Workshop and Training Program on Sampling and Detection Methods Applied to Transgenic Crops
November 17 – 19, 2011, NIN, Hyderabad, India

Design and Management of the Testing Laboratory

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Outline

- Laboratory set up and implementation
- Avoiding contamination
- Forward-flow system
- Good Laboratory Practice
- Method selection
- Proficiency testing
- Accreditation
- Quality management

In a DNA testing laboratory…

- The focus is on procedures rather than on operators/researchers
- Dedicated separated areas and common equipment
- Analytical performance must be maintained (and monitored) over time

General procedure for transgenic analysis

- Receipt of sample, and subsampling
- Preparation (grinding) of the sample
- DNA or protein extraction
- Detection of DNA or protein
- Interpreting and reporting results

One of the primary concerns in a DNA testing laboratory is:

CONTAMINATION

Deriving from:
- Cross-contamination
- Aerosols
- Dust

Precautions needed for:
- Rooms
- Equipment
- Working methods
- Personnel

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Separate Rooms Where Possible

- The various steps of the testing process should be physically isolated
- Ideally, key steps should be separated in different rooms of the building
- According to the facilities available, physical separation can be obtained by building internal divisions to separate the areas dedicated to key steps
- In all cases equipment should not be moved between areas

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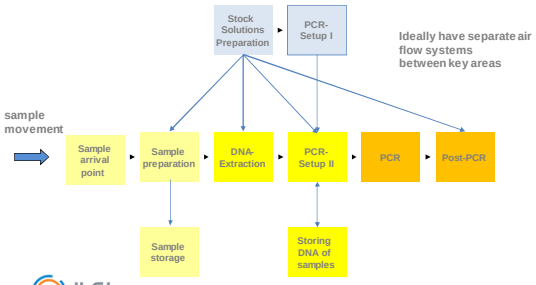
Forward-flow System



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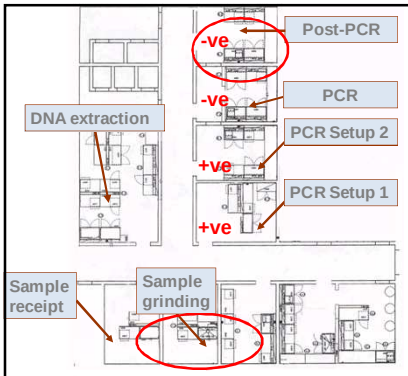
An ideal laboratory setup



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Special Equipment to Avoid Contamination

- ✓ Dedicated laboratory coats
- ✓ Disposable gloves
- ✓ Pipette tips with barrier filters protective against aerosols
- ✓ Disposable reaction and centrifuge tubes
- ✓ Decontamination aids (UV light etc.)
- ✓ Decontamination products (1% HCl, 10% bleach, 3% H_2O_2) or specific commercial products

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Good Laboratory Practice: Operating Procedures for PCR analysis

- ✓ Always wear lab coat (separate sets of lab coats for different key areas)
- ✓ Always wear and, change frequently, disposable gloves
- ✓ Always change filter tips
- ✓ Decontaminate working place and equipment before and after work
- ✓ Wash hands before leaving the laboratory
- ✓ Do not take anything with you, which you do not strictly need outside the laboratory

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Sample preparation Room

This room is **part of the laboratory**

If sample preparation is compromised here, the rest of the analysis is worthless!!!

Keep dust to a minimum

- in the air
- on the bench
- on the floor
- on the side / top of tubes
- in the blender
- on the spatula

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DNA Extraction Room

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PCR Setup

PCR setup: mastermix preparation and PCR setup under (for example) hood with UV light

Five Rules of Post-PCR

1. Nothing that has entered the Post-PCR room ever leaves it – except you !!!
2. Always wear gloves and lab coat.
3. Only your gloves should come in contact with anything in the Post-PCR room. Wear two pairs of gloves, in case you have to take one off.
4. If you contaminate anything in the room, clean it immediately.
5. If you leave the room, wash hands as soon as you are out.

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What customers expect from *testing* laboratories

- Use of officially accepted testing procedures
- Use of testing procedures with recognised quality and reliability properties
- Reliable results with indication of uncertainty levels
- Results in an acceptable time at acceptable costs

Methods selection
Proficiency testing
Accreditation

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Critical aspects for ensuring reliable analyses

Method development and optimization → Check that the method works → Check that the method is reliable → Check that labs can use the method

Performance measurement | *Validation* | *Proficiency testing*

Accreditation

Laboratory competence

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Proficiency Testing

- Proficiency Testing (PT) is a quality tool which measures the outputs of a laboratory
- PT is complementary to other quality assurance tools which are concerned with inputs such as use of CRMs, implementation of a formal Quality System, etc.
- PT is concerned with a laboratory routine methods with routine sample types
- PT is educational - there should be no "pass" or "fail"

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How does a PT work?

- The coordinator of the PT scheme distributes test samples to participating laboratories.
- PT samples resemble material normally analyzed by most laboratories in their routine work.
- Laboratories are asked to analyse the samples for the stated properties using their routine procedures
- Results are returned to the co-ordinator
- The results from all laboratories are statistically analysed and the performance of the laboratories reported

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Laboratory Accreditation

ISO defines accreditation as a procedure by which an authoritative body gives formal recognition that a laboratory operates a quality system, is technically competent, and is able to generate technically valid results.

This does not guarantee that a given analytical result is correct, but it does establish quality standards that must be met and a framework to detect non-conformities (mistakes) when they occur.

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ISO STANDARD 17025:
General requirements for the competence of testing and calibration laboratories

- Demonstrated technical competence of laboratory personnel
- Ethical behavior of laboratory staff
- Use of well defined test methodology
- Use of Certified Reference Material and participation in proficiency testing schemes
- Equipment management and calibration
- Records management and provision of adequate test reports including traceability

ISO STANDARD 17025:
General requirements for the competence of testing and calibration laboratories

MANAGERIAL issues

- Documents control, records control
- Requests, tenders and contracts, purchase
- Subcontracting
- Non-conformities, complaints corrective actions…
- Customer management
- Improvements management/ internal audits/ management review

ISO STANDARD 17025:
General requirements for the competence of testing and calibration laboratories

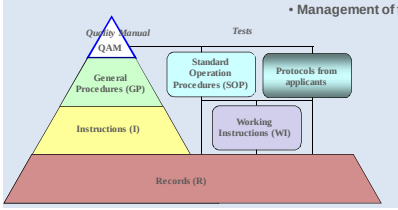
TECHNICAL issues

- Personnel (training, competence)
- Maintenance of equipment
- Accommodation and environmental conditions
- Sampling and sample management
- Method validation, uncertainty estimation….
- Quality assurance of the test results
- Reporting to the customer

Ensuring meeting customer requirements, correct results and correct transmission of results

Quality Management

- Quality policy
- Quality objectives
- Management of the documentation



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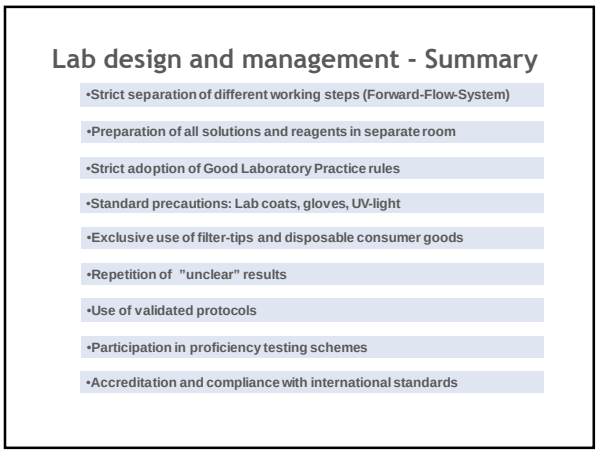
Lab design and management - Summary
•Strict separation of different working steps (Forward-Flow-System)
•Preparation of all solutions and reagents in separate room
•Strict adoption of Good Laboratory Practice rules
•Standard precautions: Lab coats, gloves, UV-light
•Exclusive use of filter-tips and disposable consumer goods
•Repetition of "unclear" results
•Use of validated protocols
•Participation in proficiency testing schemes
•Accreditation and compliance with international standards