QUALITY ASSURANCE AND ISTA ACCREDITATION

BY S.K. KOGO

SEED ENTERPRISE MANAGEMENT SHORT COURSE

UNIVERSITY OF NAIROBI
What is Quality Assurance?

QA started in the 20th century

• Complex industries with 100% reliability targets, e.g., arms, munitions, computers
• Then spread to mass production industries, e.g., cars, and to testing services

Instead of waiting until the product is made, and then checking if it is right QA is used to check all the steps in the process.

If the processes are ok then the product will be ok.
What is Quality Assurance?

• Company quality assurance (QA) is the means by which a seed company is satisfied that its products and services are maintained and enhanced, meeting customer and corporate expectations.

• Seed QA program provides a uniform and unbiased quality control systems and marketing tool for crop seeds merchandised as varieties lends or brands.

• Seed QA system makes everybody in the seed production and marketing chain responsible for seed quality.
Accreditation of Company Laboratories

Two routes:

1. Issuing domestic (national) certificates
2. Issuing international certificates

Same basic requirements in both cases

Based on QA principles
The end product of a seed testing laboratory is a seed test certificate giving the average quality of the seed lot.
The Quality revolution

React ➔ Act

Correct ➔ Prevent

Backwards check ➔ Forward check

SEMIs UoN
Seed Enterprises Management Institute
University of Nairobi
Avoiding errors

Mistakes cost money

Correcting mistakes wastes too much time

The cheapest mistakes are those that are eliminated before they happen

Think first!
Meeting the quality standard

The quality standard is achieved when all the customer’s requirements are met.

Overfulfilling customer requirements costs you money for no extra gain.

Underfulfilling leaves a dissatisfied customer
ISO Certification

ISO 9000 and ISO 9001:2008 are the standards used to CERTIFY companies in, for example, manufacturing or service industries.

Testing laboratories are certified using another standard - ISO 25 (now known as ISO/IEC 17025)

ISO 9000 and ISO 9001:2008 are the basic blueprint for Quality Assurance.

They cover areas of activity which have to be complied with in order to meet the standards
### Main elements of ISO 9000

| 1. Management Responsibilities | 11. Control of Test Equipment |
| 2. Quality System | 12. Test Status |
| 4. Design Control | 14. Corrective Actions, Error Control |
| 5. Document and Data Control | 15. Handling, Storage and Delivery |
| 6. Purchasing | 16. Quality records |
| 7. Customer supplied Products | 17. Internal Audits |
| 8. Identification and Traceability | 18. Staff Training |
From ISO 9000 to ISO 17025

The ISO 17025 standard is used for the ACCREDITATION of testing laboratories eg chemistry or molecular biology.

It is based on ISO 9000 but places extra emphasis on:

• Staff competence
• Equipment control and calibration
• Appropriate methods and method development
• Mandatory referee tests (proficiency testing)
The ISTA Standard is adapted from ISO 17025 to meet the specific needs of seed labs. It asks: “Is your system effective, are your staff competent, and are your referee tests ok?” Specific features of the ISTA Standard include:

- Sampling
- Independence of labs
- Use of ISTA Rules
- Staff competence
- Mandatory participation in the ISTA referee test programme
The 5 Ms and 1 E of Quality

Material
Man
Machines
Management
Methods
Environment

All these elements must be under control to get good quality
Building blocks of a QA system

- **Quality Manual (Level A)**
  - Describes the quality system in accordance with the stated quality policy and objectives and the accreditation standards

- **Documented quality system procedures (standard operating procedures) (Level B)**
  - Describes the activities of individual functional units

- **Other quality documents (work instructions, forms) (Level B)**
  - Consists of detailed work documents
Part of the QA documentation
Developing a QA culture

“Quality Assurance is an endless journey of improvement - it is not a destination.”

To introduce QA successfully:

- The organization must develop a “quality culture”
- Staff need to be convinced of the value of QA
- Once QA systems have been introduced, staff frequently experience greater job satisfaction
Developing a QA system

Successful introduction of QA will require the following steps:

1. Involving all staff in describing the procedures used in laboratory
2. Documenting the procedures
3. Making changes where the requirements of the quality system are not met
4. Linking documents together into a set of operating procedures based on client need
5. Monitoring the application of these procedures
6. Making changes on a continuous basis
ISTA COMPONENTS

1. Management Requirements
2. Staff
3. Environment, equipment and calibration
4. Lot identification, sampling and handling of samples
5. Methods and Procedures
6. Test Reports and Certificates
7. Records
8. Quality Assurance System
Environment, equipment and calibration

- The laboratory must be fit for the purpose of seed testing.
- A full range of equipment for the test being done should be provided.
- The equipment must be maintained in working order and where necessary, regularly calibrated.
Records

Calibration record

Temp control record for incubator
• Laboratories wishing to become members are requested to contact theISTA Secretariat for the necessary application forms. The ISTA Executive Committee will then decide about the application and grant membership.

• All accredited laboratories have to participate successfully in the ISTA Interlaboratory Proficiency Testing Programme, consisting of at least three rounds per year.

• A laboratory that wishes to become accredited must set up a Quality Assurance System including documentation following the ISTA Accreditation Standard. This standard is based on ISO/IEC 17025 Standard and especially amended to meet the needs of seed testing laboratories.

• Prior to accreditation, and every three years thereafter, the laboratories are audited by two ISTA Auditors (system and technical) and based on the auditor’s recommendation and the performance in the proficiency tests, accreditation is granted.

• After having successfully fulfilled the requirements of accreditation, authorisation to issue ISTA Certificates is obtained through agreement of the Designated Authority.

• Upon decision of the government of each country a Monitoring System could be installed for company laboratories.
The ISTA Accreditation System:

**Accreditation**

= formal recognition of a laboratory to competently carry out specific tests

**Authorisation**

= agreement of the Designated Authority of the country concerned for the laboratory to issue ISTA Certificates
The Accreditation Procedure:

1. Application for membership
   - Membership approved?
     - YES: Participation in Proficiency Test Programme
     - NO: STOP

2. Results o.k.?
   - NO: Corrective actions
   - YES: Application for accreditation

ISTA 2002
The Accreditation Procedure:

1. Submission of Q-Documents to the Secretariat

2. Documents o.k.? (YES or NO)
   - NO: Corrective actions
   - YES: Appointment of the audit team

3. Audit
The Accreditation Procedure:

1. Approval by the EC
   - YES
     - Authorisation DA?
       - YES
         - Accredited and authorized
       - NO
         - Accredited but not authorized
   - NO
     - Corrective actions o.k.?
       - YES
         - Corrective actions
       - NO
         - Accredited and authorized

Substantial Deficiencies?
   - YES
     - Corrective actions
   - NO
     - Accredited but not authorized

ISTA 2002
Proficiency testing is a key element in maintaining the competence of ISTA laboratories.
Proficiency Test Procedure:

Accreditation maintained? ✓
<table>
<thead>
<tr>
<th>Round</th>
<th>Dispatch Date</th>
<th>Species</th>
<th>Tests</th>
</tr>
</thead>
<tbody>
<tr>
<td>01-3</td>
<td>October 2001</td>
<td>Brassica napus</td>
<td>P, G, OSD</td>
</tr>
<tr>
<td>02-1</td>
<td>February 2002</td>
<td>Poa pratensis</td>
<td>P, G, OSD</td>
</tr>
<tr>
<td>02-2</td>
<td>June 2002</td>
<td>Triticum aestivum</td>
<td>P, G, OSD</td>
</tr>
<tr>
<td>02-3</td>
<td>October 2002</td>
<td>Pisum sativum</td>
<td>G</td>
</tr>
<tr>
<td>03-1</td>
<td>February 2003</td>
<td>Trifolium sp.</td>
<td>P, G, OSD, M</td>
</tr>
<tr>
<td>03-2</td>
<td>June 2003</td>
<td>Zea mays</td>
<td>G, TZ</td>
</tr>
<tr>
<td>03-3</td>
<td>October 2003</td>
<td>Lycopersicon esculentum</td>
<td>P, G, OSD</td>
</tr>
<tr>
<td>04-1</td>
<td>February 2004</td>
<td>Brassica napus</td>
<td>P, G, OSD</td>
</tr>
<tr>
<td>04-2</td>
<td>June 2004</td>
<td>Helianthus annuus</td>
<td>G</td>
</tr>
<tr>
<td>04-3</td>
<td>October 2004</td>
<td>Allium cepa</td>
<td>P, G, OSD</td>
</tr>
</tbody>
</table>

* P = Purity, G = Germination, OSD = Other Seed Determination, M = Moisture, TZ = Tetrazolium
ISTA Membership

ISTA Rules

Quality Assurance Programme

Proficiency Testing

ISTA Certificates

- Quality assurance system according to the ISTA Accreditation Standard
- ISTA audit every three years
- Audit by two ISTA auditors

Proficiency Testing

- 120 participating laboratories worldwide
- The laboratory’s performance is directly linked to its accreditation status