

# QUALITY ASSURANCE AND ISTA ACCREDITATION

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SEED ENTERPRISE MANAGEMENT

Seed Enterprise Management Institute

SHORT COURSE

University of Nairobi

SEED LEGISLATION AND ACCREDITATION

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  
eg 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

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Same basic requirements in both cases  
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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.

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Stamp of Laboratory  
Cachet du Laboratoire  
Stempel der Prüfstelle



**ISTA**  
**ORANGE INTERNATIONAL SEED LOT CERTIFICATE**  
**BULLETIN INTERNATIONAL ORANGE DE LOT DE SEMENCES**  
**INTERNATIONALER ORANGE-BERICHT ÜBER EINE SAATGUTPARTIE**

(See back - Voir au verso - Rückseite beachten)

STATED BY APPLICANT – INFORMATIONS DU REQUÉRANT – ANGABEN DES ANTRAGSTELLERS  
Without responsibility of the laboratory - Sans responsabilité du laboratoire - Ohne Verantwortung der Prüfstelle

Name of applicant  
Nom du requérant  
Name des Antragstellers

Species, cultivar, category, weight of lot etc.  
Espèce, cultivar, catégorie, poids du lot, etc.  
Art, Sorte, Kategorie, Gewicht der Partie usw.

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INFORMATION – INFORMATIONS – ANGABEN

Testing and issuing laboratory Laboratoire d'essai qui délivre le bulletin Untersuchende und berichtende Prüfstelle	<input type="checkbox"/> governmental, gouvernemental, staatlich <input type="checkbox"/> private, privé, privat <input type="checkbox"/> company, établissement, firmenreigen <input type="checkbox"/> governmental, gouvernemental, staatlich <input type="checkbox"/> private, privé, privat <input type="checkbox"/> company, établissement, firmenreigen
Sampling by Échantillonnage par Probenahme durch	Status of Certificate Nature du Bulletin Status des Berichts
Mark of lot Marques du lot Kennzeichnung der Partie	
Seal of lot Plomb du lot Versiegelung der Partie	

Number of containers Nombre de contenants Anzahl der Behälter	Date of sampling Échantillonnage effectué le Datum der Probenziehung	Date sample received Échantillon reçu le Eingangdatum der Probe	Date test concluded Analyse terminée le Datum des Prüfungsabschlusses	Test number No de l'analyse Untersuchungs-Nr.
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ANALYSIS RESULTS – RESULTATS DE L'ANALYSE – UNTERSUCHUNGSERGEBNISSE

SPECIES - ESPÈCE - ART (Scientific name - Nom scientifique - wissenschaftlicher Name):

PURITY - PURETÉ - REINHIT				GERMINATION - KEIMFÄHIGKEIT				MOISTURE CONTENT (wet basis) TENEUR EN EAUX (poids humide) FEUCHTIGKEITSGEHALT %
% Weight % Poids % Gewicht	Inert matier inertes	Other seeds d'autres plantes	Number of days	Normal seedlings Germin normaux	Hard seeds Graines dures	Fresh seeds Graines fraîches	Abnormal seedlings Germin anormaux	

Kind of inert matter - Nature des matières inertes - Art der ungeschädl. Verunreinigungen

Other seeds - Semences d'autres plantes - Andere Samen / Species (scientific names) - Espèces (noms scientifiques) - Arten (wissenschaftliche Namen)

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OTHER DETERMINATIONS – AUTRES DÉTERMINATIONS – WEITERE UNTERSUCHUNGSERGEBNISSE

(See also additional observations on back - Voir aussi observations complémentaires au verso - Siehe zusätzliche Bemerkungen auf der Rückseite)

Place and country - Localité et pays - Ort und Staat	Date - Datum	Signature - Unterschrift
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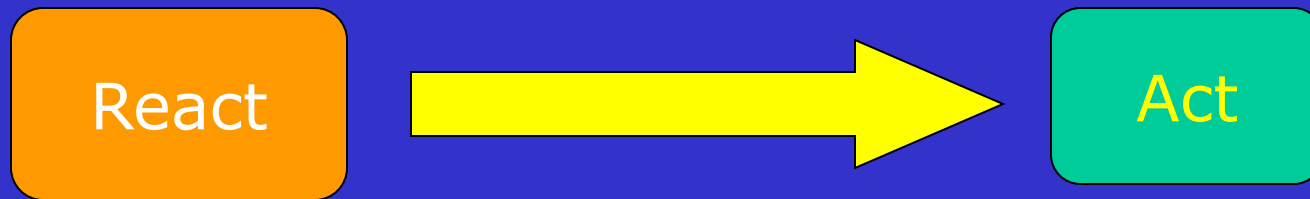
See declaration on back - Voir déclaration au verso - Siehe Erklärung auf der Rückseite

ISTA

Reg. No. 00033703

Reg.-Nr.

# The Quality revolution



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# Avoiding errors

Mistakes cost money

Correcting mistakes wastes too much time

The cheapest mistakes are those that are eliminated before they happen

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**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.

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Underfulfilling leaves a dissatisfied customer

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# 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.

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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
3. Contract Review	13. Non-conforming Products
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
9. Process Control	19. Maintenance, Warranty
10. Inspection and Testing	20. Statistics

# 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)

# From ISO 17025 to the ISTA Standard

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



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

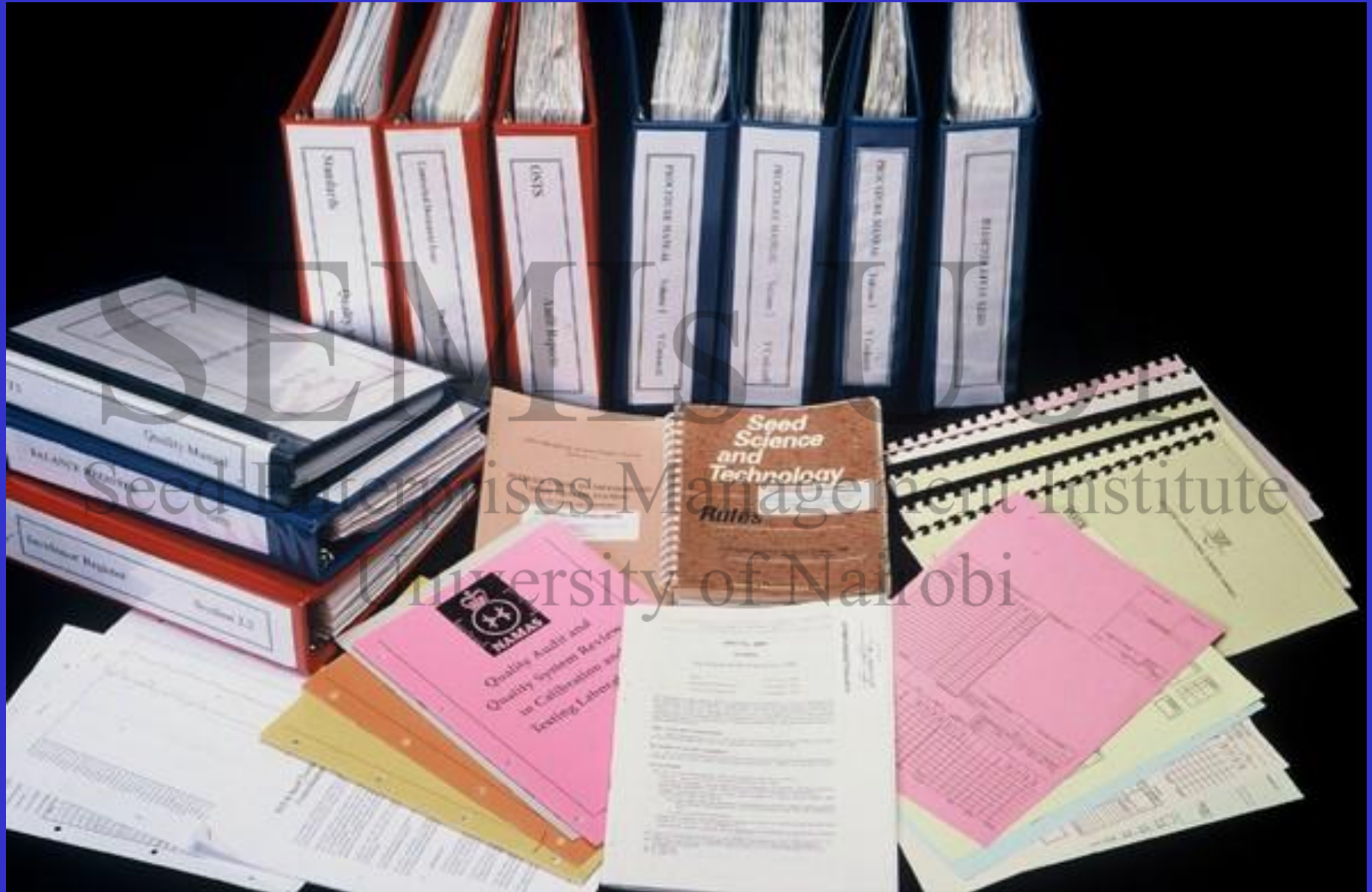
**Documented quality system procedures  
(standard operating procedures)  
(Level B)**

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

INTERNATIONAL SEED TESTING ASSOCIATION  
ASSOCIATION INTERNATIONALE D'ESSAIS DE SEMENCES  
INTERNATIONALE VEREINIGUNG FÜR SAATGUTPRÜFUNG

Secretariat, Zürichstrasse 50, P.O. Box 308, 8303 Bassersdorf, CH-Switzerland -  
Phone: +41-1-838 60 00 - Fax: +41-1-838 60 01 - Email: [ista.office@ista.ch](mailto:ista.office@ista.ch) - <http://www.seedtest.org>



ISTA Seed Testing Laboratory  
Accreditation Standard

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

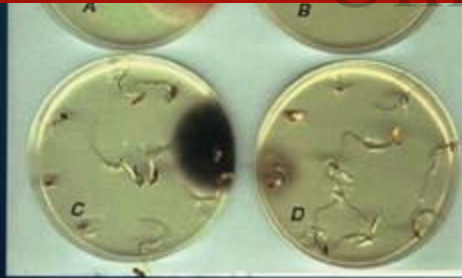
- The laboratory must be fit for the purpose of seed testing.
- A full range of equipment for the test being done should be provided
- The equipment must be maintained in working order and where necessary, regularly calibrated

25/04/99 - 01/05/99



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- (A)
- (B)
- (C)
- (D)

For Reference (optional) please

Lot no. 100, 101

Particulars	Quantity	Remarks
Lot 100	100	
Lot 101	100	

Prepared by: \_\_\_\_\_

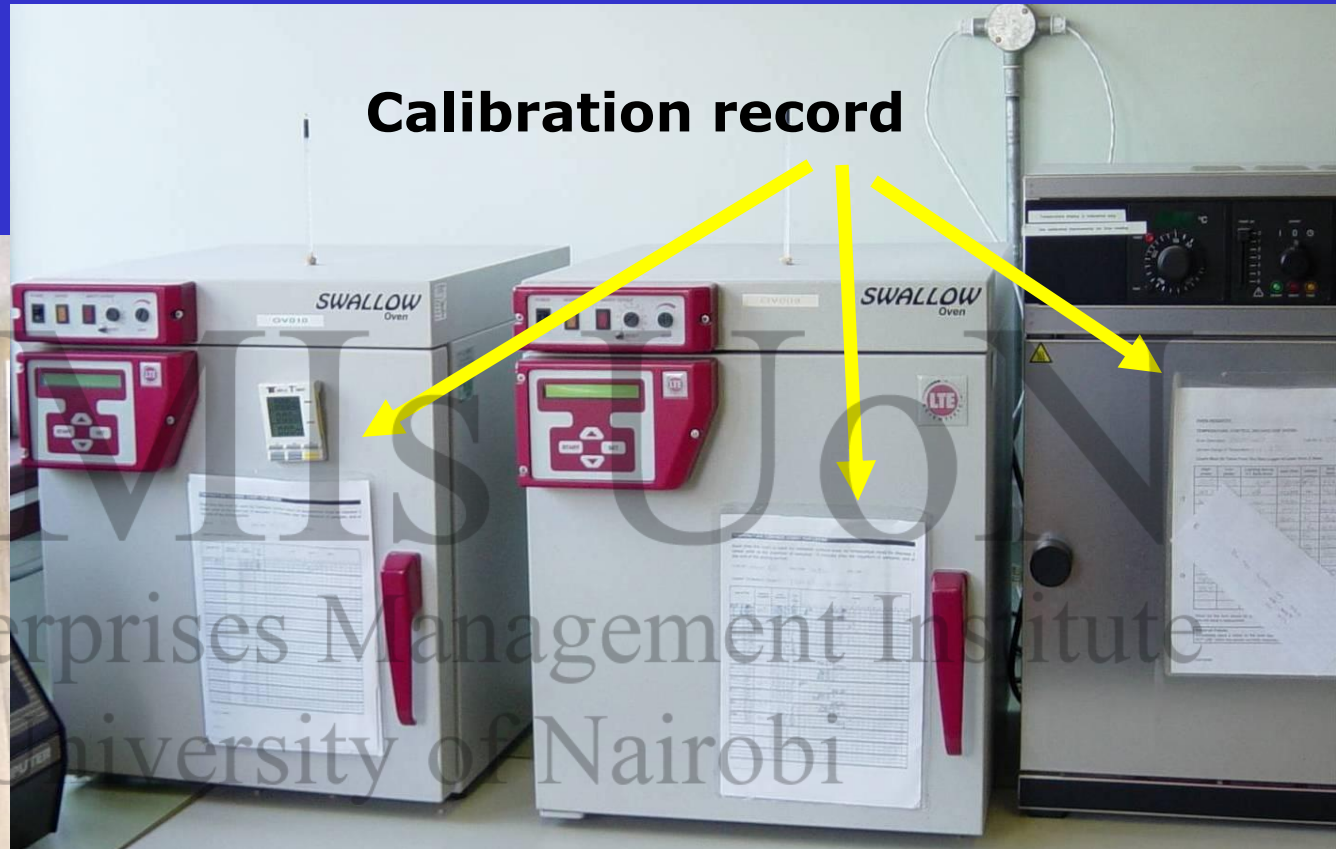
Checked by: \_\_\_\_\_

Date: \_\_\_\_\_



# Records

**Calibration record**



I/01

25/4/94 MR  
26/4/94  
27/1/90

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When full this table should be passed to the RESPONSIBLE PERSON for the equipment who will issue a replacement.

Failure on return:  
Immediately place a notice on the incubator stating "OUT OF TEMPERATURE RANGE - DO NOT USE" when the person currently responsible for incubators.

**Temp control record for incubator**



# PROCEDURE FOR ACCREDITATION INTERNATIONAL SEED TESTING ASSOCIATION ISTA

ISTA Membership

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

Participation in the  
ISTA Proficiency  
Testing Programme

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

Establishment of a  
Quality Assurance  
System

•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.

ISTA Audit

•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.

Authorisation to issue  
ISTA Certificates

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

Installation of a  
Monitoring  
Programme

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



International Seed Testing Association

## The ISTA Accreditation System:

### Accreditation

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

### Authorisation

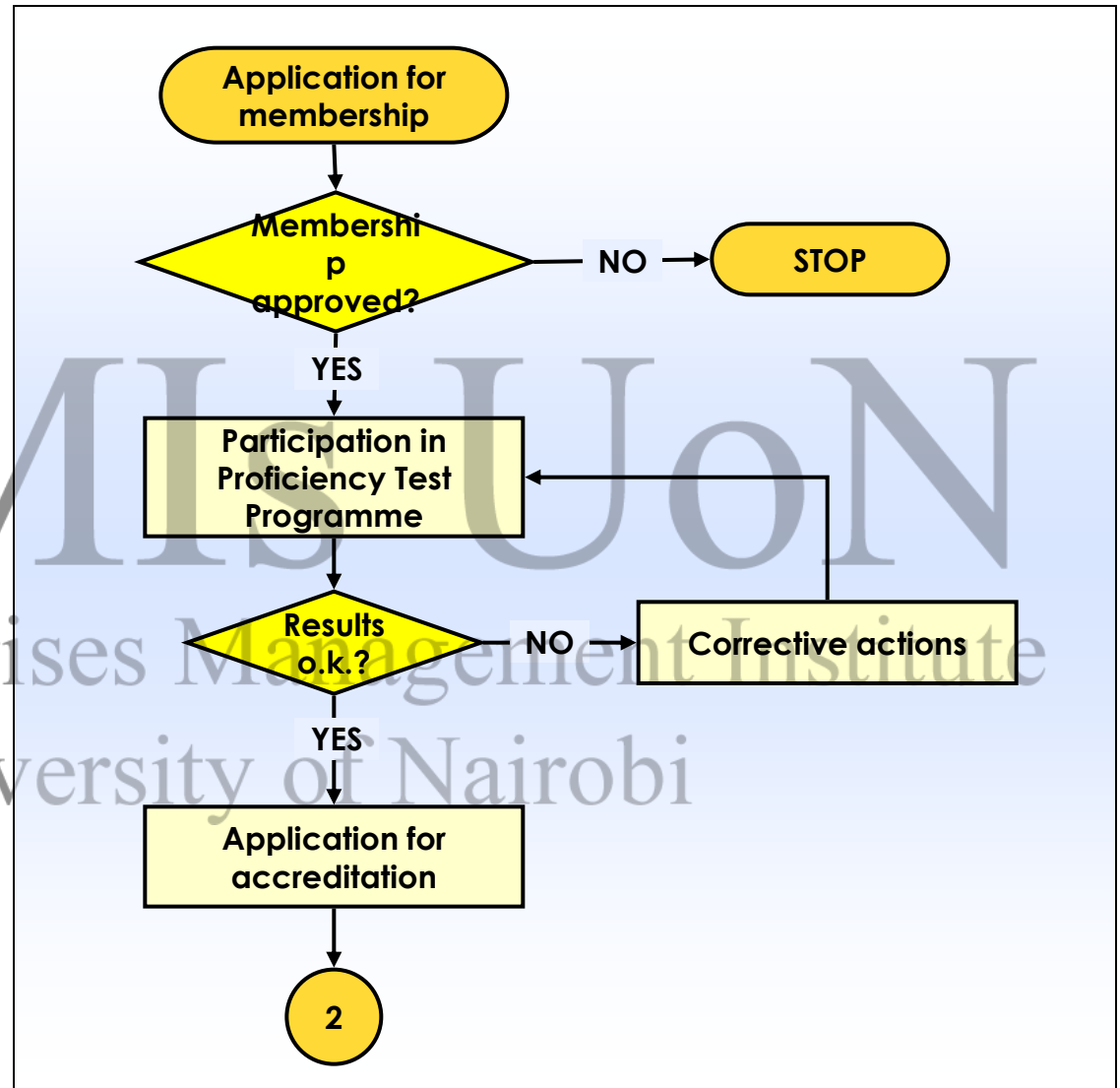
= agreement of the Designated Authority of the country concerned for the laboratory to issue ISTA Certificates





# International Seed Testing Association

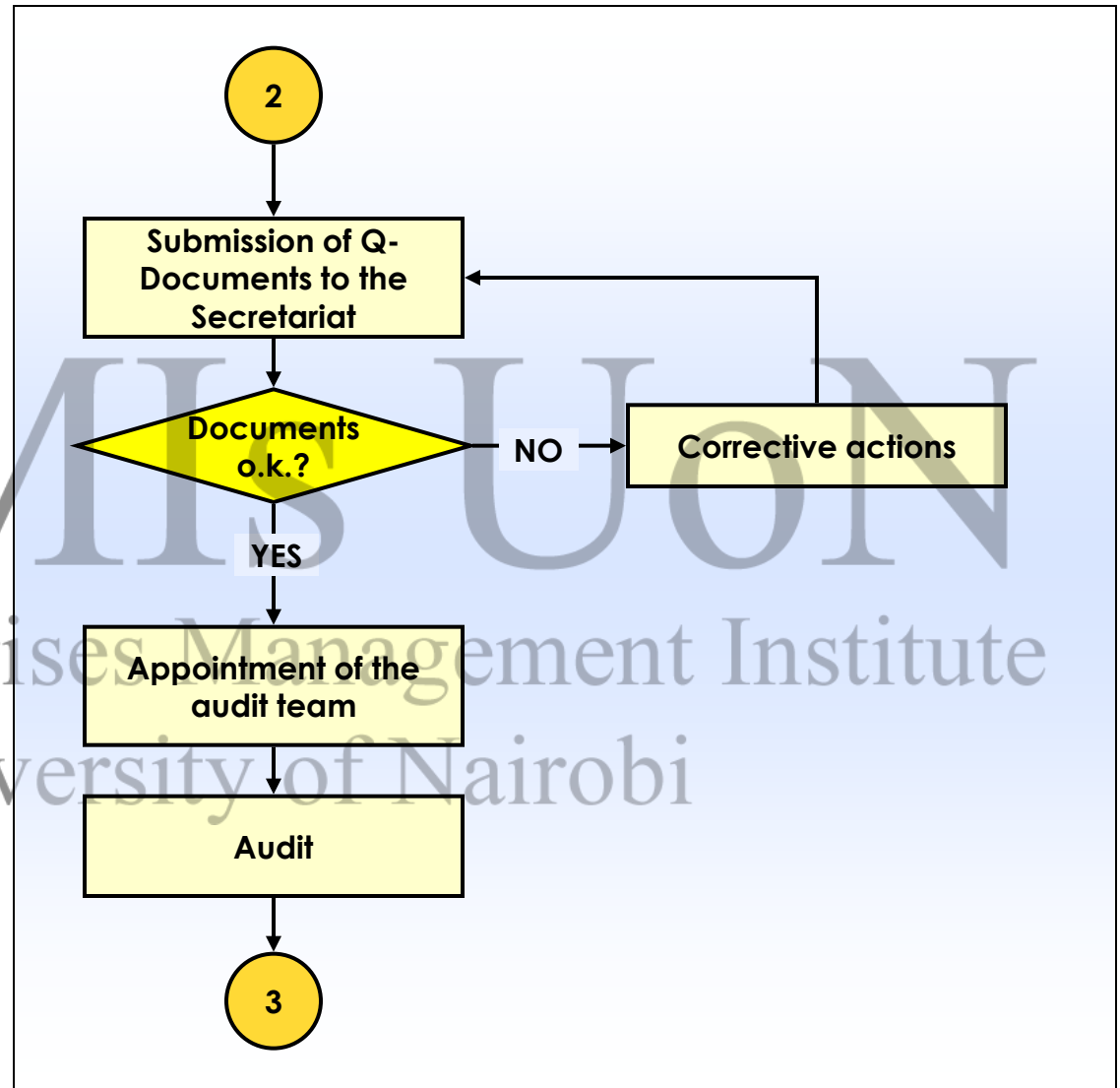
## The Accreditation Procedure:





# International Seed Testing Association

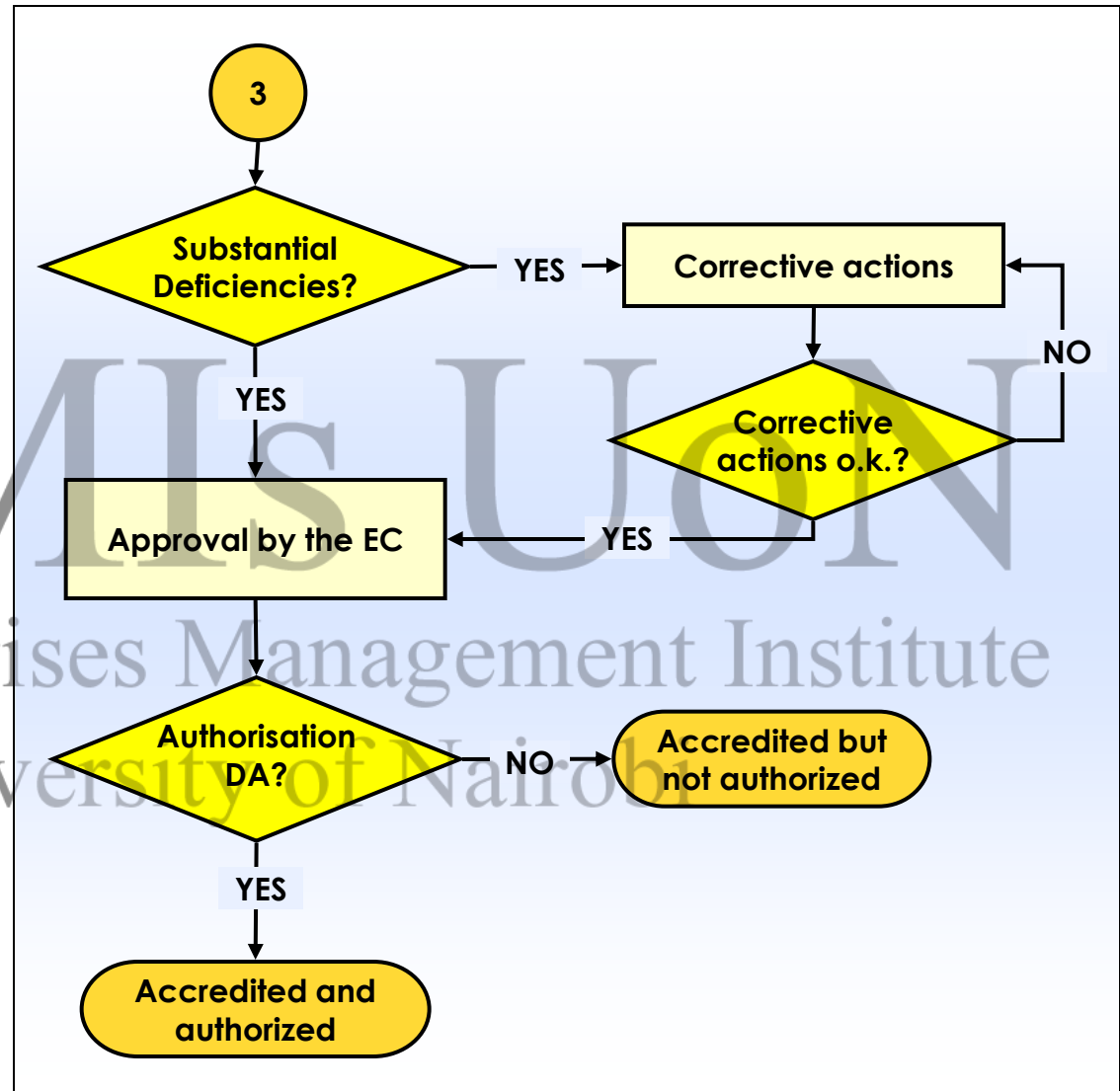
## The Accreditation Procedure:





# International Seed Testing Association

## The Accreditation Procedure:

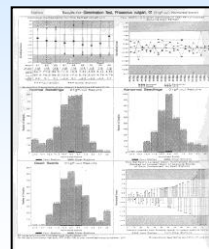
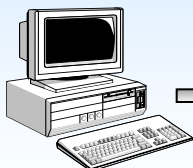
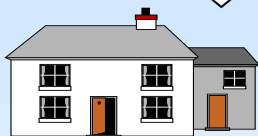
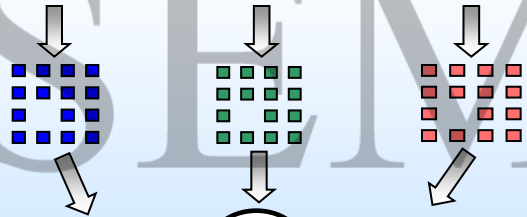


Proficiency testing is a key  
element in maintaining  
the competence of ISTA  
laboratories

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# INTERNATIONAL SEED TESTING ASSOCIATION ISTA



Accreditation maintained?

**Proficiency Test Procedure:**

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# INTERNATIONAL SEED TESTING ASSOCIATION ISTA



2001 – 2004

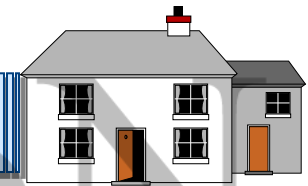
## ISTA REFEREE TEST PROGRAMME PLAN – LIST OF SPECIES AND TESTS BY ROUND

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

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



# INTERNATIONAL SEED TESTING ASSOCIATION ISTA



Seed Testing  
Laboratory

ISTA Membership

ISTA Rules

Quality Assurance Programme

Q-S-01

Proficiency Testing

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

- 120 participating laboratories world wide
- The laboratory's performance is directly linked to its accreditation status

ISTA Certificates

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**SEMMIS UoN**  
**THANK YOU**

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