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GLP Test Facilities
GLP Lead Inspectors and Inspectors
GLP Officers

STANDARDS MALAYSIA

GLP CP CIRCULAR 1/2021

GLP COMPLIANCE PROGRAMME: GUIDELINES FOR REMOTE INSPECTION

1.   Introduction and Scope

This circular is to provide guidelines to its compliant/applicant test facilities under the Department of Standards Malaysia's (Standards Malaysia) GLP Compliance Programme. This circular is applicable with any current government directive in force and Accreditation Circular 2/2021.

To ensure Standards Malaysia continued monitoring compliance of its test facilities with Organisation for Economic Co-operation and Development (OECD) Principles of Good Laboratory Practice (GLP), Standards Malaysia has established a procedure for remote inspection. Remote inspection provides the opportunity for increased efficiency, increased safety, better timing, inclusion of test facilities personnel that may not be easily accessible and avoidance of travel delays and restrictions.

For this purpose, the remote inspection is a hybrid mechanism which consist of desktop inspection and virtual inspection. The test facility shall provide information and documentation as required by GLP-P019 Checklist for Remote Inspection. If the information provided is insufficient or needs further clarification, to ensure compliance with GLP CP requirements, the test facility shall provide additional documentation prior to the inspection.

Please be informed that the expectation of this remote inspection will not be similar to the onsite inspection due to limitations in accessibility. However, sufficient evidence shall be collected to ensure GLP CP requirements are satisfactorily complied by the test facility for the remote inspection.

2.   Remote Inspection Process

The processes involved are as follows:

i)	GLP Officer will communicate with test facility on tentative date and mechanism of the virtual inspection.
ii)	Within two (2) weeks after received inspection notification by Standards Malaysia, the test facility shall upload GLP-P019 Checklist Remote Inspection and relevant/required documents via Dropbox/Google Drive/other relevant medium and share the link with Standards Malaysia.
iii)	Inspection team will review the submitted documents/records within two (2) weeks and give feedback in GLP-P019 Checklist Remote Inspection at least three (3) days before virtual inspection.
iv)	Virtual inspection consists of starting conference, discussion with test facility personnel and exit conference which normally perform within 1 to 2 days. However, for the first inspection and extra ordinary inspection (e.g. study audit), the duration of the virtual inspection may be extended depending on the complexity of the area of expertise applied.
v)	The inspection team and test facility shall agree on the medium of virtual inspection such as Google Meet, WhatsApp Video Call, Zoom etc. The test facility shall provide the link for the online session to Standards Malaysia, at least 3 days prior to the inspection date. The link should accommodate for each appointed lead inspector and inspector/s. Any findings from the inspection will be in the e-Accreditation.
vi)	Test facility shall close-out all the inspection findings within time frame stipulated in Standards Malaysia GLP CP Manual.

Flowchart of the above processes as in Appendix 1.

3.   Implementation Date

This circular is effective immediately.

Approved by,

Director of Accreditation
For the Director General
Department of Standards Malaysia

Date: 16 February 2021

Appendix 1: FLOW CHART FOR GLP CP REMOTE INSPECTION

START

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GLP Officer communicate with test facility on tentative date and inspection mechanism

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Standards Malaysia send inspection notice to test facility

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Test facility submit GLP-P019 Checklist Remote Inspection + relevant documents within 2 weeks

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Inspection team review documents within 2 weeks and give feedback in the checklist GLP-P019 at least 3 days before virtual inspection

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Conduct virtual inspection

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Lead inspector submit report and findings via e-Accreditation system

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Test facility shall close out all findings within time frame stipulated in GLP CP Manual

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Lead inspector submit complete report to AO

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Internal process for approval

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END