Inspecting Manufacturer Recalls

Step 1: **Request** the laboratory's written policy for addressing recalls.

Step 2: **Review** the written policy to identify:

- Point of contact – Who gets the recall notice?
- Process steps – What actions are taken when a recall notice is received?
- Timing/turnaround – When does the investigation need to be completed?
- Storage/retrieval – Where is the documentation kept?

Step 3: **Evaluate** training considerations – Is there formal staff education for handling recall notifications?

Step 4: **Review** records of previous recalls received to understand:

- Results – What actions were taken for recalls?
  - Did you ever have the affected product or lot number?
  - How was the inventory checked?
  - Is it possible patient results were affected?
  - Was a patient look-back completed?
  - Were providers notified?
- Documentation – Were the actions and outcomes clearly documented?

Step 5: **Assess** related documentation:

- Quality management system (QMS) – Ask if recalls are considered in the QMS and how recalls are incorporated into nonconforming events?
- Validation – If alternative testing was implemented due to a recall, how were the tests validated?

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Medical Devices	What To Cite
Review Recall Policy • Does the laboratory have a policy to address vendor defects or issues with reagents, supplies, instruments, equipment, or software that may affect patient/client services? • Is there a designated person responsible for receiving recall information? • Did the laboratory take timely action on those products that have the potential to affect testing results or laboratory services? • Does the laboratory have adequate records of product recalls? • Did the laboratory document follow-up and corrective actions in response to product recalls?	**GEN.20340**
Review Quality Management System (QMS) • Does the QMS include a process to define the scope and extent of investigation required for patients that may have been impacted by recalled products?	**GEN.20310**
Review Corrective and Preventive Actions • Did the laboratory perform an adequate patient look-back for results impacted by the product recall? • Did the laboratory notify providers of patients potentially impacted by product recalls? • Did the laboratory retest those patients impacted by product recalls? • If the laboratory implemented alternative testing due to a product recall, was the testing properly verified or validated?	**GEN.20318** (Relevant COM requirement depending on whether validation or verification was required)

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Blood Components	What To Cite
Review Recall and Quarantine Procedure • Does the laboratory have a procedure to identify and quarantine suspect blood components when notice is received of supplier recall? • Is there a designated person responsible for receiving recall information? • Did the laboratory take timely action on those products? • Does the laboratory have adequate records of product recalls? • Did the laboratory document follow-up and corrective actions in response to product recalls?	**TRM.42120** **TRM.42135**
Review QMS • Does the QMS include a process to define the scope and extent of investigation required for patients that may have been impacted by recalled products?	**GEN.20318**
Review Notifications • Does the transfusion service have a written policy for notifying and counseling recipients or their caregivers about potentially infectious blood components? • Did the laboratory notify providers of patients potentially impacted by product recalls?	**TRM.42170**

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