



Checklist – Considerations for Shipment of COVID-19 Convalescent Plasma (CCP) to Surge Storage

Based on information presented September 29, 2020:
[Considerations for Shipment of CCP to Surge Storage](#)

OVERALL SCOPE

___ Review the Blood Centers of America COVID-19 Surge Storage Capacity Plan

CRITICAL INFORMATION

___ Shipment of CCP for Surge Storage:

- Under the EUA, CCP is an authorized product but “not an approved product.” It is *not labeled as investigational CCP under the EUA*.
- FDA has confirmed CCP may be shipped across state lines by both licensed and non-licensed (registration-only) collection facilities.
- CCP must be appropriately labeled as described in section III.B.3 on page 8 of the [Sept 2020 Investigational CCP Guidance](#).
- CCP must not be labeled with a license number - Recommendation III.B.3.b on page 8.

___ **CONSIDERATIONS** as you plan for shipment to Surge Storage

___ Validation plan for shipping containers

- Determines packing scheme and volume of dry ice needed
- Must be approved by the Medical Director prior to validation and found acceptable following completion of the validation. The validation includes:
 - ___ Traceable thermometer
 - ___ Source of dry ice
 - ___ Staff training, safety (dry ice is a hazardous material) and competency

NOTE:

- It may be easier to identify a department within your facility or campus which uses, stores and holds an existing contract for dry ice.
- Such collaboration could avoid the need for an additional contract negotiation and approval, and allow for utilization of existing storage and safety training policies and procedures.

___ Development of SOPs for shipping Packing and shipping procedures
as determined during the validation process

___ **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:* [FedEx order Boxes](#), [Uline Shipping Containers](#)

SHIPPING CONTAINERS

_____ Shipping containers must be:

- Suitable to transport dry ice (properly ventilated) and maintain temperatures ≤ -18 C
- Capable of maintaining temperatures for the appropriate timeframe necessary to ship frozen plasma from a facility to the final destination.

_____ Obtain/purchase appropriate number of shipping containers:

- Purchase appropriate shipping containers OR make arrangements with a local supplier/BCA supplier – how many will you need?
- *Considering collaborating* with local suppliers if possible.

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

- Capable of accurate temperature readings in the appropriate temperature range (≤ -18 C)
- *Examples* of models available: [Traceable Products](#), [Fisher Scientific](#), [Dickson](#), [SensoScientific](#)

_____ Determine shipment method **according to BCA instructions** for various purposes - see slide 7 of PowerPoint presentation [Considerations for Shipment of CCP to Surge Storage](#), flowchart for details of shipping

- Air/Ground
 - FedEx Service – Boxes go on a flight and are delivered the next day (First, AM or Standard) based on shipper selection. Part of general shipments.
 - MNX Service – Boxes are put on commercial flights, driven or a combination based on best route and timeframe. Handled “with care.”
 - BCA has rates with both services, and both offer competitive rates.
 - BCA extends their discount to any shipper during the CCP agreement period to ensure they are receiving the discounts

NOTE: Collection centers shipping to assigned SSC should utilize MNX as the preferred next flight out service provider.

- If you need to set up an MNX account, please contact Sam Keith at BCA.

_____ 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.”

___ 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)
- **Refer to instructions from BCA**

VALIDATION PLAN

___ Write a validation plan for the shipping container

- Include forms for recording results
- Packing scheme - Dry ice above and below?
- Amount of dry ice
 - 5-10 lbs. of dry ice will sublime 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
- Maximum number of units per box
- Maximum transportation time
- Temperature recording (acceptable limits)
- SOP for shipping (including necessary forms)
- Staff training and competency
- Including safety and handling of dry ice
- Acceptance criteria and corrective action for failure

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

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

___ Perform shipping container validation as outlined in plan

___ Review results of validation against acceptability criteria defined in the validation plan

___ Determine whether the validation was acceptable or unacceptable.



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_____ 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.

Challenges, Tips and Lessons Learned: Refer to slides 19 through 23 of the [Considerations for Shipment of CCP to Surge Storage](#) presentation for an example of a real world validation plan, design and results.