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

# **EVALUATION PROCEDURES OF INSPECTION RESULTS**

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## EVALUATION PROCEDURES OF INSPECTION RESULTS

The GLP Inspections conducted by National GLP Compliance Monitoring Authority (NGCMA) are of various types as detailed in Document No. 104 “Procedures of NGCMA Secretariat”.

Detailed procedures followed by NGCMA for evaluating the results of different GLP inspections are as under:

### **Pre-Inspection:**

The findings (if any) of the pre-inspection are communicated to the Test Facility (TF) in writing during the closing conference. The report of pre-inspection is submitted to NGCMA by the inspection team within 45 days from conduct of inspection and the same is communicated to the TF thereafter.

In case deficiencies are observed during the pre-inspection, the TF shall be required to take corrective actions and submit Action Taken Report (ATR) to these deficiencies to NGCMA, within 6 months of conduct of the pre-inspection.

The ATR received from the TF will be reviewed by NGCMA in consultation with the Lead Inspector.

1. In case no deficiencies are found during the pre-inspection, the final inspection will be scheduled for the TF.
2. If all the deficiencies have been addressed satisfactorily in the ATR, the NGCMA will conduct final inspection.
3. In case satisfactory ATR is not received within 6 months, NGCMA will follow the procedure as mentioned in Document No. GLP-113 “NGCMA Policies and Procedures for taking adverse and other decisions against test facilities”.

### **Final Inspection:**

The inspection team communicates its findings (if any) in writing to the TF during the closing conference of the final inspection.

The final inspection report is submitted to NGCMA by the inspection team within 45 days of conduct of the inspection and the same is communicated to the TF thereafter.

In case deficiencies are observed during the final inspection, the TF shall be required to take corrective actions and submit ATR to these deficiencies to NGCMA, within 45 days of conduct of the final inspection.

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Depending on the observations of the final inspection, the case of final inspection for the TF would be processed, as given below:

1. In case no deficiencies are found during the final inspection, the final inspection report will recommend grant of GLP-compliance certificate to the TF. Accordingly, the final inspection report will be placed before the TC on GLP.
2. In case deficiencies are observed during the final inspection, the ATR received from the TF will be reviewed by NGCMA, in consultation with the Lead Inspector. If the ATR is found satisfactory, the final inspection report, along with the ATR, will be placed before the TC on GLP.

In case the TF does not submit a satisfactory ATR to the findings of final inspection within 45 days, NGCMA will follow procedure as per Document No. 113 “NGCMA Policies and Procedures for taking adverse and other decisions against test facilities”.

3. In case the ATR submitted by the TF requires an on-site verification, the lead inspector may recommend a verification inspection to be conducted for the TF. The final inspection report and the ATR submitted by the TF are placed before the TC on GLP for its recommendation. The TC on GLP may also recommend an on-site verification of the ATR if deemed necessary, even in the absence of a recommendation of verification inspection by the Lead inspector. A verification inspection is conducted on the recommendation of TC on GLP. The final inspection report, ATR to the final inspection and the verification inspection report will be placed before the TC on GLP.

For the above cases 1, 2 and 3, if TC on GLP is satisfied with the final inspection report, the ATR and verification inspection report, (if applicable), it would recommend grant of GLP certificate to the TF. This recommendation would be put forth to the Chairman, GLP Authority for his approval. After the Chairman’s approval, a GLP certificate will be issued to the TF.

If the TC on GLP is not satisfied with the final inspection report, the ATR and Verification Inspection report (if applicable), it can either recommend non-grant of GLP certificate or recommend some actions to be taken by the TF, which may be verified by NGCMA. In case TC on GLP recommends non-grant, the matter will be put forth to the Chairman, GLP Authority for approval. The decision of non-grant will be communicated to the TF.

### **Surveillance Inspection:**

The surveillance inspection team will communicate its findings in writing to the TF during the closing conference. The surveillance inspection report is submitted to NGCMA by the inspection team within 45 days of conduct of the inspection and the same is communicated to the TF thereafter.

In case deficiencies are observed during the surveillance inspection, the TF shall be required to take corrective actions and submit ATR to these deficiencies to NGCMA, within 45 days of conduct of the surveillance inspection.

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Depending on the observations of the surveillance inspection, the case of surveillance inspection for the TF would be processed, as given below:

1. In case no deficiencies are found during the surveillance inspection, the surveillance inspection report will recommend continuation of GLP certification to the TF till the validity of existing GLP certificate. The surveillance inspection report will be placed before the TC on GLP.
2. The ATR received from the TF will be reviewed by NGCMA in consultation with the Lead Inspector. If all the observations have been addressed satisfactorily in the ATR, the surveillance inspection report, along with the ATR received, will be placed before the TC on GLP.

In case the TF does not submit a satisfactory ATR to the findings of surveillance inspection within 45 days of conduct of surveillance inspection, NGCMA will act as per Document No. 113 “NGCMA Policies and Procedures for taking adverse and other decisions against test facilities “.

3. In case the ATR submitted by the TF requires an on-site verification, the lead inspector may recommend a verification inspection to be conducted for the TF. The surveillance inspection report and the ATR submitted by the TF are placed before the TC on GLP for its recommendation. The TC on GLP may also recommend an on-site verification of the ATR if deemed necessary, even in the absence of a recommendation of verification inspection by the Lead inspector. A verification inspection is conducted on the recommendation of TC on GLP. The surveillance inspection report, ATR to the surveillance inspection and the verification inspection report will be placed before the TC on GLP.

For all the above cases 1,2 and 3, if TC on GLP is satisfied with the surveillance inspection report, the ATR and verification inspection report, (if applicable), it would recommend continuation of GLP certification of the TF in its previously-identified area(s) of expertise till the validity of the existing GLP certificate.

If the TC on GLP is not satisfied with the surveillance inspection report, the ATR and verification inspection report, (if applicable), it can either recommend some actions to be taken by the facility, which may be verified by NGCMA or recommend NGCMA to take an Adverse decision against the TF as per Document No. GLP-113 “NGCMA Policies and Procedures for taking adverse and other decisions against test facilities” and Document No. GLP-101 “Terms & Conditions of NGCMA for obtaining and maintaining GLP Certification”.

#### **Extension in scope Inspection:**

The inspection team communicates its findings (if any) in writing to the TF during the closing conference of the extension in scope inspection. The extension in scope inspection report is

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submitted to NGCMA by the inspection team within 45 days of conduct of the inspection and the same will be communicated to the TF thereafter.

In case deficiencies are observed during the extension in scope inspection, the TF shall be required to take corrective actions and submit ATR to these deficiencies to NGCMA, within 45 days of conduct of the extension in scope inspection.

Depending on the observations of the extension in scope inspection, the case of extension in scope inspection for the TF would be processed, as given below:

1. In case no deficiencies are found during the extension in scope inspection, the extension in scope inspection report will recommend grant of GLP certification for the additional area(s) of expertise to the TF. The extension in scope inspection report will be placed before the TC on GLP.
2. In case deficiencies are observed during the extension in scope inspection, the TF will be required to take corrective actions and submit ATR with respect to these deficiencies within 45 days of conduct of the inspection to NGCMA. The ATR will be reviewed by NGCMA in consultation with the Lead Inspector. If all the deficiencies have been addressed satisfactorily in the ATR, the extension in scope inspection report, along with the ATR, will be placed before the TC on GLP.
3. In case the deficiencies observed during the extension in scope inspection require on-site verification, the lead inspector may recommend a verification inspection to be conducted for the TF. The extension in scope inspection report and the ATR submitted by the TF are placed before the TC on GLP for its recommendation. The TC on GLP may also recommend an on-site verification of the ATR if deemed necessary, even in the absence of a recommendation of verification inspection by the Lead inspector. A verification inspection is conducted on the recommendation of TC on GLP. The extension in scope inspection report, ATR to the extension in scope inspection and the verification inspection report will be placed before the TC on GLP.

For all the above cases 1,2 and 3, if TC on GLP is satisfied with the extension in scope inspection report, the ATR and verification inspection report, (if applicable), it would recommend grant of GLP certification for the additional areas of expertise, as applicable. The recommendations of the TC on GLP would be put up to Chairman, GLP Authority for approval. After the Chairman's approval, a fresh GLP certificate will be issued to the TF with the complete scope of certification (including additional areas of expertise) with the same validity as the existing GLP certificate.

If the TC on GLP is not satisfied with the extension in scope inspection report, the ATR and verification inspection report, (if applicable), it can either recommend non-grant of GLP certificate in additional area(s) or recommend some actions to be taken by the TF, which may be verified by NGCMA. In case TC on GLP recommends non-grant, the matter will be put forth to the Chairman, GLP Authority for approval. The decision of non-grant will be communicated to the TF.

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**Re-certification inspection:**

The inspection team communicates its findings (if any) in writing to the TF during the closing conference of the re-certification inspection.

The re-certification inspection report is submitted to NGCMA by the inspection team within 45 days of conduct of the inspection and the same will be communicated to the TF thereafter.

In case deficiencies are observed during the re-certification inspection, the TF shall be required to take corrective actions and submit ATR to these deficiencies to NGCMA, within 45 days of conduct of the re-certification inspection.

Depending on the observations of the re-certification inspection, the case of the TF would be processed, as given below:

1. In case no deficiencies are found during the re-certification inspection, the inspection report will recommend grant of GLP certification to the TF. The re-certification inspection report will be placed before the TC on GLP.
2. The ATR received from the TF will be reviewed by NGCMA in consultation with the Lead Inspector. If all the deficiencies have been addressed satisfactorily in the ATR, the re-certification inspection report, along with the ATR received, will be placed before the TC on GLP.
3. In case the deficiencies observed during the re-certification inspection require on-site verification of the corrective action taken by the TF, the inspection team may recommend a verification visit. The re-certification inspection report and the ATR submitted by the TF are placed before the TC on GLP for its recommendation. The TC on GLP may also recommend an on-site verification of the ATR if deemed necessary, even in the absence of a recommendation of verification inspection in the re-certification inspection report. A verification inspection is conducted on the recommendation of TC on GLP. The re-certification inspection report, ATR submitted by the TF and the Verification inspection report will be placed before the TC on GLP.

For the above cases 1, 2 and 3, if TC on GLP is satisfied with the re-certification inspection report, the ATR and verification inspection report, (if applicable), it would recommend grant of GLP certificate to the TF. This recommendation would be put forth to the Chairman, GLP Authority for his approval. After the Chairman’s approval, a GLP certificate will be issued to the TF.

If the TC on GLP is not satisfied with the re-certification inspection report, the ATR and Verification Inspection report (if applicable), it can either recommend non-grant of GLP certificate or recommend some actions to be taken by the TF, which may be verified by NGCMA. In case TC on GLP recommends non-grant, the matter will be put forth to the Chairman, GLP Authority for approval. The decision of non-grant will be communicated to the TF.

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In case of non-grant of GLP certificate, NGCMA would follow procedures as per Document No. GLP-113 “NGCMA Policies and Procedures for taking adverse and other decisions against test facilities” and Document No. GLP-101 “Terms & Conditions of NGCMA for obtaining and maintaining GLP Certification”.

**Surprise Inspection:**

The inspection team communicates its findings (if any) in writing to the TF during the closing conference of the surprise inspection.

The surprise inspection report is submitted to NGCMA by the inspection team within 45 days of conduct of the inspection and the same will be communicated to the TF thereafter.

1. In case no deficiencies are observed during the surprise inspection, the inspection report will recommend continuation of GLP certification in the previously identified area(s) of expertise till the expiry of existing GLP certificate. The report of surprise inspection will be placed before the TC on GLP.
2. In case deficiencies are observed during the surprise inspection, the TF would be required to take corrective actions and submit an ATR to NGCMA within 45 days of conduct of the surprise inspection. The ATR will be reviewed by NGCMA in consultation with the Lead Inspector. If all the deficiencies have been addressed satisfactorily in the ATR, the surprise inspection report, along with the ATR received, will be placed before the TC on GLP.

The TC on GLP may recommend continuation of GLP certification of the TF or any other decision, as deemed fit. The recommendations of the TC on GLP will be submitted to the Chairman, GLP Authority for perusal and approval. In case any adverse decision is to be taken against the TF, procedures as mentioned in Document No. GLP-113 “NGCMA Policies and Procedures for taking adverse and other decisions against test facilities” ” and Document No. GLP-101 “Terms & Conditions of NGCMA for obtaining and maintaining GLP Certification” will be followed.

**Note:**


- 1) The inspection report is sent to the TF by speed post/ e-mail/ fax.
- 2) ATR submitted should be in past tense and accompanied with documentary/ photographic evidence against each corrective action.
- 3) TF should also submit a copy (Hard/Scanned copy by e-mail) of ATR to each member of the inspection team.
- 4) In case, major deficiencies from OECD Principles of GLP are observed by the inspection team during the course of a surveillance inspection/verification inspection/surprise inspection/ inspection conducted at the request of Regulatory Authority (Indian/Foreign), the observations will be promptly reported to the NGCMA by the Lead Inspector.

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NGCMA would act as per Document No. GLP-113 “NGCMA Policies and Procedures for taking adverse and other decisions against test facilities”.

- 5) If a TF does not agree to any decision of NGCMA, it can make an appeal as per Document No. GLP-108 “Procedures for handling of Complaints, Grievances and Appeals”.

**Approved for issue by:**



(Signatures with date) 19/07/16.  
Head, NGCMA

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