



# S9.81 - Audits in Covid-19 FAQ

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## 1. Is it possible to postpone any GMP+ audits due to Covid-19?

No. Certification Bodies cannot postpone any GMP+ audits since 19<sup>th</sup> October 2020 due to the [executive decree](#) which is published on that same day.

## 2. Why is not possible to postpone audits anymore?

GMP+ International designated the Covid-19 situation as an extraordinary event in accordance with IAF ID 3:2011, and published, therefore, the latest [executive decree](#) on 19<sup>th</sup> October 2020. In this executive decree there are possibilities for full remote audit and remote audit partially on-site in accordance with IAF MD 4:2018. They can be applied for various type of audits and GMP+ scopes.

## 3. Is it possible to combine a postponed GMP+ audit and the next, new regular GMP+ audit?

No, this is not allowed. At this moment the three audits per certification cycle must be respected.

## 4. What is the procedure if the on-site part of an already postponed audit (before 19<sup>th</sup> Oct, 2020) cannot be performed due to Covid-19?

When a temporary acceptance was issued, or a surveillance/recertification audit was postponed after a successful desk assessment, GMP+ coordinators can ask for exemptions to GMP+ International. Only if the on-site part cannot be performed on-site within the period of time (in max. 6 months).

## 5. Who can decide if a full remote or remote audit partially on-site will be carried out?

It is the decision of Certification bodies if the on-site audit, full remote audit or remote audit partially on-site shall apply. Certification Bodies shall comply with the [executive decree](#) and document their motivations for the applied audits.



## 6. What are the requirements for Certification Bodies when a full remote audit or remote audit partially on-site is used?

GMP+ International has established requirements in the [executive decree](#).

## 7. Can a full remote audit or remote audit partially on-site deviate from an on-site GMP+ audit?

No, a full remote audit or remote audit partially on-site shall have the same depth as an on-site audit and it's considered only as a different way of auditing.

## 8. Can full remote audits and remote audits partially on-site be counted for GMP+ requirement that an auditor has to perform five audits per scope per year?

Yes, as declared in question number 7, full remote audits and remote audits partially on-site are equal to on-site audits.

## 9. Are there any additional requirements for the audit time for the document assessment and the on-site audit part in a full remote audit or a remote audit partially on-site?

No, it is to be decided by Certification Bodies how to divide the audit time for the document assessment and 'on-site' audit part (full remote audit or remote audit partially on-site).

## 10. Must the on-site audit part of a remote audit partially on-site, be performed simultaneously by the lead auditor off-site and the auditor on-site?

Yes. The on-site auditor is acting as 'sense' (e.g. visual, sounds, smells) of the lead auditor and must always have a live connection with the lead auditor at least during the on-site part.

## 11. How should audit time be calculated in case of remote audit partially on-site?

For example, the minimum obliged audit time for a surveillance audit Production of feed materials (less than 5 products) is 8 hours. The lead auditor should spend 8 hours of auditing independently of the auditor on-site. The audit time of the auditor on-site should not be included into the audit time calculation.



## 12. Can a full remote audit or remote audit partially on-site, also apply for unannounced audit?

Yes, Certification Bodies can perform unannounced audits according to the [executive decree](#).

- Applicable to The Netherlands: For the Covid-19 situation only, as agreed by the Dutch Food Safety Authority (NVWA), GMP+ certified production companies may have a prior notice period of one working day for the unannounced audit. In this case, Certification Bodies are requested to add the prior notice period in the "Comment" field when preparing the audit.
- Applicable to other countries: the existing requirements are still applicable.

## 13. What if rotation requirements according to GMP+ C6/CR 2.0 cannot be met when a full remote audit applies?

In footnote 3 of the [executive decree](#) states that; "The lead auditor must have audited the company involved on-site in the certification cycle". If Certification Bodies determine a conflict regarding the rotation requirements, they shall document their motivation.

## 14. What if certain requirements in the executive decree cannot be met?

For special situations, Certification Bodies can contact GMP+ International.

## 15. Can applicant GMP+ auditors be qualified based on a full remote audit or remote audit partially on-site for observer/witness audits?

At this moment, applicant GMP+ auditors must comply with qualification requirements stated in Annex 2 of GMP+ C10/CR 1.0. Full remote audit and remote audit partially on-site are not counted to observer or witness audits.

## 16. Does the Certification Body need to document any evidence of an a full remote audit or remote audit partially on-site?

Yes, Certification bodies need to document evidence. These should contain, at least the following:

1. An overview in which full remote audit and remote audit partially on-site are demonstrated.
2. Evidence that they can demonstrate that the companies have been audited.

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