and ، .reports examined during audit		
Non compliance- (s) / Observations (nil reports required)		
	Quality Manual Ref .	Category
Acceptance of non – compliance		(date)
Corrective action (s) and timescale and officer responsible for action	Timescale	Responsible Officer
Corrective Actions carried out by (name)		(date)
Confirmed by Audit Officer (signature)		(date)
Received and approved by Quality Manager (signature)		(date)

Complaints & Anomalies

- Any complaint/anomaly notified will be reported immediately to the Director who will record the problem in writing in (from CCR01) and pass it to the Quality Manager for investigation.
- The originator will be advised with the findings.
- The Quality Manager will maintain a Register of Complaints/Anomalies which will record details of the complaint.
- This Register will be presented as Agenda Item in each Management Review Meeting.

Customer:	Reference:	Verbal	Written	CCR No.

Description of complaint / anomaly:
Signed : **Date :**

Immediate curative measures:
Proposed Completion Date :
Signed : **Date :**

Relevant Section:
Action Done :
Signed : **Date :**

Proposed Corrective Action:
Proposed Completion Date:
Signed : **Date :**

Corrective Action Review :
Signed : **Date :**

Form (CCR-01)

The Accreditation Process

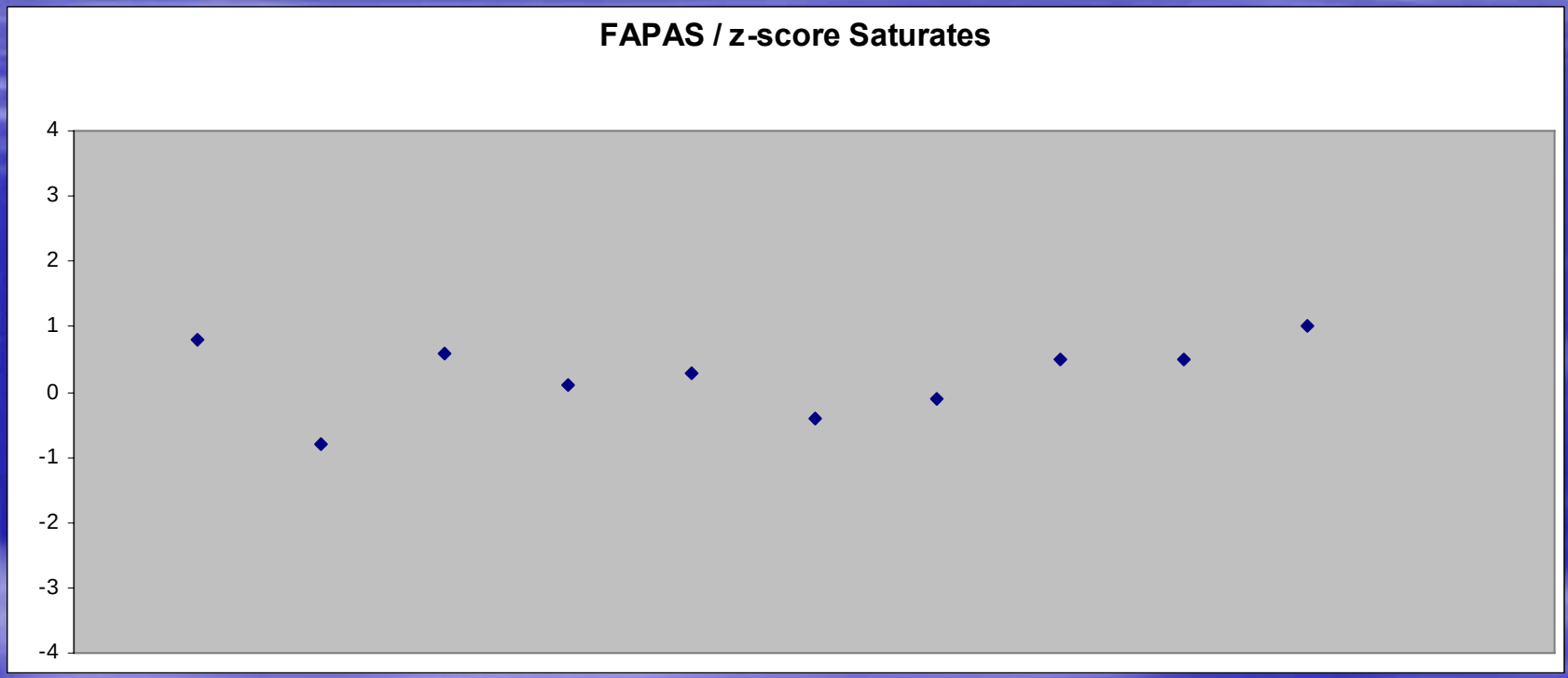
- Application
- Preliminary visit
- Assessment
- Accreditation
- Monitoring

United Kingdom Accreditation Services (UKAS)

- UKAS is a national accreditation body recognized by the government of UK to assess, against internationally agreed standards, organizations that provide certification, testing, inspection and calibration services.
- Accreditation by UKAS demonstrates the competence, impartiality and performance capability of these evaluators.
- Accreditation has a very key role to play in ensuring the competence and integrity of organizations that provide testing, certification, inspection and calibration services.

Proficiency Testing Schemes

- FAPAS & FEPAS Central Science Laboratory.
- Public Health Laboratory Service – Food EQA


FAPAS / z-score Saturates
4
3
2
1
0
-1
-2
-3
-4

Mean results for lead in cabbage mg/kg from 27 laboratories

- 0.10
- 0.14
- 0.18
- 0.22
- 0.26
- 0.34
- 0.46
- 0.50
- 0.54
- 0.58
- 0.62
- 0.66
- 0.74
- 0.82
- 1.02
- 1.18
- 1.22
- 3.60
- 3.90

Acceptable Range 0.23 – 0.41