Consultative Workshop on

Harmonization of LMO/GM Detection Activities in the Country

Proceedings

ICAR-National Bureau of Plant Genetic Resources, New Delhi
21st August, 2017

भाकृअनुप ICAR

UNEP

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प्रकृति रक्षति रक्षितः Nature Protects if She is Protected

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Supported by

UNEP-GEF Supported Phase-II
Capacity Building Project on Biosafety under the Strengthening of
Existing Capacities for LMO Detection activities

Participants and Organizers of the Consultative Workshop

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CONTENTS

ACRONYMS

CABs	Conformity Assessment Bodies
CEO	Chief Executive Officer
CRM	Certified Reference Material
DNA	Deoxyribose Nucleic Acid
EC	European Commission
ERM	European reference materials
GEF	Global Environment Facility
GM	Genetically Modified
GMO	Genetically Modified Organism
ICAR	Indian Council for Agricultural Research
IEC	International Electrotechnical Commission
ILC	Inter Laboratory Comparison
IQC	Internal Quality Control
IRMM	Institute for Reference Materials and Measurements
ISO	International Organization for Standardization
JRC	Joint Research Centre
LMO	Living Modified Organism
MoEF&CC	Ministry of Environment, Forest & Climate Change
Mol. Bio	Molecular Biology
NABL	National Accreditation Board for Testing and Calibration of Laboratories
NCs	Non Conformities
P35S	35S Promoter
PCR	Polymerase Chain Reaction
PT	Proficiency Testing
SOP	Standard Operating Procedure
TNOS	NOS terminator
UNEP	United Nations Environment Programme
UV	Ultra Violet

BACKGROUND

With the increase in approval of genetically modified (GM) crops globally with diversified traits, testing for unauthorized GM events or LMOs in the country to be undertaken in a systematic and harmonized manner. There are more than 25 LMO testing laboratories all over the country but each has its own independent methodology for GM testing. In order to facilitate efficient checking of authorized and unauthorized GM events and to check the GM status of an unknown sample, there is need to harmonize these LMO/GM detection laboratories.

In view of this, the Consultative Workshop on 'Harmonization of LMO/GM Detection Activities in the Country' was organized on 21 August, 2017 at ICAR-National Bureau of Plant Genetic Resources (NBPGR), New Delhi. The event was sponsored by the UNEP-GEF Capacity Building Phase-II Project on Biosafety and facilitated by the Ministry of Environment, Forest & Climate Change (MoEF&CC), Govt. of India.

Harmonization of GM detection activities across the laboratories is an important area and has been rather long overdue. As it is not only required at national level but also at international level especially when commodities are exported to other countries where regulatory requirements are very stringent. Such harmonized understanding is imperative under Cartagena Protocol on Biosafety, to comply with the requirements of Article 17 - "Unintentional Transboundary Movements and Emergency Measures", Article 18 - "Handling, Transport, Packaging and Identification" and Article 25 - "Illegal Transboundary Movements of LMOs".

For taking up this systematically, views and experiences sharing on LMO/GM detection among key representatives from GM detection laboratories, the National Accreditation Board for Testing and Calibration of Laboratories (NABL) assessors, accreditation personnel, research experts and regulatory bodies are required to be taken up in an open and transparent exchange.

INAUGURAL SESSION

The Workshop was inaugurated by Dr. Madhumita Biswas, Adviser, MoEF&CC, Dr. S. S. Marwaha, Former CEO of Punjab Biotechnology Incubator, Mohali also attended the inaugural session.

Dr. Kuldeep Singh, Director, ICAR-NBPGR, while welcoming the invitees and delegates from NABL and other GM detection laboratories, gave an overview of the institute activities and the details of the programme.

The programme and list of delegates/ participants representing constituent laboratories, NABL assessors, accreditation personnel, research experts and regulatory bodies are appended as Annexure-I & II.

Welcome of the Chief Guest: Dr. Madhumita Biswas, Adviser, MoEF&CC by the Director, ICAR-NBPGR

TECHNICAL SESSION

I. Overview of Harmonization of LMO/GM Detection Laboratories

Dr. Gurinderjit Randhawa presented the background of Workshop and networking of GM detection laboratories in the country. She gave an overview of three Articles of the Cartagena Protocol on Biosafety related to the transboundary movement of LMOs, Article 17- Unintentional Transboundary Movements and Emergency Measures, Article 18- Handling, Transport, Packaging and Identification and Article 25- Illegal Transboundary Movements of LMOs. Use of different DNA-based technologies including PCR, multiplex PCR, loop-mediated isothermal amplification and real-time PCR for GM detection was described along with their respective practical applicability with regard to the testing requirements. The need of screening methods along with event-specific assays to detect and quantify GMOs was also highlighted.

She also briefly apprised about the process of identification of appropriate institutes in India for establishing Network of LMO Detection Laboratories which was initially done through a Stocktaking Assessment of leading 9 National Level Institutions and Organizations by Dr. Patrik Stolt (International Expert); Dr. Lalitha Gowda (National Expert) and Dr. Murali Krishna Chimata then Project Manager, Phase-II Biosafety Project. After auditing of these nine national institutes through well-structured questionnaires, personal visits to the facilities and interactions with management/staff and also considering expertise in dealing with aspects related to detection, infrastructure available etc. the following four institutes were selected: (i) GM Detection Research Facility at ICAR-NBPGR, New Delhi (ii) DNA fingerprinting & Transgenic Crops Monitoring Laboratory, Hyderabad (iii) Punjab Biotechnology Incubator, Mohali (iv) Export Inspection Agency, Kochi. Scientists from these institutions were trained in a phased manner by MoEF&CC in India and Sweden on practical aspects related to detection of LMOs. These four laboratories were provided financial support for further strengthening the facilities to cater to the requirements of LMO detection activities and capacity built up.

Dr. Madhumita Biswas presented an overview of the activities undertaken and LMO detection laboratories strengthened

Dr. Madhumita Biswas delivering the highlights of UNEP-GEF Phase-II Capacity Building Project on Biosafety and future avenues

under UNEP-GEF Phase-II Capacity Building Project on Biosafety. She also underlined the need of need of regulation of GMOs to address related concerns on food safety, environment and health. The role of Environment (Protection) Act 1986 & Rules 1989, various competent authorities and Ministries to regulate the GMOs or biotech products in the country was highlighted. She apprised that Phase-II of the project especially aimed to strengthen the biosafety management systems in India with the view to ensure adequate level of protection in the field of safe transfer, handling and use of LMOs. She also talked about on the activities to be considered under Phase-III of the Project.

II. NABL Requirements of ISO/IEC 17025:2005 and NABL 102 in light of GM Detection

The NABL had nominated their four representatives, Mr. Ashutosh Tatwawadi, Mr. Vinay Tyagi, Mr. Soundira Pandian, Mr. Amit Kumar and assessors, Mr. Surender Pal from Tilda Riceland Pvt. Ltd., Gurgaon and Dr. V.R. Subramaniam from Jain Irrigation, Jalgaon.

An overview of NABL requirements of ISO/IEC 17025:2005 in light of GM detection was given by them, covering mainly the following points:

1. About NABL and laboratory accreditation.
2. Benefits of accreditation.
3. Core activities of NABL.
4. An overview of requirements of ISO/IEC 17025:2005 (Management & Technical requirements).
5. Overview of NABL 102 in light of LMO/GM testing.
6. Scope of accreditation in LMO/GM testing- Grouping of Test as per NABL 102.

The details of ISO/IEC 17025:2005 requirements and of NABL 102 are elaborated in Annexure III and IV.

Mr. Surender Pal gave an overview of NABL 102 document in relation to LMO/GM detection. He presented specific requirements for a GM testing laboratory covering the undermentioned major aspects:

General requirements

Forward flow for sample handling and systematic containment of the methodological steps, which could be ensured by at least 4 separately designated

work areas: (i) Work area for sample grinding and homogenization (ii) work area for extraction of nucleic acid from test material (iii) work area dedicated to set up of PCR reactions (iv) work area dedicated to subsequent processing and analysis.

Accommodation and Environment

(i) Effective separation of incompatible activities (ii) Preventive actions to ensure that no contamination is transferred between the stages of test procedure shall be documented (iii) Storage and segregation of reagents, consumables, equipment and genomic DNA (iv) All consumables should be kept at designated areas (v) Maintenance and recording of environmental conditions.

Dr. V. R. Subramaniam shared his experiences as an assessor for GM detection laboratories. He narrated instances where the accreditation was delayed mainly due to lack of fulfilling specific requirements elaborating as how to improve this aspect for smooth process. For example, accreditation could not be recommended in the case of one Laboratory due to undermentioned reasons:

1. Laboratory layout was not suitable for GMO testing, very limited space.

Presentations on NABL Requirements of ISO/IEC 17025:2005 and NABL 102 in light of GM Detection by the NABL assessors and representatives

2. No segregation/plastic curtains used.
3. Method used for testing not validated.
4. Not participated in ILC/PT.
5. CRMs were not available – Market sample of Bollgard® cotton used as CRM.
6. Mismatch in IQC checks (format vs actual).
7. The NCs were not closed in 60 days time.

The assessors shared their experiences related to assessment emphasizing the following major requirements to be further looked at in NABL 102:

1. Authorized Signatory
2. Environmental conditions
3. Sampling/Sub-sampling
4. Reporting of results

Representatives of constituent laboratories namely, Dr. Ajit Dua, Dr. Vandana, Dr. Lijo John, Dr. Jaya Krishna, and Dr. Monika Singh, shared their views on NABL 102 document underlining some of the main aspects.

III. Panel Discussions

Panel Discussions moderated by Dr. Gurinderjit Randhawa and Dr. Ajit Dua were held on 'Evolving Issues related with ISO/IEC 17025:2005' and 'Draft Training Manual on LMO Detection'.

Panel Discussions on 'Evolving Issues related with ISO/IEC 17025:2005' and 'Draft Training Manual on LMO Detection' moderated by Dr. Gurinderjit Randhawa and Dr. Ajit Dua

KEY RECOMMENDATIONS/ POINTS EMERGED

Some of the important points that emerged upon brainstorming at length to update/revise NABL 102 referred to:

NABL 102 Personnel requirements (ISO/IEC 17025: 2005 clause 5.2)

- 2.1 Minimum qualification for the technical staff in a GM testing laboratory shall be graduate in biological sciences with minimum 1 year of work experience in GMO testing. Personnel could perform tests only when they are recognized as competent to do so or working under supervision.
- 2.2 Authorized signatory shall have post-graduation degree in same field with minimum 2 years of experience or a graduate in same field with minimum 5 years of experience.
- 2.2 Note (E) For GMO, qualification in "Similar field" shall not be considered.
- 2.4 Technical competence of personnel shall be monitored objectively, where a method is not in regular use, verification of personnel performance is necessary before test is undertaken.

Observations and recommendations:

- It has been observed that in many laboratories, authorized signatory with M.Sc. Microbiology handle GMO laboratory activities, showing certificate of 2-3 days training in GM detection as their qualification criteria. Most of the laboratories don't have skilled biotechnologists and Molecular biology experts for GMO testing. At the same time, no criteria have been defined to evaluate the competency of the analysts and the authorized signatory. Minimal criteria to evaluate the competency need to be defined.

NABL 102 Accommodation and Environment (ISO/IEC 17025:2005 clause 5.3)

- 3.4 Effective separation of incompatible activities has been advised, 4 physically separated laboratory areas/compartments must for the same. The guidelines should be clear as to how to achieve the same e.g. if central air conditioner is there across all laboratory sections, it is equivalent to non-separation of various areas of the laboratory.

- 3.9 Preventive actions to ensure that no contamination is transferred across the stages of test procedure shall be documented. {These include decontamination with UV radiations, decontamination with appropriate chemicals/reagents, change of laboratory clothing and gloves, use of separate laboratory wares, equipment, consumables, reagents etc. for each laboratory area.}
- 3.9.1 Storage and segregation of reagents, plastic wares, other laboratory consumables, equipment and genomic DNA should be defined in the respective laboratory areas. All the consumables should be kept at designated areas.

Observations and recommendations

- Normally it is taken for granted that the laboratories engaged in GMO testing are aware of the basic requirements, more awareness need to be imparted through basic trainings. Good laboratory practices for GMO testing laboratories should be defined.
- Environment monitoring procedure especially for GM testing including water blank should be documented.
- Procedure for waste disposal w.r.t. to GM samples shall be documented.

NABL 102 Test Methods and Method Validation (ISO/IEC 17025:2005 clause 5.4)

4.5 The laboratory could use any standard method, kit based method, non-standard (in-house developed) method for qualitative, semi-quantitative or quantitative estimation of GMO in a particular matrix.

In the clause no. 4.5.1 Test Methods: sub-clause 4.5.1.1, it is mentioned that "Laboratories should be clear about which matrices can and cannot be tested. Laboratories should be clear about which matrices can be tested. For example, it is generally accepted that refined oils cannot be tested due to the absence of DNA and should document that such tests should normally be refused". Since DNA from different oil samples are possible and publications are also available for such methods, the above point need to be considered for revision accordingly.

In the clause no. 4.5.2.3, it is mentioned that "Commercial test systems (kits) may not require further verification if validation data based on collaborative testing are available". The above statement need to be considered for revision, as the Commercial test systems (kits) for which validation data based on collaborative testing are available are need to be verified in the intended laboratory using their machine and man.

4.5.2.4 The laboratory shall determine the method performance characteristics such as limit of detection, precision etc. for quantitative tests.

Observations and recommendations

- Minimum performance criteria to be defined for both End point PCR and Real-time PCR based methods, for both qualitative and quantitative estimation of GMO, as well as DNA extraction so that all laboratories are following the basal minimum requirements by default.

DNA extraction modules	PCR modules
1. DNA concentration	1. Specificity
2. DNA yield	2. Dynamic range
3. Structural integrity	3. Amplification efficiency
4. Purity of DNA extracts	4. Regression (R^2) coefficient
5. Absence of Inhibitors	5. Precision
	6. Limit of Detection
	7. Limit of Quantification
	8. Robustness

- Since DNA from different oil samples are possible and publications are also available for such methods, the above point need to be considered for revision accordingly.
- The statement w.r.t. 4.2.3 need to be considered for revision, as the Commercial test systems (kits) for which validation data based on collaborative testing are available are need to be verified in the intended laboratory using their machine and man.
- Appropriate controls to be used to access the integrity of reagents and freedom from contaminants as per ISO 24276:2006 specifications.
- CABs should be encouraged to also use/refer: ISO 21569; ISO 21570; ISO 21571; Compendium of Reference methods for GMO analysis - JRC / EC document; ISO 24276; ISO 15955 foodstuffs.
- Performance/validation characteristics for qualitative and quantitative analysis should be addressed clearly.

NABL 102 Equipment maintenance, Calibration, performance (ISO/IEC 17025: 2005 clause 5.5)

- The laboratory should have established procedures and schedule (cleaning and sanitization) to ensure avoidance of cross contamination arising from the equipment used to perform tests.
- 5.2.9 PCR equipment: The performance of PCR thermal cycler and spectroscopic components should be verified regularly.
- 5.3.1.6 The laboratory could source the reference material from; National measurement institute, ISO guide 34 accredited reference material producers; reputed chemical suppliers (kit manufactures, pure biochemical); Customer supplied reference material with certificate; in-house produced reference material.
- 5.4.4.5 Chemicals and reagents involved from sample preparation down to PCR testing shall be molecular biology grade or equivalent

and free from contaminating nucleic acids or nucleases (both DNase and RNase).

- To the above statement it may be considered to include consumables and plasticwares like microtips (aerosol barrier), tubes etc. also free from contaminating nucleic acids or nucleases (both DNase and RNase).

Observations and recommendations

- Indicative list of minimum equipment required for GM testing should be included
- Calibration & intermediate check frequency along with traceability criteria should be addressed in line with NABL 102.
- Minimum criteria for evaluation of Real-time PCR calibration status to be defined as various laboratories use their own judgement to define the calibration status of real-time PCR e.g. spectral calibration, thermal validation, performance validation etc.
- There is great difficulty faced by GMO testing laboratories regarding the availability of Certified Reference materials. IRMM (ERM) and AOCS are the two CRM providers for GMOs and CRMs in all the matrices for GMO testing are not available with these providers. Also many of CRMs may not be available at all the time.
- Regarding the validity, it is mentioned in the certificate of IRMM (ERM) is that, the "Certificate is valid for one year after purchase" and in case of AOCS, regarding the stability of CRM it is mentioned as "Stability of these CRMs has been listed as 1 year from the introduction date. The materials were sealed and stored in the dark at 4°C, therefore not exposed to air and are expected to be stable for longer than the estimated expiration date. The stability of the leaf DNA extract material will be re-evaluated annually. If the samples still test positive for the presence of the trait, the certificates are extended".

  In view of above reasons, some guidelines for the use of GMO CRMs for more than one year if stability is verified and established can be considered to be included in NABL 102.

Measurement traceability (ISO/IEC 17025:2005 clause 5.6)

- Documentation of Procedure for procuring and evaluation of critical supplies should be made mandatory.
- Clarity about usage of Reference Material after expiry with verification check.

NABL 102 Sampling (ISO/IEC 17025:2005 clause 5.7)

6.1 In many cases, the testing laboratories are not responsible for sampling. The customers taking their own samples should be made aware of proper storage, sampling and transport facilities. Customers to be informed if the sample received is too small for meaningful analysis.

Observations and recommendations

For GMO testing, the minimum sample size for a specified matrix should be defined

Products	Recommended laboratory sample size
Seeds	Mass equivalent of 3000 kernels (see table below for mass equivalent of 1000 kernels)
Commodity grains	Mass equivalent of 10000 grains (see table below for mass equivalent of 1000 kernels)
First transformation product (semolina, flour, grits, oilcake etc.)	From 100 g to 1 kg
Liquids	500 ml
Doughy and viscous products	500 g
End products (e.g. packed rice noodles)	From 100 g to 1 kg

Plant species	Mean mass of 1000 kernels (in g)
Barley	37
Linseed	6
Millet	23
Oat	32
Maize	285
Rapeseed	4
Rice	27
Rye	30
Soybean	200
Sugar beet	11
Sunflower	100
Wheat	37

(Table adapted from JRC technical report EU, guidelines for sample preparation procedures in GMO analysis).

NABL 102 Assuring the quality of test results (ISO/IEC 17025: 2005 clause 5.9)

- 9.5.1 In process control checks: NABL defines that the controls specified under 9.5.1.1 – 9.5.1.6 (Extraction blank, negative control, Detection limit control, Positive control, replicate analysis, number of primer sets) to be run at minimum once for each test run.
- 9.5.1.5 "PCR test samples shall be analysed in at least duplicate for quantitative, semi-quantitative and qualitative testing".
- To the above statement, clarity can be brought by mentioning whether duplicate extraction and single PCR from each extraction or duplicate extraction and duplicate PCR from each extraction need to be carried out.
- 9.5.1.6 "It is normally expected that test results are based on the results of at least two, different GM-specific primer sets, each providing consistent result. The requirement of using at least two primer sets may be relaxed provided that other options for confirming the identity of an amplicon on a gel, e.g. restriction enzyme cutting to produce fragments of the expected size, shall be established to confirm test results".

Observations and recommendations

1. The original observations should include the results from the controls, should be verified by the auditor.
2. Sample deposition plan to be made mandatory for all the GMO testing work.
3. GMO result interpretation matrix to be introduced, this should include the assay validation with the use of controls and the test sample interpretation using a defined matrix e.g.

Interpretation of Controls for a valid assay

Control	Negative Control (NC)	No Template Control (NTC)	Positive Control (PC)	Extraction Blank	Environment Control
Target status	Undetected	Undetected	Detected	Undetected	Undetected

Interpretation of Samples

Test sample	Negative control	Extraction blank control	Positive DNA target control	Interpreted results
Negative	Undetected	Undetected	Detected	Negative
Positive	Undetected	Undetected	Detected	Positive
Positive	Undetected	Detected	Detected	Inconclusive, repeat from extraction
Negative	Detected	Detected	Detected	Inconclusive
Negative	Undetected	Undetected	Undetected	Inhibited, repeat

9.5.1.6 The above statement need clarity. Whether the number of primer sets is denoting to the number of target elements like P35S and TNOS or for each target two different primer sets need to be used. Further, the use of restriction enzyme are mentioned, which can be used in case of end point PCR analysis and electrophoresis, but what will be the alternate in case of Real time PCR. Hence more clarity about no. of primer sets to be used, (refer 9.5.1.6)

Reporting the Results (ISO/IEC 17025:2005 clause 5.10)

Under the clause no. 10.3.9 of NABL 102, regarding Reporting the Results it is mentioned that "The sample preparation procedure should be given for the proper interpretation of test results in GMO testing laboratory's test reports".

The above statement may be considered to be reviewed. Because sample preparation procedure may vary in different cases in different laboratories when dealing with different kind of samples. This may be usually in-house methods/kits/standard methods. Wherever, in-house methods/kits are used the SOP number can be mentioned in the report, however, this may not give any useful information in interpretation of test results for the customer.

Observations and recommendations

- Primer sequences need not be given in the report.
- In the GMO testing SOP, must define the minimum sample size for various matrices in case sampling is not in the scope of the lab. The same should be represented in the test report. The laboratory should define the procedure for test sample preparation.

Availability of reference material/certified reference material

- Reference materials for new GM events along with the assay for GM testing may be provided to ICAR-NBPGR, which would be further distributed to three other GM detection laboratories as per the requirement.

Appendix A: Classes of test in Biological Discipline

- GM testing should be checked/reconsidered for its appropriate group.
- Audit of GM testing laboratories to be conducted by auditors specialized in GMO testing.

DRAFT TRAINING MANUAL ON GM DETECTION

Dr. Lijo and Dr. Vandana shared the overview of different modules on the Draft Training Manual on GM Detection. The following modules were discussed:

- Module 3: Sample Preparation & Extraction
- Module 4: Techniques for detection & identification
- Module 5: Introduction to Quality Assurance/Quality Control Standards
- Module 6: Reporting

RECOMMENDATIONS

- Project Proposals to sustain GM detection activities may be submitted to the MoEF&CC, Govt. of India.
- The Meetings/Brainstorming Sessions/Workshops need to be organized on regular basis for harmonization of GM detection activities at national level.

VALEDICTORY SESSION

All the participants were honoured with the Appreciation Certificates given by Dr. Madhumita, Adviser, MoEF&CC, and Dr. Kuldeep Singh, Director, ICAR-NBPGR.

During the closure of program, Dr. Gurinderjit Randhawa wrapped up the session and Dr. Monika Singh, proposed formal vote of thanks.

Distribution of Appreciation Certificates

PROGRAM OF WORKSHOP

Time	Details
10.00 - 10.20	*Opening & Welcome Remarks* **Dr. Kuldeep Singh,** Director, ICAR-NBPGR
10.20 - 10.40	*Brief background of Workshop and Networking of LMO Detection Laboratories* **Dr. Gurinderjit Randhawa,** Principal Scientist, ICAR-NBPGR
10.40 - 11.00	*An Overview of Activities Undertaken and Strengthened LMO Detection Laboratories in UNEP-GEF Phase II Project on Biosafety* **Dr. Madhumita Biswas,** Adviser, MoEF&CC
11.00 - 11.15	***Tea & Group Photo***
11. 15 am - 12.00 noon	*An overview of NABL, Requirements of ISO/IEC 17025:2005 and NABL 102 in light of LMO/GM testing* **Mr. Amit Kumar,** Asst. Director, NABL; **Mr. Vinay Tyagi,** Deputy Director, NABL; **Mr. Ashutosh,** Deputy Director, NABL; **Mr. Soundira Pandian,** Deputy Director NABL
12.00 - 12.20	*Overview of NABL 102 in relation to LMO/ GM Detection* **Mr. Surender Pal,** AGM (Quality Assurance), Tilda Riceland Pvt Ltd., Gurgaon
12.20 - 12.40	*Experience Sharing for assessment of GM Detection Laboratories* **Dr. V. R. Subramaniam,** Jain Irrigation, Jalgaon

Time	Details
12.40 - 1.30	*Laboratory's Representatives' View Points on NABL 102* **Dr. Ajit Dua,** Senior Scientist, PBTI, Mohali; **Dr. Lijo John,** Asst. Director (Tech.), EIA, Kochi; **Dr. Jaya Krishna,** Asst. Director of Agriculture, DFTCML, Hyderabad **Dr. Monika Singh,** Scientist, ICAR-NBPGR
1.30 - 2.30	***Lunch Break***
2.30 - 3.00	*Experience Sharing of participation in Asia-Pacific Workshop on the Detection & Identification of LMOs (20-24 March, 2017, Kuala Lumpur)* **Dr. Lijo John,** EIA, Kochi
3.00 - 4.00	*Overview of Draft Training Manual on LMO Detection* Module 3: Sample Preparation & Extraction Module 4: Techniques for detection & identification Module 5: Introduction to Quality Assurance/Quality Control Standards Module 6: Reporting **Dr. Vandana,** Scientist, PBTI, Mohali **Dr. Lijo John,** EIA, Kochi
4.00 - 4.20	***Tea***
4.20 - 5.30	*Panel Discussions* i Evolving Issues related with ISO/IEC 17025: 2005 ii Draft Training Manual on LMO Detection **Dr. G.J. Randhawa, Dr. Ajit Dua,** (*Moderators*)

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ISO/IEC 17025:2005 REQUIREMENTS

Management Requirements

4.1 Organization

4.2 Management System

4.3 Document control

4.4 Review of requests, tenders and contracts

4.5 Subcontracting of tests and calibrations

4.6 Purchasing services and supplies

4.7 Service to Customer

4.8 Complaints

4.9 Control of nonconforming work

4.10 Improvement

4.11 Corrective actions

4.12 Preventive actions

4.13 Control of records

4.14 Internal audits

4.15 Management reviews

Technical Requirements

5.1 General

5.2 Personnel

5.3 Accommodation and environmental conditions

5.4 Test and calibration methods and method validation

5.5 Equipment

5.6 Measurement traceability

5.7 Sampling

5.8 Handling of test and calibration items

5.9 Assuring quality of test and calibration results

5.10 Reporting the results

ISO/IEC 17025:2005 REQUIREMENTS AS PER NABL 102

NABL 102 document describes specific requirements that a biological testing laboratory has to meet, in addition to the requirements of ISO/IEC 17025: 2005, including:

1. Introduction and Scope of Document
2. Personnel
3. Accommodation and Environment
4. Test Methods and Method Validation
5. Equipment - Maintenance, Calibration and Performance
6. Sampling
7. Sample Handling
8. Disposal of Contaminated Waste
9. Assuring Quality of Test Results
10. Reporting the Results

Dr. Kuldeep Singh, Director, ICAR-NBPGR welcoming the participants