USER MANUAL
OF
CRYO-SHIPPER EXTRA CAPACITY
WITH IATA / DOT / UN
INFECTIOUS SUBSTANCE PACKAGING CERTIFICATION

CHART

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Ref: 10779450 Rev. A
SECTION

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2. DOT/UN Infections Substance Packaging Certification with vials

3. DOT/UN Infections Substance Packaging Certification with blood bags

4. DOT/UN, ICAO Internal Hydrostatic Pressure Testing Certification

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6. How to packaging the blood bags

7. How to pre-cooling and packaging the secondary container

8. How to packaging the plastic shipping container

9. Caution Instructions

10. How to fill & test MVE IATA Cryoshipper
### Specifications:

<table>
<thead>
<tr>
<th>MODEL</th>
<th>Cryo-shipper Extra Capacity w/ IATA</th>
</tr>
</thead>
<tbody>
<tr>
<td>p/n</td>
<td>10777411</td>
</tr>
<tr>
<td>Maximum working cavity dimensions</td>
<td>8-1/2&quot; dia * 12&quot; deep</td>
</tr>
<tr>
<td>IATA secondary container dimensions</td>
<td>7-3/8&quot; dia * 8-3/4&quot; deep</td>
</tr>
</tbody>
</table>

### MAXIMUM STORAGE CAPACITY

| Number of secondary containers       | 1                                    |
| Number of 1 ml vials                 | 450 (5 level bulk)                   |
| Number of 2 ml vials                 | 350 (4 level bulk)                   |
| Number of 3 ml vials                 | 250 (3 level bulk)                   |
| Number of 4 ml vials                 | 250 (3 level bulk)                   |
| Number of blood bags stored          | 22                                   |

### PERFORMANCE

| Liquid nitrogen capacity (liters)     | 11.8                                 |
| Static evaporation rate (liters/day) | 0.80                                 |
| Static holding time (days)           | 14                                   |

### UNIT DIMENSIONS

| Neck opening (in / mm)               | 8.5 / 216                            |
| Overall height (in / mm)             | 24 / 610                             |
| Outside diameter (in / mm)           | 15 / 381                             |
| Weight empty (lbs / kg)              | 29 / 13.1                            |
| Weight full (lbs / kg)               | 50.5 / 22.9                          |
DOT / UN INFECTIOUS SUBSTANCE PACKAGING CERTIFICATION

TEN-E PACKAGING SERVICES, INC. certifies that the MVE CMD-20 Infectious Substance Cryogenic Packaging with Vials has passed the standards of the DEPARTMENT OF TRANSPORTATION'S TITLE 49 CFR; Section.173.196(f) and the Performance Test Requirements for Infectious Substance Packaging of Section 178.609. This package is also certified under ICAO/IATA Regulations. It is the responsibility of the end user to determine authorization for use under these regulations. The use of other packaging methods or components other than those documented in this report may render this certification invalid.

<table>
<thead>
<tr>
<th>PACKAGE DESCRIPTION:-</th>
<th>CMD-20 Infectious Substance Cryogenic Packaging with Vials</th>
</tr>
</thead>
<tbody>
<tr>
<td>TEST REPORT NUMBER (S):</td>
<td>15331, 15071, 14017</td>
</tr>
<tr>
<td>UN MARKING: (ICAO Part 7;2.2.2)</td>
<td>u n</td>
</tr>
<tr>
<td>PACKAGING IDENTIFICATION CODE:</td>
<td>IH2/Class 6.2. (Infectious Substance)</td>
</tr>
<tr>
<td>YEAR OF MANUFACTURE:</td>
<td>** (Insert year the package is manufactured)</td>
</tr>
<tr>
<td>STATE AUTHORIZING TEE MARK:</td>
<td>USA</td>
</tr>
<tr>
<td>PACKAGING CERTIFICATION AGENCY:</td>
<td>(+AA) TEN-E Packaging Services, Inc.</td>
</tr>
<tr>
<td>THIRD PARTY PACKAGE IDENTIFICATION:</td>
<td>+AA1748</td>
</tr>
</tbody>
</table>

Dale Johnson  
Packaging Engineer  
TEN-E Packaging Services, Inc.

ALL OTHER WARRANTIES, EXPRESSED OR IMPLIED, INCLUDING ANY WARRANTY THAT THE PACKAGING TESTED IS MERCHANTABILITY OR FIT FOR A PARTICULAR PURPOSE, ARE DISCLAIMED. In no event shall TEN-E Packaging Services, Inc. Liability exceed the total amount paid by MVE for services rendered. In the event of future changes to the above referenced test standard, it is the responsibility of MVE to determine whether additional testing or updating of past testing is necessary to verify that the packaging we have tested remains in compliance with those standards.

Section 2
DOT / UN INFECTIONOUS SUBSTANCE PACKAGING CERTIFICATION

TEN-E PACKAGING SERVICES, INC. certifies that the MVE CMD-20 Infectious Substance Cryogenic Packaging with Blood Bags has passed the standards of the DEPARTMENT OF TRANSPORTATION'S TITLE 49 CFR; Section.173.196(f) and the Performance Test Requirements for Infectious Substance Packaging of Section 178.609. This package is also certified under ICAO/IATA Regulations. It is the responsibility of the end user to determine authorization for use under these regulations. The use of other packaging methods or components other than those documented in this report may render this certification invalid.

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<tr>
<th>PACKAGE DESCRIPTION:-</th>
<th>CMD-20 Infectious Substance Cryogenic Packaging with Blood Bags</th>
</tr>
</thead>
<tbody>
<tr>
<td>TEST REPORT NUMBER:</td>
<td>15330</td>
</tr>
<tr>
<td>UN MARKING: (ICAO Part 7;2.2.2)</td>
<td>u n IH2/CLASS 6.2/** USA/+AA1749</td>
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<tr>
<td>PACKAGING IDENTIFICATION CODE:</td>
<td>IH2/Class 6.2. (Infectious Substance)</td>
</tr>
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<td>** (Insert year the package is manufactured)</td>
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<tr>
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<td>USA</td>
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<td>+AA1749</td>
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</tbody>
</table>

Dale Johnson
Packaging Engineer
TEN-E Packaging Services, Inc.

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Section 3
TEN-E PACKAGING SERVICES, INC. certifies that the previously described testing services have been performed in accordance with standard good laboratory practices and that the packaging tested has passed the standards of the **DEPARTMENT OF TRANSPORTATION’S TITLE 49 CFR; SECTION 173.27(c)(2)**, and the **ICAO Technical Instructions on the Safe Transport of Dangerous Goods by Air, Part 3 1.1.6.1.** However, it is the responsibility of the end user to determine authorization for use under these regulations. **ALL OTHER WARRANTIES, EXPRESSED OR IMPLIED, INCLUDING ANY WARRANTY THAT THE PACKAGING TESTED IS MERCHANDABLE OR FIT FOR A PARTICULAR PURPOSE, ARE DISCLAIMED.** In no event shall TEN-E Packaging Services, Inc. liability exceed the total amount paid by MVE, Inc for services rendered.

In the event of future changes to the above referenced test standard, it is the responsibility of Chart, Inc to determine whether additional testing or updating of past testing is necessary to verify that the packaging we have tested remains in compliance with those standards.

Dale A. Johnson  
Packaging Engineer

Section 4
Testing was completed by Ten-E Packaging Services, Inc. on April 10, 1997. The following dimensions, weights and material audits were performed by Ten-E Packaging Services to document the package design:

### PRIMARY - 4 mL Cryovial

**CLOSURE**
- **Description:** 12 mm Threaded Cap
- **Material:** Polypropylene  
  - **Density:** .852 g/cc
- **Tare Weight:** .638 Grams
- **Markings:** 5
- **Gasket:** Material: Silicone Rubber  
  - **Tare Wt.:** .076 Grams  
  - **Thickness:** .041"  

**Overall & Thread Dimensions**

![Thread Dimensions Diagram]

### VIAL

- **Description:** 4 mL Cryovial®
- **Material:** Polypropylene; Natural  
  - **Tare Weight:** 2.6 Grams
- **Capacity:**  
  - **Overflow:** 5.0 mL  
  - 98% of Overflow: 4.9 mL
- **Density:** .913 g/cc
- **Markings:** SPI "5" PP Recycling Symbol 5

**Overall & Finish Dimensions**

![Finish Dimensions Diagram]

### ABSORBENT

- **Description:** (1) Sheet Absorbent folded
- **Dimensions:** 11-5/8" x 4"  
  - **Tare Weight:** 2 Grams
- **Usage:** Placed on top of vials in plastic box

*Section 5*
**Primary Receptacle**

**4 mL CRYOVIAL**

**DESCRIPTION:**
Cryovial® T310-4A Self Standing Vial

**MATERIAL:**
- Closure: Polypropylene
- Vial: Polypropylene

**CAPACITY:** 4 mL

**TARE WEIGHT:**
Not Specified

**CLOSURE GASKET:**
Silicone seal fitted at base of the cap

**DIMENSIONS:**
- Diameter (O.D.): 12.5 mm
- Height: 78 mm

**NO USED/PACKAGE:** (238)* 4 mL Cryovials

**SUPPLIER:** Simport Plastics

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**ABSORBENT**

**DESCRIPTION:**
Paper fiber absorbent material

**DIMENSIONS:**
11-5/8" (length) x 4" (width)

**USAGE:**
(1) sheet folded 4-times, placed on top of vials in plastic box

**SUPPLIER:** Not specified

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**PLASTIC BOX**

**DESCRIPTION:**
2-Piece plastic box

**DIMENSIONS:**
2-3/4" x 2-3/4" x 3-1/8"

**TARE WEIGHT:**
63 Grams

**USAGE:**
*Bottom 3 boxes contain 21 plastic vials, remaining (7) boxes contain 25 plastic vials. All boxes contain (1) sheet of absorbent material on top of vials.*

Section 5
**STAINLESS STEEL CAN**

**COVER**

DESCRIPTION: Stainless Steel Cover with Pressure Release Valve and (6) screws
Release Pressure at 15 PSI

MATERIAL: Stainless Steel SS304

OVERALL DIMENSIONS:
- Height: 2.125” (W/Handle)
- Diameter: 8.375”

GASKET:
Teflon Gasket placed in groove on top of can

SUPPLIER: Not Specified

**CAN**

DESCRIPTION: Round Stainless Steel Can

MATERIAL: Stainless Steel SS304

TARE WEIGHT: Not Specified

CAPACITY:
- Nominal: Not Specified
- Overflow: Not Specified

OVERALL DIMENSIONS:
- Height: 9.375”
- Diameter: 8.375” (Top)
- Thickness: 0.029”

SUPPLIER: Not Specified

**ABSORBENT**

DESCRIPTION:
Paper fiber absorbent material

DIMENSIONS:
11-5/8” (length) x 4” (width)

USAGE:
(4) Sheets placed on bottom, (27) Sheets used to fill void area

SUPPLIER: Not Specified

Section 5
Testing was completed by Ten-E Packaging Services, Inc. on April 10, 1997. The following dimensions, weights and material audits were performed by Ten-E Packaging Services to document the package design:

### PRIMARY - Blood Bag in Aluminum Cassette (20 Used/Shipper)

<table>
<thead>
<tr>
<th><strong>BLOOD BAG</strong></th>
<th></th>
<th><strong>CASSETTE</strong></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Description:</strong></td>
<td>Baxter Cryocyte™ Bag with manifold set</td>
<td><strong>Description:</strong></td>
<td>Freezing and Storage Cassette for Individual Blood Bag. Cassette has rivet hinge and thumb latch</td>
</tr>
<tr>
<td><strong>Material:</strong></td>
<td>PL-269 Plastic; Single-Ply</td>
<td><strong>Material:</strong></td>
<td>Aluminum</td>
</tr>
<tr>
<td><strong>Gross Weight</strong></td>
<td>33 Grams (with simulated product)</td>
<td><strong>Tare Weight:</strong></td>
<td>88 Grams</td>
</tr>
<tr>
<td><strong>Thickness:</strong></td>
<td>.013&quot;</td>
<td><strong>Markings:</strong></td>
<td>None</td>
</tr>
</tbody>
</table>

**Overall Dimensions**

- **BLOOD BAG**
  - Overall: 2.875" x 9.000"

- **CASSETTE**
  - Overall: .500" x 3.500" x 6.000"

### ABSORBENT

| **Description:** | (1) Sheet Paper Fiber Absorbent |
| **Dimensions:** | 11-5/8" x 4" |
| **Tare Weight:** | 2 Grams Each |

**Usage:** Placed in Cassette

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Section 6
BLOOD BAG

DESCRIPTION:
50 mL Cryocyte™ Freezing Container fitted with male and female syringe adapters to facilitate aseptic filling and removal of contents

MATERIAL:
• Bag: PL 269 Plastic
• D-Ring Port Seals: Silicone

NOMINAL SIZE:
50 mL

FREEZING CAPACITY:
10-20 mL

TARE WEIGHT:
Not Specified

SEALING:
Pre-attached Fill Tube is sealed using a dielectric sealer

DIMENSIONS:
Not specified

NO. USED:
20

SUPPLIER/ID:
Baxter/4R9951

ABSORBENT

DESCRIPTION:
Paper Fiber Absorbant Material

DIMENSIONS:
11-5/8" (length) x 4" (width)

USAGE:
(1) sheet folded 4-times, placed next to blood bag in cassette

CASSETTE

DESCRIPTION:
Freezing and Storage Cassette for use with Baxter Healthcare Minicyrocyte Container Cat. #4R9951

MATERIAL:
Aluminum

THICKNESS:
.032"

DIMENSIONS (ID):
5.85" (L) x 3.36" (W) x .47" (H)

FEATURES:
Aluminum Rivit Hinge
Aluminum Thumb Latch
1/4" Close Cell Rubber Spring
20 mL Volume

NO. USED:
20

SUPPLIER/ID:
CWF Incorporated/#CW-199-1-2

Section 6
## Secondary Packaging

### STAINLESS STEEL CAN

**DESCRIPTION:** Stainless Steel Cover with Pressure Release Valve and (6) screws
Release Pressure at 15 PSI

**MATERIAL:** Stainless Steel SS304

**OVERALL DIMENSIONS:**
- Height: 2.125” (W/Handle)
- Diameter: 8.375”

**GASKET:** Teflon Gasket placed in groove on top of can

**SUPPLIER:** Not Specified

### CAN

**DESCRIPTION:** Round Stainless Steel Can

**MATERIAL:** Stainless Steel SS304

**TARE WEIGHT:** Not Specified

**CAPACITY:**
- Nominal: Not Specified
- Overflow: Not Specified

**OVERALL DIMENSIONS:**
- Height: 9.375”
- Diameter: 8.375” (Top)
- Thickness: 0.029”

**SUPPLIER:** Not Specified

### ABSORBENT

**DESCRIPTION:** Paper fiber absorbent material

**DIMENSIONS:** 11-5/8” (length) x 4” (width)

**USAGE:** (8) sheets total, 6 sheets folded and placed on bottom, 2 sheets folded and placed between cassette layers

**SUPPLIER:** Not Specified

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Section 6
Cryo-shipper extra capacity unit

DESCRIPTION:
Slip-Fit Cover with 7-1/2" (diameter) Neck Tube

MATERIAL:
Aluminum; Painted Blue

OVERALL DIMENSIONS:
• Height: Not specified
• Diameter: Not specified

NECK TUBE:
8-1/2" Diameter Expanded Polystyrene Tube

SUPPLIER / MANUFACTURER & ID:
MVE

Cryo-shipper extra capacity / tank

DESCRIPTION:
CMD-20 Vacuum Insulated Vapor Shipper

MATERIAL:
• Outer Shell: Aluminum
• Outside Wall/Inner Shell: Aluminum
• Inside Wall/Inner Shell: Stainless Steel

ABSORBENT:
Cab-o-Sil Absorbent Material placed between outside and inside wall of inner shell

VAPOR SHIPPER WEIGHTS:
• Empty: Not specified
• Liquid Nitrogen Charged: 50.05 Lbs.
• Liquid Nitrogen Capacity: Not specified
• Liquid Nitrogen Capacity: Not specified

DIMENSIONS:
Inner Shell:
• Diameter/ID: 8-1/2"
• Diameter/OD: 12-7/8"
• Height: 12-3/4"

Body:
• Height (w/cover): 22"
• Diameter: 22"
• Neck Opening: 8-1/2"

SUPPLIER / MANUFACTURER & ID:
MVE

Section 7
Cryo-shipper extra capacity unit

DESCRIPTION:
CMD-20 Plastic Shipping Container with Domed Cover attached to overpack using (3) bolted metal latch assemblies

MATERIAL:
Medium Density Polyethylene

PIGMENT:
Tan

DIMENSIONS:
Cover:
• Height: 5-1/2"
• Diameter: 22"

Body:
• Height: 22"
• Diameter: 22"

Overall:
• Height: 27-1/2"
• Diameter: 22"

SUPPLIER / MANUFACTURER & ID:
MVE

Section 8
Caution

• After removing secondary container from cryogenic vessel, ALWAYS release pressure/vacuum inside this container immediately by LIFTING UP THE HANDLE of relief valve.

• Always LIFT UP THE HANDLE of relief valve, before opening the lid of secondary container.

• Always seal the lid with six screws.

• Remove secondary container when filling liquid nitrogen into vessel.

• Do not put dry ice or liquid nitrogen in secondary container.

• Keep top flange dry before sealing secondary container.

• Pre-cool secondary container in liquid nitrogen vapor phase or -70°C mechanical freezer, before placing samples inside.
GENERAL DESCRIPTION:
The SC and XC vapor series dewar is a vacuum insulated container of aluminum with fiberglass neck construction providing you with the highest efficiency possible in nitrogen vapor storage. Use the container for inert fluids only. Liquid oxygen is not compatible with fiberglass material and should not be stored.

These high quality vacuum insulated units are constructed of durable material, compatible with the divergent temperature extremes and broad applications of cryobiology. The absorbent material used in construction after 1993 is hydrophobic (will not absorb water) which unlike calcium silicate does not need to be periodically heated to remove absorbed moisture.

A) SAFETY

Note: Fill the container with a funnel or transfer line when possible. Avoid spilling liquid nitrogen over the vacuum cap near the neck as this can shrink the seal and allow air to leak into the vacuum space.

CAUTION: (Using Aluminum SC or XC vapor shipper series). To avoid injury by frostbite use extreme care whenever handling liquid nitrogen, liquid nitrogen storage or transfer vessels, or any objects which have come in contact with liquid nitrogen.

- Leave no area of skin exposed.
- Always wear proper safety attire over clothing: face shield, cryogenic gloves, cryogenic apron.
- Never overfill vapor shippers with liquid nitrogen.
- Always keep vapor shippers in upright position.
- Do not tightly seal liquid nitrogen container or prevent nitrogen gas from escaping.
- Use extreme care to prevent spilling and splashing liquid nitrogen during transfer.
- Immediately remove any clothing or safety attire on which liquid nitrogen has spilled.
- Get immediate medical attention for any frostbite injuries due to liquid nitrogen.

B) FILLING INSTRUCTIONS

To ensure maximum performance from your MVE vapor dewar simply follow the listed steps just prior to shipping to final destination:

1. Open container that dewar is in and remove cork/cover (do not twist).
2. Fill unit to bottom of neck tube.
   a) Follow established safety practices and procedures for transferring LN.
   b) Transfer using LN hose with phase separator or pouring container and approved funnel.
   c) Canisters are to remain inside.
3. Replace cork/cover and allow unit to stand for 24 hours (cooling down unit).
4. Weigh unit (first weight) and record.
5. Pour off excess liquid just prior to shipment.

TO TEST FOR DEWAR EFFICIENCY FOLLOW STEPS 1 - 4 AND PROCEED TO #6.

6. Allow filled unit to sit for another 24 hours.
7. Weigh second time.
8. Never overfill your dewar with liquid nitrogen. Overfilling the tank may cause immediate or premature vacuum failure to occur.
9. Calculate evaporation rate. The difference between the first weight and the second weight is the evaporation rate in lbs. This can be converted to liters by multiplying lbs. x .5606. This figure roughly signifies the N.E.R. (first weight - second weight) x .5606 = liters/day.
   a) Also, during this time take note of any uncommon occurrences such as excess frosting or sweating along the outside of dewar. Take note of excess nitrogen boil off especially after the second weight. LN should settle (cease boiling) after an hour.

MVE vapor shippers were primarily designed as vapor shipping containers; however, they can also be used for immersion of samples. A sharp blow to the outer vessel can damage the neck tube or start a vacuum leak. Use caution and common sense in handling the container. Use the weight table below as a general guide to determine if your vapor shipper is fully charged.

<table>
<thead>
<tr>
<th>Model</th>
<th>Empty Weight</th>
<th>Sugg. Wt. Full</th>
<th>Static Hold Time Days</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cryoshipper XC IATA</td>
<td>30</td>
<td>47</td>
<td>14</td>
</tr>
</tbody>
</table>

Section 10
C) REPLACEMENT PARTS

<table>
<thead>
<tr>
<th>Models</th>
<th>Cryo XC</th>
</tr>
</thead>
<tbody>
<tr>
<td>Canister</td>
<td>see brochure</td>
</tr>
<tr>
<td>Cork / Cover</td>
<td>10509556</td>
</tr>
</tbody>
</table>

WARNING: the venting of nitrogen vapors will create a dilution of the air’s oxygen concentration necessary to support life. Exposure to this diluted atmosphere can cause asphyxiation or even death. Do not store or use container in areas that have poor ventilation. Place container in a well-ventilated area. Failure to comply with this warning may cause serious personal injury including death.

D) SHIPPING INSTRUCTIONS

Dewar is charged for 24 hours for full absorption capacity. Generally dewar will be 60% charged at 8 hours, 80% charged at 12 hours and 100% charged at 24 hours. Prior to packaging dewar for shipment the entire contents of liquid nitrogen must be removed. This is usually done by pouring out excess liquid nitrogen until no liquid is visible on the bottom of the inner dewar. Place in bio samples, package dewar and ship. The plastic shipping container provided by MVE/Chart is recommended to help keep dewar in upright position. IF DEWAR IS SHIPPED ON ITS SIDE IT WILL ONLY PROVIDE 40% OF THE SPECIFIED HOLD TIME. IF SHIPPED UPSIDE DOWN IT WILL ONLY PROVIDE 10% OF HOLD TIME CAPACITY. Remember that all MVE vapor shippers can also be used for liquid nitrogen storage as well, so it is imperative that all liquid nitrogen be removed so dewar remains classified as a vapor shipper. If liquid nitrogen is visible in the bottom of the inner it then becomes a liquid shipper and the exception status is void. The liquid inside is now classified as hazardous material.

Because of the manner in which it is absorbed and because there is no free liquid present in the packaging, the liquid nitrogen does not exhibit the characteristic of a "cryogenic liquid" as defined in 49 CFR 173.115(g) and does not pose a hazard in transportation. Therefore, it is not subject to regulation under the Department of Transportation’s Hazardous Material Regulations.

However, if the packaging is improperly offered for transportation WITH free liquid present, it would be subject to regulation when offered for transportation by air (see 49CFR 173.320) and must be offered in accordance with the International Civil Aviation Organization’s (ICAO) Technical Instructions. The packaging does not conform to ICAO Packaging Instruction 202 and therefore, is not an authorized packaging when containing free liquid.

In consideration of the above, consultation with the Research and Special Programs Administration of the DOT has determined that the use of nitrogen refrigerated liquid charged “dry shipper” containers for the shipment of samples falls within the regulation exception provided in 49CFR 173.320 paragraph (a) of the section states the requirements of this subchapter do not apply to atmospheric gases and helium when used in the operation of the process system, such as a refrigeration system. Paragraph (c) of 173.320 pertains to air transport of same refrigeration system. For exception status of air shipments please refer to IATA-Dangerous Goods Regulations for nitrogen refrigerated liquid. This falls in the class of 2.2 non-flammable gas, packing instructions 202 with special provisions A-800. For answers to questions regarding shipping regulations contact a MVE, Al-Cryobiological Tech Service Representative @ 886-819-5897.

Section 10