

**ASSESSMENT REPORT FOR RECOGNITION OF TISSUE CULTURE
PRODUCTION FACILITIES UNDER NCS-TCP (Revised on June, 2011)**

Applicant:		
Head of the Organization:		
Mailing Address:		
City:	State/Province:	Pin Code:
Tel:	Fax:	E-mail:
In-charge of Unit:		
Inspected by:		
1. Name & Designation:		

2. Name & Designation:		

2. Name & Designation:		

Dates of Inspection of Facility:		

Instruction for Accreditation Panel (AP):

Completion of Report: This format has been designed as an aid to auditors to ensure that the essential elements outlined in the standard '**Guidelines for Recognition for Tissue Culture Production facilities under NCS-TCP**' established by the **Department of Biotechnology, Ministry of Science & Technology** are complied with.

Submission of Report:

1. The AP should complete the report form for each parameter.
2. This Assessment Report should be submitted to: **The Head, Accreditation Unit, Biotech Consortium India Limited, 5th Floor, Anuvrat Bhawan, 210, Deen Dayal Upadhyaya Marg, New Delhi-110002**

ASSESSMENT REPORT FOR RECOGNITION OF TISSUE CULTURE PRODUCTION FACILITY UNDER NCS-TCP

(*marked parameters are mandatory requirements for consideration of application for registration. Site visit would be organized on compliance with mandatory requirements during self assessment. Shaded column to be filled by applicant as self assessment)

PART-1

S. No.	Particulars	Self Assessment by the applicant				Comments of the expert committee during on-site visit
		Yes	No	NA	Descriptive Information (please enclose separate sheet, if required)	
	Part 1A: Minimum requirement to apply for Recognition					
1.	Total annual production capacity more than 0.5 million plant.					
2.	Total Annual Production of last year Millions					
3.	<p>Infrastructure*</p> <p>Lab Facilities:</p> <p>Do you have the following areas clearly demarcated*</p> <ul style="list-style-type: none"> ▪ Washing room Specify area ▪ Media Preparation room Specify area ▪ Acclimatization 					

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4.	<p>Do you have special entry to the clean area consisting of following three areas*:</p> <p>i. Media store room(s)* Specify area</p> <p>ii. Inoculation room(s)* Specify area</p> <p>iii. Growth room(s)* Number and area of individual room</p> <ul style="list-style-type: none"> ▪ Transfer/Grading area* Specify area ▪ Greenhouse(s)/ Poly-house(s)* Number & area of individual Greenhouses ▪ Do you have a separate misting facilities If so, its area ▪ Do you have fire fighting system and emergency exit at your facility If so, are they maintained regularly 					

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5.	<p>Power backup (% needs met by electricity generation)</p> <p>Do you have provision for restricted entry to tissue culture production facility and within different segment of facility?</p>					

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1.	<p>Part 1B: Area Wise Operations and Quality Requirements:</p> <p><u>Mother plant and Explant material:</u></p> <p>Are you following listed procedures:</p> <p>1.1. Do you have clearly defined criteria (species wise) for the selection of elite plants</p> <p>1.2. Do you keep proper records (such as unique code no. and passport data of the mother plant)</p> <p>1.3. Are you sending the stock cultures/ mother plant tissue for virus testing for all the known viruses?* <i>If so, details of the lab where testing is done.</i></p> <p>1.4. Are you importing/procuring stock cultures from different sources <i>If yes! Give the details of testing (institute, test result etc.</i></p>					

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2.	<p><u>Washing and drying:</u></p> <p>2.1. Do you have dedicated washing room?*</p> <p>2.2. Is washing room well connected with the media preparation room for transfer of washed vessel* (Connected through pass box or a closed corridor)</p> <p>2.3. Is washing done mechanically/manually?</p> <p>2.4. Do you have availability of running tap water?</p> <p>2.5. Do you have separate basins for keeping glassware at different stages of washing?</p> <p>2.6. Do you have provision for separate dipping of jars from the hardening area/infected cultures?</p> <p>2.7. Whether washing is done in close or open area:</p> <p>2.8. Is cleanliness being maintained?</p> <p>2.9. Is drying of glasswares done in ovens or at room Temperature</p>					

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3.	<p><u>Discard of used agar:</u></p> <p>3.1. Do you autoclave the contaminated culture/media <i>If no, please specify the procedure of decontamination</i></p> <p>3.2. Do you keep records of decontamination/autoclaving of infected cultures</p> <p>3.3. Do you treat used agar at site</p> <ul style="list-style-type: none"> - Procedure being followed - Discard at Pit which is to be used as nutrient for bio-fertilizer <p>3.4. Do you keep records of material being discarded</p>					
4.	<p><u>Media Preparation:</u></p> <p>4.1. Do you have all the basic equipments* (including electronic weighing balance, pH meter, conductivity meter, microwave oven, de-ionizer/distillation unit/RO water facility, autoclave etc.)</p> <p>4.2. Do you suitable water purification system such as RO/distillation units</p>					

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	<p>4.3. Equipment details:</p> <ul style="list-style-type: none"> - Autoclave <ul style="list-style-type: none"> ▪ Number ▪ Single door/double door <p>4.4. Calibration of all analytical and measuring equipments</p> <p>4.5. Are you keeping proper records for:</p> <ul style="list-style-type: none"> - Stock solution preparation - Media preparation - Autoclave cycle - Calibration of equipments <p>4.6. Do you label the individual jar/tray</p> <p>4.7. Do you use the AR/tissue culture grade chemicals</p> <p>4.8. Do you have suitable mechanism for transfer of media into media storage room immediate after the autoclaving without entering into the other area</p> <p>4.9. Do you give emphasis on efficiency of the operators engaged in media preparation (volume, number of jars, filled etc.)</p>					

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5.	<p><u>Media storage:</u></p> <p>5.1. Are you maintaining class 100,000 sterility level?* Mention the installed facility (pressure module/AHU/ HVAC).</p> <p>5.2. Do you maintain particle count data in support of sterility class 100,000</p> <p>5.3. Do you monitor the airborne microbe through microbial plating? If so, its frequency.</p> <p>5.4. Adequate space for media storage (to store the media for at least 3 days)</p> <p>5.5. Do you have provision of UV lights in the room</p> <p>5.6. Range of number of days (minimum 3-4 days)for which media is stored prior to inoculation</p> <p>5.7. Do you keep records routine screening of media for any contamination</p> <p>5.8. Do you have plastic paint/water proof emulsion on the wall</p>					

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	5.9. Do you fumigate the room periodically with the Sterilant					
6.	<p><u>Inoculation</u></p> <p>6.1. Are you maintaining class 100,000 sterility level?* Mention the installed facility (pressure module/AHU/HVAC)</p> <p>6.2. Do you maintain particle count data in support of sterility class 100,000</p> <p>6.3. Do you monitor the airborne microbe through microbial plating? If so, its frequency.</p> <p>6.4. Are you following the maintenance schedule for laminar air-flow cabinets</p> <ul style="list-style-type: none"> - Cleaning of pre-filters - Checking air flow - Checking efficiency of HEPA filters by exposing plates <p>6.5. Do you have plastic paint/water proof emulsion on the wall</p> <p>6.6. Do you fumigate the room periodically with the</p>					

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	<p>sterilant</p> <p>6.7. Do you use glass bead sterilizer for sterilization of forceps/scalpel</p> <p>6.8. Record keeping for</p> <ul style="list-style-type: none"> - Efficiency of operators (through monitoring number of jars handled, multiplication rate, contamination losses, rooting percentage and general health of the culture etc.) - Calculating multiplication fold at the end of each passage - Contaminated cultures - Particle count data for maintaining class 100,000 					
7.	<p><u>Incubation: Growth room related activities</u></p> <p>7.1. Are you maintaining class 100,000 sterility level?* Mention the installed facility (pressure module/AHU/HVAC)</p>					

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	<p>7.2. Do you maintain particle count data in support of sterility class 100,000</p> <p>7.3. Do you monitor the airborne microbe through microbial plating? If so, its frequency.</p> <p>7.4. Is the temperature in the growth room uniform</p> <p>7.5. Do you fumigate the room periodically with the sterilant</p> <p>7.6. Record keeping for:</p> <ul style="list-style-type: none"> - Contamination - Continuous temperature recording device - Light intensity/duration <p>7.7. Do you make production schedules based on the protocol efficiency</p> <p>7.8. Do you have plastic paint/water proof emulsion on the walls</p>					

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8.	<p><u>Power back up:</u></p> <p>8.1. Do you have power backup arrangement If so what percentage would be covered by power back in case of power failure?</p>					
9.	<p><u>Transfer of plantlets from lab to hardening facility:</u></p> <p>9.1. Do you have dedicated transfer area*</p> <p>9.2. Do you have arrangement of washing of plantlets to remove culture medium</p> <p>9.3. Are plants graded? If so do you have organized grading system such as working table with pictorial map of the handled plant species</p>					
10.	<p><u>Hardening:</u></p> <p>Mist chamber, Green house/Polyhouse</p> <p>10.1. Do you have double door to entry*</p> <p>10.2. Do you have facilities for monitoring*:</p> <ul style="list-style-type: none"> - Temperature - Humidity - Light intensity and duration 					

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	<p>10.3. Do you monitor plants for their growth or any other feature?</p> <p>10.4. Do you keep record of dead plants</p> <p>10.5. Do you maintain record of any treatments given to the plants (fertilizer applications; sprays etc?)</p> <p>10.6. Do you have yellow sticky traps for insect pest monitoring</p> <p>10.7. Do you label individual hardening trays conveying the details of number of plants, date of transfer, batch number etc.</p> <p>10.8. Do you use potable water/ good quality water for watering of plantlets. Please specify the TDS level</p> <p>10.9. Do you avoid excessive watering and water-logging</p> <p>10.10. Do you have raised bed/ to avoid contact of roots with ground soil</p>					

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11.	<p><u>Nursery and sales/ dispatch of plants for planting</u></p> <p>11.1. Double door to check infection*</p> <p>11.2. Availability of net house* (to provide partial shade and prevent insect entry). If so, its mesh size.</p> <p>11.3. Availability of reliable clean water source</p> <p>11.4. Do you monitor plants for their growth or any other feature?</p> <p>11.5. Do you keep record of dead plants</p> <p>11.6. Do you maintain record of any treatments given to the plants (fertilizer applications; sprays etc?)</p> <p>11.7. Do you have yellow sticky traps for insect pest monitoring</p> <p>11.8. Do you label individual batch conveying the details of number of plants, date of transfer, batch number and batch size etc.</p> <p>11.9. Do you avoid excessive watering and water-logging with drainage system</p> <p>11.10. Do you undertake regular weeding and remove</p>					

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	<p>dead plants</p> <p>11.11. Do you maintain records to trace back the history of plants.</p>					
1.	<p>Part 1C: Quality Management Aspects</p> <p><u>Virus indexing of TC raised plants (advisable during first application)</u></p> <p>Are you routinely getting following done:</p> <p>1.1. Virus indexing of tissue culture raised plants If yes, give details of the laboratory where this testing is done.</p>					
2.	<p><u>Genetic Fidelity testing</u></p> <p>2.1. Are you restricting number of multiplication cycles?</p> <p>2.2. Are you strictly monitoring the procedures while transferring plantlets from:</p> <ul style="list-style-type: none"> - Growth room to transfer area - Greenhouse to shade area 					

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	<p>- At the time of dispatch</p> <p>2.3. Are you getting the genetic fidelity testing done through molecular markers (advisable)</p> <p>2.4. Do you preserve leaf samples preserved for future reference and genetic fidelity studies(advisable)</p>					
3.	<p><u>Overall technical management</u></p> <p>3.1. Competent technical supervision and effective monitoring of entire production process: Indicate management/operational structure & their qualification. Please also specify their role & responsibilities</p> <p>3.2. Do you have separate in-charge/supervisor for at least lab facilities and hardening facilities</p> <p>3.3. Do you provide training to the supervisor/operators If so, internal training or external training</p>					
4.	<p><u>Overall Quality of Plants</u></p> <p>4.1. Do you ensure that plants are fully hardened and transplantable size at the time of dispatch</p>					

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	<p>4.2. In case of ex-agar plants, it is ensured that plantlets should be appropriate size to ensure their survival during transport/transplantation in greenhouse/nursery</p> <p>4.3. Do you provide handout to the farmers along with plants covering the package of practices for cultivation of particular species</p> <p>4.4. Do you have mechanism for receiving and addressing the feedback/complaints from farmers?</p> <p>4.5. Maintenance of records of farmers feedback/data regarding field performance (if any)</p>					

PART- 2

CORRECTIVE ACTIONS

(To be filled in duplicate and one copy to be handed over to the company after site visit)

Date	Name of organization	Registration Number:
S. No.	List of non-conformities	

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S. No.	Additional suggestion/advise of Accreditation Panel (if any):
	Time frame for taking corrective action as per above non conformity (ies):
	<p><u>Lead Auditor</u></p> <p>Name & Designation: _____ Signature: _____</p> <p><u>Auditee</u></p> <p>The above nonconformity report has been understood and is being acknowledged here with.</p> <p>Name & Designation: _____ Signature: _____</p>

Note: The observations/recommendations of Accreditation Panel are subject to approval of Department of Biotechnology, Govt. of India. The final decision would be conveyed in due course of time.

