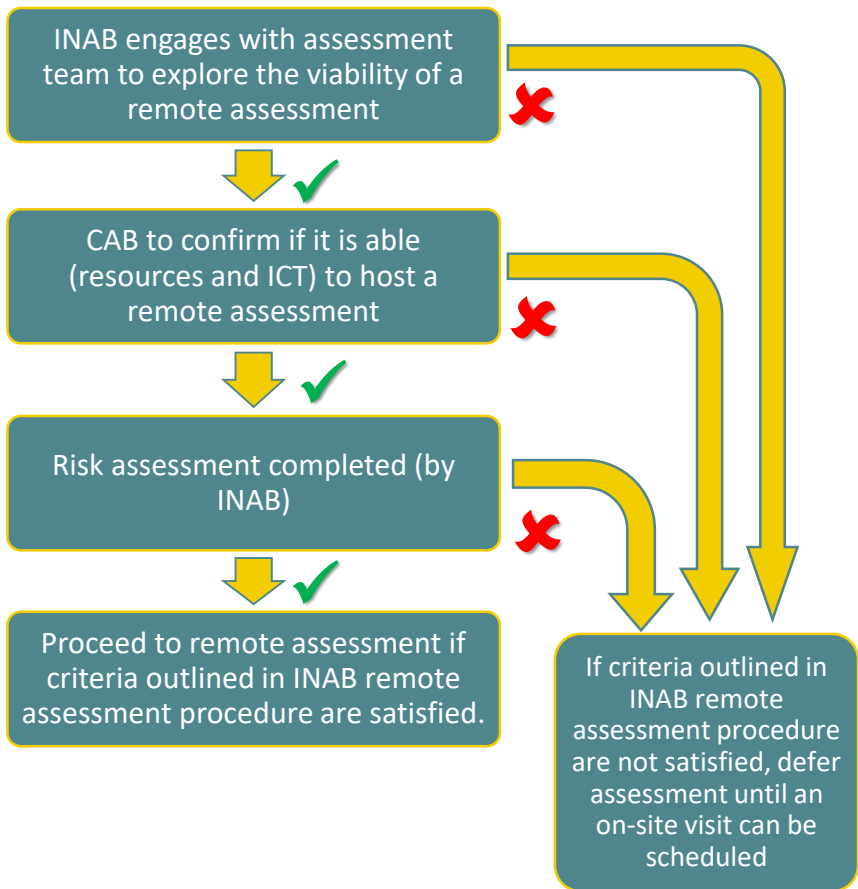


A remote assessment has many similarities with a typical on-site assessment with the main difference being that the assessors will review documentation off-site. For the tests/standards indicated in CRM, a review of documentation will be carried out instead of a physical onsite assessment. Otherwise the assessment will progress like any other on-site assessment.

Microsoft Teams will be used to facilitate our opening and closing meetings, and any other group discussions, where required. Where this is not possible, this can be substituted for phone calls. However, MS Teams is the preferred option.

On the day of the assessment, we will require an appropriate contact for each assessor on the team i.e. someone who will be able to answer questions or find/upload documents as the assessors require them. Please provide these details, and phone number for the individuals to your relevant INAB assessment manager.



## Documents required for a remote assessment

### Documents to be uploaded to the INAB Portal – PS10

- 4 - Documents required for each team member on the day of the visit
- 5 - Documents For Submission: ALL CABs

### Additional documentation for upload - specific CAB types – PS10

- 6 - Documents for Submission: Laboratories
- 7 - Documents For Submission: Certification Bodies, Inspection Bodies (CB) for Head Office visits
- 8 - Documents for Submission: Reference Material Producers (RMP)
- 10 - Documentation for Submission: Notified Bodies

### Laboratories

- Agreed audits - specified prior to the remote assessment
- Records relating to specified NCs
- Customer complaints
- Records of the most recent management review
- IQC, EQA, change control records for tests listed in the visit plan.
- Documentation for a vertical audit – details specified by the INAB team
- Flexible scope – master list changes and related records.
- Haemovigilance and Traceability – a vertical audit for a specified unit
- List of completed risk assessments or risk register
- Video recordings of tests being performed

### Certification/Inspection bodies

- Records of internal audits specified by INAB prior to the visit.
- Records relating to specified NCs
- Customer complaints
- Documentation for file reviews – details to be specified by the INAB team
- Competence records for new staff
- Records of the most recent management review

#### INAB Procedures:

[PS 10](#) Submission of Documentation For INAB Assessment Preparation

#### INAB approach informed by:

[IAF MD 4:2018](#) IAF mandatory document for the use of information and communication technology (ICT) for auditing/assessment purposes

[IAF ID 12:2015](#) Principles on Remote Assessment

[IAF ID 3: 2011](#) IAF Informative Document For Management of Extraordinary Events or Circumstances Affecting ABs, CABs and Certified Organizations

## Recommendations

- Check the Wifi connection is strong in the location where you will participate in the remote assessment. If possible use cable connection.
- Please consider running in-house tests with MS Teams prior to the remote assessment; INAB can assist if needed
- Ensure you have supplied the INAB assessment manager with staff contact details for each technical assessor (direct phone and email)
- Please be available for the entire day
- Ensure all requested documents are uploaded in the CRM portal (CAB) and you can access them (assessor)
- Please consider if you need to have your IT department on standby for assistance (CAB)
- Revert to phone if you have to or use the dial-in number in the MS Teams invite
- A CAB can add multiple users to the CRM portal to assist with work during the day
- Please consider having a dedicated staff member for handling requests on the day, who can retrieve and upload documents to the CRM portal
- Be aware that if documents are not readily accessible because of the remote assessment set-up, INAB will raise minor nonconformities and the evidence can be submitted after the event, through the normal process.
- INAB will also need to see 'live' documents during the remote assessments: Options to do this effectively include
  - assessors may set up separate MS Teams meetings to discuss with individual CAB personnel;
  - take screenshots and send to assessors;
  - stagger assessor/CAB interactions;
  - provide access to CAB systems directly to the INAB team, for the duration of the remote assessment only. Screen sharing will be required
- As there may be a lot of documents to upload, consider organising into folders. i.e. 'Nonconformities', 'Training' etc

## Please avoid...

- Multiple applications running during MS Teams time
- Late upload of requested documents on the CRM; please note 6 week timeline (PS10) still applies
- Large numbers of participants will affect the connection. Have only the core team logged in for the opening and closing meetings
- Stay on mute unless you need to speak to avoid background noise