

**Assessment/Audit Report for Renewal of Recognition of
Tissue Culture Production Facility under NCS-TCP
(Revised on June, 2011)**

| | | |
|-----------|--|--|
| 1. | Name & Address of Recognized Tissue Culture Production Facility Registration No. Certification No. | |
| 2. | 2.1. Head of Tissue culture production facility (Name & Designation/ contact number/e-mail): 2.2. Sectional In charges (Managers) | |
| 3. | Assessment for renewal period of recognition | |
| 4. | Date of assessment: | |
| 5. | Audited by (Name & Designation) | |

PART-1

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

| S. No. | Particulars | Self Assessment by the applicant | | | | Comments of the expert committee during on-site visit. |
|--------|--|--|---|--|---|--|
| | | Status of compliance as per previous site visit (Yes/No) | Present Status (to be filled by company) (Yes/No) | If no, then type of deviation from Previous Status (to be filled by company) | Reasons for deviation (to be filled by company) | |
| A1. | <p>Part 1A: 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?*</p> <p><i>If so, details of the lab where testing is done.</i></p> | | | | | |

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| | 1.4. Are you importing/procuring stock cultures from different sources <i>If yes, Give the details of testing (institute, test result etc.)</i> | | | | | |
| A2. | <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> | | | | | |

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| | <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> | | | | | |
| A3. | <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> | | | | | |

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| | 3.3. Do you treat used agar at site <ul style="list-style-type: none"> - Procedure being followed - Discard at Pit which is to be used as nutrient for bio-fertilizer 3.4. Do you keep records of material being discarded | | | | | |
| A4. | <u>Media Preparation:</u> 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.) 4.2. Do you suitable water purification system such as RO/distillation units | | | | | |

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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> | | | | | |

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| | 4.9. Do you give emphasis on efficiency of the operators engaged in media preparation (volume, number of jars, wastage etc. | | | | | |
| A5. | <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> | | | | | |

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| | 5.6. Range of number of days (Minimum 3-4 days) for which media is stored prior to inoculation 5.7. Do you keep records routine screening of media for any contamination 5.8. Do you have plastic paint/ water proof emulsion on the wall 5.9. Do you fumigate the room periodically with the sterilant | | | | | |
| A6. | <u>Inoculation</u> 6.1. Are you maintaining class 100,000 sterility level?* Mention the installed facility (pressure module/AHU/ HVAC) 6.2. Do you maintain particle count data in support of sterility class 100,000 | | | | | |

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| | <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 sterilant</p> <p>6.7. Do you use glass bead sterilizer for sterilization of forceps/scalpel</p> | | | | | |

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| | <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 | | | | | |
| A7. | <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> <p>7.2. Do you maintain particle count data in support of sterility class 100,000</p> | | | | | |

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| | <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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| A8. | <p><u>Power back up:</u></p> <p>8.1. Do you have power backup arrangement <i>If so what percentage would be covered by power back in case of power failure?</i></p> | | | | | |
| A9. | <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? <i>If so do you have organized grading system such as working table with pictorial map of the handled plant species</i></p> | | | | | |

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| A10. | <p><u>Hardening:</u></p> <p>Mist chamber, Green house/Polyhouse</p> <p>10.1. Do you have double door entry*</p> <p>10.2. Do you have facilities for monitoring*: - Temperature - Humidity - Light intensity and duration</p> <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> | | | | | |

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| | <p>10.6. Do you have sticky yellow traps for insect pest monitoring</p> <p>10.7. Do you label individual hardening trays convening 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 with drainage system</p> <p>10.10. Do you have raised bed/ provision to avoid contact of roots with ground soil</p> | | | | | |

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| A11. | <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). <i>If so, its mesh size.</i></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 sticky yellow traps for insect pest monitoring</p> | | | | | |

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| | <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 dead plants</p> <p>11.11. Do you maintain records to trace back the history of plants.</p> | | | | | |

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| B1. | <p>Part 1B: 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 <i>If yes, give details of the laboratory where this testing is done.</i></p> | | | | | |
| B2. | <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 - At the time of dispatch <p>2.3. Are you getting the genetic fidelity testing done through molecular markers (advisable)</p> | | | | | |

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| | 2.4. Do you preserve leaf samples preserved for future reference and genetic fidelity studies(advisable) | | | | | |
| B3. | <p><u>Overall technical management</u></p> <p>3.1. Competent technical supervision and effective monitoring of entire production process: <i>Indicate management/operational structure & their qualification. Please also specify their role & responsibilities</i></p> <p>3.2. Do you have accountable in-charge/supervisor for at least lab facilities and hardening facilities</p> <p>3.3. Do you provide training to the supervisor/operators <i>If so, internal training or external training</i></p> | | | | | |

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| B4. | <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> <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> | | | | | |

| <u>PART-1 C</u> | | | |
|------------------------|---|--|---|
| C. | Standard Operating Procedure (SOPs) in terms of | Type of non-conformity observed | Suggested corrective Action / prevent measures |
| C.1 | Minimum organization structure | | |
| C.2 | Deviations from the SOPs provided by AU (if yes, please enclose a separate sheet stating that whether the Deviation is justified) | | |
| 2. | Additional Information | | |
| 2.1 | Crop wise actual production | Crop | Production (Million/annum) |
| | | | Total For Domestic |
| | | | |
| 2.2 | Future projections: | | |
| 2.3 | Any change in the scientific staff and managers since last visit | | |
| 2.4 | Any expansion in production capacity | | |

PART-2

List of non- conformities observed during the site visit:

Auditee:

The above nonconformity report has been understood and is being acknowledged here with.

Name & Designation:

Signature:

Signature/Name/Designation of Auditors with date:

1. _____

2. _____

3. _____

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.

RECOMMENDATION OF ACCREDITATION PANEL

(Tick any one)

- 1) **Recommended for Renewal of Recognition:** If the company complies with all the mandatory parameters (marked as *) along with other parameters listed in the assessment form.
- 2) **Not Recommended for Renewal and suggested to reapply for Recognition:** If the company does not comply with even one of the mandatory parameter (marked as *). In such case company would be asked by AU to bear the cost of site visit in addition to prescribed fee.
- 3) **Recommended for Renewal of Recognition subject to completion of corrective action (s):** If the company complies with all the mandatory parameters (marked as *) except non mandatory parameters, company would be advised to complete the corrective actions within one month in order to be considered for recognition under NCS-TCP.

Additional Remark (if any):

| | |
|----------------------|-----------------------------|
| 1. _____ | _____ |
| (Name & Designation) | (Signature of Auditor/date) |
| 2. _____ | _____ |
| (Name & Designation) | (Signature of Auditor/date) |
| 3. _____ | _____ |
| (Name & Designation) | (Signature of Auditor/date) |

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.

Recommendation of auditor on completion of corrective/preventive action

Any comment of expert for the improvement of format: