



**Government of India**  
**Ministry of Science & Technology**  
**Department of Science & Technology**  
**National Good Laboratory Practice (GLP) Compliance Monitoring Authority**

***POLICIES AND PROCEDURES OF  
NGCMA FOR TAKING ADVERSE  
AND OTHER DECISIONS  
AGAINST TEST FACILITIES***

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**NATIONAL GLP COMPLIANCE MONITORING AUTHORITY**  
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**POLICIES AND PROCEDURES OF NGCMA FOR TAKING  
ADVERSE AND OTHER DECISIONS AGAINST TEST  
FACILITIES**

**1. Objective**

This document describes various policies and procedures of National GLP Compliance Monitoring Authority (NGCMA) for taking adverse decisions against applicant and GLP Certified Test Facility (TF).

**2. Scope**

NGCMA Secretariat shall monitor the applicant/ GLP certified TF(s) for compliance with the OECD Principles of GLP. The issues that fall under the scope of this document are related to situations wherein applicant/ GLP certified TF has not complied with one or more terms and conditions as well as any of the applicable requirements. This document lists the adverse and other decisions taken by National GLP Compliance Monitoring Authority (NGCMA) against GLP certified/ applicant Test Facilities (TFs) and the conditions under which these decisions are taken.

**3. Responsibility**

NGCMA Secretariat shall monitor the TFs for any information that casts doubt on the suitability of awarding or maintaining GLP certification. NGCMA may consider an appropriate action in each case, taking into account the objective evidence against and facts available and comparing them with the related clauses as mentioned in this document.

**4. Classification of decisions:**

The various categories of decisions are as follows:

1. Adverse decisions against applicant TFs
  - a) Rendering the GLP application Inactive
  - b) Closing of a GLP application
  - c) Denial of GLP certification
2. Adverse decisions against certified TFs
  - a) Denial of GLP re-certification
  - b) Scope Reduction
  - c) Shifting of re-certification date {for TF(s) which apply less than 6 months before expiry of existing GLP certificate}
  - d) Re-enrolment of TF(s) (which apply for re-certification after expiry of existing GLP certificate)
  - e) Suspension

National Good Laboratory Practice Compliance Monitoring Authority		
Document No: GLP-113	Policies and Procedures of NGCMA for taking Adverse and other Decisions against Test Facilities	
Issue No: 02	Issue Date: 19.07.2016	Page 2 of 10

- f) Forced withdrawal
- 3. Other decisions for certified TFs
  - a) Voluntary withdrawal
  - b) Extension of validity of GLP certificate

**PROCEDURE TO BE FOLLOWED FOR TAKING ADVERSE DECISIONS AGAINST APPLICANT TEST FACILITIES**

**a) RENDERING THE GLP APPLICATION INACTIVE**

**Conditions:**

1. When a TF has submitted incomplete application and has not submitted required information, application fee etc. within three months of issuance of communication by NGCMA.
2. When a TF has not undergone pre-inspection within three months of submitting complete application, due to TF not agreeing for a pre-inspection
3. When a TF has not submitted satisfactory Action Taken Report (ATR) to the findings of pre-inspection within stipulated time period.
4. When a TF has not undergone final inspection within three months of submission of satisfactory ATR to the findings of pre-inspection, due to TF not agreeing for a final inspection.
5. When the final inspection of the TF has been conducted and TF has not submitted an ATR to the same within stipulated time period.
6. When an applicant TF does not adhere to NGCMA’s Document No. GLP-101 “Terms & Conditions of NGCMA for obtaining and maintaining GLP certification by a test facility” including misrepresentation of facts such as giving false information on its website, etc.

**Actions by NGCMA:**

1. For conditions mentioned at Points No. 1-5 above, a communication is sent to the TF that its GLP application has put under “Inactive”, category and it will be “closed” if the TF does not respond within 1 month of issuance of communication by NGCMA.
2. For the condition mentioned at Point No. 6 above, a warning letter is sent to the TF to adhere to Document No. GLP-101 “Terms & Conditions of NGCMA for obtaining and maintaining GLP Certification”. The TF will have to respond to the warning letter of NGCMA within 1 month of its issuance, failing which application will be closed.

National Good Laboratory Practice Compliance Monitoring Authority		
Document No: GLP-113	Policies and Procedures of NGCMA for taking Adverse and other Decisions against Test Facilities	
Issue No: 02	Issue Date: 19.07.2016	Page 3 of 10

**Restoration to ‘active’ status:**

1. The status of the TF’s GLP application is changed to “Active” after the TF has satisfactorily resolved the issues raised by NGCMA within 1 month from the date of imposition of “Inactive” status.
2. The TF need not pay additional application fee, while it returns to “Active” status.
3. The application file no. remains the same. However, the effective date for application shall be the date of restoration to “Active” status.
4. The TF’s GLP application can be put to “Inactive” status only once during the processing of application.

**b) CLOSING OF A GLP APPLICATION**

**Conditions:**

1. When a TF continues to be in “Inactive” status for more than 1 month and the TF has not responded to the communication of NGCMA which rendered it “Inactive”.
2. When the TF voluntarily withdraws its application for GLP certification.
3. When NGCMA has sought for clarifications on ATR/ organized a verification inspection and the TF has not provided appropriate clarifications/ agreed for a verification visit within a period of 1 month.

**Actions by NGCMA:**

1. If no response is received from the TF, the status of the TF’s GLP application is changed to “Closed”.
2. The “Closed” status is imposed on the TF and is notified in writing.

**Re-enrolment by TF:**

1. The TF can apply afresh at a later date. It is then treated as a new TF and has to pay the requisite fee, as applicable at that time. A new Application File no. will be issued to the TF.

**c) DENIAL OF GLP CERTIFICATION**

**Condition:**

1. When the TC on GLP has not recommended and Chairman, GLP Authority has not approved grant of GLP certification to the TF based on the final

National Good Laboratory Practice Compliance Monitoring Authority		
Document No: GLP-113	Policies and Procedures of NGCMA for taking Adverse and other Decisions against Test Facilities	
Issue No: 02	Issue Date: 19.07.2016	Page 4 of 10

inspection report/ verification inspection report (if applicable) and ATR submitted by the TF.

**Action by NGCMA:**

1. The TF is notified in writing giving reasons of denial and the application shall be closed.

**Re-enrolment by TF:**

1. The TF can apply afresh by submitting a new application along with applicable application fee and giving valid justification on earlier denial.

**PROCEDURE TO BE FOLLOWED FOR TAKING ADVERSE DECISIONS AGAINST CERTIFIED TFs**

**a) DENIAL OF GLP RECERTIFICATION**

**Conditions:**

2. When the TC on GLP has not recommended and Chairman, GLP Authority has not approved grant of re-certification to the TF based on the re-certification inspection report / verification inspection report (if applicable) and ATR submitted by the TF.
3. Non submission / Failure of TF to submit satisfactory ATR to the deficiencies of the re-certification inspection within stipulated time.
4. When TF does not provide satisfactory clarification as desired by NGCMA / shows inability to undergo proposed verification within 30 days of the formal communication from NGCMA.
5. TF's failure to adhere to Document No. GLP-101 "Terms & Conditions of NGCMA for obtaining and maintaining GLP certification by a test facility"

**Actions by NGCMA:**

1. The decision will be formally communicated to the TF.
2. NGCMA's website will be updated accordingly.
3. The information concerning the non-grant of GLP re-certification to the TF will be communicated to the OECD Secretariat.

**Re-enrolment by TF:**

1. The TF can apply afresh by submitting a new application along with applicable application fee and giving valid justification on earlier denial.

National Good Laboratory Practice Compliance Monitoring Authority		
Document No: GLP-113	Policies and Procedures of NGCMA for taking Adverse and other Decisions against Test Facilities	
Issue No: 02	Issue Date: 19.07.2016	Page 5 of 10

## **b) SCOPE REDUCTION**

### **Conditions:**

1. When the inspection team/ NGCMA observes major deficiencies/ observations from OECD Principles of GLP or guidelines of NGCMA (where applicable) for a particular area of expertise during any GLP inspection of the TF during its GLP certification cycle, which is expected to adversely influence the studies conducted by the TF.
2. When a TF fails to demonstrate its competence to conduct GLP studies in a particular area of expertise during a surveillance inspection, wherein GLP studies in that particular area of expertise have not been conducted for more than 1 year.
3. When a TF voluntarily reduces its scope of GLP certification from the scope of its GLP certification at any stage during a certification cycle.

### **Actions by NGCMA:**

1. The decision will be formally communicated to the TF. The TF will be required to return the original GLP certificate.
2. A new GLP certificate will be issued to the TF with revised scope.
3. NGCMA website will be updated accordingly.

### **Procedure for restoration of Scope:**

1. When the TF has fully addressed to the deficiencies, which had originally led to scope reduction, it may apply for extension in scope as mentioned in NGCMA's Document No. GLP-101 "Terms & Conditions of NGCMA for obtaining and maintaining GLP certification by a test facility" and GLP-104 "Procedures of NGCMA Secretariat".

## **c) SHIFTING OF RE-CERTIFICATION DATE (FOR TF(S) WHICH APPLY LESS THAN 6 MONTHS BEFORE EXPIRY OF EXISTING GLP CERTIFICATE)**

### **Condition**

1. If a TF has not applied for GLP re-certification 6 months prior to the expiry of existing GLP certificate but applied within certification period.

### **Actions by NGCMA**

1. GLP re-certification will be granted only when the TF undergoes the re-certification inspection before the expiry of its current GLP certificate, is able to submit satisfactory ATR against the observations of re-certification

National Good Laboratory Practice Compliance Monitoring Authority		
Document No: GLP-113	Policies and Procedures of NGCMA for taking Adverse and other Decisions against Test Facilities	
Issue No: 02	Issue Date: 19.07.2016	Page 6 of 10

inspection, (if any), the TC on GLP recommends and Chairman, GLP Authority approves the grant of GLP re-certification. In case the existing GLP certificate of the TF has expired before the grant of GLP re-certification, the date of certification shall be the date on which the Chairman, GLP Authority approves the recommendation of TC on GLP. The GLP certificate shall be valid for a period of three years.

2. The status of GLP compliance of GLP studies conducted between the period of expiry of earlier GLP certificate and grant of subsequent GLP certificate (if applicable), will be decided by the concerned Regulatory Authority. An inspection/ study audit for such studies would be undertaken by NGCMA, if required or requested by the concerned Regulatory Authority.

**d) RE-ENROLMENT OF TF(S) (WHICH APPLY FOR RE-CERTIFICATION AFTER EXPIRY OF EXISTING GLP CERTIFICATE)**

**Condition**

1. If a TF has not applied before the expiry of current GLP certificate and is unable to complete formalities for re-certification.

**Actions by NGCMA**

1. The TF will not remain in the List of GLP Certified TFs and its name would be removed from the NGCMA's website.
2. No re-certification will be granted in case the TF applies for GLP re-certification after the expiry of current GLP certification.
3. The GLP application will be processed as a fresh case, if it agrees. Otherwise, it will be returned to the TF.
4. The status of GLP compliance of GLP studies conducted between the period of expiry of one GLP certificate and grant of subsequent certificate, if applicable, will be decided by the concerned Regulatory Authority. A special study audit for such studies would be undertaken by NGCMA, if required or requested by the concerned Regulatory Authority.

**e) SUSPENSION**

**Conditions**

1. When a TF violates the condition of maintaining GLP certification such as:
  - Non adherence to NGCMA's Document No. GLP-101 "Terms & Conditions of NGCMA for obtaining and maintaining GLP certification by a test facility" and/or OECD Principles of GLP.

National Good Laboratory Practice Compliance Monitoring Authority		
Document No: GLP-113	Policies and Procedures of NGCMA for taking Adverse and other Decisions against Test Facilities	
Issue No: 02	Issue Date: 19.07.2016	Page 7 of 10

- Non-compliance to OECD Principles of GLP, which is found during any GLP inspection conducted by NGCMA during a certification cycle.
- Refusal to allow examination of studies/ data/ documents/ records during conduct of a GLP inspection, etc.
- Denial of access to NGCMA’s GLP Inspectors to its facility/ studies/ data
- Wrong representation of scope of GLP certification
- Misuse of GLP certification
- Misleading reporting of facts
- Bringing NGCMA into disrepute in any manner.
- Result of complaint analysis or any other information, which proves that the TF no longer complies with the terms and conditions of NGCMA & OECD Principles of GLP.

**Actions by NGCMA**

1. The TF is notified about the charges against it in writing through a “Show Cause Notice”, to be replied within 1 month.
2. If the TF does not reply to the “Show Cause Notice” or replies unsatisfactorily, a suspension letter is issued.
3. A TF can remain in suspension status for a maximum period of three months for entire scope of GLP certification, however the minimum period of suspension is 1 month. The duration of suspension and conditions of re-enrolment will be as recommended by the TC on GLP and approved by Chairman, GLP Authority.
4. If the TF does not respond to the actual suspension letter or refuses to meet the conditions to lift the suspension, procedure of ‘Forced Withdrawal’ is initiated.
5. During the period of suspension, the TF cannot use GLP certification and claim to be GLP certified.
6. The suspension of GLP certification is published on NGCMA website.

**f) FORCED WITHDRAWAL**

**Condition:**

1. When a TF remains in “Suspended” status for three months and has not met the condition for lifting the suspension even after three months.

National Good Laboratory Practice Compliance Monitoring Authority		
Document No: GLP-113	Policies and Procedures of NGCMA for taking Adverse and other Decisions against Test Facilities	
Issue No: 02	Issue Date: 19.07.2016	Page 8 of 10



**Actions by NGCMA:**

1. The TF is notified in writing.
2. The withdrawal status is published on NGCMA website.
3. In case the TF has been withdrawn from the GLP certification programme, it is debarred to participate in the GLP certification programme for at least 1 year. The TF can be re-apply in the programme by giving valid justification of earlier withdrawal.
4. After the TF GLP certification status is withdrawn, the TF shall not claim GLP certification.

**OTHER DECISIONS FOR CERTIFIED TFs**

**a) VOLUNTARY WITHDRAWAL**

**Condition:**

1. When a TF does not wish to continue their GLP certification and requests in writing that its GLP certification be voluntarily withdrawn.

**Actions by NGCMA:**

1. NGCMA accepts the request of TF and maintains the record under 'Voluntary Withdrawal Category'.
2. A communication to this is sent to the TF that it has been put under 'Voluntary Withdrawal Category'.
3. The Voluntary withdrawal status is published on NGCMA website.

**Re-enrolment:**

1. If a TF decides to re-gain the GLP certification status, after it has sought voluntary withdrawal, it has to apply afresh.

**b) EXTENSION OF VALIDITY OF GLP CERTIFICATE**

**Condition:**

1. If a TF has applied for re-certification six months before expiry of current GLP certificate, extension of validity of certification may be granted for any of the following reasons:
  - Where re-certification inspection has been completed, but the meeting of TC on GLP is yet to take place.
  - Where there is delay in conducting re-certification inspection for reasons beyond the control of NGCMA.

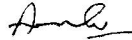
National Good Laboratory Practice Compliance Monitoring Authority		
Document No: GLP-113	Policies and Procedures of NGCMA for taking Adverse and other Decisions against Test Facilities	
Issue No: 02	Issue Date: 19.07.2016	Page 9 of 10

- When the TC on GLP has recommended verification inspection/ clarification from Inspection Team/ TF leading to delay in the decision, beyond the control of NGCMA.

**Actions by NGCMA:**

1. An extension of validity for maximum three months to current GLP certificate is granted and a letter to this effect is sent to the TF.
2. In case of grant of GLP certificate the date of re-certification will be in continuation to the existing GLP certificate.
3. In case of non-grant of GLP certificate, the TF shall be informed, immediately to stop claiming GLP certification status. NGCMA website will be updated to show the expired status of GLP certificate.

**Approved for issue by:**



(Signatures with date) 19/7/16.  
Head, NGCMA

National Good Laboratory Practice Compliance Monitoring Authority		
Document No: GLP-113	Policies and Procedures of NGCMA for taking Adverse and other Decisions against Test Facilities	
Issue No: 02	Issue Date: 19.07.2016	Page 10 of 10