

EVALUATION PROCEDURE(S) OF INSPECTION RESULTS

Pre-Inspection

The findings of the pre-inspection will be communicated to the Test Facility (TF) in writing during the exit meeting. The formal report of pre-inspection will be communicated to the TF within 45 days from completion of inspection. The pre-inspection report may or may not recommend the test facility for final inspection, depending on the nature and extent of non-compliance found during the pre-inspection.

In case deficiencies are observed during the pre-inspection, the TF shall be required to take corrective actions and submit an Action Taken Report (ATR) to these deficiencies within 6 months of completion of pre-inspection. If ATR is not received from the TF within 6 months, the TF will have to apply afresh.

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 Head, NGCMA would appoint Inspectors to conduct the final inspection. In case the TF is unable to address deficiencies completely in the ATR, the TF would be required to correct these deficiencies. In case satisfactory ATR is not received within 6 months, the facility will have to apply afresh.

In case no deficiencies are found during the pre-inspection, the final inspection will be scheduled for the TF.

Final Inspection

The Final Inspection of the TF will be carried out after the pre-inspection, if the TF is found to follow the GLP principles, as recommended in pre-inspection report. The inspection team will communicate its findings in writing to the TF during the exit meeting after the final inspection is over.

The final inspection report will be communicated within 45 days of completion of the inspection.

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. The final inspection report will then be placed before the Technical Committee for final recommendation.
2. In case deficiencies are observed during the inspection, the TF will be required to take corrective actions and submit an ATR to these deficiencies within 45 days of completion of the inspection to NGCMA. 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 final inspection report, along with the ATR received, will be placed before the Technical Committee for final recommendation.

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3. In case the deficiencies observed during the final inspection require an on-site verification of the corrective action taken by the TF, the inspection team may recommend a verification visit in the final inspection report. NGCMA, in consultation with Technical Committee (if required) will decide if an on-site verification visit is required after receiving the ATR from the TF. If required, a verification inspection will be conducted. The final inspection report, ATR to the final inspection report and the verification inspection report will be reviewed by NGCMA and will be placed before the Technical Committee for final recommendation.

For all the above cases 1, 2 and 3, if Technical Committee is satisfied with the final inspection report, the ATR and verification inspection report, (if applicable), it would recommend award of GLP compliance certificate. This recommendation would be put forth to Chairman, NGCMA for his approval. After the Chairman's approval, a GLP compliance certificate would be issued to the TF by the Head, NGCMA.

If the Technical Committee is not satisfied with the final inspection report, ATR and the Verification Inspection report (if applicable), it can either refuse grant of GLP-compliance certificate or recommend some actions to be taken by the TF, which may be verified by NGCMA. In case of refusal, the matter will be put up to the Chairman, NGCMA for approval. The decision of refusal will be communicated by the Head, NGCMA.

If a TF does not agree to the decision of refusal, it can make an appeal to the National GLP Office as per Document No. GLP-108 "Appeal Procedures of National GLP Compliance Monitoring Authority".

Surveillance Inspection

Surveillance inspection of TF will be undertaken once every year after the TF has been awarded a GLP-compliance certificate by NGCMA.

The inspection team will communicate its findings in writing to the TF during the exit meeting after completion of the surveillance inspection. The surveillance inspection report will be communicated within 45 days of completion of the inspection.

1. In case deficiencies are not found during the surveillance inspection, the surveillance inspection report shall recommend continuation of GLP-compliance status of the TF. The surveillance inspection report will also be placed before the Technical Committee.
2. In case deficiencies are observed during the inspection, the TF will be required to take corrective actions and submit an ATR with respect to these deficiencies within 45 days of completion of the inspection to NGCMA. The ATR received from the TF will be reviewed by NGCMA in consultation with the Lead Inspector. If all the non-compliance have been addressed satisfactorily in the ATR, the surveillance inspection report, along with the ATR received, will be placed before the Technical Committee. In case the TF does not submit an ATR to the findings of surveillance inspection within 45 days, Head, NGCMA will initiate action based on the surveillance inspection report.

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3. In case the deficiencies observed during the surveillance inspection require on-site verification of the corrective action taken by the TF, the inspection team may recommend a verification visit in the surveillance report. NGCMA, in consultation with Technical Committee (if required) will decide if an on-site verification visit is required after receiving the ATR from the TF. If required, a verification inspection will be conducted. The surveillance inspection report, ATR submitted by the TF to the surveillance inspection report and the verification inspection report for the surveillance will be reviewed by NGCMA in consultation with the lead Inspector and will be placed before the Technical Committee.

For all the above cases 1,2 and 3, if Technical Committee is satisfied with the surveillance inspection report, the ATR and verification inspection report, (if applicable), it would recommend the continuation of GLP accreditation of the facility for one more year. This recommendation would be put up to Chairman, NGCMA for his approval/information. After the Chairman's approval, the test facility will be informed about the status of its GLP-compliance status for one more year by Head, NGCMA.

If the Technical Committee is not satisfied with the surveillance inspection report, the ATR and verification inspection report, (if applicable), it can either refuse continuation of GLP-compliance status or recommend some actions to be taken by the facility, which may be verified by NGCMA. In case of refusal, the matter will be put up to the Chairman, NGCMA for his approval. In case the Chairman approves the refusal to continue the GLP-compliance status, the GLP certificate will be suspended with effect from the date of surveillance inspection according to Document No. GLP-108. The facility will be communicated the decision of refusal by the Head, NGCMA.

If a TF does not agree to the decision of refusal, it can make an appeal to the National GLP Office as per Document No. GLP-108 "Appeal Procedures of National GLP Compliance Monitoring Authority".

Inspection for Re-certification

In case a fresh application for GLP certification is received from the TF prior to 6 months from the validity of the existing GLP certificate, NGCMA will undertake an inspection for re-certification before the expiry of the existing certificate.

The inspection team will communicate its findings in writing to the TF during the exit meeting after the final inspection is over.

The report of inspection for re-certification would be prepared within 45 days of completion of the inspection.

1. In case deficiencies are not found during the inspection for re-certification, the inspection report will recommend grant of GLP-accreditation to the TF. The report of inspection for re-certification will be placed for consideration before the Technical Committee.
2. In case deficiencies are observed during the inspection for re-certification, the TF would be required to take corrective actions and submit an ATR with respect to these non-compliance within 3 months from the expiry of the earlier GLP certificate. The ATR received from the TF will be reviewed by NGCMA in consultation with the lead Inspector. If all the deficiencies have

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been addressed satisfactorily in the ATR, the final inspection report, along with the ATR received, will be placed before the Technical Committee.

3. In case the deficiencies observed during the inspection for re-certification require on-site verification of the corrective action taken by the TF, the inspection team may recommend a verification visit in the report of inspection for re-certification. NGCMA, in consultation with Technical Committee (if required) will decide if an on-site verification visit is required after receiving the ATR from the test facility. If required, a verification inspection will be conducted. The report of inspection for re-certification, ATR submitted by the test facility to this report and the verification inspection report will be reviewed by NGCMA and will be placed before the Technical Committee for final recommendation.

For all the above cases 1, 2, and 3, if the Technical Committee is satisfied with the report of inspection for re-certification and the ATR and verification inspection report, (if applicable), it would recommend award of GLP compliance certificate. This recommendation would be put forth to the Chairman, NGCMA for approval. After the Chairman's approval, a GLP compliance certificate will be issued to the test facility by Head, NGCMA.

If the Technical Committee is not satisfied with the report of inspection for re-certification and the ATR, it can either refuse grant of GLP-compliance certificate or recommend some actions to be taken by the facility, which may be verified by NGCMA. In case of refusal, the matter will be put up to the Chairman, NGCMA for his approval. The TF will be communicated the decision of refusal by Head, NGCMA.

If a TF does not agree to the decision of refusal, it can make an appeal to the National GLP Office as per Document No. GLP-108 "Appeal Procedures of National GLP Compliance Monitoring Authority".

Inspections conducted at the request of the Indian Regulatory Authorities or Monitoring Authorities of foreign GLP Authorities

If NGCMA receives a request to conduct a GLP inspection or study audit (SA) from the GLP Monitoring Authority of foreign countries or the Indian Regulatory Authorities, procedure mentioned in Document No. GLP-104 "Procedures of National GLP Office" will be followed.

The inspection report will be submitted to the Technical Committee for its recommendation and Chairman, NGCMA for his approval. After the approval it will be sent to the regulatory authority/ GLP Monitoring Authority of the foreign country.

Surprise Inspections:

The NGCMA reserves the right to conduct surprise inspections, if deemed necessary. Such inspections would be proposed by NGCMA and would be undertaken after the approval of Chairman, NGCMA. The team for the inspection and duration would be decided by Head, NGCMA. A member from National GLP Office would always be present during such inspections as a part of the inspection team.

The list of observations/deficiencies/non-compliance(s) observed during the surprise inspection will be duly signed by the inspection team and test facility management during the exit meeting.

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The TF will have to submit an ATR (if any) to the findings of the surprise inspection within 45 days of completion of the inspection to NGCMA.

The inspection report of surprise inspections will be submitted to the Chairman, NGCMA for perusal and final decision

Procedure followed by NGCMA when major deficiencies are reported during a certification cycle

In case, major deficiencies from GLP Principles 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. Head, NGCMA would assess, if the deviations affect the validity of the data being generated at the concerned TF.

A meeting of the Technical Committee would then be called, for reviewing the deficiencies. The recommendation of the Technical Committee will be put up to the Chairman, NGCMA for his consideration and decision. The decision of the Chairman, NGCMA will be communicated by the Head, NGCMA to the concerned TF, Indian/Foreign Regulatory Authority(ies) and the OECD Secretariat.

Final responsibility for evaluating the inspection results lies with NGCMA.


Action by NGCMA on such major deficiencies will be taken as soon as possible and may include (but are not limited to) the following:

- Issuance of a statement giving details of the inadequacies or faults found which might affect the validity of studies conducted in the TF
- Issuance of a recommendation to a regulatory authority that a study be rejected
- Suspension of TF's GLP certification or study audit and withdrawal of the TF's GLP certification from the register of National GLP Programme
- Requiring that a statement detailing the deviations be attached to specific study reports

Note:

- 1) The inspection team communicates its findings in writing to the TF during the exit meeting with the TF. Detailed inspection report is sent to the TF by speed post/scanned copy through e-mail or 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.

Approved for issue by:


(Signature with date)

Dr. Vinita Sharma
Head, NGCMA