NATIONAL CERTIFICATION SYSTEM FOR TISSUE CULTURE RAISED PLANTS



Department of Biotechnology Ministry of Science & Technology Government of India

Developed on: First Revision on: Second Revision on: October 2006 September 21, 2007 May 14, 2008

National Certification System for Tissue culture Plants (NCS-TCP)

1. Introduction

Plant Tissue Culture Technology offers great promise for the production of quality planting material on account of disease free and true to type plants produced through micropropagation techniques. The need for a certification programme for the tissue culture plants is imperative since inadvertent micropropagation of virus infected plants will not only result in its poor performance, but also in undesirable spread of viruses wherever such plants are grown. Also, failure to use prescribed standard protocols will result in variations in the plants produced. The most deleterious variants in tissue culture raised plants are those that effect yield, genetic fidelity and carry infection of viruses, and other fastidious pathogens, which are difficult to diagnose. This is an area of great concern, and requires a well-structured system be put in place to provide support to the tissue culture industry for the commercialization of tested virus free and high quality planting material.

Ministry of Agriculture has vide Gazette of India Notification dated 10th March 2006 notified that "In exercise of the powers conferred under section 8 of the seeds Act, 1966 (54 of 1966), the Central Government hereby authorizes Department of Biotechnology, Ministry of Science and Technology, Government of India to act as Certification Agency for the purpose for certification of the tissue culture-raised propagules up to laboratory level and to regulate its genetic fidelity as prescribed by them".

Accordingly a National Certification System for Tissue Culture Plants (NCS-TCP) has been developed for the first time, not only in the Country but also globally, where currently no such organized structure exists for certification of Tissue Culture material.



2. <u>Role and Responsibility</u>

i. <u>Tissue Culture Certification Agency (TCCA)</u>

The Certification Agency (DBT) is responsible for implementing the National Certification System for Tissue Culture Plants (NCS-TCP) in the Country. An **Accreditation Unit** has been setup for undertaking Accreditation of Test Laboratories for testing of Virus and Genetic Fidelity and also Certification of Tissue Culture Production Facilities, based on the established guidelines and criteria. **Referral Laboratories** have been identified for carrying out confirmatory tests, if required, and also for developing standard protocols, maintenance of referral material, training etc. The Certification Agency is overall responsible for developing standard tests, production protocols/guidelines and manuals. It will also set-up a **Project Management Unit** has been set up for coordination of various components of NCS-TCP

ii. <u>Accreditation Unit (AU):</u>

An Accreditation Unit (AU) has been established by the Certification Agency at Biotech Consortium India Limited (BCIL), 5th Floor, Anuvrat Bhawan, 210 Deendayal Upadhyaya Marg, New Delhi-110002. for undertaking Accreditation of laboratory facilities for virus diagnosis and genetic fidelity testing of tissue culture raised plants and Certification of Tissue Culture Production Facilities.

iii. <u>Accreditation Panel (AP):</u>

The AU will maintain a panel of experts to undertake initial assessment of laboratory facilities for virus diagnosis and genetic fidelity testing for accreditation/and or periodical auditing of accredited facilities for granting renewal/revalidation/ reinstatement. The Accreditation Panel would also make an assessment of the tissue culture production facility. The panel comprises experts specialized in plant tissue culture/plant biotechnology/plant virology/plant bacteriology/ molecular biology and a phytosanitary expert. The Accreditation Panel will submit its assessment report based on established criteria/guidelines to the accreditation unit for grant of accreditation/ certification. **The guidelines for Accreditation of laboratory facilities for Virus diagnosis and genetic fidelity testing and for Certification of tissue culture production facilities are at Annexure-I. The AU should ensure that the essential criteria are met with prior to initial assessment of facility for accreditation/certification.**

iv. <u>Referral Laboratory (RL):</u>

The DBT has designated **Referral laboratory** (ies) for virus diagnosis/genetic fidelity testing of tissue cultures plants.

- Referral Center for Virus Diagnosis Indian Agriculture Research Institute (IARI), New Delhi
- Referral Centers for Genetic Fidelity Centre for DNA Fingerprinting and Diagnostics (CDFD), Hyderabad.

The referral laboratory is responsible for carrying out confirmatory tests in the event of dispute or nonconformity of test results. The referral laboratory usually will not involve in routine virus diagnosis/genetic fidelity testing of tissue culture raised plants, however as per the decision of the Project Management Unit, the Referral Laboratories will undertake random testing of samples at different Test Laboratories.

v. <u>Accredited Test Laboratories (ATL)</u>:

Test laboratories will be Accredited entities of the public sector, responsible for testing the Tissue Culture material for virus diagnosis and genetic fidelity, for purpose of certification. The Test laboratory will prepare a Test Report based on tests conducted in conformity with the standards/protocols/guidelines. Based on the Test Report, each Accredited Test Laboratories will be authorized to issue the Certificate of Quality for the Tissue Culture Plant (CQ-TCP) on behalf of the Certification Agency. ATL will be responsible for maintaining all diagnostic kits, primer, probes etc required for routine testing. **Each ATL would perform both tests-for virus diagnosis and true-to-type.**

vi. <u>Appellate Authority (AA)</u>:

An **Appellate Authority** under the Chairpersonship of <u>Secretary, DBT</u> established to review the decision taken with regard to Accreditation of Test laboratories, certification of Tissue Culture production facilities and also for Certification of tissue culture material. The Nodal Officer designated by the Certification Agency will act as Member Secretary. The members represented in the appellate panel will include:

- a. Officer in-charge, Accreditation Unit
- b. Chairperson, Project Monitoring and Evaluation Committee
- c. Two Co-opted non-officio expert by Chairperson (Virology and Genetic fidelity Testing)

3. Modalities of Implementation

a. <u>Accreditation of Laboratories and Certification of Production Facility:</u>

The Applicant will register its application with the Accredited Unit (BCIL) (NCS-TCP Form 1&2). Presently only public sector laboratories, universities, Government funded institute, NGO's would be considered for Accreditation as Test Laboratories. For Certification of Tissue Culture Production Facility, all laboratories in the Public sector/private sector/NGOs are eligible to apply. The requisite fee as indicated in the Application Form (NCS-TCP Form 2) will need to be deposited. The Accreditation Unit will examine the applications and refer it to the Accreditation Panel for further processing. The criteria for Accreditation of Test Laboratories and Certification of tissue culture production units are provided at Appendix-I and Appendix-II respectively. Based on the report of the Accreditation Panel, the Certificate / Accreditation will be issued. Accreditation and Certification would be for a period of Two years .Thereafter it would be assessed for renewal





b. Certification of Tissue Culture Plants:

The Tissue Culture Production Facility will register its application for Certification of Tissue Culture material with the nearest **ATL** (NCS-TCP Form 3). Only Certified Production facilities will be eligible to register for certification of plant tissue culture raised material. The **ATL** will examine the application and if found complete in all respect it will intimate the applicant (in two working days), regarding requirements for sending the samples. Guidelines for dispatch of material, sample size etc will be provided. The **ATL**, will arrange for site inspection, receipt of samples, testing etc as per prescribed format. The fees for certification will be deposited along with the sample at the ATL. The ATL will generate the Test Report within the prescribed time frame and based on the test report the Certificate of quality will be issued as per prescribed norms. The fee structure charged by ATL will vary depending on the plant species, sample size etc.



c. Standards for Production of Tissue Culture Material:

Standards/Guidelines for production of Tissue Culture material are currently being prepared for different crops as per requirements, by DBT in consultation with scientists/institutes, working in the area. The Accredited Test Laboratories will issue the certificates only if Tissue Culture material is produced in conformity with these notified guidelines. The Guidelines for potato have already been notified by Ministry of Agriculture. Guidelines have been approved for other crops like Banana, Sugarcane, Apple, Citrus, Vanilla and Black pepper. These guidelines are given at **Annexure II**

Guidelines for Accreditation of Test Laboratory for virus diagnosis and genetic fidelity testing of tissue culture raised plants and Certification of Tissue Culture Production Facility

1. Scope & purpose

This standard provides guidance on requirements and procedures for Accreditation of Test Laboratory for virus diagnosis and genetic fidelity testing of tissue culture raised plants and Certification of Tissue Culture production facility .The purpose of this standard is to facilitate production of quality planting material through virus diagnosis and genetic fidelity testing and to ensure that the tissue culture raised plants are free from viruses and other fastidious pathogen and also that the tissue culture raised plants are true to the type.

2. Background

The advent of tissue culture/micropropagation technology has made it possible to produce genetic fidelity planting material to meet the domestic needs as well as international trade. However the tissue culture propagation, does not exclude the infection of viruses, viroids, phytoplasmas and bacteria unless the parental material used for tissue culture production are tested and maintained free from above mentioned pathogens as well as stock-cultures maintained free from above pathogens. It is therefore essential that proper testing of material is done for purpose of certification. It is also essential that the laboratory producing the tissue culture material has the required infrastructure and expertise and is complying with prescribed standards. The laboratory facilities established for virus diagnosis and genetic fidelity testing of tissue culture raised plants should have essential equipments and facilities and competent technical staff to perform the tests.

The requirements for Accreditation system include establishment of

- i. Accreditation Unit within the administrative Department/ Ministry for initialization and implementation of accreditation process
- ii. Accreditation Panel of technical experts for undertaking initial/periodical audit or examination of entities for accreditation
- iii. **Referral Laboratory** for confirmatory tests, preparing standards organize training etc.

iv. Appellate Authority for reviewing the decision

The accreditation process will involve the technical evaluation of applicant entity, initial audit of facilities and equipments and examination of technical competency of staff in performance of virus diagnosis and genetic fidelity tests and production of Tissue Culture material based on standard protocols/guidelines. Identification of training needs, documentation procedures of sampling and process control and maintenance of test records would also be done by Accreditation Unit. The accreditation process provide for a appeal in the decision in the matter to the Appellate Authority.

3. <u>Procedures</u>

3.1 Accreditation of Test Laboratories and Certification of Production Facility

3.1.1 Application:

An application for Accreditation of Laboratory facilities for virus diagnosis/genetic fidelity testing of tissue culture plants and for certification of facilities for production of Tissue Culture plants will be made to AU in form prescribed (NCS-TCP Form-1 and NCS-TCP Form-2 respectively) along with the requisite fee (There is no registration fee for accreditation of test laboratories). The Applications received by the office of AU will be entered in an appropriate register. If the application is for renewal/revalidation of accreditation, the application will be assigned with previously allotted number or else the new ones will be assigned a unique identification number. The office of AU will scrutinize the application to ensure correctness and completeness of information furnished in the application based on the criteria established for certification of production facility accreditation of laboratory facilities for virus diagnosis/genetic fidelity testing. If the application is incomplete, the deficiencies will be communicated to the applicant and the application complete in all respects will be registered and further subject to technical evaluation.

3.1.2 Technical Evaluation:

The AU will nominate an **Accredited Panel** of 2-3 experts from the list of panel of experts maintained. The Accreditation Panel (AP) will evaluate the application for overall competence

and feasibility following the established procedure. Those applicants which fulfill the essential requirements will be further processed.

3.1.3 Initial Assessment/Periodical Audit:

The AU will contact the applicant entity to organize an 'in situ' evaluation. The AP will prepare an audit checklist based on the criteria established for accreditation of laboratory facilities for production and for virus diagnosis and genetic fidelity testing of tissue cultures of plants and relevant national regulations (Appendix I & II). The AP will conduct audit/examination of test facility production center. Such audit will include open meeting with management authority to review the audit agenda and explain the methodology of audit. The AP will utilize the checklist for noting compliance and comments, interview technical personnel to judge the technical competency and skills, review the records, procedures and documents. At the end AP will present an audit summary, observation of non-confirming activities and inform the date of audit report submission. If there are non-conformities, the AP will advise corrective actions and the date to implement corrective actions. The AP will prepare the audit/ examination report that includes: area/ audited activity, participants, objective and scope, reviewed documents, summary of activities, non-conformities and requests for corrective action. The AP will provide the report to the applicant/accredited entity during the closing meeting, and will send a copy to the AU. The lead auditor will verify the implementation and efficacy of corrective actions through either documentation or "in situ" verification. The lead auditor will close the report of corrective actions if the corrections have been made and will submit a follow up report to the AU. Based on the report of the AP, the AU will issue the Accreditation Certificates.

3.1.4 Time Frame

As per the guidelines of the NCS-TCP the time frame is given within which the Accredited Test Laboratories would be required to test the Tissue Culture planting material and issue the certificate

(A) Procedure and time frame for certification of Tissue Culture facilities and Accreditation of Test Laboratories under NCS-TCP

Steps	Procedure	Time frame (days)
1	Receipt of application complete in all respect, assessment and registration	1
2	Communication with experts and concerned companies/institutions regarding date of site visit	7
3	Planning and subsequently arrangement of travel and accommodation	7
4	Undertaking of site visit by Accreditation Panel	3
5	Processing and organizing meeting of the committee for obtaining approval on the recommendation of Accreditation Panel	12
6	Communicating the entity in case of approved case	5
7.	Printing, signature of authority and issuance of Certificate	10
	Total	45 working days

NOTE: In case of Non-conformities certificates can be issued within 45 days after formal communication of their corrective actions.

(B) Time frame for virus indexing and/or quality testing of tissue culture raised plants by Accredited Test Laboratories (ATLs) from the date of receipt of sample

STEPS	PROCEDURE	TIME FRAME (Days)
1	Receipt of the sample/Recording sample details, storage and planning for conducting test	1
2	Conducting virus and quality test	2
3	Preparation of test report/ Review of procedure and report	1
4	Repeat the tests if needed and prepare second test report/ Dispatch of test report and certificate to the customer (TCU)	2
	Total	6 working days

3.1.5Certification of multiple hardening centers of certified Tissue Culture Production Units

It has been observed that many large tissue culture companies have more than one hardening centers. Some companies have more than 10 hardening centers in different states which are difficult to evaluate and certify during one site visit. At present as a part of the Certificate of Recognition issued to the production facilities, recognition is being given to the main hardening units in close proximity of the lab after thorough assessment of compliance. However, to ensure the distribution of quality planting material it is necessary that all the hardening centers should be in conformity with guidelines under NCS-TCP. In such cases sublevel Accreditation Panel consisting of Scientists may audit nearby hardening centers and submit their reports to the Accreditation unit.

3.1.6 Suspension/Appeal/Reinstatement

An applicant/accredited entity may appeal against the decision taken by the AU within a maximum period of 30 days giving grounds of appeal. The office of AU will receive and record the appeal. In the case of suspension or cancellation, the accredited entity will not be allowed to conduct activities until the final decision is taken in the matter. A technical expert of AP will review the appeal request and make a preliminary report. The AU will submit the appeal request and preliminary report to Appellate Authority. The Member Secretary of Appellate panel will schedule a meeting of appellant with appeal panel. The appellant will be given an opportunity to present his case before appeal panel. The appeal panel will make a decision and notify the AU of its final decision. A favorable decision to the appeal may contain conditions that the entity must consider, the head of AU will review the earlier decision and notify appellant regarding revised decision in the matter.

3.2 Training Needs

The AU will identify internal training needs and establish a programme for internal training for undertaking accreditation and quality systems auditing. The AU will also organize external training in virus diagnosis and quality testing of tissue cultures of plants for technical experts of entities in collaboration with the referral laboratory.

Definitions & Terms

Accreditation Unit	An official unit responsible for accreditation of laboratory facilities for virus diagnosis/genetic fidelity testing of tissue culture raised plants
Accredited Entity	A public sector, institute/organization granted accreditation
Appellate Authority	An administrative Department/Ministry to consider the appeal in decision taken by the Accreditation Unit or certification Center
Appeal Panel	A group of experts nominated by the Administrative Department/ Ministry to review the decision taken by the Accreditation unit/Certification Center
Applicant Entity	Institute/organization seeking accreditation.
Accreditation Panel	A team of technical experts with knowledge about audit techniques and criteria for accreditation of laboratory facilities for virus diagnosis/genetic fidelity testing of tissue cultures of plants.
Certification Agency	An Agency responsible for Certification of Tissue Culture Raised Material
Certification Monitoring Unit Corrective Action	A Unit notified for monitoring of certificates of genetic fidelity for Tissue Culture material by Accredited Test Centers Any action taken to correct the deficiency/deviation from the requirements of this standard
Controlled Document	Documents formally identified, which are registered, maintained and their change, as well as, their implementation is regulated.
Controlled Record	Record that requires to be kept and maintained under safeguard for future reference in an audit and/or for traceability of a result.
Document	Standards, Procedures, work instructions, references, specifications or regulatory material for the administration of the system.
Procedure	Document that describes, "who does the job", "when", "where", and "why".
Initial Audit (Assessment)	'in situ' evaluation of the applicant entity for accreditation to verify if the accreditation criteria have been implemented.
Non-conformity	Any observed deficiency/deviation from the requirements of this standard

Periodical Audit (Surveillance Audit)	Periodical evaluation of accredited entities to verify the accreditation criteria are being followed.
Quality Manual	A written document by the applicant, in which their genetic fidelity system is described.
Quality System	A process control system to ensure the genetic fidelity of product. The genetic fidelity system describes its policy, organization, working procedures and test protocols.
Standard Protocol	A standardized/validated test procedure established either nationally/internationally.
Record	Document (electronic or print), product or sample statement, which will confirm that a procedure (or part of the procedure) has been carried out.
Reinstatement	An action taken for restoring the (business) activities of an entity for which accreditation was granted.
Reinstatement Audit	A scheduled audit that was carried out for reinstatement of accredited entity following a period of suspension.
Renewal/Revalidation	An extension of validity of accreditation granted to an entity.
Reference Laboratory	An official laboratory for the performance of confirmatory tests in the event of dispute of test results.
Suspension	An action taken for temporary with holding of (business) activities of entity for which accreditation was granted.
Test Laboratories	A Laboratory Accredited for testing of tissue culture material for virus diagnosis and genetic fidelity unit
Work Instruction	Document that identifies the procedures to perform a task or activity.

<u>Appendix-I</u>

Criteria for Accreditation of Laboratory Facilities for Virus Diagnosis/Quality Testing of Tissue Cultures of Plants

- (1) Public Sector, Govt. funded Institute/University having adequate capacities in both virology and molecular biology, which is not engaged in commercial tissue culture activity
- (2) Laboratory should be headed by trained virologist with experience in molecular diagnostics / molecular biologist working on molecular marker related technologies
- (3) Laboratory should have at least one trained Scientist and one Technical Assistant having expertise in the area of virology/molecular markers and have experience with regard to the latest techniques/tools to be adopted for the test procedures.
- (4) Minimum infrastructure required for basic virology / molecular marker laboratory <u>General Equipments:</u>
 - Common laboratory glassware and instruments
 - Digital top pan/analytical balance
 - pH meter
 - Distilled and sterile//millipore water
 - Gas burners
 - Autoclave
 - Laminar flow hoods
 - Incubation chambers
 - Freezer (-20° C)
 - Refrigerator 4^o C
 - Vortex mixer
 - micropippettes

Specific Equipments

- DNA extraction equipment
- DNA probes

- Tissue grinder
- Centrifuge / Microcentrifuge
- PCR
- Horizontal Gel Electrophoresis
- Gel documentation unit
- Equipments for DNA fingerprinting

(5) Reagents

- Dignostic reagents
- cDNA probes
- Polyclonal / monoclonal anti-bodies for diagnostic for commonly occurring Viruses
- Primers
- (6) Applicable test methods as per prescribed norms
- (7) ISO-17025 Certification would be preferred

STANDARDS FOR CERTIFICATION OF TISSUE CULTURE PRODUCTION UNITS UNDER NATIONAL CERTIFICATION SYSTEM FOR TISSUE CULTURE RAISED PLANTS (NCS-TCP)

The standard parameters which need to be complied with for certification of the Tissue Culture Production Units have been categorized into critical and non critical parameters. The conformity of Tissue Culture Unit to the standards is assessed by the Accreditation Panel (AP) through a site visit. The recommendation for certification is based on conformity with all the critical and non critical parameters. In case of non conformity the Accreditation Panel advises the TC Units for the corrective actions fulfilling which they are eligible for certification. Depending upon the nature of non conformity either a site visit is made to ascertain compliance or the documented evidence is accepted.

S. No.	Particulars	Marks
1.	Infrastructure	
	Lab Facilities	
	Washing room	
	Media Preparation room	
	• Inoculation room,	5
	Growth room	5
	• Power back up	10
		10
	Hardening facilities	5
	• Transfer area, greenhouse, shade area	
	• Nursery	10
		5
2.	Technical supervision and monitoring	
	Monitoring of the production process and technical	
	competence of the production staff (operators and	10
	supervisory staff)	
3.	Quality control	
	• Selection of clones and maintenance of germplasm	
	• Virus indexing	
	• Number of multiplication cycles and Clonal	8
	uniformity	10
	• Overall quality of the plants	10
		12
	Total	100

Score Card for Assessing TC Units:

CRITERIA FOR EVALUATION OF TISSUE CULTURE PRODUCTION FACILITIES

Particulars	Requirement	Compliance (Y/N/NA)	Marks Allotted	Remark (if any)
		· · ·		
Lab Facilities				
(i) Washing	Critical:			
room	1. Good quality of washing: whether it is			
	done manually or through a machine.			
Marking:	2. The glassware must be washed under			
Non-critical- 1	3 Contaminated cultures should not be			
	stored. They should be washed as soon as possible.			
	autoclaved before washing with a			
	detergent			
	5. Overall cleanliness must be maintained.			
	Non-critical:			
	1. Drying of washed jars, petriplates and other glassware			
	2. There should be a proper mechanism			
	for disposal of used agar			
(ii) Media Preparation				
Marking:	Critical:			
Critical- 4 Non-critical- 1	 Availability of basic equipments such as weighing balance (electronic). _PH meter, conductivity meter, microwave oven, de-ionizer/distillation unit/RO water facility, autoclave etc. Maintenance of the media record and proper labeling of jars/trays/racks Storage of media for 2-3 days sterility (Class 1,00,000) of media room 			
	 Non-critical: 1. The chemicals should be of AR/Tissue culture grade 2. Operational efficiency of the workers/operators 			

Particulars	Requirement	Compliance	Marks	Remark
		(Y/N/NA)	Allotted	(if any)
(iii) Inoculation room				
Marking: Critical- 8 Non-critical- 2	 Critical: Maintenance of proper record of species, clone, passage number, media, operator name, etc. Minimum sterility level of Class 100,000. Regular monitoring of air borne microbes Periodically checking of the airflow of the laminar airflow cabinet 			
	 Non-critical: 1. The room must be fumigated periodically with sterilant 2. Besides flaming, the tools (forceps, scalpels, etc.) should also be autoclaved periodically 3. Use of glass bead sterilizers instead of rectified spirit 4. Restricted entry 5. Handling of only one clone/genotype during sub-culturing at a time 6. Emphasis on the qualitative efficiency of the operators (the number of jars handled, multiplication rates, contamination losses, etc.) 			

Particulars	Requirement	Compliance	Marks	Remark
		(Y/N/NA)	Allotted	(if any)
(iv) Growth room				
Marking: Critical- 8 Non-critical- 2	Critical:1. Controlled temperature, light and2. High sterility levels (Class 100,000) with periodic check on airborne contaminants			
	Non-critical: 1. Periodically disinfection 2. Restricted entry			
<u>(v)Power</u> <u>Back-</u> <u>up</u>	Critical			
Marks: 5	 Availability of sufficient and continuous power back-up where load shedding is a problem. 			
<u>Hardening</u> <u>Facilities</u>				
(i) Transfer area				
Marking: Critical- 4 Non-critical- 1	Critical:1. Proper labeling of hardening trays2. Maintenance of all records pertaining to number of plants transferred, date of transfer, etc.			
	 Non-critical: 1. Only one clone to be washed at a time 2. Selection of the hardening container and potting mix as per the requirement of the species 3. Avoiding wilting of plants 4. Avoiding excessive watering 5. Proper consideration to the texture and pH of the substrate used for hardening 			

Particulars	Requirement	Compliance (Y/N/NA)	Marks Allotted	Remark (if any)
(ii) <u>Green</u> <u>House/Poly</u> <u>House</u> Marking: Critical- 4 Non-critical- 1	 Critical: Monitoring of plants for their growth and presence of any disease or pest Proper record of any kind of treatment given to the plant such as fertilizers, fungicides, pesticides, etc. Facility for ventilation to control excess of RH during monsoon Quality of water used for irrigation of primary hardened plants Double door to check infection Proper record of fungal infestation, subsequent spray and any mortality 		Anoted	
	 Avoiding excessive watering of plants Immediately removal of dead plants 			
<u>(iii)</u> <u>Nursery</u> Marking: Critical- 4 Non-critical- 1	 Critical: 1. Use of proper potting mixture 2. Nursery should have partial shade area with proper irrigation facilities 3. Insect monitoring and management 			
	Non-critical 1. avoiding of water-logging 2. Regular weeding			

Particulars		Requirement	Compliance	Remark
2.	Quality Control(i) Selection of clones and maintenance of germplasm and explantsMarking: Critical- 8	 Critical 1. Record of following points while selecting the mother plant Geographical location of the mother plant or the area where mother plant is growing Microclimatic conditions prevailing in that area Various growth attributes of the mother plant (height, diameter of the stem, yield, etc.) Origin of the mother plant (seedling raised or vegetatively raised) Characteristic feature 2. maintenance of mother plant stock 		

Particulars	Requirement	Compliance (V/N/NA)	Marks Allotted	Remark (if any)
			moticu	(ii uiiy)
(iii) Virus indexing Marking: Critical- 10	Critical: Virus indexing of material at the time of culture establishment 			
	2. Virus indexing of tissue culture raised plants			
(iv)Number of multiplication cycles and clonal uniformity Marking: Critical- 6 Non-critical- 4	Critical: 1. Multiplication cycles within the limit as per prescribed unit. (Since, this number is not fixed and would vary with the species)			
	 Non-critical: Testing of genetic fidelity is desirable with the help of molecular techniques after certification. (This may be done in house however for certification purpose, it should be done at the established test centre). Maintenance of at least 10 aliquots of leaves from the original mother plants for reference 			

Particula rs	Requirement	Compliance (V/N/NA)	Marks Allotted	Remark (if any)
15			Anoticu	(II ally)
(v) Overall quality of the plants Marking: Critical- 7 Non-critical- 5	 Critical At the time of dispatch it must be ensured that the plants are fully hardened and are of transplantable size. <u>In case of ex agar plants, these plantlets should be appropriate size to ensure their survival after transplantation</u> Non-critical: A small hand out giving all necessary information about after-care of the tissue cultured plant of that particular species should be provided to all 			
	growers for reference			
(vi) Technical supervision and monitoring				
Marking: Critical- 8 Non-critical- 2	 Critical: 1. Strict monitoring of the entire production process covering all the activities that are performed in media lab, inoculation lab, growth room and hardening area is a must 2. The managers, scientists and the supervisory staff involved in production must have sound technical knowledge of the subject 3. Training of the supervisors and the professional staff 			
	 Non-critical: 1. There should be at least two supervisors (one in the clean area to monitor lab activities and one in the hardening area for after care and for monitoring field activities) in the production facility. 			

APPLICATION FORMS UNDER NCS-TCP

NCS-TCP Form-1

Application for Accreditation of Laboratory Facilities for Virus Diagnosis and Genetic Fidelity Testing of Tissue Culture Plants

1. Applicant Entity (Institute/Organization)				
Name:				
Address:				
City:				
State:				
Tel/Fax/E-mail				
2. Laboratory-In charge				
Name:				
Position:				
Address:				
City				
State Tel/Fax/ E-mail:				
3. Scientific expertise available for				
Virus testing				
Genetic Fidelity Testing				
(please enclose detailed biodata)				
4. Particulars of Laboratory				
• University				
National Laboratory				
• Others				
5. Laboratory Information (Space/Facilities)-(please provide details)				
- Laboratory & Glasshouse				
- Equipment available				
- Expertise / Staff				
6. Test Methods developed and used at the laboratory				
• Diagnostic probes available (list the pathogen and diagnostic probe)				
• Molecular markers available for determining genetic purity of different plant species (list the				
species)				
7. Is it Accredited under ISO:17025 Yes/No				
(II yes give details) Details may be provided as non associal requirement criteria				
Detans may be provided as per essential requirement criteria				
Signature of Technical Manager/Laboratory—In Charge Signature (Authorized Entity Representative)				

Head of the Institute

To be submitted by Laboratory in Public Sector/Not-for-Profit Organizations, Government funded Institutes/Universities having strength in Virology/Molecular Biology as per criteria enclosed. (Appendix 1)

NCS-TCP Form-2

Application f	or Certification	of Tissue	Culture	Production	Facility
1 ppmcation 1			Cuivaiv	I I Oudection	I activy

1. Applicant Entity (Institute/Organization)				
Name:				
Address:				
City:				
State:				
Tel/Fax/E-mail				
2. Laboratory-In charge				
Name:				
Position:				
Address:				
City				
State Tel/Fa	x/ E-mail:			
3. Particulars of Laboratory				
Public Sector				
- National Laboratories (CSIR/ICAR etc)				
- State Funded Laboratories				
- Universities				
Private Sector				
NGO				
Others				
4. Production Capacity				
5. Annual Turnover (for last three years)				
6. Plant species being multiplied				
Domestic Market				
Export Market				
(please indicate if it is on buy back arrangement)				
7. Infrastructure available (please provide details	including list of major equipments and instruments,			
Capacity)				
- Laboratory(Media preparation room, Inocu	lation roomand Growth room)			
- Green House				
- Nulsely/shade house	ification and valouant armanianas of technical and			
o. Stall Details (please provide details about qual research staff)	incation and relevant experience of technical and			
- Production (Technical and Non-technical)			
- Research	,			
9. Reporting system for technical supervision ar	nd monitoring of production process			
10. Inhouse mechanism for quality control and quality assurance				
	·			
Signature of Technical Manager/Laboratory—In Charge	Signature (Authorized Entity Representative)			

Head of the Institute

To be submitted by any production facilities located in the Public Sector, not-for-profit organization or Private Sector having minimum half million capacity. Criteria for Assessment of Tissue Culture Production Facility is enclosed (Appendix – II)

Application for Certification of Tissue Culture Material

- a. Name of Tissue Culture Production Facility:
- b. Certificate No.:
- c. Plant species / variety to be tested:
- d. Source of Mother explant
- e. Details of production technology as per standard procedures notified Yes/No
- f. Total production (no. of plants per lot)

Signature of Technical Manager/Laboratory—In Charge

Signature (Authorized Entity Representative)

To be submitted by a Certified Tissue Culture Production Facility to the Accredited Test Laboratory

FEE STRUCTURES UNDER NCS-TCP

(A) Fee structure for Certification of Tissue Culture Production Facilities

(Figures in Rs.)

	Small-scale companies (Upto 1X10 ⁶ plantlets/annum)	Medium-scale companies (1 to 3 million plantlets/annum)	Large-scale companies (> 3 X10 ⁶ plantlets/annum)
Registration fee	1000*	1000*	1000*
Inspection and report preparation	1000	3000	5000
Processing and Certification	5000	5000	5000

Period of validity of Certification is Two Years

* Registration renewal fee will be charged @ 25% of the registration fee.

- Only Registration fee to be deposited at the time of Application submission,
- Fee will be payable as Demand Draft in favour of "Biotech Consortium India Ltd."

(B) Fee for Certification of only hardening units :

Registration Fee: Rs. 1000/- (not required in the pre registered companies)

Site Visit Fee: Rs. 1500/- per hardening center

Certification Fee: Rs. 5000/- (for all hardening centers eligible for certification as per guidelines)

(C) Fee structure for second visit of experts to TCPUs for verification of corrective actions

Fee will be charged for the verification of the corrective action taken by the production unit as per the fee structure given below

Small scale Company	Rs. 1000/-
Medium scale company	Rs. 1500/-
Large scale company	Rs. 2500/-

PROCEDURE AND CONDITIONS FOR USE OF LOGO

RESPONSIBILITY:

• DBT is responsible to establish, implement and amend this procedure. The Accreditation Unit, Referral Laboratories, Accredited Test Laboratories are responsible to comply with the procedure.

DESIGN OF THE LOGO:

- The design of the logo is enclosed at appendix 'A'. The design specifies the proportions of the logo and the colour combinations in which it can be reproduced.
- The logo shall be reproduced in the colours as indicated in appendix 'A'. The size of the logo shall not normally be reduced below the size15x12mm.

CONDITIONS FOR REPRODUCTION OF LOGO:

- The Accreditation Unit, Referral Laboratories, Accredited Test Laboratories can reproduce the logo of NCS-TCP on its certificates, stationary, written announcements and any other requirement specified by DBT.
- The logo shall be reproduced based on the master supplied to each of the accredited Test Laboratories. Redrawn masters should not be used.

USE OF LOGO:

- The logo shall be used in all certificates and all certified products.
- The logo shall not be displayed on vehicles except in publicity material like part of a large advertisement.
- The logo shall not be used or displayed on buildings and flags.
- The Accredited Test Laboratories (ATLs) upon suspension or withdrawl of its accreditation shall discontinue use of logo.

CONTRAVENTION OF THE CONDITIONS:

• In situations of contravention, the Certification Agency may withdraw the Accreditation. In case if the Accredited Test Laboratory does not take suitable action against the wrong use of the logo, the Certification Agency may suspend/withdraw the accreditation.

ACTION ON SUSPENSION OR TERMINATION:

- Upon the **suspension** of the accreditation by the Certification Agency, the Accredited Test Laboratory shall immediately cease to use its stationary, certificates and other publicity material that has logo on it. The use can be restarted only after the suspension is revoked by the Certification Agency.
- Upon **termination** of the Accreditation on account of non-renewable/ withdrawal of the accreditation, the Accredited Test Laboratory shall immediately cease to use logo in any form including use of stationary, certificates and other publicity material that has logo on it.



Audit criteria and audit schedule

i. Constitution of technical audit team: Technical audit team will consist of at least two experts and one representative from the Accreditation Unit.

ii. Types of technical audit:

- a. Scheduled audit: Once in a year with proper intimation to the concerned entity
- b. Unscheduled audits: As per the requirement at a short notice or without intimating the concerned entity

iii. Time schedule:

- a. Accredited Test Laboratories (ATLs): It would be conducted annually. First technical audit would be undertaken after the completion of training programme.
- b. Tissue Culture Production Facilities (TCPFs): It would be conducted annually.
 First technical audit would be undertaken after 3 months of the operationalization of ATLs
- iv. Criteria: Criteria would be similar based on which accreditation/recognition has been given to the ATLs/TCPFs respectively. Compliance with the Standard Operating Procedure would also be assessed based on the available records and documents.