Overview of the inspection closeout process

Inspection close out process

Conduct inspection

Potential safety issue (risk of harm to consumers) Refer to Director, Inspection Section within 24 hrs, including during inspection, for escalation within TGA.

No Deficiencies found

Leave list of deficiencies

No deficiencies

4 weeks after inspection provide inspection report including:
- Next inspection date
- Inspection duration (takes into account inspection of actions)

A1 manufacturer
Inspection closed out **4 weeks** after end of inspection

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0 major deficiencies

2 weeks after inspection issue:
- Final list of deficiencies
- Request list of actions to be provided in **4 weeks**.

4 weeks after receipt of list of actions provide inspection report including:
- Next inspection date
- Inspection duration (takes into account inspection of actions)

A1 manufacturer
Inspection closed out **10 weeks** after end of inspection

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1 - 5 major deficiencies

4 weeks after inspection issue:
- Final list of deficiencies
- Request CAPA plan to be provided in **4 weeks** (first response)

Up to max. 2 additional requests for information. Requests sent 4 weeks after receipt of response.

Is CAPA plan acceptable?* — **No**

Yes

* If after three responses CAPA plan is not acceptable, referral to Review Panel

4 weeks after receipt of CAPA plan or additional information provide inspection report including:
- Next inspection date
- Inspection duration (takes into account inspection of CAPAs)

A2 manufacturer - acceptable
Inspection closed out:
- one response **12 weeks**
- two responses **20 weeks**
- three responses **28 weeks**

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6 - 10 major deficiencies

4 weeks after inspection issue:
- Final list of deficiencies
- Request CAPA plan to be provided in **4 weeks** (first response)

Up to max. 2 additional requests for information. Requests sent 4 weeks after receipt of response.

Is CAPA plan acceptable? — **No**

Yes

After three responses CAPA plan is not acceptable

6 weeks after receipt of CAPA plan or additional information provide inspection report including:
- Next inspection date
- Inspection duration (takes into account inspection of CAPAs)

A3 manufacturer- acceptable subject to acceptable CAPAs
Inspection closed out:
- one response **14 weeks**
- two responses **22 weeks**
- three responses **30 weeks**

>10 major deficiencies and/or ≥1 critical deficiency

Review Panel assessment

Conduct close out inspection

If UNACCEPTABLE determine appropriate regulatory action

Sufficient evidence of effective CAPAs? — **No**

Yes

A1 manufacturer – fast track close out

A2 manufacturer – acceptable

A3 manufacturer – acceptable only if CAPA plan is acceptable

Unacceptable manufacturing steps