



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. 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 of National GLP Compliance Monitoring Authority (NGCMA). This document lists the adverse and other decisions taken by NGCMA against GLP applicant/ certified Test Facilities (TFs) and the conditions under which these decisions are taken.

2. 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.

3. Classification of decisions:

The various categories of decisions that may be taken by NGCMA are as follows:

1. Decisions w.r.t. applicant TFs
 - a) Rendering the GLP application Inactive
 - b) Closing of a GLP application
 - c) Denial of GLP certification
2. Decisions w.r.t. 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 from National GLP Programme
 - f) Forced withdrawal of GLP certificate
3. Other decisions for certified TFs
 - a) Voluntary withdrawal of GLP certificate
 - b) Extension of validity of GLP certificate

PROCEDURE TO BE FOLLOWED FOR TAKING DECISIONS AGAINST APPLICANT TEST FACILITIES

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: 03	Issue Date: 09.05.2022	Page 2 of 9

a) RENDERING THE GLP APPLICATION INACTIVE

Conditions:

1. When a TF has submitted incomplete application and has not submitted required information, requisite 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 TF has not submitted satisfactory Action Taken Report (ATR) to the findings of final inspection 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 been 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 its GLP application will be closed.

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 TF's GLP application can be put to "Inactive" status only once during its processing.

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: 03	Issue Date: 09.05.2022	Page 3 of 9

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 satisfactorily 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 and the TF has not provided appropriate clarifications within the stipulated time period / when NGCMA has organized a verification inspection and the TF has not agreed for the same.

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 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 along with applicable application fee.

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: 03	Issue Date: 09.05.2022	Page 4 of 9

PROCEDURE TO BE FOLLOWED FOR TAKING ADVERSE DECISIONS AGAINST CERTIFIED TFs

a) DENIAL OF GLP RE-CERTIFICATION

Conditions:

1. 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 and/or verification inspection (if applicable) and ATR submitted by the TF.
2. Non-submission/ Failure of TF to submit satisfactory ATR to the observations of the re-certification inspection within stipulated time.
3. When TF does not provide satisfactory clarification as desired by NGCMA
4. The TF shows inability to undergo proposed verification within 30 days of the 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 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 along with applicable application fee.

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/ jeopardize the results of 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.

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: 03	Issue Date: 09.05.2022	Page 5 of 9

3. When a TF voluntarily reduces its scope of GLP certification (as certified by NGCMA) at any stage during a certification cycle.

Actions by NGCMA:

1. The decision will be communicated to the TF.
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 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)

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: 03	Issue Date: 09.05.2022	Page 6 of 9

Condition

1. If a TF has not applied before the expiry of current GLP certificate.

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 FROM NATIONAL GLP PROGRAMME

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.
 - 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 applicable studies/ data/ documents/ records during conduct of a GLP inspection, etc.
 - Denial of access to NGCMA's GLP Inspectors to its applicable facility/ studies/ data.
 - Wrong representation of scope of GLP certification
 - Misuse of GLP certification claim
 - 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

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: 03	Issue Date: 09.05.2022	Page 7 of 9

1. The TF is notified about the charges against it in writing through a “Show Cause Notice”, to be replied within one 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 one 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 of GLP Certificate’ is initiated.
5. During the period of suspension, the TF cannot use its GLP certificate and cannot claim to be GLP certified.
6. The suspension of GLP certification is published on NGCMA website.

f) FORCED WITHDRAWAL OF GLP CERTIFICATE

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.

Actions by NGCMA:

1. The TF is notified in writing.
2. The withdrawal status of GLP certificate 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 one year. The TF can re-apply for GLP certification only after one year of the withdrawal of GLP certificate.
4. After the TF GLP certification 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 its GLP certification and requests in writing that its GLP certification be voluntarily withdrawn.

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: 03	Issue Date: 09.05.2022	Page 8 of 9

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 in any of the following cases:
 - 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.
 - 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.

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: 03	Issue Date: 09.05.2022	Page 9 of 9