

The following message was sent to Australian GLP facilities by e-mail on 6 April 2020

Dear GLP Facilities,

Further to the communication from NATA's CEO, Jennifer Evans, on 24 March 2020, this is to advise that GLP assessment activities have currently been postponed due to COVID-19. A decision to conduct an in-office activity for GLP facilities will be made after June 2020.

This email also includes information that should be considered to ensure GLP compliance if studies are in progress or being conducted at this time.

Amendments and deviations

It is important that compliance with the principles of GLP continues to be maintained. Any issues encountered due to COVID-19 that could potentially impact the GLP status of a study should be managed, fully assessed and documented via existing amendment and deviation procedures.

Quality Assurance (QA)

Maintaining an adequate QA programme is essential and it is recommended that a risk based approach be used to prioritise QA activities. A risk assessment can be used to identify where to focus resource and adapt audit programmes. If planned QA audits cannot be conducted or are delayed due to lack of available resource or travel restrictions, the impact this has on the study should be assessed and documented by the Study Director. The use of remote technology such as video calls as an alternative to physical presence would be considered acceptable provided there is enough detail within study records to reconstruct activities and that the method of observation can be identified. The use of remote observation methods should be fully risk-assessed to ensure they provide a similar level of oversight as a physical audit.

Communication of significant issues

Please continue to inform NATA via your client manager of any significant changes to the premises, activities or management of a Test Facility.

We hope to resume on-site activities as soon as possible. If you have any questions please contact me.

Yours sincerely
Louise Calder

**Accreditation Manager
GLP Program Adviser**



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