Association for the Advancement of Blood & Biotherapies

Considerations for Shipping Container Validation

01/19/22

Key considerations for processes and SOPs:

1) Develop a validation plan for shipping containers:
   - A validation plan determines packing scheme and volume of ice, dry ice or other appropriate material necessary to maintain an acceptable temperature during shipment.
   - Must be approved by the Medical Director prior to validation and found acceptable following completion of the validation
   - Requires to use of a traceable thermometer

Key considerations for processes and SOPs:

2) Identify a source of ice, dry ice or other appropriate material. Make it simple!
   - ➢ See if another department uses ice or dry ice.
     - Collaborate with another department to use an existing dry ice supplier contract to avoid contract negotiation and approval, with existing storage, and the safety training developed by your institution.
   - ➢ Some blood centers use room temperature saline (1 liter IV bags) to help maintain temperature when shipping platelets.
   - ➢ Talk with your blood supplier to see if they can assist you.

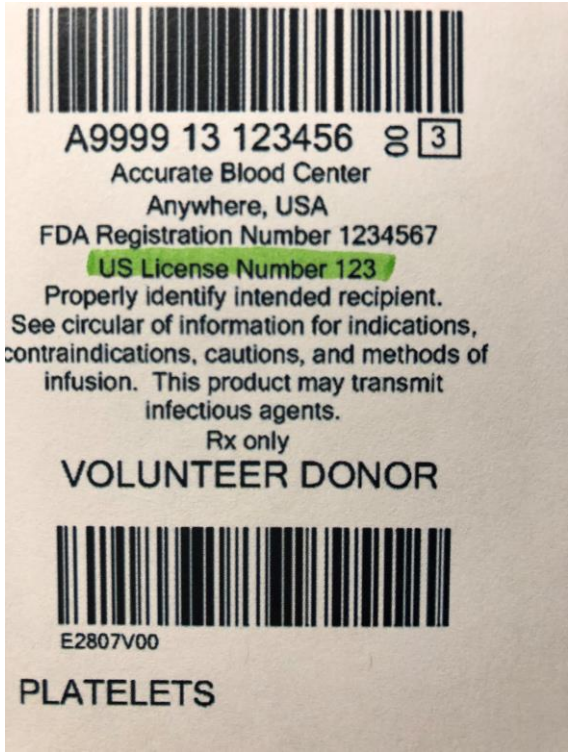
Key considerations for processes and SOPs:

3) Development of SOPs:
   - Follow packing and shipping procedures ***as determined during the validation process. Your SOPs and validation go hand-in-hand.***

4) Staff training:
   - Packing process
   - Safety (dry ice is a hazardous material)
   - Documentation of Competency
   - Courier training?

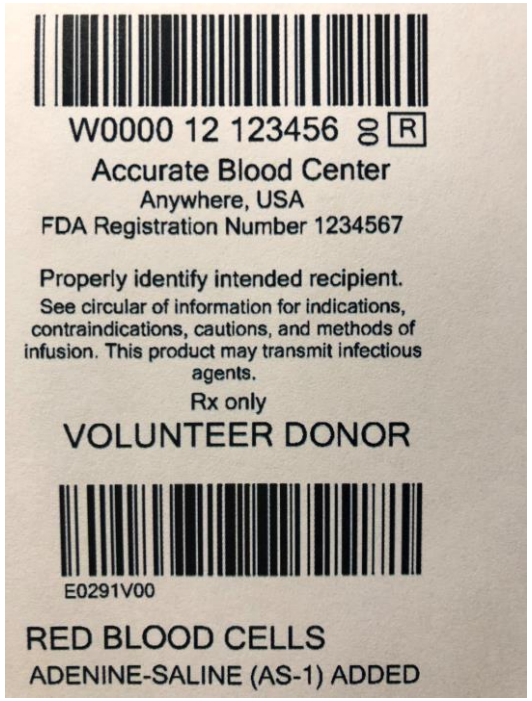
Reminder: Critical Information on Labeling

- Only licensed blood products, labeled with the manufacturer's license number may be shipped across state lines:



Reminder: Critical Information on Labeling

- Blood products which are <u>not labeled</u> with an FDA License number <u>CANNOT</u> be shipped across state lines. They may only be shipped within (intrastate) the state.



Shipping Containers:

Shipping containers should be:

- suitable to transport the blood component and capable of maintaining temperatures for the appropriate timeframe necessary to reach the final destination.

Obtain/purchase the appropriate number of shipping containers:

- Purchase appropriate shipping containers – how many will you need?
- *Consider collaborating* with local suppliers if possible.

Data Logger or Temperature Device

Obtain/purchase traceable data logger or temperature device for your validation process:

- Capable of accurate temperature readings in the appropriate temperature range: [21 CFR 600.15]
  - Red Blood Cells (1-10 C)
  - Platelets (20-24 C as close as possible)
  - Frozen Plasma Products (≤ -18 C)
- *Examples* of models available: Traceable Products, Fisher Scientific, Dickson, SensoScientific

Shipping Red Blood Cells:

- Red Blood Cells (RBCs) should be:

  - maintained at a temperature of 1-10 C during shipment.
  - shipped using wet ice or another appropriate material.
  - **NOTE:** Do not allow the RBCs to come into direct contact with the ice or other cooling material. This can cause hemolysis.

Shipping Platelet Products:

- Platelets should be:

  - maintained at a temperature of 20-24 C (as close as possible) during shipment.
  - shipped using a material appropriate to maintain temperature.
  - NOTE: Maximum time without agitation is 30 hours (BBTS Reference Standard 5.1.8A)

Shipping Frozen Plasma Products:

- Frozen Plasma Products should be shipped on dry ice
- Resources for shipping with dry ice:

  DOT-Check the Box: Is it Hazmat?
  49 CFR 173.217 Carbon dioxide, solid (dry ice)
  UPS – Coolants and Refrigerants (Dry Ice)
  UPS-How to Ship with Dry Ice (video)
  Dangerous Goods (FedEx Express)
  Shipping Dry Ice (FedEx)
  USPS Packaging Instruction 9A

- *Examples of Boxes Available:* **Uline Shipping Containers**, **FedEx order Boxes**

Shipping Frozen Plasma Products:

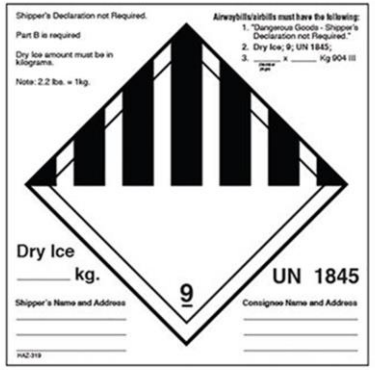
Does your facility require courier training on transport of frozen plasma packed on dry ice??

- REVIEW: Dry ice is classified as a hazardous material by the Department of Transportation.
- **Drivers should be aware:** U.S. Department of Transportation states, “Packaging: Dry ice is solid carbon dioxide that releases carbon dioxide gas as it cools. Because of this, dry ice and the other contents of your package need to be packaged securely in a sturdy packaging that permits the release of carbon dioxide gas. This will prevent the buildup of pressure from the dry ice that could rupture the packaging.”

Shipping Frozen Plasma Products:

Is there proper ventilation in the courier vehicle?

- REVIEW: 49 CFR 173.217 Carbon dioxide, solid (dry ice)
- Labeling of a shipping container containing dry ice
    - Depending on the method of transportation and the carrier, additional hazardous material labeling may be needed. (i.e. hazard Class 9 DOT Miscellaneous Dangerous Good label UN 1845, and net weight of dry ice in kilograms)



Validation Plan

Write a validation plan for the shipping container including:

- Forms for recording results
- Packing scheme – Ice, Dry ice or other suitable material above and below?
- Amount of ice, dry ice or other suitable material

  Note: 5-10 lbs. of dry ice will sublimate every 24 hours. The exact sublimation rate will depend on the density of the insulating container used (source: UPS)
- Assume there will be shipping delays. Build in extra time.
- Determine maximum number of units per box
- Determine maximum transportation time
- How and when will temperatures be recorded? (establish acceptable limits)
- Written SOP for shipping (including necessary forms)
- Staff training and competency
- Safety and handling of dry ice (when used)
- Acceptance criteria and corrective action for failure

Medical Director Review and Approval Prior to Start of Validation

Obtain Medical Director review and approval with signature prior to start of validation and as defined in your Quality Plan:

- Validation plan
- SOP for packing and shipping
- Plan for staff training and competency

Perform Shipping Container Validation

- Perform shipping container validation as outlined in your validation plan.
- Review results of validation against acceptability criteria defined in the validation plan
- Determine whether the validation was acceptable or unacceptable.
- If acceptable, send for final review and approval as defined by your quality plan and outlined in the validation.
- If unacceptable, determine corrective action and repeat the validation.

Questions?

Contact AABB's Regulatory Affairs staff:
regulatory@aabb.org