Biological Deviation and System overrides

Objectives

Understand FDA reportable requirements

Understand reasons for Supervisor triggers

Understand when it is appropriate to override

Trouble shooting messages triggered by Blood Bank system

Terms

FDA= Federal Drug Administration

CGMP= Current good manufacturing practice

ISBT=International Society of Blood Transfusion

FDA oversight

In addition to CLIA and CAP regulatory requirements Blood products also fall under the authority of the FDA

Biological Product Deviation Reporting for Blood and Plasma Establishments

- Blood Transfusion is overseen by the FDA (Federal Drug Administration)
- The role is to ensure safe administration of blood products

Resources:

FDA Biological Deviations website

Policy Medical (Site policy: Key words “FDA notification”, “Biological”, “Deviation”

What do I Report?

- Under 21 CFR 606.171(b), you must report any event, and information relevant to the event, associated with the **manufacturing**, to include **testing**, **processing**, **packing**, **labeling**, or **storage**, or with the **holding or distribution**, of both licensed and unlicensed blood or blood components, including Source Plasma, if that event meets all the following criteria:

- (1) Either
  - (i) Represents a deviation from CGMP, applicable regulations, applicable standards, or established specifications that may affect the safety, purity, or potency of that product; or
  - (ii) Represents an unexpected or unforeseeable event that may affect the safety, purity, or potency of that product; and
    - (2) occurs in your facility or a facility under contract with you; and
    - (3) involves distributed blood or blood components.

Timeline for Reporting

- Deviations or potential deviations should be reported to your supervisor or above immediately
  - MIDAS should be placed

- To FDA
  - Fatalities- within 1 business day
  - Biological Product Deviation-45 days

Reporting

What specifically should I report? : (NOT an all inclusive list see FDA biological reporting website for details)

- Errors in Deferral screening
- Unit Labeling deviations
- Routine testing deviations
- Transfusion-Transmitted infection Testing
- Failure to Quarantine
- Component Prep deviations
- Transfusion Tag Labeling deviations
- Shipping and storage
- Expiration date deviations
- Sterility compromised

Evaluate and investigate

- You are required to **evaluate and investigate**, as appropriate, unexplained discrepancies and failures to meet specifications, and to maintain complaint records, including records of investigations and follow-up (21 CFR 606.100, 211.192 and 211.198).

- Procedures for the investigation of any unexplained discrepancy or the failure of a lot or unit to meet any of its specifications should include provisions for:

• a timely investigation;
• an appropriate corrective action plan to prevent recurrence;
• procedures to gain control of unsuitable products in a timely manner;
• appropriate disposition of all affected products (in-date and expired);
• an assessment of the donor's eligibility to serve as a donor in the future, for deviations and discrepancies associated with donor eligibility.

Tools to keep patients safe

- Blood Bank Computer system design
- Policies and Procedures
- Automation (when available use it)
  - Auto-verification
- Training (never sign off if you don't understand)
- Competency (if you don't feel competent escalate)

Tools to keep patients safe

Blood Bank Computer System

- Assumptions
  - The computer build is designed to prevent us from harming a patient
    - *Understand the warnings*
  - Whatever the computer believes to be true, is true and is what will be in the record.
    - *Reconcile rather than override whenever possible*

Tools to keep patients safe

Policies and Procedures

- Only your CLIA Director or a pathologist they delegate to can permit a deviation from policy.
- Only your CLIA Director or a pathologist they delegate to can provide you with guidance when a policy doesn't address a specific scenario.

Flags and Possible Rationale

Alert Reason	Level override required	Rationale
Approp XM not done	User	If Emergency Release and the unit type is appropriate, this is appropriate to override
Biohazardous	Supervisor	No routine rationale to override
Cmp bld att not conf	Supervisor	Appropriate if reference lab testing is performed and entered into the record
Cmp bld typ not conf	User	Appropriate if reference lab testing is performed and entered into the record
Cmp lbl not verified	Supervisor	No routine rationale to override
Component expired	Supervisor	No routine rationale to override
Deriv lot expired	Supervisor	No routine rationale to override
Emrgcy compat fail	Supervisor	Must understand reason for trigger and have path approval
Intended use proh	Supervisor	No routine rationale to override
Med rec num changed	Supervisor	No routine rationale to override; obtain new clot; Emergency release only
No current visit	Supervisor	No routine rationale to override
Other don type avail	Supervisor	Override according to appropriate inventory and pathology approval for emergent release
Pat TxRxn unresolved	Supervisor	Enter TXRXN if available, override only with path consult
Patient name changed	Supervisor	No routine rationale to override; obtain new clot; Emergency release only
Prd bld attr unknown	Supervisor	Should not occur; quarantine unit resolve issue
Prod not compatible	Supervisor	In least incompatible "warm auto" situations. Requires consult with pathologists during work-up
Spec needs not met	Supervisor	No routine rationale to override; appropriate in emergency release to override. In consultation with pathologists for certain complicated patients require override.
Specimen expired	Supervisor	No routine rationale to override
Specimen rejected	Supervisor	No routine rationale to override
Visual Insp not okay	Supervisor	No routine rationale to override
XM intrp not compat	Supervisor	No routine rationale to override
XM test invalid	User	Ok to override for Emergency release

User/Supervisory override

- You should avoid supervisor overriding your own work.
- Understand what is causing the message flag.
- Do no assume by the message you know what is causing the issue.
- Do not take the word of a co-worker what is causing the issue
  - ALWAYS work to remove the flag whenever possible

Case Study 1-Choose the best answer

- You are a blood establishment that contracts with another blood establishment (referred to as an irradiator) to perform irradiation of blood products. You sent a product to the irradiator. After irradiation, the product was returned to you. The unit contains a sticker that indicates it was irradiated, but the unit's ISBT label does not indicate an irradiated unit.
- You should:

  A. Depends on the urgency of the unit need. If Hem/Onc needs it and we can see that it was irradiated you should go ahead and issue as long as you verify that it was irradiated.

  B. Notify the doctor the unit is not irradiated as the order stated and let them decide.

  C. Report to distributor, Temple can fix remotely and you can just reprint the ISBT.

  D. Its ok, the unit is clearly marked as irradiated and is safe for the patient.

Case Study 1-Choose the best answer

- You are a blood establishment that contracts with another blood establishment (referred to as an irradiator) to perform irradiation of blood products. You sent a product to the irradiator. After irradiation, the product was returned to you. The unit contains a sticker that indicates it was irradiated, but the unit's ISBT label does not indicate an irradiated unit.
- You should:

  A. Depends on the urgency of the unit need. If Hem/Onc needs it and we can see that it was irradiated you should go ahead and issue as long as you verify that it was irradiated. No, in order for the patient's record to be accurate Safetrace must be updated, if you do this it is an FDA reportable Deviation.

  B. Notify the doctor the unit is not irradiated as the order stated and let them decide.

  C. Report to distributor, Temple can fix remotely and you can just reprint the ISBT.

  D. Its ok, the unit is clearly marked as irradiated and is safe for the patient.

Case Study 1-Choose the best answer

- You are a blood establishment that contracts with another blood establishment (referred to as an irradiator) to perform irradiation of blood products. You sent a product to the irradiator. After irradiation, the product was returned to you. The unit contains a sticker that indicates it was irradiated, but the unit's ISBT label does not indicate an irradiated unit.
- You should:
  A. Depends on the urgency of the unit need. If Hem/Onc needs it and we can see that it was irradiated you should go ahead and issue as long as you verify that it was irradiated.
  B. Notify the doctor the unit is not irradiated as the order stated and let them decide. No, the order was clear we need to provide the floor with the appropriate Unit type
  C. Report to distributor, Temple can fix remotely and you can just reprint the ISBT.
  D. Its ok, the unit is clearly marked as irradiated and is safe for the patient.

Case Study 1-Choose the best answer

- You are a blood establishment that contracts with another blood establishment (referred to as an irradiator) to perform irradiation of blood products. You sent a product to the irradiator. After irradiation, the product was returned to you. The unit contains a sticker that indicates it was irradiated, but the unit's ISBT label does not indicate an irradiated unit.
- You should:
  A. Depends on the urgency of the unit need. If Hem/Onc needs it and we can see that it was irradiated you should go ahead and issue as long as you verify that it was irradiated.
  B. Notify the doctor the unit is not irradiated as the order stated and let them decide.
  C. Report to distributor, Temple can fix remotely and you can just reprint the ISBT. Yes, Temple can quickly rectify the issue. Austin may have to pick up the unit or bring a new label, but they can also fix the problem. If it is emergent, you would release as emergent to MD with notice that technically it is not irradiated.
  D. Its ok, the unit is clearly marked as irradiated and is safe for the patient.

Case Study 1-Choose the best answer

- You are a blood establishment that contracts with another blood establishment (referred to as an irradiator) to perform irradiation of blood products. You sent a product to the irradiator. After irradiation, the product was returned to you. The unit contains sticker that indicates it was irradiated, but the unit ISBT label does not indicate an irradiated unit.
- You should:
  A. Depends on the urgency of the unit need. If Hem/Onc needs it and we can see that it was irradiated you should go ahead and issue as long as you verify that it was irradiated.
  B. Notify the doctor the unit is not irradiated as the order stated and let them decide.
  C. Report to distributor, Temple can fix remotely and you can just reprint the ISBT.
  D. Its ok, the unit is clearly marked as irradiated and is safe for the patient.

  No, in order for the patient's record to be accurate Safetrace must be updated, if you do this it is an FDA reportable Deviation.

Case Study 2-Choose the best answer

- You are working on a patient who is bleeding in ICU. You get a request for transfusion of platelets. However, the only unit you have on hand requires pathology to approve per our policy.

A. Issue the unit so you can take care of the patient, but make sure you immediately get pathology approval.
B. Call the pathologist and request approval to issue.
C. Issue as emergency release so the physician taking care of the patient takes the responsibility for the unit.
D. Tell the nurse we do not have a unit available and call to get a compatible unit from the blood center.

Case Study 2-Choose the best answer

- You are working on a patient who is bleeding in ICU. You get a request for transfusion of platelets. However, the only unit you have on hand requires pathology to approve per our policy.

A. Issue the unit so you can take care of the patient, but make sure you immediately get pathology approval.

   No, the policy requires approval prior to issue not after.

B. Call the pathologist and request approval to issue.

C. Issue as emergency release so the physician taking care of the patient takes the responsibility for the unit.

D. Tell the nurse we do not have a unit available and call to get a compatible unit from the blood center.

Case Study 2-Choose the best answer

- You are working on a patient who is bleeding in ICU. You get a request for transfusion on platelets. However, the only unit you have on hand requires pathology to approve per our policy.

A. Issue the unit so you can take care of the patient, but make sure you immediately get pathology approval.

B. Call the pathologist and request approval to issue.

Yes, this is the correct process

C. Issue as emergency release so the physician taking care of the patient takes the responsibility for the unit.

D. Tell the nurse we do not have a unit available and call to get a compatible unit from the blood center.

Case Study 2-Choose the best answer

- You are working on a patient who is bleeding in ICU. You get a request for transfusion on platelets. However, the only unit you have on hand requires pathology to approve per our policy.

A. Issue the unit so you can take care of the patient, but make sure you immediately get pathology approval.
B. Call the pathologist and request approval to issue.
C. Issue as emergency release so the physician taking care of the patient takes the responsibility for the unit.

No, unless after consultation the pathologists request this action you should follow the policy.

D. Tell the nurse we do not have a unit available and call to get a compatible unit from the blood center.

Case Study 2-Choose the best answer

- You are working on a patient who is bleeding in ICU. You get a request for transfusion of platelets. However, the only unit you have on hand requires pathology to approve per our policy.

A. Issue the unit so you can take care of the patient, but make sure you immediately get pathology approval.
B. Call the pathologist and request approval to issue.
C. Issue as emergency release so the physician taking care of the patient takes the responsibility for the unit.

D. Tell the nurse we do not have a unit available and call to get a compatible unit from the blood center.

No, unless after consultation the pathologists request this action you should follow the policy.

Case Study 3-Choose the best answer

- A co-worker calls you over to clear a message that requires a supervisor override but at first glance you cannot understand why the message triggered.

A. Ask the employee if they know why the message is flagging and override accordingly.

B. Review the issue and as long as you understand the flag provide the override.

C. Call the pathologist and ask if it is ok to override the message.

D. Have the employee walk you through each screen on this patient and unit until you understand the flag then make a decision to rectify the issue or override.

Case Study 3-Choose the best answer

- A co-worker calls you over to clear a message that requires a supervisor override but at first glance you cannot understand why the message triggered.

A. Ask the employee if they know why the message is flagging and override accordingly. No, supervisor overrides should be limited to critical issues and you must understand separately from the other tech what you are overriding.

B. Review the issue and as long as you understand the flag provide the override.

C. Call the pathologist and ask if it is ok to override the message.

D. Have the employee walk you through each screen on this patient and unit until you understand the flag then make a decision to rectify the issue or override.

Case Study 3-Choose the best answer

- A co-worker calls you over to clear a message that requires a supervisor override but at first glance you cannot understand why the message triggered.

A. Ask the employee if they know why the message is flagging and override accordingly.

B. Review the message, if you have seen it before and it presents not safety issue provide the override. No, supervisor overrides should be limited to critical issues and we should attempt to rectify the issue whenever possible before deciding to override.

C. Call the pathologist and ask if it is ok to override the message.

D. Have the employee walk you through each screen on this patient and unit until you understand the flag then make a decision to rectify the issue or override.

Case Study 3-Choose the best answer

- A co-worker calls you over to clear a message that requires a supervisor override but at first glance you cannot understand why the message triggered.

A. Ask the employee if they know why the message is flagging and override accordingly.

B. Review the message, if you have seen it before and it presents not safety issue provide the override.

C. Call the pathologist and ask if it is ok to override the message. No, supervisor overrides require that the person understand the blood bank system build and what safety precaution is being bypassed. Any consultation with the pathologists should have already occurred.

D. Have the employee walk you through each screen on this patient and unit until you understand the flag then make a decision to rectify the issue or override.

Case Study 3-Choose the best answer

- A co-worker calls you over to clear a message that requires a supervisor override but at first glance you cannot understand why the message triggered.

A. Ask the employee if they know why the message is flagging and override accordingly.

B. Review the message, if you have seen it before and it presents not safety issue provide the override.

C. Call the pathologist and ask if it is ok to override the message.

D. Have the employee walk you through each screen on this patient and unit until you understand the flag then make a decision to rectify the issue or override. Yes, having the employee walk through the issue will allow you the ability to agree with their logic and steps. If you go in by yourself you may miss a step or error they made that created the error. Always try to fix the issue rather than override.