



Australian Government

Department of Health

Therapeutic Goods Administration

GMP Inspections during the Pandemic – an Australian perspective

Local & International Remote Auditing during the COVID-19 Pandemic

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TGA Health Safety
Regulation

Current status of inspection programs

Domestic Inspection Program

No stoppage of inspections

Maintained current local inspection schedule

Conducting on-site, hybrid and remote inspections since March 2020

– some interruption due to different state or area lockdowns

Overseas Inspection Program

Inspection program interrupted from March-August 2020

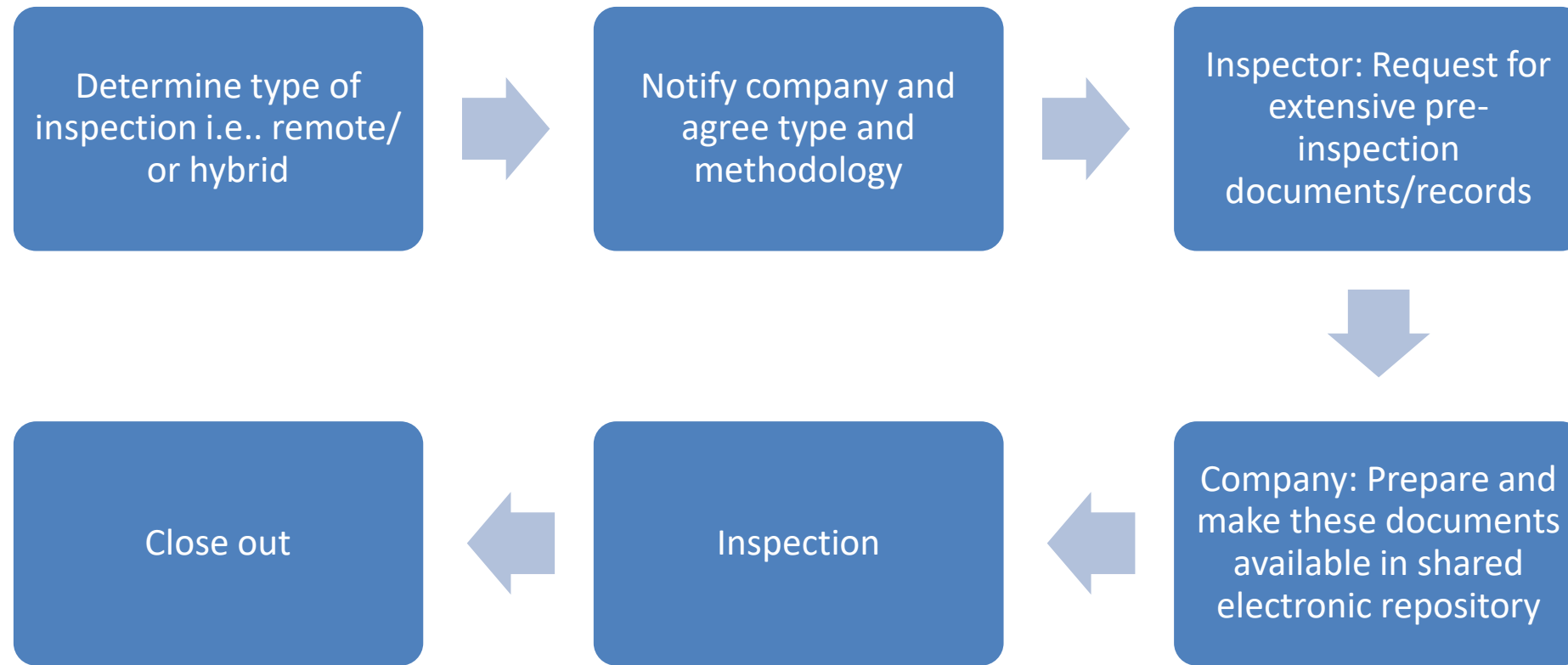
Current backlog is being addressed

More challenges than domestic inspections; language, culture, time zone, connection/bandwidth issues

Remote inspections only, no option of a hybrid or on-site inspection for the foreseeable future

Using PIC/S member health authority inspections where possible

Process



Inspection process

Scope

Default – same as on-site

To be determined on a case by case basis

Inspection Methodology

Use same inspection plan but prioritise areas of > risk first i.e.. Customer complaints, Deviations, etc.

Increased pre-inspection document request and review

Length of Inspection

Same allocated hours
May take more days, but cumulative hours will be as if on-site

If major/critical non-compliance observed – duration may be more than originally planned or may include an on-site component at a later date.

Inspection process (2)

Response to
deficiencies observed

No change to process

Compliance level
achieved

Not better than the
previous (on-site)
inspection

Can be lower than
the previous (on-site)
inspection

Technology and limitations

Conducting Inspection

- Video Conference(VC) apps; MS Teams (Company hosted only), WebEx (TGA or Company hosted),
- Phone (if no other option)

Document Sharing/Review

- Using MS Teams, WebEx or direct OneDrive shared repositories (TGA or Company hosted)
- VC screen sharing
- Hard copy scanning or document camera
- Emails (not preferred)

Facility review

- Live streaming using meeting apps, phone, tablet
- Photos and pre-recorded videos

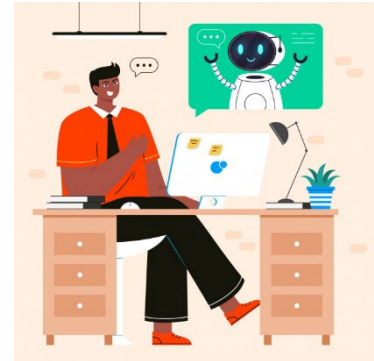


Dependent on connection bandwidth

Recommendations

Electronic Platform for Video Conferencing/Document Sharing :

- Preferably use application manufacturer is familiar with
- Understand your Agency's and the company's IT restrictions with
- For hard copy records, request use of document/pedestal
- Ensure sufficient bandwidth
- Test communications prior to Inspection. Include:
 - Meeting room video conferencing
 - Document sharing (electronic & video)
 - Verify plant video suitability
- Ensure access to electronic document repository



Recommendations (cont.)

General Inspection Conduct

- Utilise pre-inspection document review/Detailed Review of previous Inspection
- Request/ensure VC/Audio not recorded
- Minimise video streaming
- Poor Wi-Fi/interference in facilities
- Document/Pedestal camera for hard-copy documents/records review
- Compromise on time zone differences
- Use time off-line during Inspection
- Be flexible with manufacturers availability (particularly with changing COVID impacts)
- Consider Closing Meeting after Inspection



Recommendations (cont.)

Inspection Plan

- Prioritise Inspection Plan requirements
- Focus on high risk areas first
- Consider excluding scope that has been previously covered (and found satisfactory)
- Consider excluding general low risk areas
- Use daily debrief to confirm areas covered/issues found
- Consider extending inspection if significant issues identified

- Maintain shared electronic repository until closeout
- Confirm SME availability for planned topics





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