Joint Service

REGULATION

Defense Logistics Agency
Department of the Army
Department of the Navy
Department of the Air Force

DLAR (JP) 4145.21
TB MED 284
NAVSUPINST 4610.31B
AFI 41-208
Effective Date: November 20, 2018

Accountable Office: Headquarters DLA, Technical and Policy Division, J344

SUBJECT: Preparation of Medical Temperature-Sensitive Products Requiring Cold Chain Management for Shipment

References: See Enclosure 1

1. PURPOSE. This regulation reissues reference (d) and establishes the policies and procedures for the application of cold chain management principles in the packaging, handling, marking, shipping and storage of temperature-sensitive medical products.

2. APPLICABILITY. This regulation is applicable to the Military Services and the Defense Logistics Agency (DLA) that handle medical materiel.

3. DEFINTIONS. See Glossary.

4. POLICY. All perishable medical products will be afforded the degree of protection required to prevent deterioration or other damage due to hazards to which the items may be subjected during shipment.

5. RESPONSIBILITIES.

a. THE DIRECTOR, DLA LOGISTICS POLICY AND STRATEGIC PROGRAMS (J34). The Director, J34 will:

(1) Publish and keep this regulation current.

(2) Provide overall policy and direction.

b. THE COMMANDER, DLA TROOP SUPPORT. The Commander, DLA Troop Support will:

(1) Designate items subject to requirements of this regulation.

(2) Notify all services and DLA J344 when changes are made.

(3) Ensure the correct Item Type Storage Code (ITSC) is assigned in the Federal Logistics Information System (FLIS).

(4) Identify items in the "Characteristics" tab or the "Special Storage and Handling Requirements" field in the Medical Master Catalog (MMC).

c. THE MILITARY SERVICES AND DLA. The Military Services and DLA will:

(1) Establish internal controls to assure compliance with this regulation.

(2) Ensure training is provided to personnel working with temperature-sensitive medical items to maintain familiarity.

d. ALL DOD PERSONNEL PERFORMING COLD CHAIN MANAGEMENT FUNCTIONS. DoD Personnel shall check the cold chain packaging website https://www.medical.dla.mil/Portal/Pharmaceutical/ColdChainPackaging.aspx prior to packaging an item to determine weather conditions at customer's location and determine proper packaging protocol for shipment.

e. THE COMMANDERS, DLA DISTRIBUTION AND DLA TROOP SUPPORT. The Commanders shall develop and maintain cold chain management training module(s) to be utilized by packers and handlers. This requirement will include authorized contractors performing Government work.

6. PROCEDURES. See Enclosure 2.

7. INFORMATION REQUIREMENTS.

a. Access may be required for DSS, EDA, and WebFLIS and Service Item Data websites.

8. INTERNAL CONTROLS.

a. DLA J344 and DLA Troop Support Medical will review DLA Distribution packaging systems and procedures for compliance during cold chain packaging field assistance visits, either with a technical assistance and operational review program, or separately, on an as-needed basis to evaluate the adequacy of field packaging operations, and conformance to this regulation.

b. DLA J344 will review DLA Troop Support Medical procedures for distributor and contractor compliance and will participate in packaging field assistance visits on an as needed basis to evaluate the adequacy of field packaging operations, and conformance to this regulation.

9. RELEASEABILITY. UNLIMITED. This regulation is approved for public release and is available on the DLA Issuances Internet Website.

10. EXPIRATION DATE. This Regulation will be reissued or canceled by the fifth anniversary of its publication date. If not, it will automatically expire effective November 20, 2028.

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WILLIAM M. BOWERS
Director
DLA Transformation

Enclosures(s)
- Enclosure 1 – References
- Enclosure 2 – Procedures
- Enclosure 3 – Packaging Protocols
- Enclosure 4 – Labels and Forms

Glossary
Acronyms
Definitions

ENCLOSURE 1

REFERENCES

(a) Title 49, Code of Federal Register, Parts 100-180, "Transportation"[1]
(b) International Air Transport Dangerous Goods Regulations[2]
(c) AFMAN 24-204_IP/TM 38-250/NAVSUP PUB 505/MCO 4030.19K/DLAI 4145.3, "Preparing Hazardous Materials for Military Air Shipments", July 13, 2017[3]
(d) DLAR 4145.21, Preparation of Medical Materiel Requiring Freeze or Chill Environment for Shipment, March 26, 2008.
(e) Medical Master Catalog[4]
(f) Defense Transportation Regulation (DTR) 4500.9-R-Part II, Cargo Movement[5]
(g) Medical Marking Standard Number 1C, November 2, 2017[6]
(h) Commercial Item Description A-A-59195-Container, Thermal, Shipping, for Medical Material Requiring Controlled Temperature Ranges, September 1, 2015[7]
(i) Compressed Gas Association (CGA) G-6.2, Commodity Specification for Carbon Dioxide, July 2013[8]
(j) ASTM International Standard D5486/8486M, Standard Specification for Pressure-Sensitive Tape for Packaging, Box Closure, and Sealing[9]
(k) Armed Services Blood Program-Joint Blood Program Handbook: Army Technical Manual (TM) 8-227-12; Navy Medical Publication 6530 (NAVMED P-6530); Air Force Joint Handbook 44-152_IP, December 1, 2011[10]
(l) MIL-STD-129R w/change 1, "Standard Practice, Military Marking for Shipment and Storage", May 24, 2018
(m) Temperature Monitoring Device Specification Sheet No. 1[11]

[1]Title 49 CFR may be obtained: https://www.ecfr.gov/cgi-bin/text-idx?tpl=/ecfrbrowse/Title49/49tab_02.tpl
[2]IATA publication may be obtained: http://www.iata.org/
[3]AFMAN 24-204 publication may be obtained: http://www.e-publishing.af.mil/
[4]Medical Master Catalog may be obtained: https://www.medical.dla.mil/Portal/Homepages/MedicalMasterCatalog.aspx
[5]Defense Transportation Regulation (DTR) may be obtained: http://www.ustranscom.mil/dtr/part-ii/dtr_part_ii_toc.pdf
[6]Medical Marking Standard 1 may be obtained: https://www.medical.dla.mil/Portal/Pharmaceutical/ColdChainPackaging.aspx
[7]Commercial Item Description A-A-0059195 may be obtained: https://www.medical.dla.mil/Portal/Pharmaceutical/ColdChainPackaging.aspx
[8]Compressed Gas Association (CGA) G-6.2 may be obtained: http://www.cganet.com/
[9]ASTM International Standard D5486/5486M may be obtained: http://www.astm.org/
[10]Armed Services Blood Program-Joint Blood Program Handbook: Army Technical Manual (TM) 8-227-12; Navy Medical Publication 6530 (NAVMED P-6530); Air Force Joint Handbook 44-152_IP may be obtained: http://www.militaryblood.dod.mil/Staff
[11]Temperature Monitoring Device Specification No. 1 may be obtained: https://www.medical.dla.mil/Portal/Pharmaceutical/ColdChainPackaging.aspx

ENCLOSURE 2

PROCEDURES

1. BACKGROUND. Temperature-sensitive medical products can be compromised by many factors. Major contributors to the loss of product include, but are not limited to freezing, improper temperature control during shipment, improperly calibrated storage temperature control systems, improper packaging, contamination, and lack of knowledge of cold chain management procedures by personnel handling the products. Care must be exercised in shipment preparation and planning to provide for temperature variations, multiple handling and extended periods of time in transit. Packaging protocols and forms are used to reduce the risk of damage. Suggested sources for containers, coolant materials, and temperature monitoring devices may be found on the DLA Troop Support Medical Pharmaceutical Cold Chain website listed in Enclosure 1, 5.d.1.

a. For FSC 6505 Pharmaceuticals, 6550 Laboratory Materials, and other designated items requiring application of more stringent cold chain management principles, specialized packaging protocols have been developed. Protocols designed for shipment of specific temperature-sensitive medical products requiring stringent storage temperatures may be found in Enclosure 3.

b. The appropriate regulations for the mode of transportation will be followed per references (a), (b), and (c). This regulation will be used as guidance for the type and quantity of containers and refrigerant used to maintain viable medical materiel.

c. Proper methods of preparation for shipment prescribed herein are dependent upon alert personnel experienced in properly handling, shipping, and storing the items, and the conditions to which the medical products will be exposed prior to delivery to the customer.

2. PRINCIPLES. Cold Chain Management Principles include use of validated shipping containers; inclusion of temperature monitoring devices; rapid movement of products; proper conditioning and use of authorized materials; and key involvement with knowledgeable customers.

3. EXCEPTIONS. The following categories of materiel are not addressed in this regulation:

a. Blood and blood products that required a refrigerated (chill) or freeze environment will be prepared for shipment as specified in reference (k).

b. Infectious substances, diagnostic specimens, biological products, regulated medical waste dispatched from military medical healthcare and research facilities, and environmental specimens that require a chill or freeze environment will be prepared for shipment as specified in the local or sampling protocol. Medical waste shipments will also be tracked in accordance with applicable federal, state and local laws and regulations. Additional information may be obtained from the U.S Environmental Protection Agency.

4. EMERGENCY RESPONSE INFORMATION. Hazardous materials shall not be transported,

stored or handled unless emergency response information is available at all times. The shipper must provide a 24-hour emergency response telephone number that is monitored at all times by personnel who are knowledgeable of the hazards and characteristics of the materials being shipped. This information is required in the event of an emergency involving the material and shall be provided on the Shipper's Declaration for Dangerous Goods as specified in para. 6. For shipments originating from DoD activities, the following numbers shall be used:

a. For Class 1 material, contact The Army Operations Center, (703) 697-0218/0219. Ask for the Watch Officer.

b. For radioactive material, contact Rock Island Arsenal, (309) 782-3510. Call collect. Ask for the Staff Duty Officer.

c. For all other hazardous materials, contact The DoD Emergency Response Hotline, (800) 851- 8061 (toll free) or (804) 279-3131.

For shipments originating from non-DoD activities, use the company, safety organization, or other contact telephone number applicable to the material shipped. As specified in para. 6, the number must include the international access code, the country code and the city code for the point of contact.

5. MILITARY AIR SHIPMENTS OF CHILLED/FROZEN MEDICAL MATERIEL. When shipments of chilled/frozen medical materiel are by military air, each shipment will be accompanied by a properly completed DD Form 1387-2, Special Handling Data/Certification.

6. HAZARDOUS MATERIAL (HAZMAT). HAZMAT shall be packaged, labeled, and certified in accordance with reference (a). In addition, temperature-sensitive HAZMAT shall be prepared for shipment as specified in para. 7; however, HAZMAT designated to receive more stringent cold chain management principles shall be prepared for shipment as specified in para 8.

a. For commercial air or military air shipments, each HAZMAT shipment will be accompanied by a properly executed Shipper's Declaration for Dangerous Goods certification. The certification will be completed as described in reference (c). Emergency point of contact information shall be included on the Shipper's Declaration for Dangerous Goods in the section headed "Additional Handling Information". The complete telephone number shall be listed; the number shall include the international access code, the country code and the city code.

b. For military air shipment, each HAZMAT shipment will also meet all packaging, marking, and labeling requirements described in reference (c).

7. NON-STRINGENT PACKAGING REQUIREMENTS. This section is applicable to packaging of temperature-sensitive medical products that are identified as not requiring stringent cold chain management principles, unless otherwise specified in the contract or order. Exterior shipping containers will conform to the applicable requirements of reference (h).

a. Freezer Products. Products, which are identified as freezer items in WebFLIS or reference (e), will be stored and shipped in a constant frozen state. Dry ice shall be used and containers will be pre-cooled to 4ºC (40ºF) before packaging. Items selected for shipment should be placed in one or more of the containers listed in reference (h). Container size will allow sufficient space for the required amount of dry ice. Dry ice will conform to reference (i). The required amount of dry ice to be used for each size container, as shown in Table I, will maintain the required temperature (below -4° C) for up to 96 hours.

TABLE I. FROZEN – DRY ICE	
SIZE	POUNDS OF DRY ICE
SMALL	14 lbs (6.4 kg)
MEDIUM	21 lbs (9.5 kg)
LARGE	42 lbs (19.1 kg)
X-LARGE	55 lbs (25 kg)

(1) Package individual unit packages into the pre-cooled insulated shipping container snugly, taking advantage of all available space. Fill all void space with dry ice. Add the required amount of dry ice on top. When re-icing is required, it will be done without handling the items.

(2) Diluents and component parts of freezer products will be packaged in separate containers normally used for non-freezer products. Set assembly markings will be used in these cases.

(3) Refer to para.7. e. for marking and labeling requirements. Unless otherwise specified, a copy of DD Form 1502N, Notice for Frozen Medical Materiel Shipments will be placed inside each shipping container prior to closure.

(4) Copies of the DD Form 1348-1 DoD Single Line Item Release/Receipt Document/DD Form 1348-1A, Issue Release/Receipt Document shall accompany each shipment (sample form may be found in reference (f).

(5) Closure of container will be by tape not less than 2 inches wide conforming to reference (j). The three-strip method will be used with one strip over the length of the center seam and extending a minimum of 2 inches over the end panels. One strip will be used to seal each edge of seam to within 1 inch of corner, thus leaving space at each corner for ventilation of the dry ice. A copy of DD Form 1502, Frozen Medical Materiel Shipment, annotated with all required information, shall be securely affixed to the sealed container, either on the top of the container, or adjacent to the shipping label.

b. Refrigerated (chilled) Products Requiring Constant Refrigeration. Products, which are identified as refrigerated (chill) items in the WebFLIS and in reference (e), will be packaged in containers as specified reference (h). The storage temperature for these products shall be between 2ºC and 8ºC (36º and 46ºF). Refrigerant Packs (Table II) will be used and containers will be pre-cooled to 4ºC (40ºF) before packaging. Items selected for shipment should be placed in one or more of the containers listed in reference (h). Container size will allow sufficient space for the required amount of refrigerant packs. The required amount of refrigerant packs to be used for

each size container, as shown in Table III, will maintain the required temperature (2° – 8° C) for up to 72 hours.

TABLE II. REFRIGERANT PACKS		
SIZE	WEIGHT	DIMENSIONS
MEDIUM	24 oz	8” x 6” x 1.25”
LARGE	48 oz	10.25” x 8” x 1.5”

TABLE III. CHILL – REFRIGERANT PACKS	
SIZE	POUNDS OF DRY ICE
SMALL	12 lbs (5.4 kg)
MEDIUM	19.5 lbs (8.8 kg)
LARGE	51 lbs (21.1 kg)
X-LARGE	81 lbs (36.7 kg)

(1) A copy of DD Form 1502-1N, Notice for Chilled Medical Materiel Shipments will be placed into each shipping container prior to closure. DD Form 1502-1N is not required for shipments of laboratory or environmental specimens.

c. Refrigerated (chilled) Products Not Requiring Constant Refrigeration. Certain refrigerated (chill) items may be shipped out of refrigeration for 4, 7, or 18 days, as identified in WebFLIS or reference (e). These products, packaged as specified in para. 7.b., may be shipped out of refrigeration for the indicated time, provided temperature range of 0º to 35º C (32º to 95º F) can be assured during shipment. Unless otherwise specified, a copy of DD Form 1502-2N, Notice for Limited Unrefrigerated Medical Materiel Shipments will be placed in each shipping container. Special caution should be exercised in hot weather conditions. To protect items in transit during weather that exceeds 32º C (90º F), or for shipments destined to hot climates, follow constant chill procedures as specified in para. 7.b. When constant chill is used, a copy of DD Form 1502-1N (in lieu of DD Form 1502-2N) will be placed inside each shipping container.

d. Refrigerated (chilled) Products Subject to Damage by Freezing. Care shall be taken during packaging to insure that adequate barriers are used in the shipping container to protect refrigerated (chill) items subject to damage by freezing.

e. Marking. Each exterior (shipping) container will be marked as specified in reference (g). When specified in the contract/purchase order, marking will include the lot (control) number, expiration date, and applicable storage legend(s).

(1) The proper perishable form will be applied to each exterior (shipping) container as specified in reference (g). When completing the perishable form, use the complete date and the local time, including the time zone (i.e., Eastern Standard Time (EST), Pacific Standard Time (PST), etc.). For example, the date and time a shipment was prepared at Defense Distribution Depot Susquehanna, Pennsylvania, at 8:00 AM on 10 August 2005 would be shown as "10 AUGUST 2005, 8:00 AM EST.

(2) For medical materiel subject to damage by freezing, marking on each exterior (shipping) container will also include the legend "DO NOT PERMIT TO FREEZE" or a similar commercial legend.

(3) In addition to the above, "ARROW" and "FRAGILE" markings, as specified in reference (g), will be applied to each exterior (shipping) container.

8. STRINGENT PACKAGING REQUIREMENTS. This section is applicable to packaging of temperature-sensitive medical products that are identified as requiring application of stringent cold chain management principles. Exterior shipping containers will conform to the applicable requirements of reference (h). Specialized protocols shall be followed for packaging of FSC 6505 Pharmaceuticals, 6550 Laboratory Materials, and other designated medical items requiring application of more stringent cold chain management principles. Additional information regarding these items, guidance regarding appropriate protocol use, and approval of alternative protocols is available from DLA Troop Support Medical (DSN 444-5537). Specialized packaging protocols that are qualified for 72hrs, with general performance out to 120hrs, are contained in Enclosure 3. DD Forms 1502, 1502-1 and 1502-2 and DD Forms 1502N, 1502-1N and 1502-2N shall not be used for shipments of materiel packaged according to these stringent principles. Containers will be pre-conditioned to room temperature unless shown in Table IV.

TABLE IV. CONTAINER PRE-CONDITIONING REQUIREMENTS

SIZE	PROTOCOL
SMALL	MODERATE
LARGE	WARM
X-LARGE	WARM and MODERATE
Note: Pre-cooled to 4ºC (40ºF) for a minimum of 24 hours, not to exceed 72 hours, before packaging.	

a. Freezer Products. Enclosure 3 contains specialized protocols designed for temperature-sensitive products requiring storage temperatures between -10ºC and -25ºC (14ºF and -13ºF). The required amount of suppressed temperature gel packs (Table V) to be used for each size container is shown on each individual protocol diagram. Suppressed temperature gel packs will be properly frozen at -25ºC (-13ºF), for at least 24 hours prior to use. Note that these protocols are designed to be packed inside a walk-in refrigerator. Approval of alternative options are available from DLA Troop Support Medical (DSN 444-5537).

TABLE V. SUPPRESSED TEMPERATURE GEL PACKS

SIZE	WEIGHT	DIMENSIONS
MEDIUM	16 oz	7” x 5.5” x 1”
X-LARGE	32 oz	8” x 8” x 1”

(1) For shipments where the receiving site temperature is constantly below 55ºF, use the “Cold Weather Packaging Protocol”; for shipments where the receiving site temperature is between 55ºF and 77ºF use the “Moderate Weather Packaging Protocol", and for shipments where the receiving site temperature is constantly above 77ºF use the “Warm Weather Packaging

Protocol". If protocols are required for more extreme environments, or to get approval for alternative protocols, contact DLA Troop Support Medical for assistance.

(2) While the exterior shipping containers will conform to reference (h), the inside cargo dimensions shall be as shown in Table VI.

TABLE VI. STRINGENT FREEZE – INSIDE CARGO SPACE	
SIZE	DIMENSIONS (L x W x H)
MEDIUM	9" x 5.5" x 3.25"
LARGE	13.5" x 9.5" x 5.75"
X-LARGE	12.5" x 12.25" x 6.25"

(3) Each container of temperature sensitive medical materiel requiring stringent cold chain management shall contain a temperature monitoring device programmed to monitor a range of -10ºC to -25ºC (14ºF to -13ºF). Proper placement is indicated in each packaging protocol in Enclosure 3. Temperature monitors will be pre-cooled, outside of their packaging at -17ºC (1ºF) for a minimum of 24 hours prior to being activated. Refer to manufacturer's instructions for operating details.

b. Refrigerated (chilled) Products. Enclosure 3 contains specialized protocols designed for temperature-sensitive products requiring storage temperatures between 2ºC and 8ºC (36ºF and 46ºF). The required amount of refrigerant packs (Table II) to be used for each size container is shown on each individual protocol diagram. Refrigerant packs will be properly chilled at 4ºC (39ºF – 40ºF), or frozen at -17ºC to -20ºC (1ºF to -4ºF), as applicable, for at least 24 hours prior to use. Note that these protocols are designed to be packed inside a walk-in refrigerator. Approval of alternative options are available from DLA Troop Support Medical (DSN 444-5537).

(1) For shipments where the receiving site temperature is constantly below 55ºF, use the "Cold Weather Packaging Protocol"; for shipments where the receiving site temperature is between 55ºF and 77ºF use the "Moderate Weather Packaging Protocol", and for shipments where the receiving site temperature is constantly above 77ºF use the "Warm Weather Packaging Protocol". If protocols are required for more extreme environments, or to get approval for alternative protocols, contact DLA Troop Support Medical for assistance.

(2) Each container of temperature sensitive medical materiel requiring stringent cold chain management shall contain a temperature monitoring device programmed to monitor a range of 2ºC to 8ºC (36ºF to 46ºF) and meet the requirements of reference (m). Proper placement is indicated in each packaging protocol in Enclosure 3. Temperature monitors will be pre-cooled, outside of their packaging at 4ºC (39ºF) for a minimum of 24 hours prior to being activated. Refer to manufacturer's instructions for operating details.

c. Hybrid (either frozen or refrigerated) Products. Enclosure 3 contains specialized protocols designed for temperature-sensitive products that can be stored between -20ºC and 8ºC (-4ºF and 46ºF). The required amount of refrigerant packs (Table II) to be used for each size container is

shown on each individual protocol diagram. Refrigerant packs will be properly frozen at -17ºC (1ºF) for at least 24 hours prior to use. These packaging protocols are universal and remain the same regardless of season. If protocols are required for more extreme environments, or to get approval for alternative protocols, contact DLA Troop Support Medical for assistance. Note that these protocols are designed to be packed inside a walk-in refrigerator. Approval of alternative options are available from DLA Troop Support Medical (DSN 444-5537).

(1) Each container of temperature sensitive medical materiel requiring stringent cold chain management shall contain a temperature monitoring device programmed to monitor a range of -20ºC to 8ºC (-4ºF to 46ºF) and meet the requirements of reference (m). Proper placement is indicated in each packaging protocol in Enclosure 3. Temperature monitors will be pre-cooled, outside of their packaging at -17ºC (1ºF) for a minimum of 24 hours prior to being activated. Refer to manufacturer's instructions for operating details.

d. Controlled Room Temperature Products. Enclosure 3 contains specialized protocols designed for temperature-sensitive products requiring storage temperatures between 15ºC and 30ºC (59ºF and 86ºF). For warm and moderate protocols, the required amount of refrigerant packs (Table II) to be used for each size container is shown on each individual protocol diagram. Refrigerant packs will be properly stored at 18ºC to 22ºC (64ºF to 72ºF) for at least 24 hours, or until temperature stabilized with the environment, prior to use. For cold weather protocols, the required amount of phase change materials (Table VII) to be used for each size container is shown on each individual protocol diagram. Phase change materials will be properly pre-conditioned at 30ºC (86ºF) for at least 24 hours, or until completely melted, prior to use.

TABLE VII. PHASE CHANGE MATERIALS

SIZE	WEIGHT	DIMENSIONS
LARGE PANEL	24.6 oz	9.25" x 7" x 0.875"

(1) For shipments where the receiving site temperature is constantly below 55ºF, use the "Cold Weather Packaging Protocol;" for shipments where the receiving site temperature is between 55ºF and 77ºF use the "Moderate Weather Packaging Protocol," and for shipments where the receiving site temperature is constantly above 77ºF use the "Warm Weather Packaging Protocol." If protocols are required for more extreme environments, or to get approval for alternative protocols, contact DLA Troop Support Medical for assistance.

(2) Each container of temperature sensitive medical materiel requiring stringent cold chain management shall contain a temperature monitoring device programmed to monitor a range of 15ºC to 30ºC (59ºF to 86ºF) and meet the requirements of reference (m). Proper placement is indicated in each packaging protocol in Enclosure 3. Temperature monitors will be stored at room temperature prior to activation. Refer to manufacturer's instructions for operating details.

e. Marking. Each exterior (shipping) container will be marked with one of the Department of Defense Cold Chain Management labels, as appropriate (DD Forms 3035-1 through 3035-4, Enclosure 4), adjacent to the address label. To get approval for alternative labels, contact DLA Troop Support Medical for assistance.

(1) Labels will include the pack location, date of pack, and in-transit and receiving site instructions. The “If After This Date” field entry will be calculated by adding five calendar days to the date of packaging. For example, if the date a shipment was prepared at DLA Distribution Susquehanna, Pennsylvania was on 10 August 2015 the entry would be "15 AUGUST 2015”.

(2) For refrigerated and controlled room temperature medical materiel subject to damage by freezing, marking on each exterior (shipping) container will also include the legend "DO NOT PERMIT TO FREEZE" or a similar commercial legend.

9. HANDLING INSTRUCTIONS. For each container of temperature-sensitive medical products, a copy of the appropriate Handling Instructions for Returning Temperature Monitors will be placed inside each container. Current versions can be obtained from DLA Troop Support Medical or found at https://www.medical.dla.mil/Portal/Pharmaceutical/ColdChainPackaging.aspx .

10. TRAINING.

a. Hazardous Materials. Packers and handlers involved with preparing medical materiel for shipment require job-specific training when shipping medical materiel in dry ice or to ship other hazardous materials. Per reference (a), only personnel who have successfully completed training at a DoD- approved school may sign the shipping papers for hazardous materials, e.g. Shipper’s Declaration for Dangerous Goods or DD Form 836, Dangerous Goods Shipping Paper.

b. Stringent Cold Chain Management Shipments. Packers and handlers involved with preparing medical materiel for shipment require training in the use of the applicable packaging protocols to insure that these shipments are properly prepared, packaged and handled. DLA Troop Support Medical and DLA Distribution will develop and maintain training programs. Training developed by DLA Distribution must be reviewed and approved by HQ DLA J344 and DLA Troop Support Medical. DLA Distribution will conduct training of DLA Distribution packers and handlers annually; training at other DLA/DoD sites will be conducted by DLA Troop Support Medical as needed.

ENCLOSURE 3

PACKAGING PROTOCOLS

Packaging Protocols for Temperature Sensitive Medical Products Requiring Storage and Transportation Temperatures Between -10ºC and -25ºC (14ºF and -13ºF)

IMPORTANT NOTICE!!

DD Forms 1502/1502-1/1502-2 & 1502N/1502-1N/1502-2N SHALL NOT BE USED with these protocols.

Cold Weather Packing Protocol

- Cold Weather Configuration is used when the ambient temperature at the **receiving site** is consistently below 55°F.
- Protocols are designed to keep temperature sensitive products requiring freezing temperatures between -10°C and -25°C within these temperature ranges during transportation, for a minimum of 72 hours.
- 16oz. and 32oz. Suppressed Temperature gel packs are used in all boxes for layering.
- Inert packing material (i.e. peanuts and paper) can be used as void space filler in the cargo area space (avoid bubble wrap).
- Coolant material must be placed in layers according to attached diagrams. Configurations use **all frozen gel packs**. (See cold weather packing configuration diagrams.)
- Please note that **ONLY** the Medium, Large, and Extra Large containers can be used for this ambient temperature range.

Cold Weather Packing Protocol Procedures

The Cold Weather Packing Protocol is used whenever the ambient or outside temperature at the receiving site consistently remains below 55 degrees Fahrenheit. Begin the Cold Weather packing protocol by:

o Placing a layer of frozen gel packs at the bottom of the box.

o Next item will be the product.

o Place frozen gel packs around the product's side(s) to fill in gap between product and the insulated walls of the box.

o This is followed by placing an activated temperature monitor inside the cargo area space. Activate the temperature monitor and adhere it to the underside of the cargo area space box lid, centered over the top of the product (avoid adhering the temperature monitor to the product directly)

o Follow with additional layers of frozen gel packs.

o Finally, insert the foam plug to seal the contents of the box.

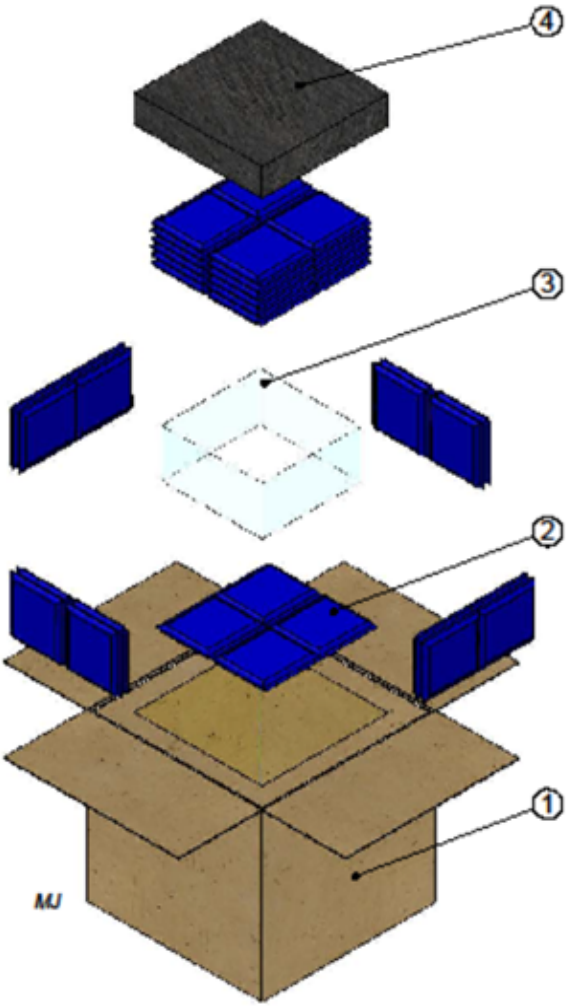
Notes:
o Follow procedures according to each protocol diagram of box used.

o To precondition the frozen gel packs, place them in a layer (no more than two high) inside a freezer running at -25°C for at least 24 hours prior use.

Extra Large – Cold Weather Packing Protocol Diagrams

ITEM NO.	PRODUCT LOAD	DESCRIPTION	UNIT WEIGHT REF.	QTY	TOTAL WEIGHT REF.	PRE-CONDITION (24HRS)
1	XLg	POLYURETHANE SHIPPER - ID: 18 1/2" x 18 1/4" x 16 3/4" w/FOAM PLUG	15.8	1	15.8	22°C ± 3°C
2	Coolant	SUPPRESSED TEMPERATURE GEL PACKS	2.0	44	88.0	-25°C ± 3°C
3	PRODUCT LOAD XLg	PRODUCT LOAD AREA, 12 1/2" x 12 1/4" x 6 1/4"	N/A	1	N/A	-20°C ± 4°C
4	FOAM PLUG XLg	FOAM PLUG, OD-18 1/2" x 18 1/4" x 4"	0.1	1	0.1	22°C ± 3°C
EMPTY SYSTEM WEIGHT (REF).					103.9	

UNLESS OTHERWISE SPECIFIED: DIMENSIONS ARE IN INCHES AND WEIGHTS ARE IN LBS.



SUPPRESSED TEMPERATURE GEL PACKS IN BLUE ARE FROZEN

PACK-OUT INSTRUCTIONS:

A. PLACE FOUR GEL PACKS (2) INTO BOTTOM OF MOLDED SHIPPER BASE (1).

B. PLACE PRODUCT LOAD (3) ON TOP OF THE PREVIOUSLY PLACED GEL PACKS (2).

C. PLACE FOUR GEL PACKS (2) ON EACH OF THE FRONT, BACK, LEFT & RIGHT OF PRODUCT LOAD (3) AS SHOWN IN THE DIAGRAM (16 TOTAL).

D. PLACE TWENTY FOUR GEL PACKS (2) ON TOP OF THE PRODUCT LOAD (3) AS SHOWN IN THE DIAGRAM (4 PER LAYER, 6 LAYERS HIGH).

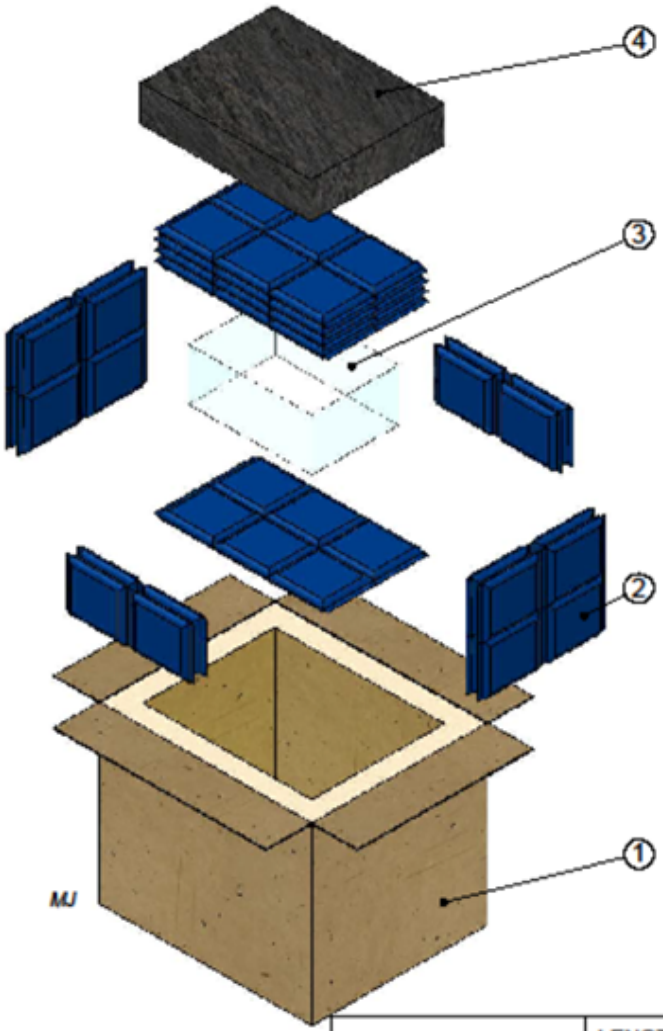
E. PLACE FOAM PLUG (4) ONTO THE TOP OF GEL PACKS, AND CLOSE AND SEAL OUTER CORRUGATE BOX (1).

	LENGTH	WIDTH	HEIGHT	VOLUME FT³	DIMENSIONAL WEIGHT *(FACTOR OF 195)*	
SHIPPING SYSTEM OD	23.3	23.0	24.0	7.4		**65.1**
PAYLOAD AREA	12.5	12.3	6.3	0.6		

Large – Cold Weather Packing Protocol Diagrams

ITEM NO.	PART NUMBER / NAME	DESCRIPTION	UNIT WEIGHT REF.	QTY	TOTAL WEIGHT REF.	PRE-CONDITION (24HRS)
1	Lg	POLYURETHANE SHIPPER - ID: 18 1/2" x 14 1/2" x 12" w/ FOAM PLUG	7.6	1	7.6	22°C ± 3°C
2	Coolant	SUPPRESSED TEMPERATURE GEL PACKS	1.0	54	54.0	-25°C ± 3°C
3	PRODUCT LOAD Lg	PRODUCT LOAD AREA - 13 1/2" x 9 1/2" x 5 3/4"	N/A	1	N/A	-20°C ± 4°C
4	FOAM PLUG, Lg	FOAM, PLUG, OD=18 3/4" x 14 3/4" x 4"	0.3	1	0.3	22°C ± 3°C
EMPTY SYSTEM WEIGHT (REF)					61.9	

UNLESS OTHERWISE SPECIFIED: DIMENSIONS ARE IN INCHES AND WEIGHTS ARE IN LBS.



SUPPRESSED TEMPERATURE GEL PACKS IN BLUE ARE FROZEN

PACK-OUT INSTRUCTIONS:

A. PLACE SIX GEL PACKS (2) INTO BOTTOM OF MOLDED SHIPPER BASE (1).

B. PLACE PRODUCT LOAD (3) ON TOP OF THE PREVIOUSLY PLACED GEL PACKS (2).

C. PLACE FOUR GEL PACKS (2) ON EACH OF THE FRONT & BACK, OF PRODUCT LOAD (3) (2 x 2). ALSO, PLACE EIGHT GEL PACKS (2) ON EACH OF THE LEFT & RIGHT OF THE PRODUCT LOAD (3) AS SHOWN IN THE DIAGRAM.

D. PLACE TWENTY FOUR GEL PACKS (2) ON TOP OF THE PRODUCT LOAD (3) AS SHOWN IN THE DIAGRAM (6 PER LAYER, 4 LAYERS HIGH).

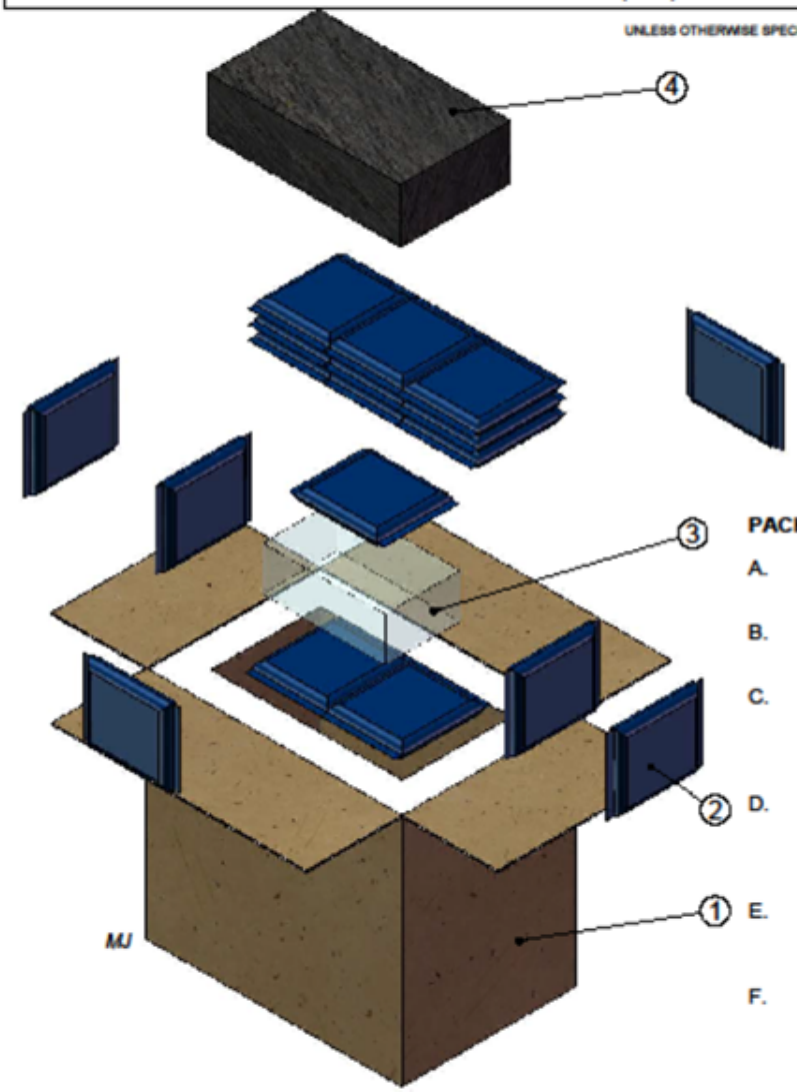
E. PLACE THE FOAM PLUG (4) ONTO TOP OF GEL PACKS, AND CLOSE AND SEAL OUTER CORRUGATE BOX (1).

SHIPPING SYSTEM OD	LENGTH	WIDTH	HEIGHT	VOLUME FT³	DIMENSIONAL WEIGHT *(FACTOR OF 195)*	44.5
	23.3	19.3	19.3	5.0		
PAYLOAD AREA	13.5	9.5	5.8	0.4		

Medium – Cold Weather Packing Protocol Diagrams

ITEM NO.	PART NUMBER / NAME	DESCRIPTION	UNIT WEIGHT REF.	QTY	TOTAL WEIGHT REF.	PRE-CONDITION (24HRS)
1	Med	POLYURETHANE SHIPPER - ID: 14" X 8" X 10" w/FOAM PLUG	6.6	1	6.6	22°C ± 3°C
2	Coolant	SUPPRESSED TEMPERATURE GEL PACKS	1.0	18	18.0	-25°C ± 3°C
3	PRODUCT LOAD Med	PRODUCT LOAD AREA - 9" x 5 1/2" x 3 1/4"	N/A	1	N/A	-20°C ± 4°C
4	FOAM PLUG, Med	FOAM PLUG, OD-18 3/4" x 14 3/4" x 4"	0.1	1	0.1	22°C ± 3°C
EMPTY SYSTEM WEIGHT (REF)					24.7	

UNLESS OTHERWISE SPECIFIED: DIMENSIONS ARE IN INCHES AND WEIGHTS ARE IN LBS.



SUPPRESSED TEMPERATURE GEL PACKS IN BLUE ARE FROZEN

PACK-OUT INSTRUCTIONS:

A. PLACE TWO GEL PACKS (2) INTO BOTTOM OF MOLDED SHIPPER BASE (1).

B. PLACE PRODUCT LOAD (3) ON TOP OF THE PREVIOUSLY PLACED GEL PACKS (2).

C. PLACE ONE GEL PACK (2) ON EACH OF THE FRONT, BACK & TOP OF THE PRODUCT LOAD (3) AS SHOWN IN THE DIAGRAM.

D. PLACE TWO GEL PACKS (2) ON EACH OF THE LEFT & RIGHT SIDE OF THE PRODUCT LOAD (3) AS SHOWN IN THE DIAGRAM.

E. PLACE NINE GEL PACKS (2) ON TOP OF THE PRODUCT LOAD (3) AS SHOWN IN THE DIAGRAM (3 x 3 HIGH).

F. PLACE FOAM PLUG (4) ONTO TOP OF GEL PACKS, AND CLOSE AND SEAL OUTER CORRUGATE BOX (1).

	LENGTH	WIDTH	HEIGHT	VOLUME FT³		
SHIPPING SYSTEM OD	18.8	12.8	17.3	2.4	DIMENSIONAL WEIGHT *(FACTOR OF 195)*	**21.3**
PAYLOAD AREA	9.0	5.5	3.25	0.1		

Moderate Weather Packing Protocol

- Moderate Weather Configuration is used when the ambient temperature at the **receiving site** is between 55°F and 77°F.
- Protocols are designed to keep temperature sensitive products requiring freezing temperatures between -10°C and -25°C within these temperature ranges during transportation, for a minimum of 72 hours.
- 16oz. and 32oz. Suppressed Temperature gel packs are used in all boxes for layering.
- Inert packing material (i.e. peanuts and paper) can be used as void space filler in the cargo area space (avoid bubble wrap).
- Coolant material must be placed in layers according to attached diagrams. Configurations use **all frozen gel packs**. (See moderate weather packing configuration diagrams.)
- Please note that **ONLY** the Medium, Large, and Extra Large containers can be used for this ambient temperature range.

Moderate Weather Packing Protocol Procedures

The Moderate Weather Packing Protocol is used whenever the ambient or outside temperature at the receiving site is between 55 degrees Fahrenheit and 77 degrees Fahrenheit. Begin the Moderate Weather packing protocol by:

o Placing a layer of frozen gel packs at the bottom of the box.

o Next item will be the product.

o Place frozen gel packs around the product's side(s) to fill in gap between product and the insulated walls of the box.

o This is followed by placing an activated temperature monitor inside the cargo area space. Activate the temperature monitor and adhere it to the underside of the cargo area space box lid, centered over the top of the product (avoid adhering the temperature monitor to the product directly)

o Follow with additional layers of frozen gel packs.

o Finally, insert the foam plug to seal the contents of the box.

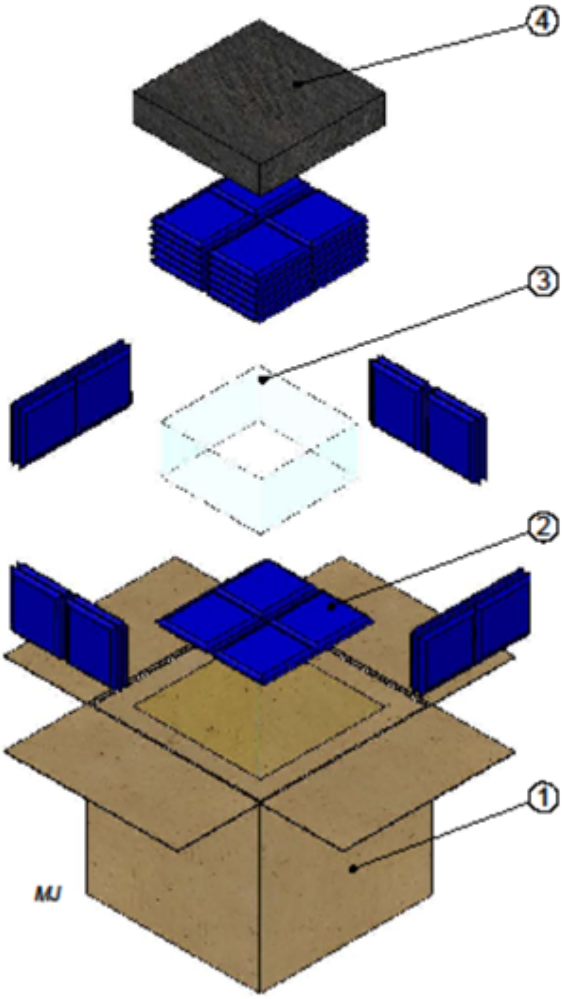
Notes:
o Follow procedures according to each protocol diagram of box used.

o To precondition the frozen gel packs, place them in a layer (no more than two high) inside a freezer running at -25°C for at least 24 hours prior use.

Extra Large – Moderate Weather Packing Protocol Diagrams

ITEM NO.	PRODUCT LOAD	DESCRIPTION	UNIT WEIGHT REF.	QTY	TOTAL WEIGHT REF.	PRE-CONDITION (24HRS)
1	XLg	POLYURETHANE SHIPPER - ID: 18 1/2" x 18 1/4" x 16 3/4" w/FOAM PLUG	15.8	1	15.8	22°C ± 3°C
2	Coolant	SUPPRESSED TEMPERATURE GEL PACKS	2.0	44	88.0	-25°C ± 3°C
3	PRODUCT LOAD XLg	PRODUCT LOAD AREA, 12 1/2" x 12 1/4" x 6 1/4"	N/A	1	N/A	-20°C ± 4°C
4	FOAM PLUG XLg	FOAM PLUG, OD-18 1/2" x 18 1/4" x 4"	0.1	1	0.1	22°C ± 3°C
EMPTY SYSTEM WEIGHT (REF).					103.9	

UNLESS OTHERWISE SPECIFIED: DIMENSIONS ARE IN INCHES AND WEIGHTS ARE IN LBS.



SUPPRESSED TEMPERATURE GEL PACKS IN BLUE ARE FROZEN

PACK-OUT INSTRUCTIONS:

A. PLACE FOUR GEL PACKS (2) INTO BOTTOM OF MOLDED SHIPPER BASE (1).

B. PLACE PRODUCT LOAD (3) ON TOP OF THE PREVIOUSLY PLACED GEL PACKS (2).

C. PLACE FOUR GEL PACKS (2) ON EACH OF THE FRONT, BACK, LEFT & RIGHT OF PRODUCT LOAD (3) AS SHOWN IN THE DIAGRAM (16 TOTAL).

D. PLACE TWENTY FOUR GEL PACKS (2) ON TOP OF THE PRODUCT LOAD (3) AS SHOWN IN THE DIAGRAM (4 PER LAYER, 6 LAYERS HIGH).

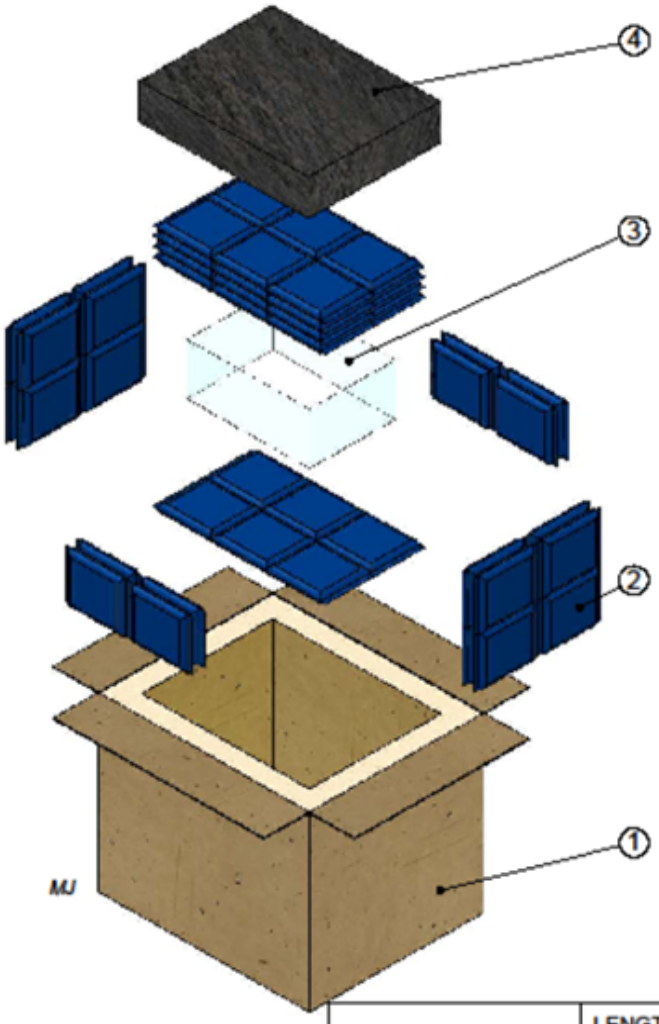
E. PLACE FOAM PLUG (4) ONTO THE TOP OF GEL PACKS, AND CLOSE AND SEAL OUTER CORRUGATE BOX (1).

	LENGTH	WIDTH	HEIGHT	VOLUME FT³		
SHIPPING SYSTEM OD	23.3	23.0	24.0	7.4	DIMENSIONAL WEIGHT *(FACTOR OF 195)*	65.1
PAYLOAD AREA	12.5	12.3	6.3	0.6		

Large – Moderate Weather Packing Protocol Diagrams

ITEM NO.	PART NUMBER / NAME	DESCRIPTION	UNIT WEIGHT REF.	QTY	TOTAL WEIGHT REF.	PRE-CONDITION (24HRS)
1	Lg	POLYURETHANE SHIPPER - ID: 18 1/2" x 14 1/2" x 12" w/ FOAM PLUG	7.6	1	7.6	22°C ± 3°C
2	Coolant	SUPPRESSED TEMPERATURE GEL PACKS	1.0	54	54.0	-25°C ± 3°C
3	PRODUCT LOAD Lg	PRODUCT LOAD AREA - 13 1/2" x 9 1/2" x 5 3/4"	N/A	1	N/A	-20°C ± 4°C
4	FOAM PLUG, Lg	FOAM, PLUG, OD=18 3/4" x 14 3/4" x 4"	0.3	1	0.3	22°C ± 3°C
EMPTY SYSTEM WEIGHT (REF)					61.9	

UNLESS OTHERWISE SPECIFIED: DIMENSIONS ARE IN INCHES AND WEIGHTS ARE IN LBS.



SUPPRESSED TEMPERATURE GEL PACKS
IN BLUE ARE FROZEN

PACK-OUT INSTRUCTIONS:

A. PLACE SIX GEL PACKS (2) INTO BOTTOM OF MOLDED SHIPPER BASE (1).

B. PLACE PRODUCT LOAD (3) ON TOP OF THE PREVIOUSLY PLACED GEL PACKS (2).

C. PLACE FOUR GEL PACKS (2) ON EACH OF THE FRONT & BACK, OF PRODUCT LOAD (3) (2 x 2). ALSO, PLACE EIGHT GEL PACKS (2) ON EACH OF THE LEFT & RIGHT OF THE PRODUCT LOAD (3) AS SHOWN IN THE DIAGRAM.

D. PLACE TWENTY FOUR GEL PACKS (2) ON TOP OF THE PRODUCT LOAD (3) AS SHOWN IN THE DIAGRAM (6 PER LAYER, 4 LAYERS HIGH).

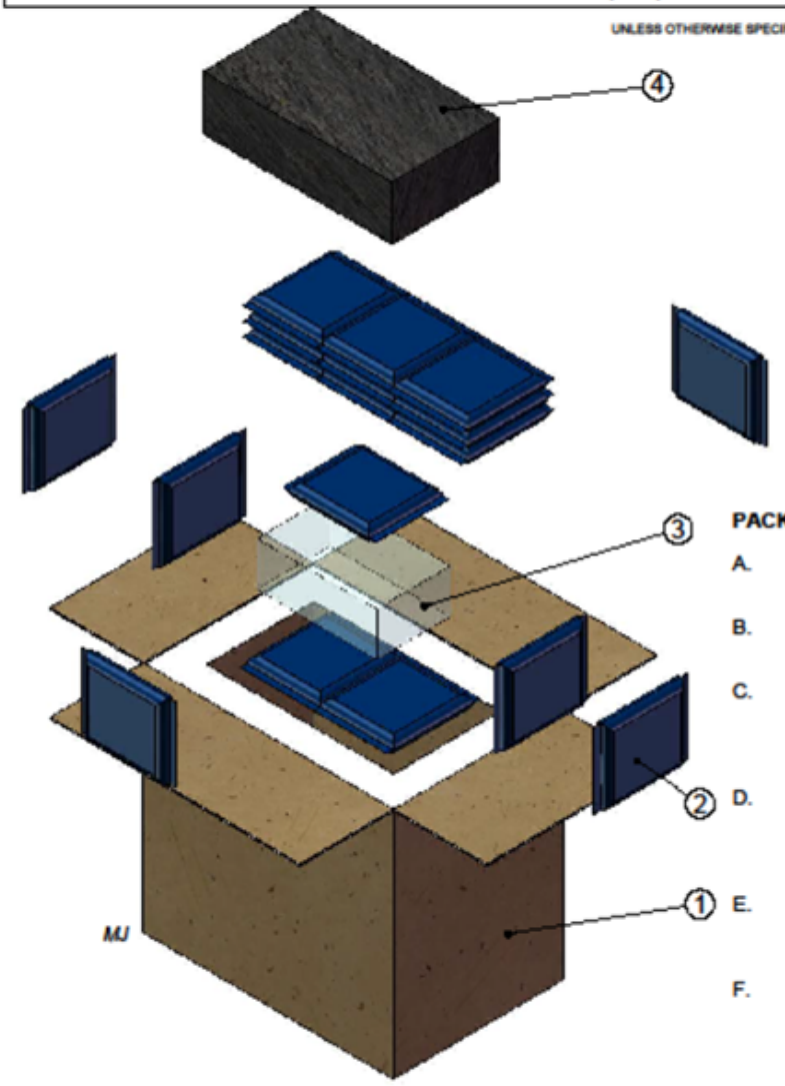
E. PLACE THE FOAM PLUG (4) ONTO TOP OF GEL PACKS, AND CLOSE AND SEAL OUTER CORRUGATE BOX (1).

	LENGTH	WIDTH	HEIGHT	VOLUME FT³		
SHIPPING SYSTEM OD	23.3	19.3	19.3	5.0	DIMENSIONAL WEIGHT *(FACTOR OF 195)*	**44.5**
PAYLOAD AREA	13.5	9.5	5.8	0.4		

Medium – Moderate Weather Packing Protocol Diagrams

ITEM NO.	PART NUMBER / NAME	DESCRIPTION	UNIT WEIGHT REF.	QTY	TOTAL WEIGHT REF.	PRE-CONDITION (24HRS)
1	Med	POLYURETHANE SHIPPER - ID: 14" X 8" X 10" w/FOAM PLUG	6.6	1	6.6	22°C ± 3°C
2	Coolant	SUPPRESSED TEMPERATURE GEL PACKS	1.0	18	18.0	-25°C ± 3°C
3	PRODUCT LOAD Med	PRODUCT LOAD AREA - 9" x 5 1/2" x 3 1/4"	N/A	1	N/A	-20°C ± 4°C
4	FOAM PLUG, Med	FOAM PLUG, OD-18 3/4" x 14 3/4" x 4"	0.1	1	0.1	22°C ± 3°C
EMPTY SYSTEM WEIGHT (REF)					24.7	

UNLESS OTHERWISE SPECIFIED: DIMENSIONS ARE IN INCHES AND WEIGHTS ARE IN LBS.



SUPPRESSED TEMPERATURE GEL PACKS IN BLUE ARE FROZEN

PACK-OUT INSTRUCTIONS:

A. PLACE TWO GEL PACKS (2) INTO BOTTOM OF MOLDED SHIPPER BASE (1).

B. PLACE PRODUCT LOAD (3) ON TOP OF THE PREVIOUSLY PLACED GEL PACKS (2).

C. PLACE ONE GEL PACK (2) ON EACH OF THE FRONT, BACK & TOP OF THE PRODUCT LOAD (3) AS SHOWN IN THE DIAGRAM.

D. PLACE TWO GEL PACKS (2) ON EACH OF THE LEFT & RIGHT SIDE OF THE PRODUCT LOAD (3) AS SHOWN IN THE DIAGRAM.

E. PLACE NINE GEL PACKS (2) ON TOP OF THE PRODUCT LOAD (3) AS SHOWN IN THE DIAGRAM (3 x 3 HIGH).

F. PLACE FOAM PLUG (4) ONTO TOP OF GEL PACKS, AND CLOSE AND SEAL OUTER CORRUGATE BOX (1).

SHIPPING SYSTEM OD	LENGTH	WIDTH	HEIGHT	VOLUME FT³	DIMENSIONAL WEIGHT *(FACTOR OF 195)*	**21.3**
	18.8	12.8	17.3	2.4		
PAYLOAD AREA	9.0	5.5	3.25	0.1		

Warm Weather Packing Protocol

- Warm Weather Configuration is used when the ambient temperature **at the receiving site** is consistently above 77°F.
- Protocols are designed to keep temperature sensitive products requiring freezing temperatures between -10°C and -25 C within these temperature ranges during transportation, for a minimum of 72 hours.
- 16oz. and 32oz. Suppressed Temperature gel packs are used in all boxes for layering.
- Inert packing material (i.e. peanuts and paper) can be used as void space filler in the cargo area space (avoid bubble wrap).
- Coolant material must be placed in layers according to attached diagrams. Configurations use **all frozen gel packs** (See warm weather packing configuration diagrams.)
- Please note that **ONLY** the Large and Extra Large containers can be used for this ambient temperature range.

Warm Weather Packing Protocol Procedures

The Warm Weather Packing Protocol is used whenever the ambient or outside temperature at the receiving site is consistently above 77 degrees Fahrenheit. Begin the Warm Weather packing protocol by:

o Placing a layer of frozen gel packs at the bottom of the box.

o Next item will be the product.

o Place frozen gel packs around the product's side(s) to fill in gap between product and the insulated walls of the box.

o This is followed by placing an activated temperature monitor inside the cargo area space. Activate the temperature monitor and adhere it to the underside of the cargo area space box lid, centered over the top of the product (avoid adhering the temperature monitor to the product directly)

o Follow with additional layers of frozen gel packs

o Finally, insert the foam plug to seal the contents of the box.

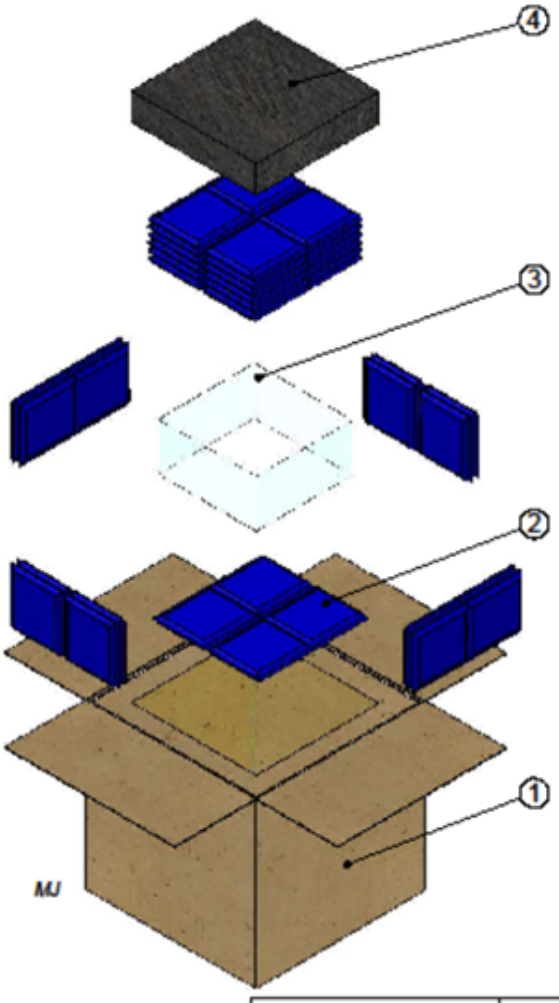
Notes:
o Follow procedures according to each protocol diagram of box used.

o To precondition the frozen gel packs, place them in a layer (no more than two high) inside a freezer running at -25°C for at least 24 hours prior use.

Extra Large – Warm Weather Packing Protocol Diagrams

ITEM NO.	PRODUCT LOAD	DESCRIPTION	UNIT WEIGHT REF.	QTY	TOTAL WEIGHT REF.	PRE-CONDITION (24HRS)
1	XLg	POLYURETHANE SHIPPER - ID: 18 1/2" x 18 1/4" x 16 3/4" w/FOAM PLUG	15.8	1	15.8	22°C ± 3°C
2	Coolant	SUPPRESSED TEMPERATURE GEL PACKS	2.0	44	88.0	-25°C ± 3°C
3	PRODUCT LOAD XLg	PRODUCT LOAD AREA, 12 1/2" x 12 1/4" x 6 1/4"	N/A	1	N/A	-20°C ± 4°C
4	FOAM PLUG XLg	FOAM PLUG, OD-18 1/2" x 18 1/4" x 4"	0.1	1	0.1	22°C ± 3°C
EMPTY SYSTEM WEIGHT (REF).					103.9	

UNLESS OTHERWISE SPECIFIED: DIMENSIONS ARE IN INCHES AND WEIGHTS ARE IN LBS.



SUPPRESSED TEMPERATURE GEL PACKS
IN BLUE ARE FROZEN

PACK-OUT INSTRUCTIONS:

A. PLACE FOUR GEL PACKS (2) INTO BOTTOM OF MOLDED SHIPPER BASE (1).

B. PLACE PRODUCT LOAD (3) ON TOP OF THE PREVIOUSLY PLACED GEL PACKS (2).

C. PLACE FOUR GEL PACKS (2) ON EACH OF THE FRONT, BACK, LEFT & RIGHT OF PRODUCT LOAD (3) AS SHOWN IN THE DIAGRAM (16 TOTAL).

D. PLACE TWENTY FOUR GEL PACKS (2) ON TOP OF THE PRODUCT LOAD (3) AS SHOWN IN THE DIAGRAM (4 PER LAYER, 6 LAYERS HIGH).

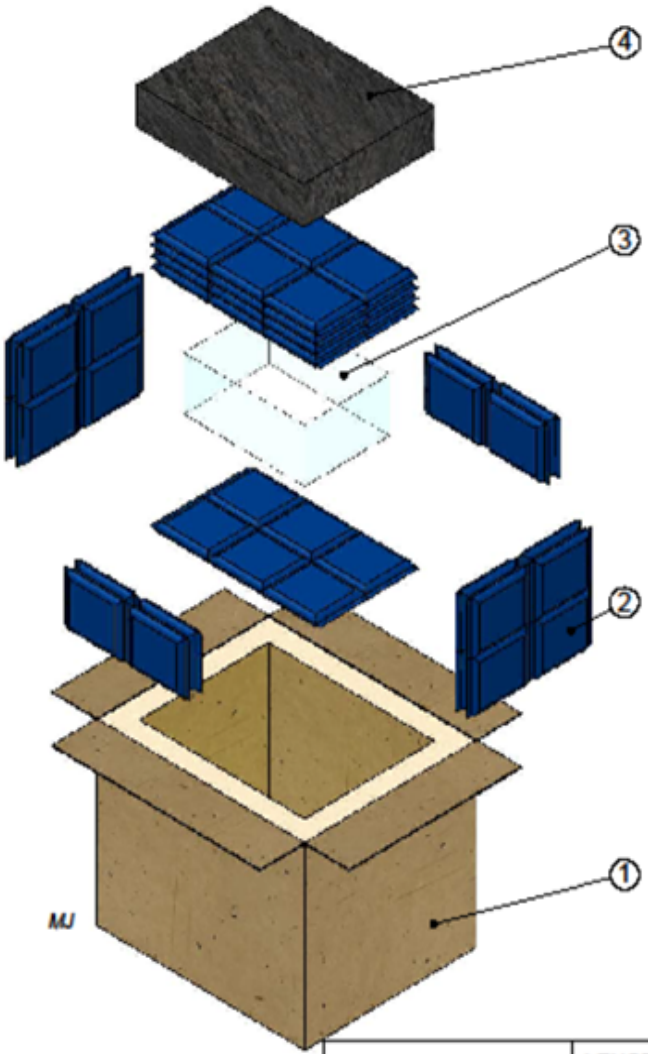
E. PLACE FOAM PLUG (4) ONTO THE TOP OF GEL PACKS, AND CLOSE AND SEAL OUTER CORRUGATE BOX (1).

SHIPPING SYSTEM OD	LENGTH	WIDTH	HEIGHT	VOLUME FT³	DIMENSIONAL WEIGHT *(FACTOR OF 195)*	65.1
	23.3	23.0	24.0	7.4		
PAYLOAD AREA	12.5	12.3	6.3	0.6		

Large – Warm Weather Packing Protocol Diagrams

ITEM NO.	PART NUMBER / NAME	DESCRIPTION	UNIT WEIGHT REF.	QTY	TOTAL WEIGHT REF.	PRE-CONDITION (24HRS)
1	Lg	POLYURETHANE SHIPPER - ID: 18 1/2" x 14 1/2" x 12" w/ FOAM PLUG	7.6	1	7.6	22°C ± 3°C
2	Coolant	SUPPRESSED TEMPERATURE GEL PACKS	1.0	54	54.0	-25°C ± 3°C
3	PRODUCT LOAD Lg	PRODUCT LOAD AREA - 13 1/2" x 9 1/2" x 5 3/4"	N/A	1	N/A	-20°C ± 4°C
4	FOAM PLUG, Lg	FOAM, PLUG, OD=18 3/4" x 14 3/4" x 4"	0.3	1	0.3	22°C ± 3°C
EMPTY SYSTEM WEIGHT (REF)					61.9	

UNLESS OTHERWISE SPECIFIED: DIMENSIONS ARE IN INCHES AND WEIGHTS ARE IN LBS.



SUPPRESSED TEMPERATURE GEL PACKS IN BLUE ARE FROZEN

PACK-OUT INSTRUCTIONS:

A. PLACE SIX GEL PACKS (2) INTO BOTTOM OF MOLDED SHIPPER BASE (1).

B. PLACE PRODUCT LOAD (3) ON TOP OF THE PREVIOUSLY PLACED GEL PACKS (2).

C. PLACE FOUR GEL PACKS (2) ON EACH OF THE FRONT & BACK, OF PRODUCT LOAD (3) (2 x 2). ALSO, PLACE EIGHT GEL PACKS (2) ON EACH OF THE LEFT & RIGHT OF THE PRODUCT LOAD (3) AS SHOWN IN THE DIAGRAM.

D. PLACE TWENTY FOUR GEL PACKS (2) ON TOP OF THE PRODUCT LOAD (3) AS SHOWN IN THE DIAGRAM (6 PER LAYER, 4 LAYERS HIGH).

E. PLACE THE FOAM PLUG (4) ONTO TOP OF GEL PACKS, AND CLOSE AND SEAL OUTER CORRUGATE BOX (1).

	LENGTH	WIDTH	HEIGHT	VOLUME FT³		
SHIPPING SYSTEM OD	23.3	19.3	19.3	5.0	DIMENSIONAL WEIGHT *(FACTOR OF 195)*	**44.5**
PAYLOAD AREA	13.5	9.5	5.8	0.4		

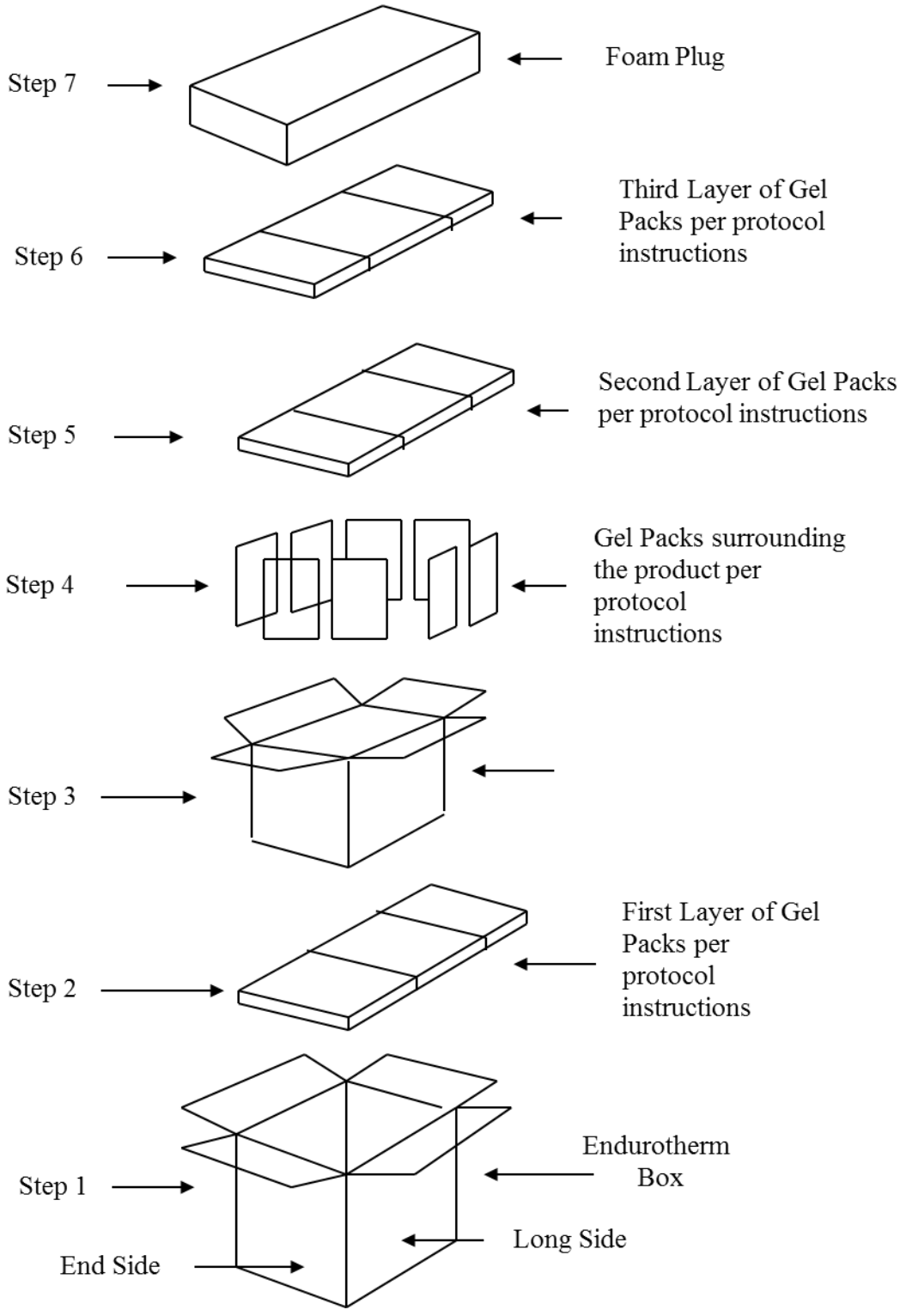
Packaging Protocols for Temperature Sensitive Medical Products Requiring Storage and Transportation Temperatures Between -20ºC and 8ºC (-4ºF and 46ºF)

IMPORTANT NOTICE!!

DD Forms 1502/1502-1/1502-2 & 1502N-1/1502-1N/1502-2N <u>SHALL NOT BE USED</u> with these protocols.

Box Packing Steps

The packing or layering of the boxes is the same in principle for all four sizes (extra large, large, medium and small).



Packing Protocol

- Protocols are designed to keep temperature sensitive products requiring temperatures between -20°C and 8°C within these temperature ranges, year-round, during transportation, for a minimum of 72 hours.
- 48oz. and 24oz. refrigerant gel packs are used in all boxes for layering and void space filler.
- Coolant material must be placed in layers according to attached diagrams. **All configurations only use frozen gel packs** (see packing configuration diagrams).
- Please note that this is a Universal Pack Out that **can be used year-round, regardless of the ambient temperature at the destination.**

Packing Protocol Procedures

Begin the packing protocol by:

o Placing a layer of frozen gel packs at the bottom of the box.

o Next item will be the product.

o Place frozen gel packs around the product's side(s) to fill in gap between product and the insulated walls of the box.

o This is followed by placing an activated temperature monitor inside the cargo area space. Activate the temperature monitor and adhere it to the underside of the cargo area space box lid, centered over the top of the product (avoid adhering the temperature monitor to the product directly)

o Follow with another layer of frozen gel packs.

o Add a final layer of frozen gel packs above the previous layer.

o Finally, insert the foam plug to seal the contents of the box.

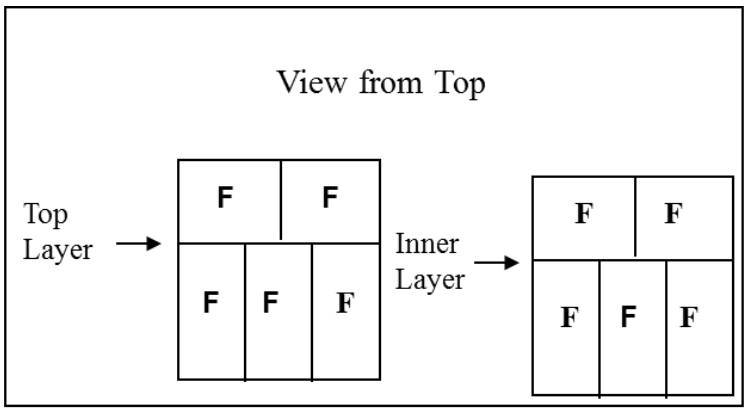
Notes:

o Follow procedures according to each protocol diagram of box used.

o To precondition the Frozen gel packs, place them in a layer (no more than two high) inside a freezer running between -17°C and -20°C for at least 24 hours prior to use (lay them flat to ensure they maintain their original shape once they are frozen) .

Extra-Large Packing Protocol Diagrams

Total amount of frozen Gel Packs = 27
Approximate Weight:
Max load = 145 lbs
Min load = 120 lbs



Layer 3:

5 Large Frozen Gel Packs (48 oz. each)

Foam Plug

Layer 2:

5 Large Frozen Gel Packs (48 oz. each)

Temperature Monitor

Cargo area space in cubic inches is:
(Product)
18" L x 14 1/2" W x 12" H

Use a total of 12 Large Frozen Gel Packs (6 on each long side 48 oz. Each)

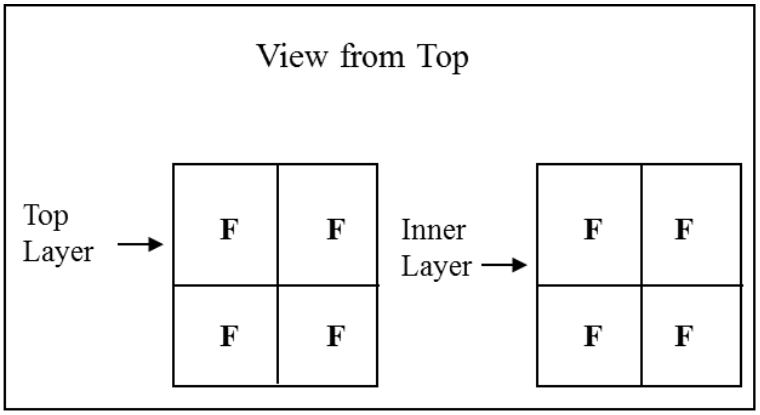
Cargo area touches the two ends only, other sides are filled in with Gel packs .

Layer 1: 5 Large Frozen Gel Packs (48 oz. each)

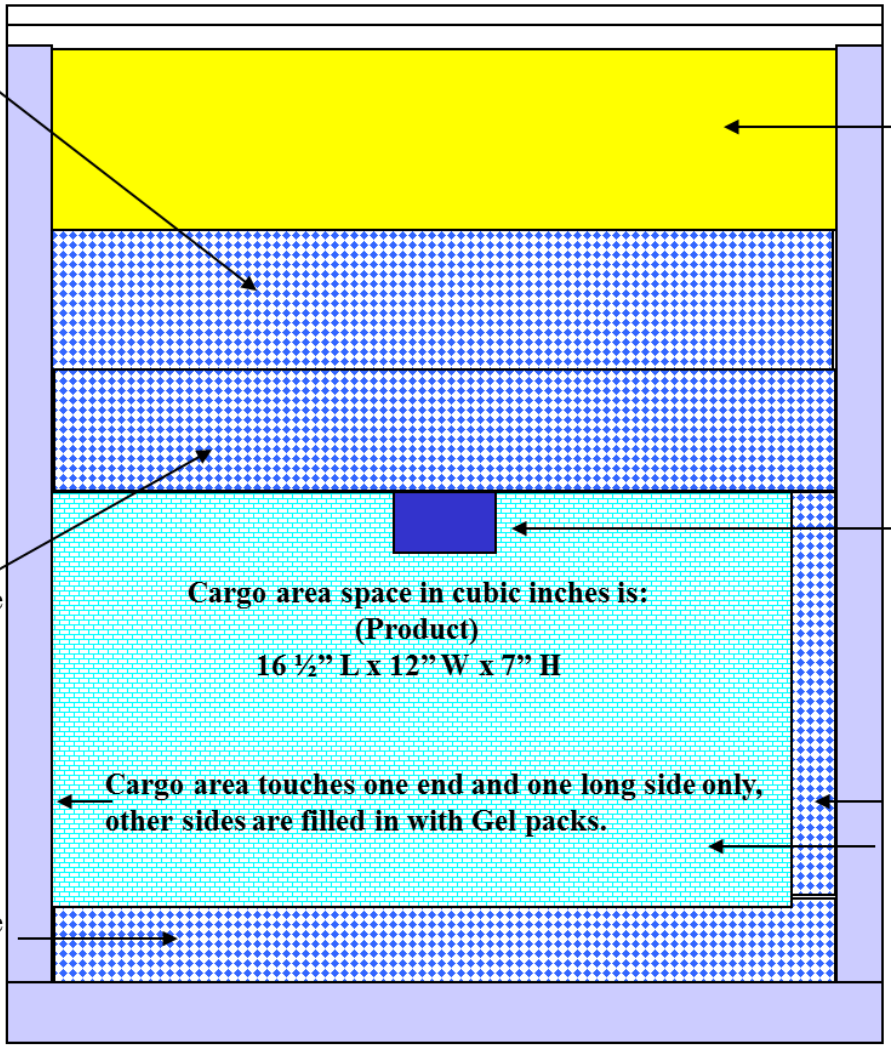
Side View

Large Packing Protocol Diagrams

Total amount of frozen Gel Packs = 17
Approximate Weight:
Max load = 75 lbs
Min load = 50 lbs



Layer 3:
4 Large Frozen Gel Packs (48 oz. each)



Layer 2: 4 Large Frozen Gel Packs (48 oz. each)

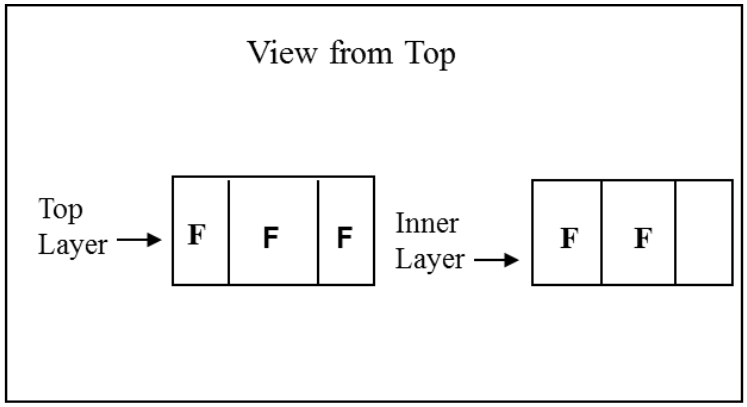
Use a total of 5 Large Frozen Gel Packs (2 in one end and 3 in one long side 48 oz each)

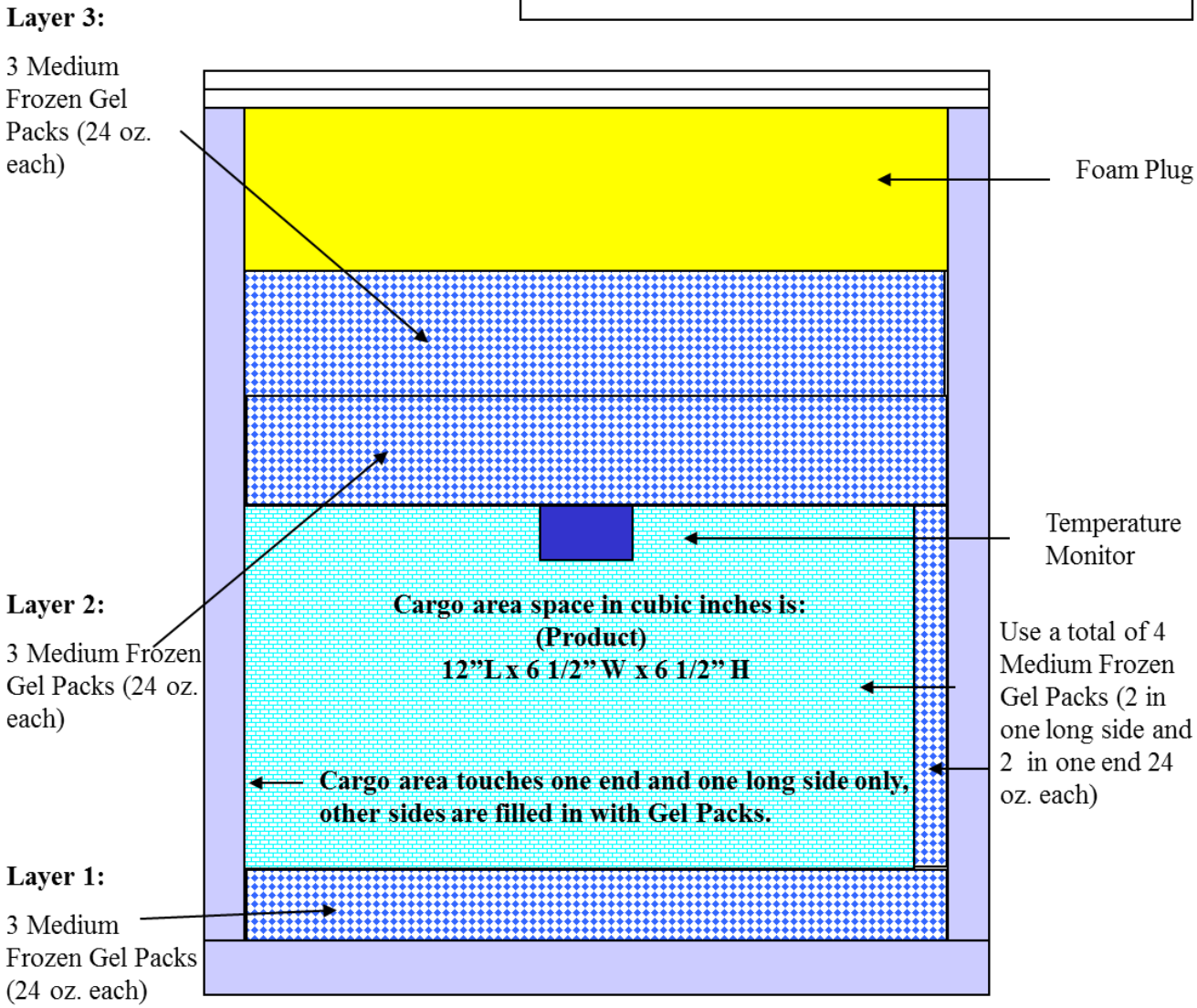
Layer 1: 4 Large Frozen Gel Packs (48 oz. each)

Side View

Medium Packing Protocol Diagrams

Total amount of frozen Gel Packs = 13
Approximate Weight:
Max load = 40 lbs
Min load = 30 lbs

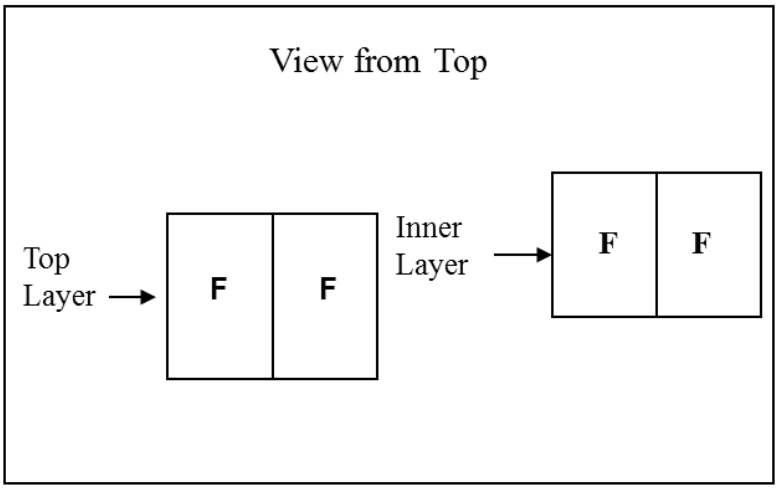




Side View

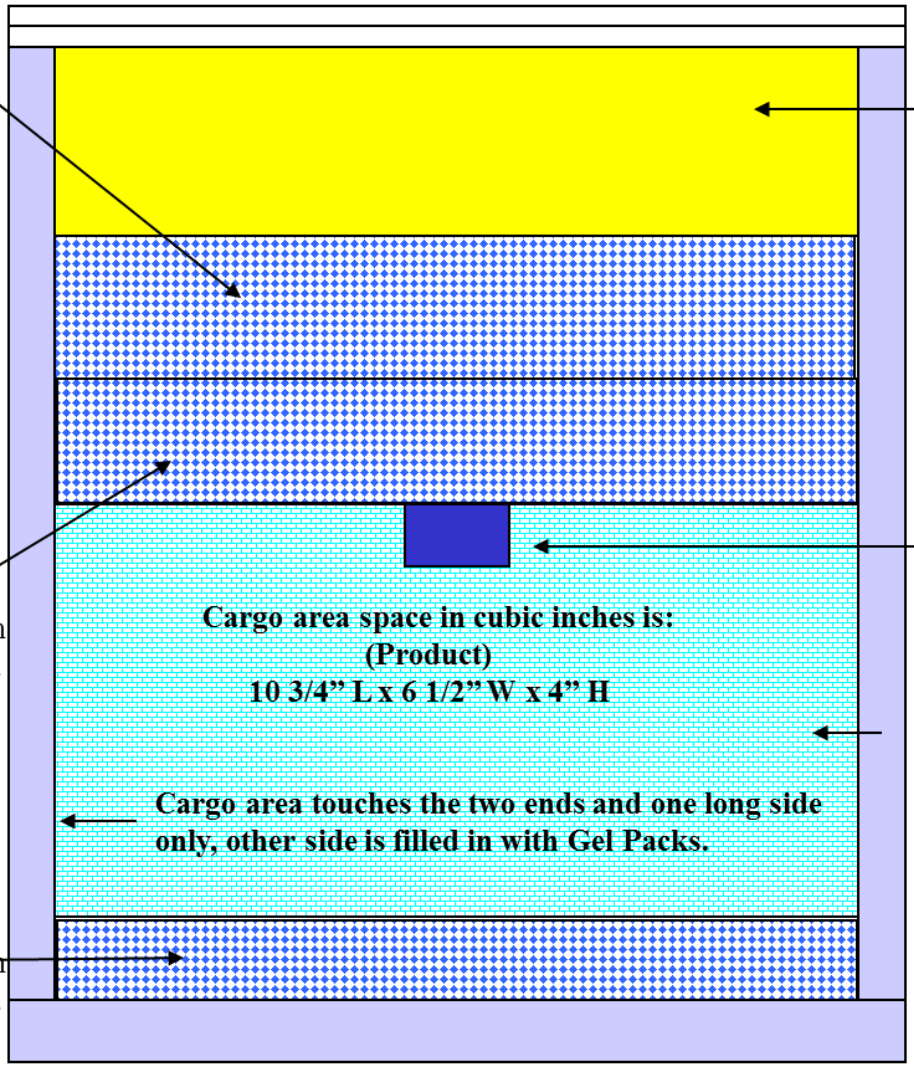
Small Packing Protocol Diagrams

Total amount of frozen Gel Packs = 8
Approximate Weight:
Max load = 20 lbs
Min load = 15 lbs



Layer 3:

2 Medium Frozen Gel Packs (24 oz. each)



Layer 2:

2 Medium Frozen Gel Packs (24 oz. each)

Layer 1:

2 Medium Frozen Gel Packs (24 oz. each)

Side View

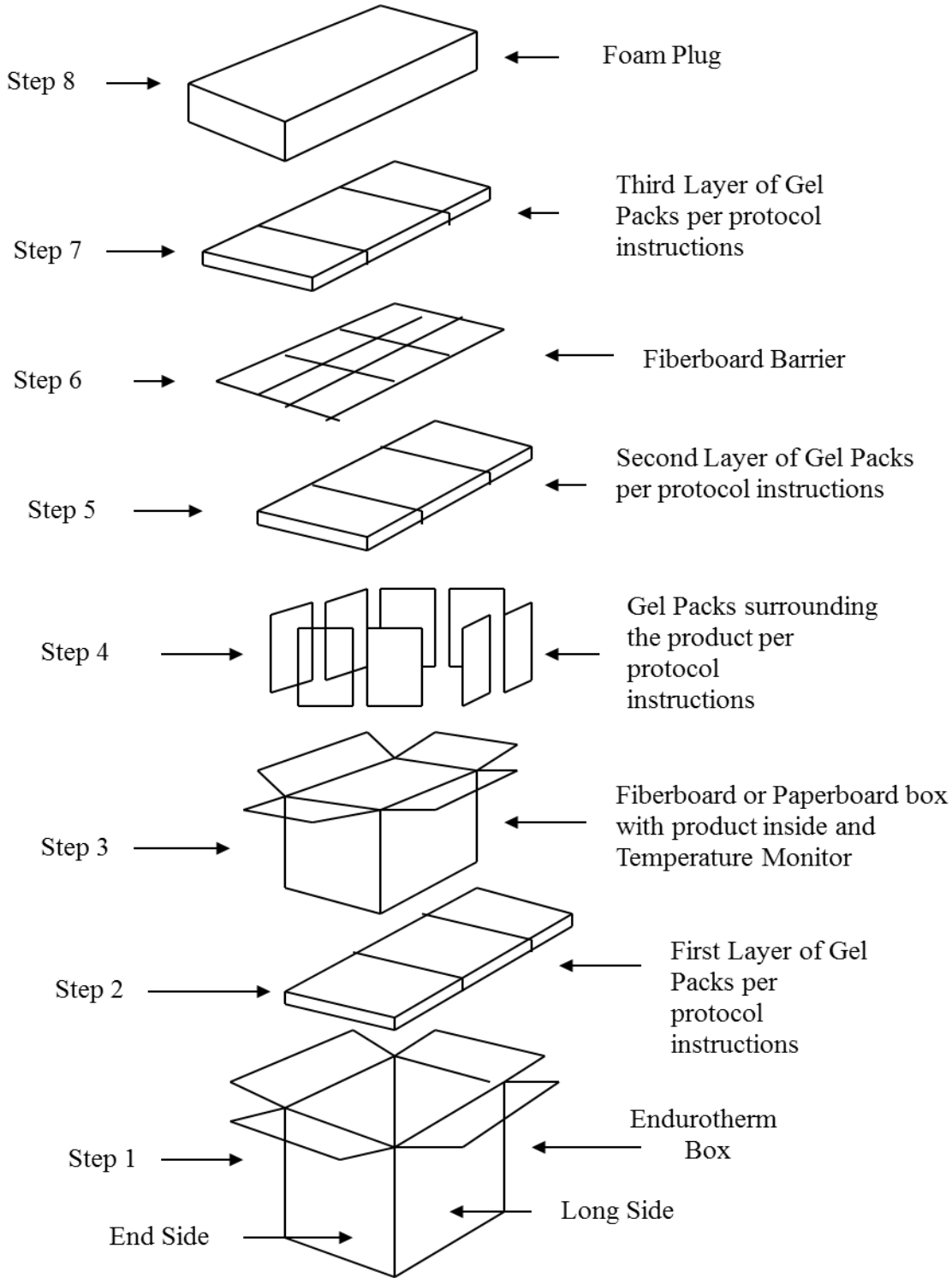
Packaging Protocols for Temperature Sensitive Medical Products Requiring Storage and Transportation Temperatures between 2ºC and 8ºC (36ºF and 46ºF)

IMPORTANT NOTICE!!

DD Forms 1502/1502-1/1502-2 & 1502N/1502-1N/1502-2N SHALL NOT BE USED with these protocols.

Endurotherm Box Packing Steps

The packing or layering of the Endurotherm boxes is the same in principle for all three sizes (large, medium and small).



Cold Weather Packing Protocol

- Cold Weather Configuration is used when the ambient temperature at the **receiving site** is consistently below 55°F.
- Protocols are designed to keep temperature sensitive products requiring refrigeration temperatures between 2°C and 8°C within these temperature ranges during transportation, for a minimum of 72 hours.
- 48oz. and 24oz. refrigerant gel packs are used in all boxes for layering.
- Inert packing material (i.e. peanuts and paper) can be used as void space filler in the cargo area space (avoid bubble wrap).
- Coolant material must be placed in layers according to attached diagrams. Cold Weather configurations only use refrigerated gel packs. (See cold weather packing configuration diagrams.)

Cold Weather Packing Protocol Procedures

The Cold Weather Packing Protocol is used whenever the ambient or outside temperature at the receiving site consistently remains below 55 degrees Fahrenheit. Begin the Cold Weather packing protocol by:

o Placing a layer of refrigerated gel packs at the bottom of the box.

o Next item will be the product.

o Place gel packs around the product's side(s) to fill in gap between product and the insulated walls of the box.

o This is followed by placing an activated temperature monitor inside the cargo area space. Activate the temperature monitor and adhere it to the underside of the cargo area space box lid, centered over the top of the product (avoid adhering the temperature monitor to the product directly)

o Follow with another layer of refrigerated gel packs.

o Above the second layer of refrigerated gel packs insert a fiberboard barrier.

o Add a final layer of refrigerated gel packs above the fiberboard barrier.

o Finally, insert the foam plug to seal the contents of the box.

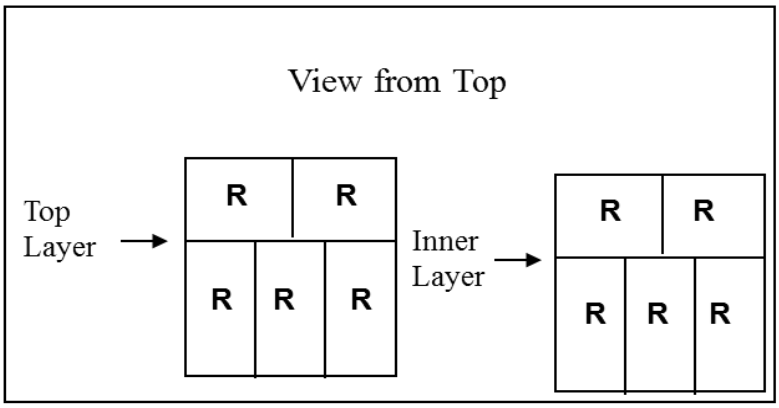
Notes:

o Follow procedures according to each protocol diagram of box used.

o To precondition the gel packs, place them in a layer (no more than two high) inside a refrigerator running at 4° C for at least 24 hours prior use.

Extra Large – Cold Weather Packing Protocol Diagrams

Total amount of refrigerated Gel Packs = 27
Approximate Weight:
Max load = 145 lbs
Min load = 120 lbs



Layer 3:

5 Large Refrigerated Gel Packs (48 oz. each)

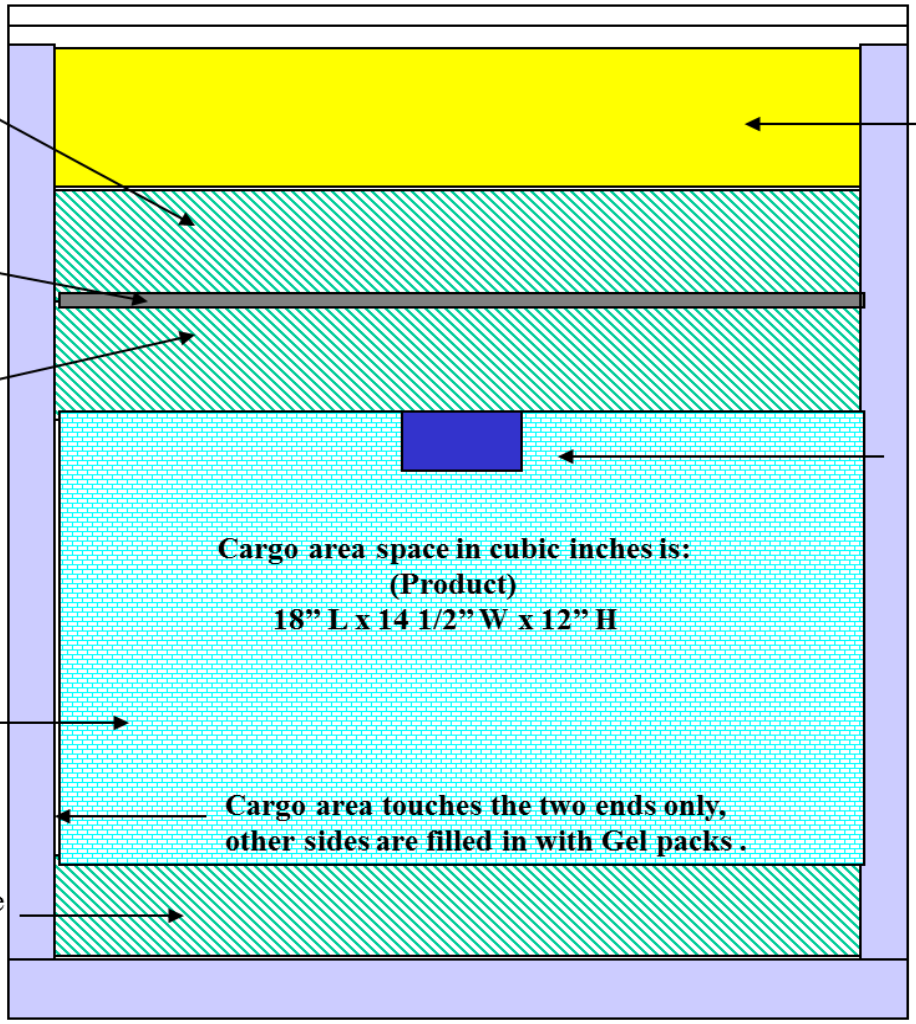
Fiberboard Barrier

Layer 2:

5 Large Refrigerated Gel Packs (48 oz. each)

Use a total of 12 Large Refrigerated Gel Packs (6 on each long side 48 oz. Each)

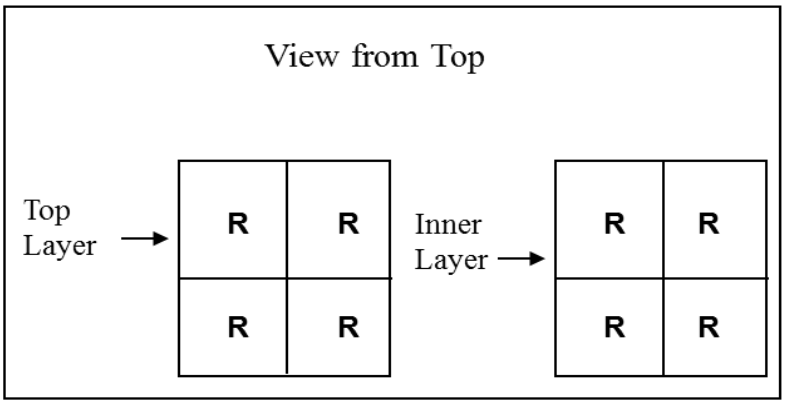
Layer 1: 5 Large Refrigerated Gel Packs (48 oz. each)



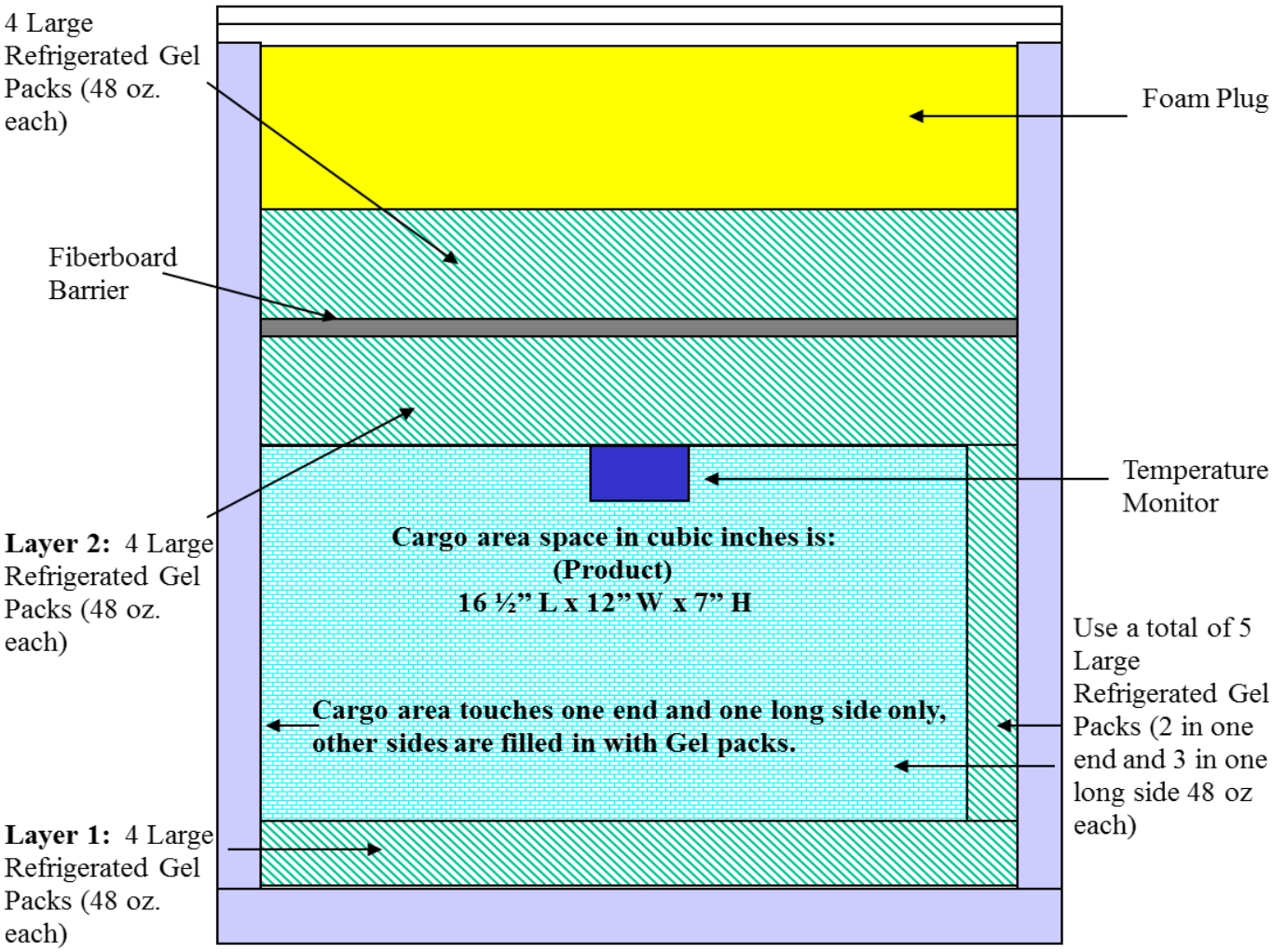
Side View

Large – Cold Weather Packing Protocol Diagrams

Total amount of refrigerated Gel Packs = 17
Approximate Weight:
Max load = 75 lbs
Min load = 50 lbs



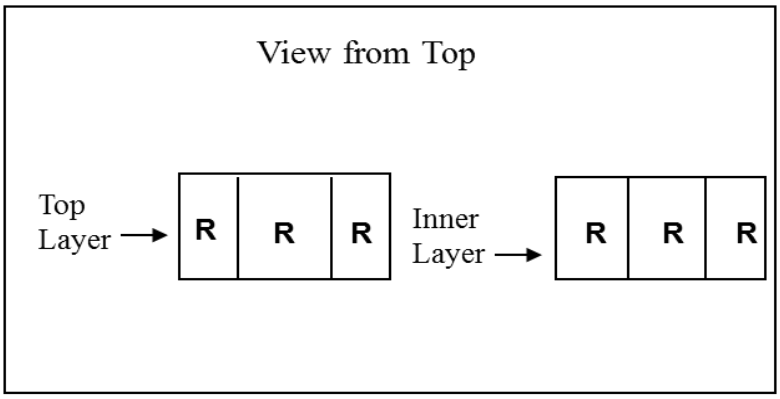
Layer 3:

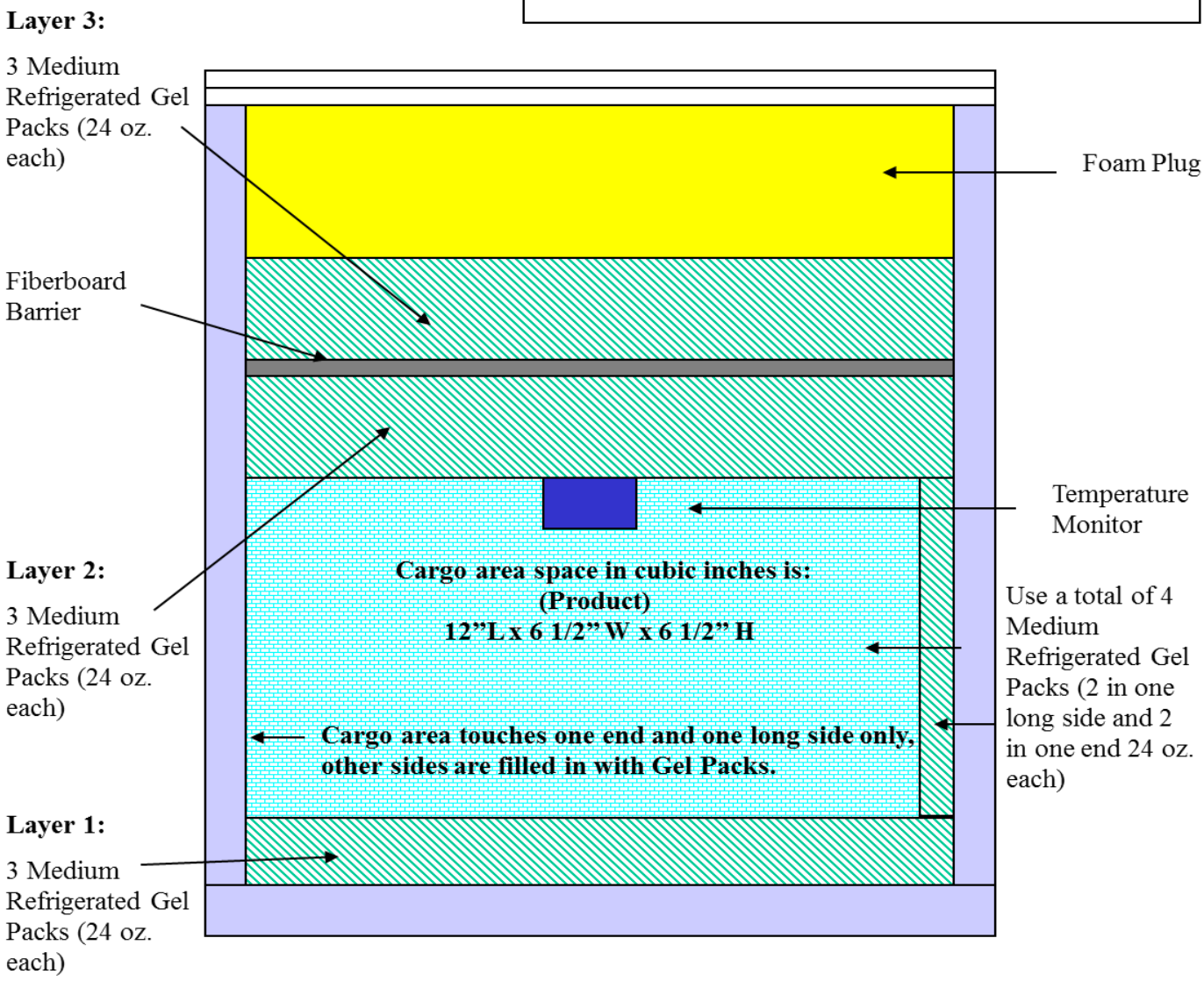


Side View

Medium – Cold Weather Packing Protocol Diagrams

Total amount of refrigerated Gel Packs = 13
Approximate Weight:
Max load = 40 lbs
Min load = 30 lbs

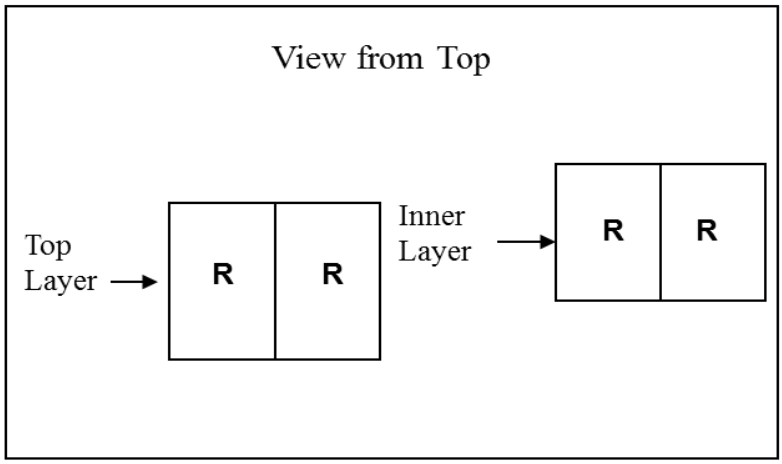




Side View

Small – Cold Weather Packing Protocol Diagrams

Total amount of refrigerated Gel Packs = 8
Approximate Weight:
Max load = 20 lbs
Min load = 15 lbs



Layer 3:

2 Medium Refrigerated Gel Packs (24 oz. each)

Foam Plug

Fiberboard Barrier

Temperature Monitor

Layer 2:

2 Medium Refrigerated Gel Packs (24 oz. each)

Cargo area space in cubic inches is:
(Product)
10 3/4" L x 6 1/2" W x 4" H

2 Medium Refrigerated Gel Packs in one long side only (24 oz each).

Cargo area touches the two ends and one long side only, other side is filled in with Gel Packs.

Layer 1:

2 Medium Refrigerated Gel Packs (24 oz. each)

Side View

Moderate Weather Packing Protocol

- Moderate Weather Configuration is used when the ambient temperature at the **receiving site** is between 55°F and 77°F.
- Protocols are designed to keep temperature sensitive products requiring refrigeration temperatures between 2°C and 8°C within these temperature ranges during transportation, for a minimum of 72 hours.
- 48oz. and 24oz. refrigerant gel packs are used in all boxes for layering and fill in.
- Inert packing material (i.e. peanuts and paper) can be used as void space filler in the cargo area space (avoid bubble wrap).
- Coolant material must be placed in layers according to attached diagrams. **Frozen gel packs are always above the Fiberboard Barrier**. (See moderate weather packing configuration diagrams.)

Moderate Weather Packing Protocol Procedures

The Moderate Weather Packing Protocol is used whenever the ambient or outside temperature at the receiving site is between 55 degrees Fahrenheit and 77 degrees Fahrenheit. Begin the Moderate Weather packing protocol by:

o Placing a layer of refrigerated gel packs at the bottom of the box.

o Next item will be the product.

o Place gel packs around the product's side(s) to fill in gap between product and the insulated walls of the box.

o This is followed by placing an activated temperature monitor inside the cargo area space. Activate the temperature monitor and adhere it to the underside of the cargo area space box lid, centered over the top of the product (avoid adhering the temperature monitor to the product directly)

o Follow with another layer of refrigerated gel packs.

o Above the second layer of refrigerated gel packs insert a fiberboard barrier.

o Add a final layer of a combination of refrigerated and frozen gel packs above the fiberboard barrier.

o Finally, insert the foam plug to seal the contents of the box.

Notes:

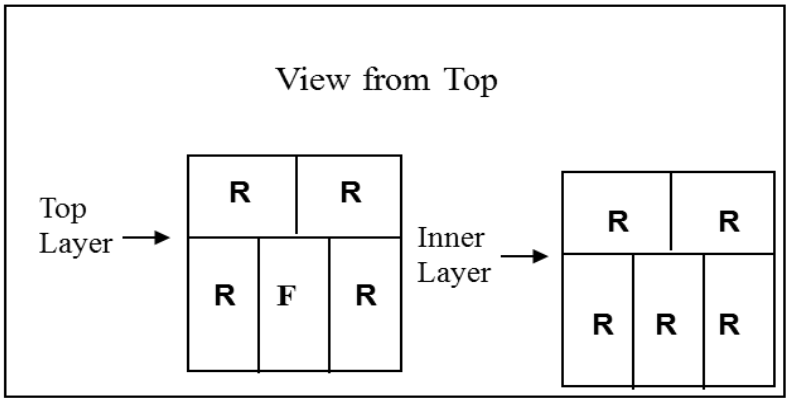
o Follow procedures according to each protocol diagram of box used.

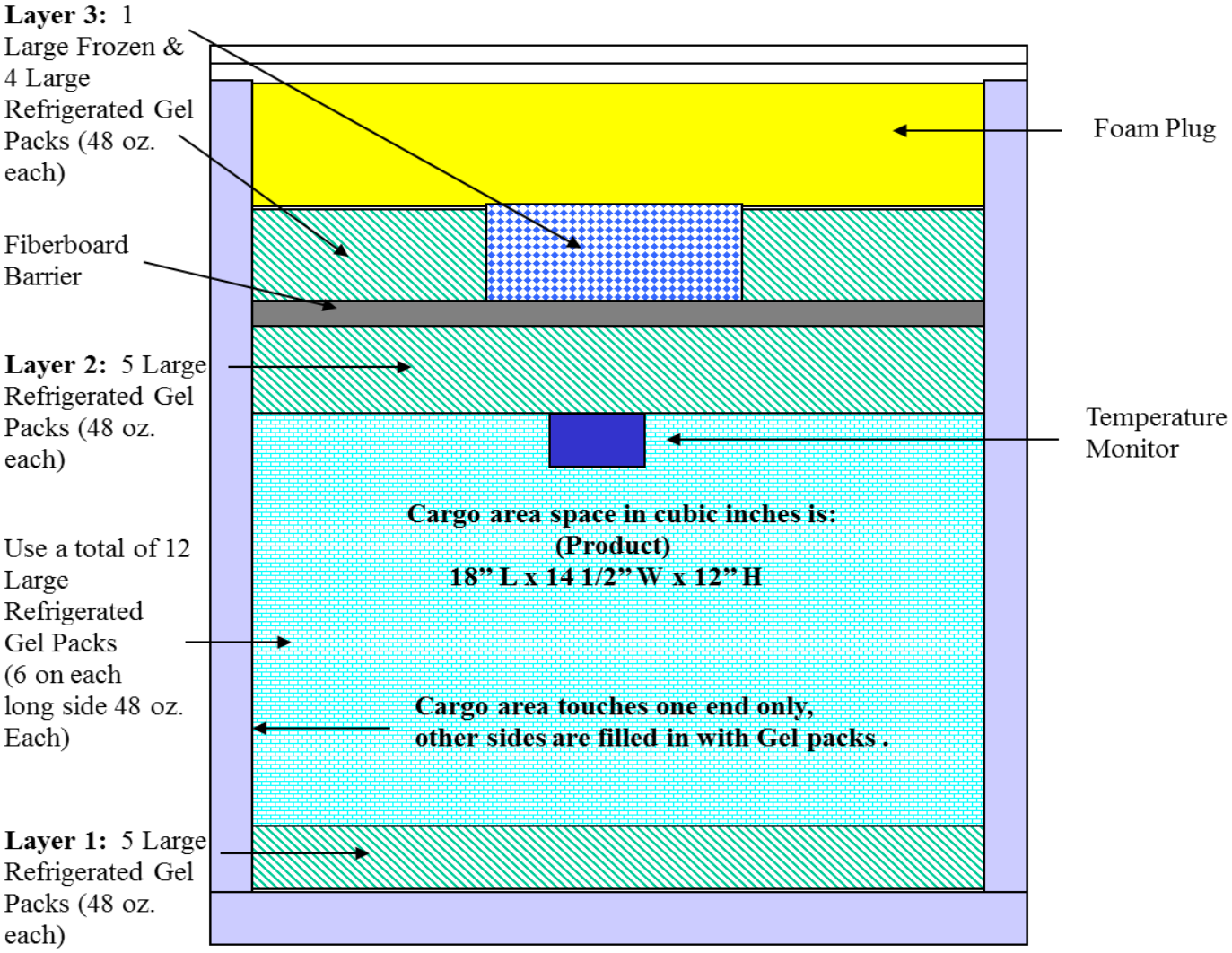
o To precondition the Refrigerated gel packs, place them in a layer (no more than two high) inside a refrigerator running at 4°C for at least 24 hours prior use.

o To precondition the Frozen gel packs, place them in a layer (no more than two high) inside a freezer running between -17°C and -20°C for at least 24 hours prior to use (lay them flat to ensure they maintain their original shape once they are frozen) .

Extra Large – Moderate Weather Packing Protocol Diagrams

Total amount of Gel Packs:
Refrigerated = 26
Frozen = 1
Approximate Weight:
Max load = 145 lbs
Min load = 120 lbs

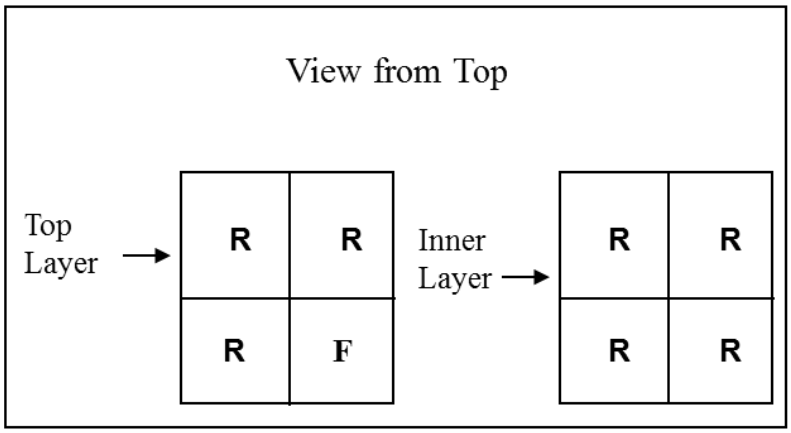


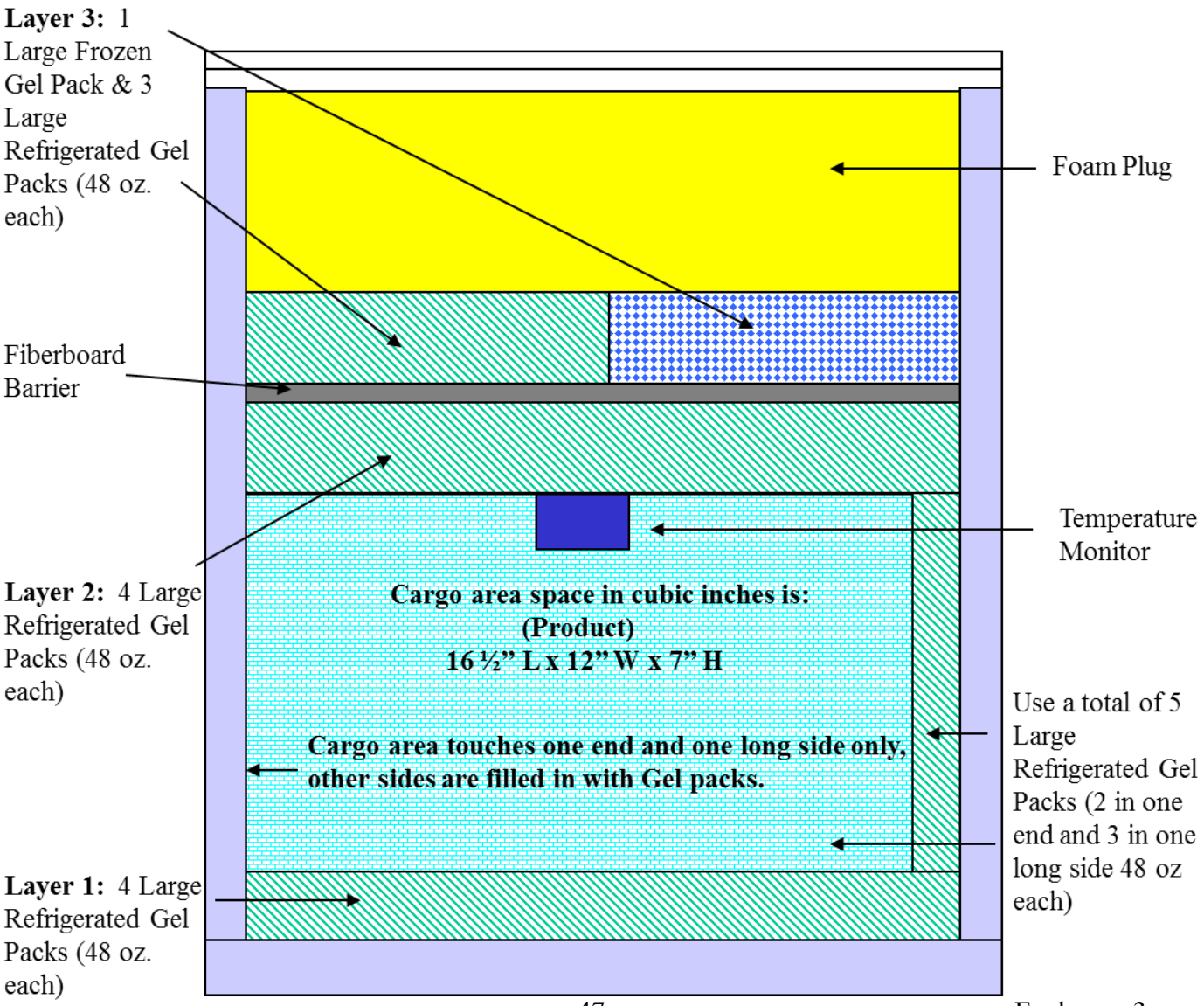


Side View

Large – Moderate Weather Packing Protocol Diagrams

Total amount of Gel Packs:
Refrigerated = 16
Frozen = 1
Approximate Weight:
Max load = 75 lbs
Min load = 50 lbs

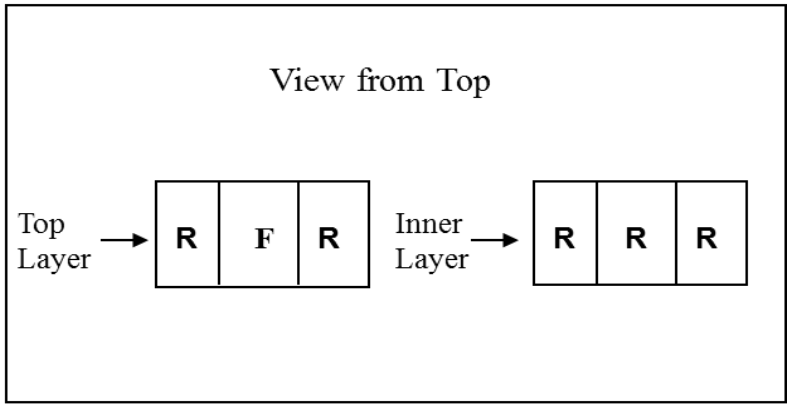


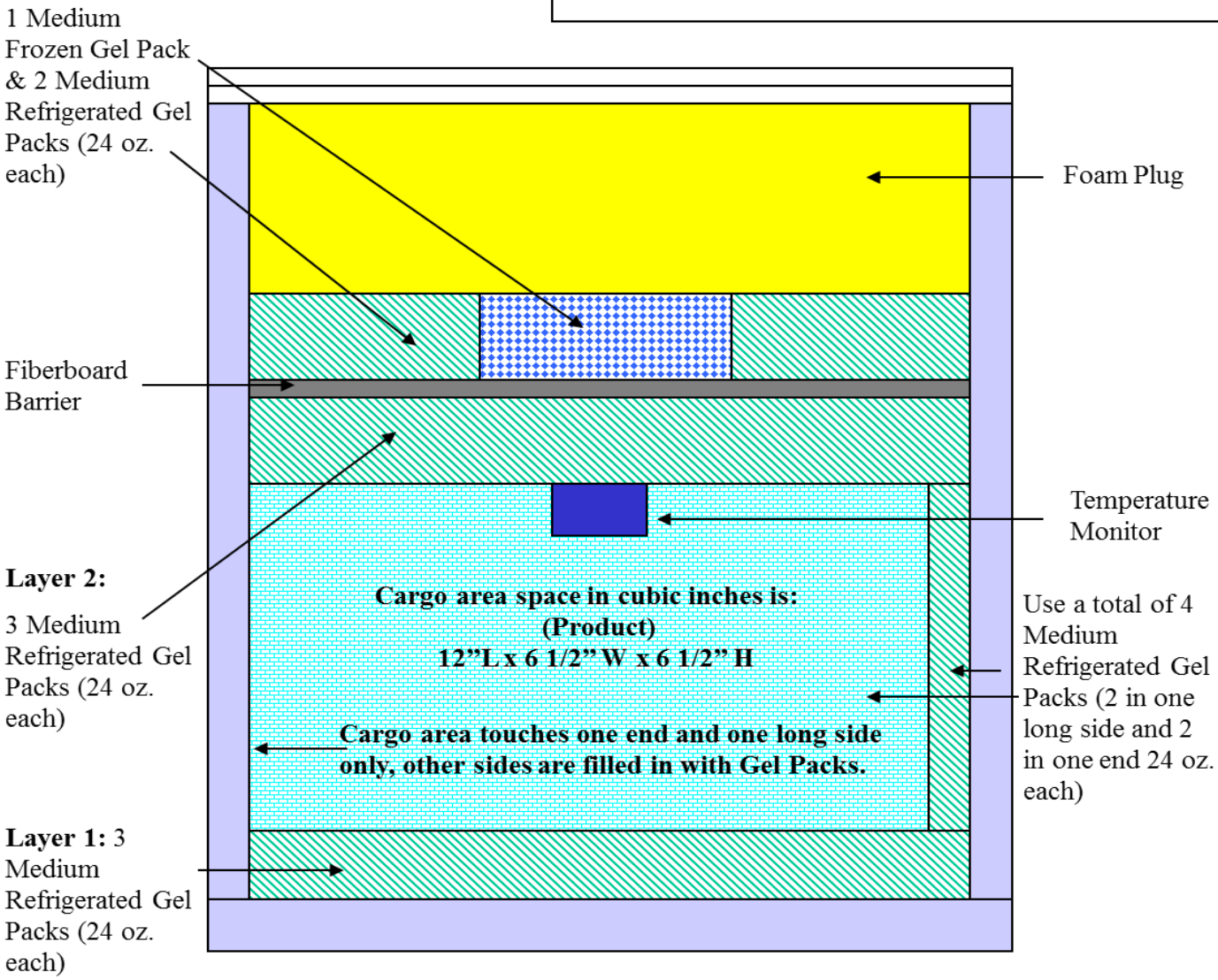


Side View

Medium – Moderate Weather Packing Protocol Diagrams

Total amount of Gel Packs = 13
Refrigerated = 12
Frozen = 1
Approximate Weight:
Max load = 40 lbs
Min load = 30 lbs

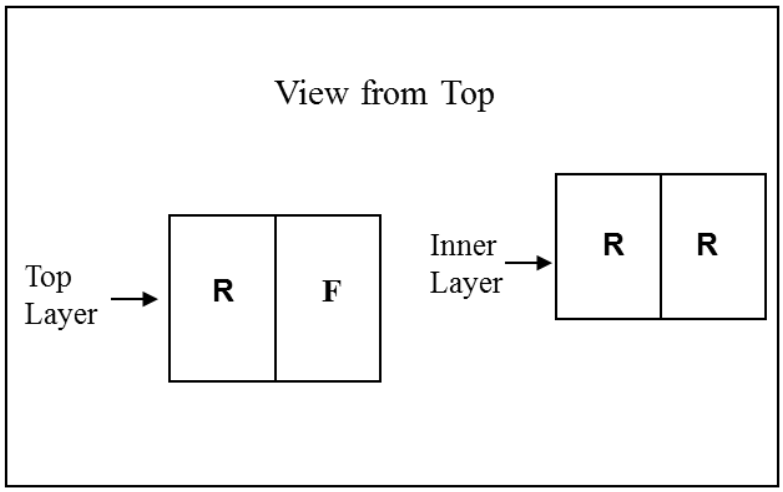




Side View

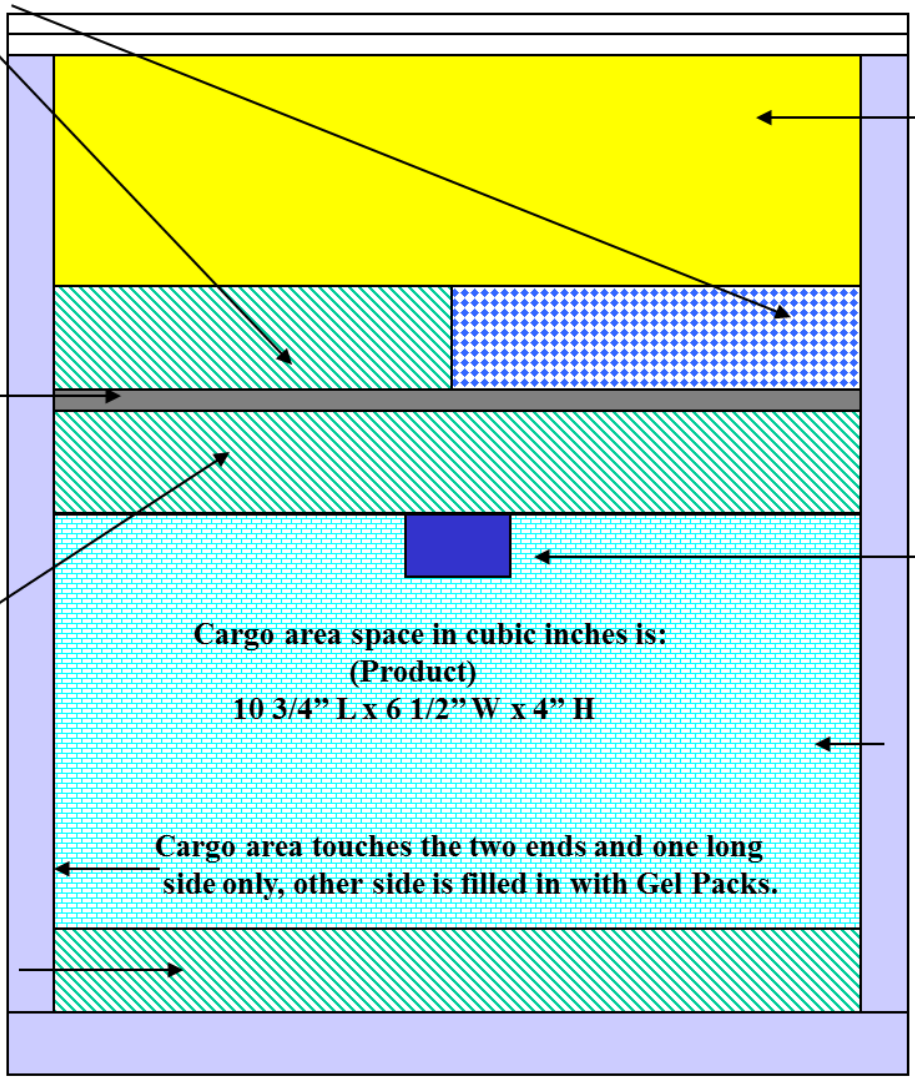
Small – Moderate Weather Packing Protocol Diagrams

Total amount of Gel Packs = 8
Refrigerated = 7
Frozen = 1
Approximate Weight:
Max load = 20 lbs
Min load = 15 lbs



Layer 3:

1 Medium Frozen Gel Pack & 1 Medium Refrigerated Gel Pack (24 oz. each)



Layer 2:

2 Medium Refrigerated Gel Packs (24 oz. each)

Layer 1:

2 Medium Refrigerated Gel Packs (24 oz. each)

Side View

Warm Weather Packing Protocol

- Warm Weather Configuration is used when the ambient temperature **at the receiving site** is consistently above 77°F.
- Protocols are designed to keep temperature sensitive products requiring refrigeration temperatures between 2°C and 8°C within these temperature ranges during transportation, for a minimum of 72 hours.
- 48oz. and 24oz. refrigerant gel packs are used in all boxes for layering and fill in.
- Inert packing material (i.e. peanuts and paper) can be used as void space filler in the cargo area space (avoid bubble wrap).
- Coolant material must be placed in layers according to attached diagrams. **Frozen gel packs are always above the Fiberboard Barrier**. (See warm weather packing configuration diagrams.)

Warm Weather Packing Protocol Procedures

The Warm Weather Packing Protocol is used whenever the ambient or outside temperature at the receiving site is consistently above 77 degrees Fahrenheit. Begin the Warm Weather packing protocol by:

o Placing a layer of refrigerated gel packs at the bottom of the box.

o Next item will be the product.

o Place gel packs around the product's side(s) to fill in gap between product and the insulated walls of the box.

o This is followed by placing an activated temperature monitor inside the cargo area space. Activate the temperature monitor and adhere it to the underside of the cargo area space box lid, centered over the top of the product (avoid adhering the temperature monitor to the product directly)

o Follow with another layer(s) of refrigerated gel packs.

o Above the second layer of refrigerated gel packs insert a fiberboard barrier.

o Add a final layer of a combination of refrigerated and frozen gel packs above the fiberboard barrier.

o Finally, insert the foam plug to seal the contents of the box.

Notes:

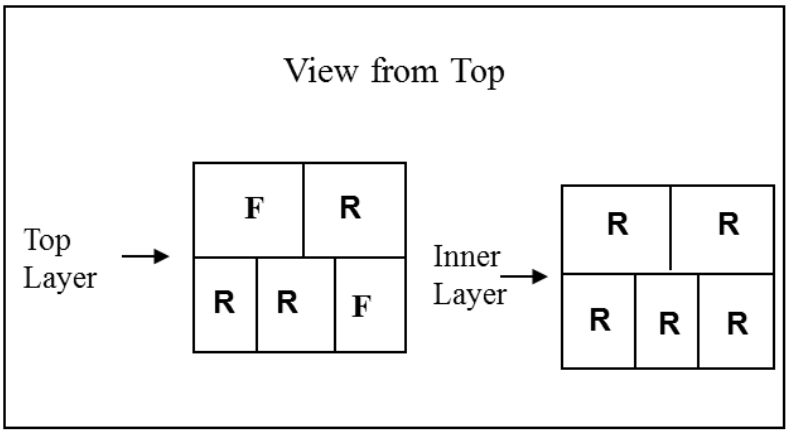
o Follow procedures according to each protocol diagram of box used.

o To precondition the Refrigerated gel packs, place them in a layer (no more than two high) inside a refrigerator running at 4°C for at least 24 hours prior use.

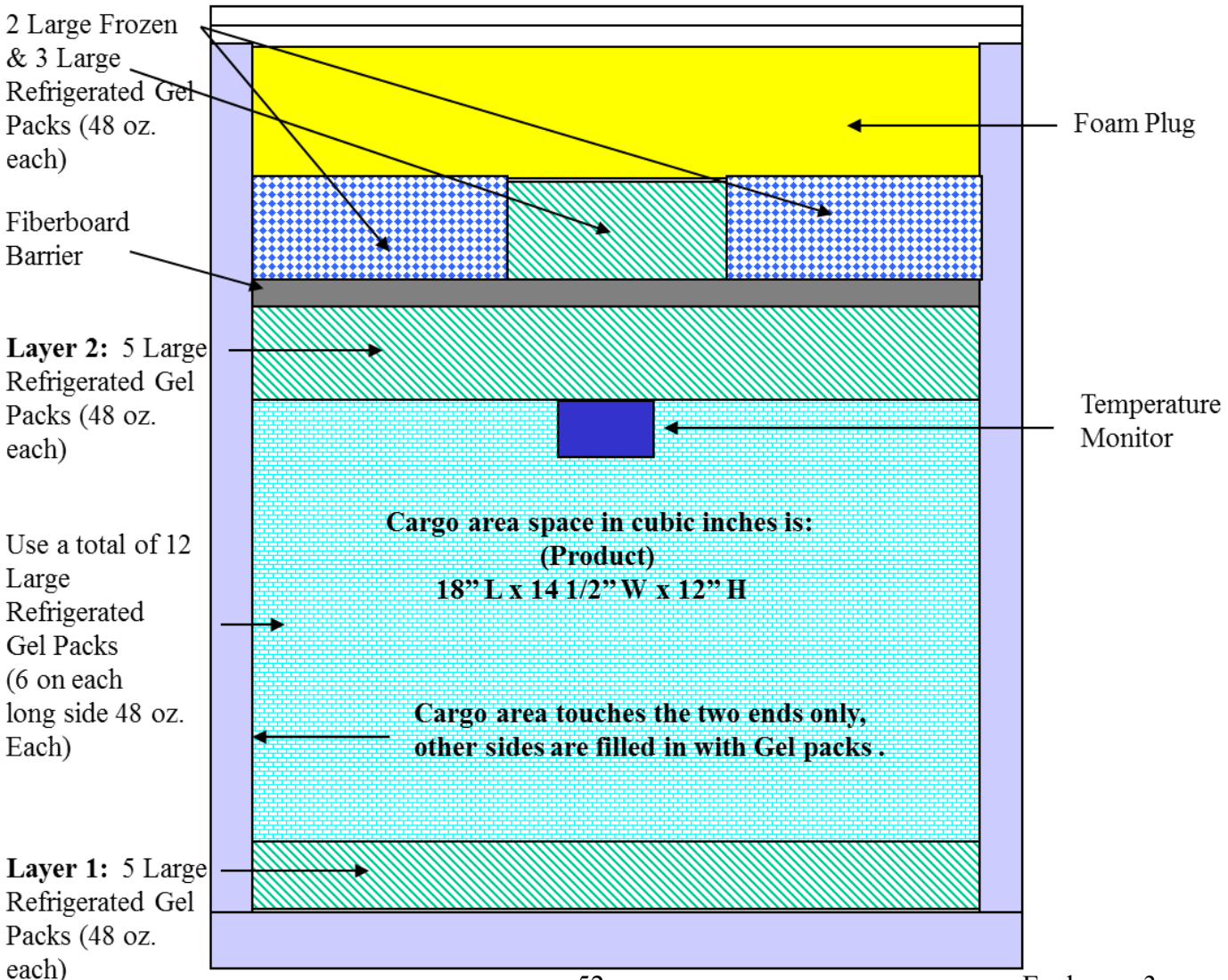
o To precondition the Frozen gel packs, place them in a layer (no more than two high) inside a freezer running between -17°C and -20°C for at least 24 hours prior to use (lay them flat to ensure they maintain their original shape once they are frozen) .

Extra Large – Warm Weather Packing Protocol Diagrams

Total amount of Gel Packs = 27
Refrigerated = 25
Frozen = 2
Approximate Weight:
Max load = 145 lbs
Min load = 120 lbs



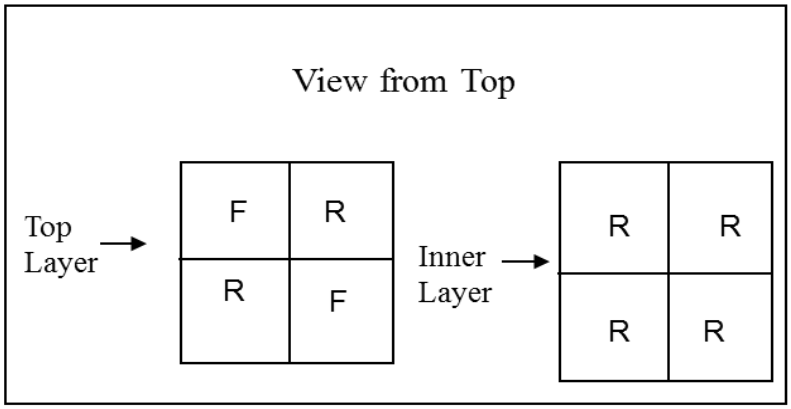
Layer 3:



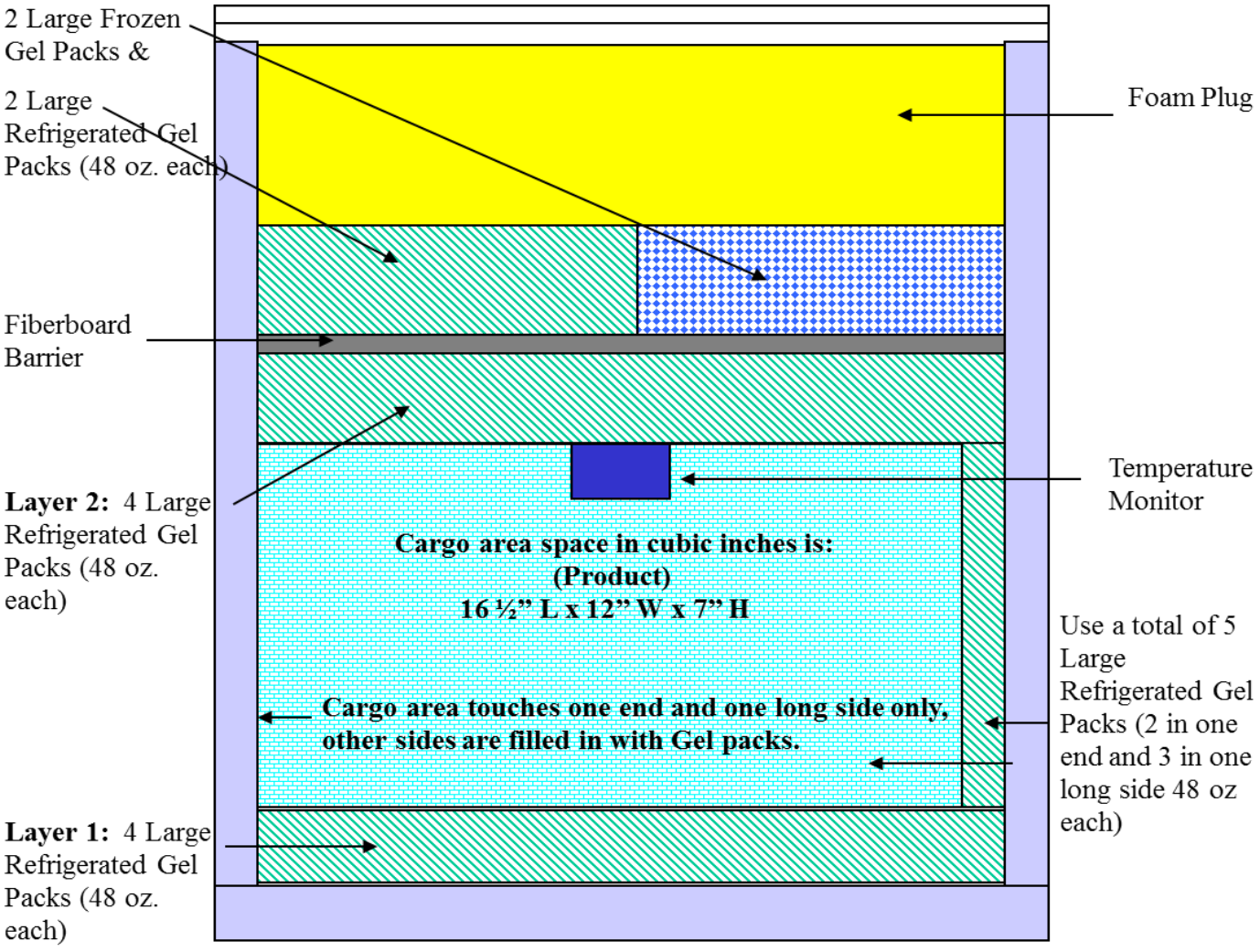
Side View

Large – Warm Weather Packing Protocol Diagrams

Total amount of Gel Packs:
Refrigerated = 15
Frozen = 2
Approximate Weight:
Max load = 75 lbs
Min load = 50 lbs



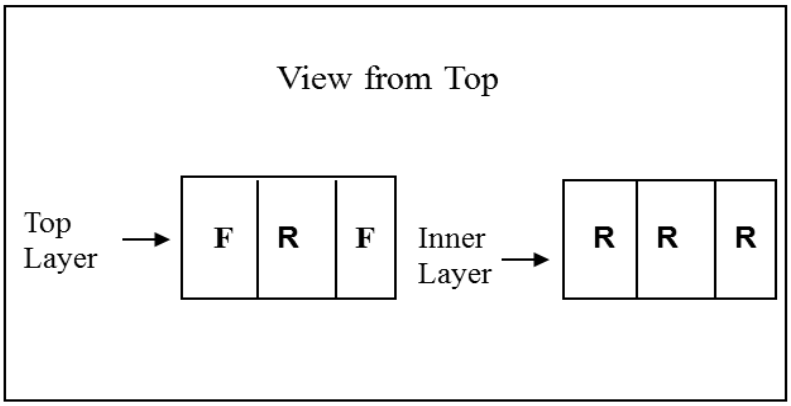
Layer 3:

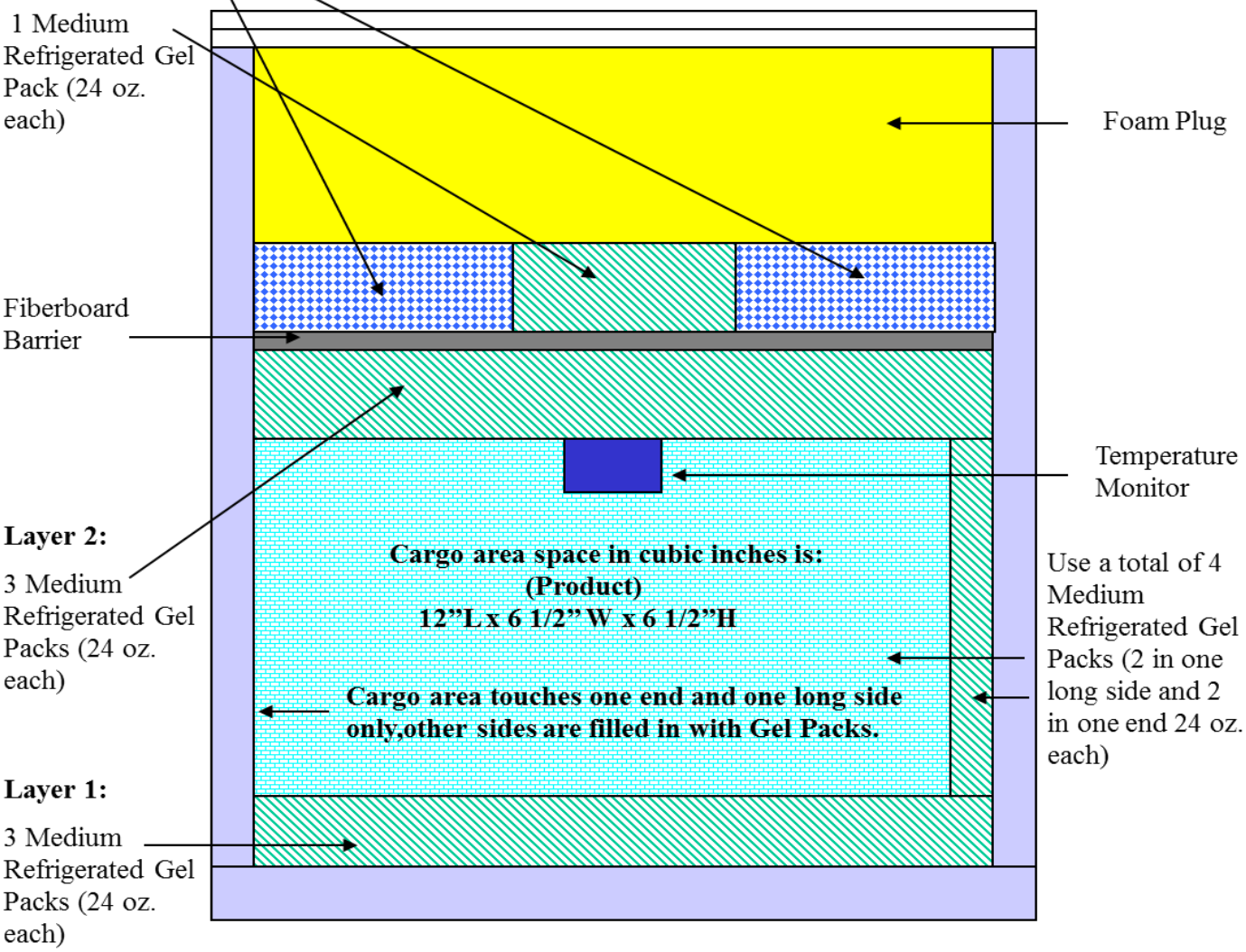


Side View

Medium – Warm Weather Packing Protocol Diagrams

Total amount of Gel Packs = 13
Refrigerated = 11
Frozen = 2
Approximate Weight:
Max load = 40 lbs
Min load = 30 lbs

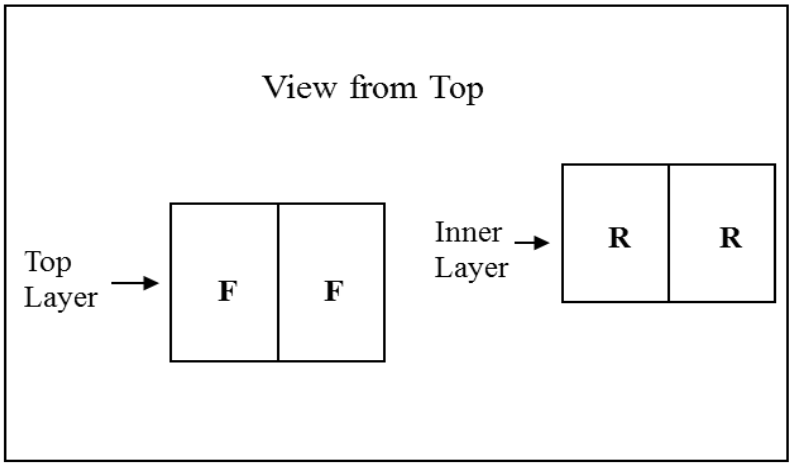


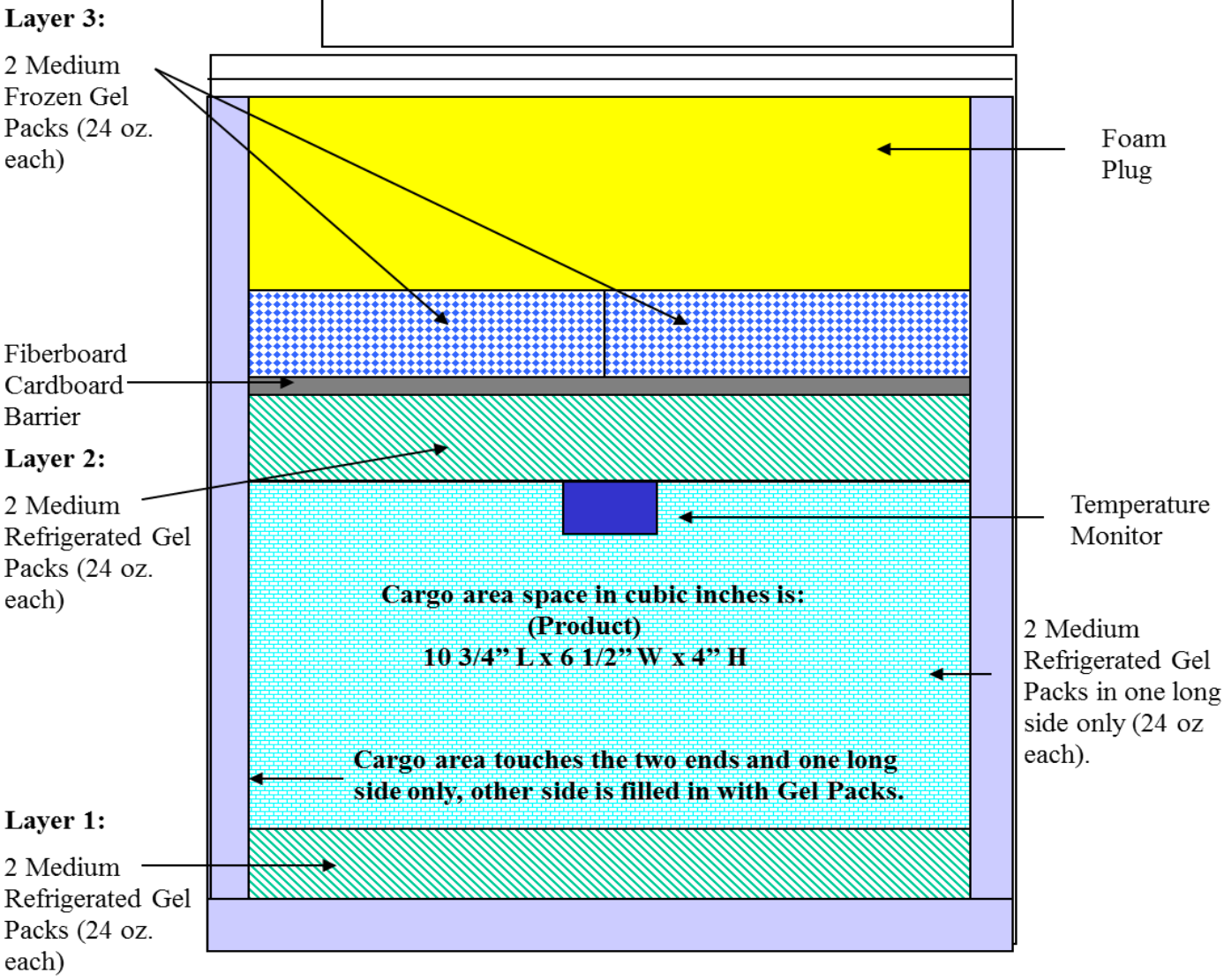


Side View

Small – Warm Weather Packing Protocol Diagrams

Total amount of Gel Packs = 8
Refrigerated = 6
Frozen = 2
Approximate Weight:
Max load = 20 lbs
Min load = 15 lbs





Side View

Packaging Protocols for Temperature Sensitive Medical Products Requiring Storage and Transportation Temperatures Between 15°C and 30°C (58°F and 86°F)

IMPORTANT NOTICE!!

DD Forms 1502/1502-1/1502-2 & 1502N/1502-1N/1502-2N
SHALL NOT BE USED with these protocols.

Cold Weather Packing Protocol

- Cold Weather Configuration is used when the ambient temperature at the **receiving site** is consistently below 55°F.
- Protocols are designed to keep temperature sensitive products requiring Controlled Room Temperature between 15°C and 30°C during transportation, for a minimum of 72 hours.
- 24.6oz. Phase Change Panels are used in all boxes for layering.
- Inert packing material (i.e. peanuts and paper) can be used as void space filler in the cargo area space (avoid bubble wrap).
- Phase Change Panels must be placed in layers according to attached diagrams. (See cold weather packing configuration diagrams.)

Cold Weather Packing Protocol Procedures

The Cold Weather Packing Protocol is used whenever the ambient or outside temperature at the receiving site consistently remains below 55 degrees Fahrenheit. Begin the Cold Weather packing protocol by:

o Placing layers of heated Phase Change Panels at the bottom of the box.

o Next item will be the product.

o When applicable, place heated panels around the product's side(s) to fill in gap between product and the insulated walls of the box

o This is followed by placing an activated temperature monitor inside the cargo area space. Activate the temperature monitor and adhere it to the underside of the cargo area space box lid, centered over the top of the product (avoid adhering the temperature monitor to the product directly)

o Follow with additional layers of heated panels.

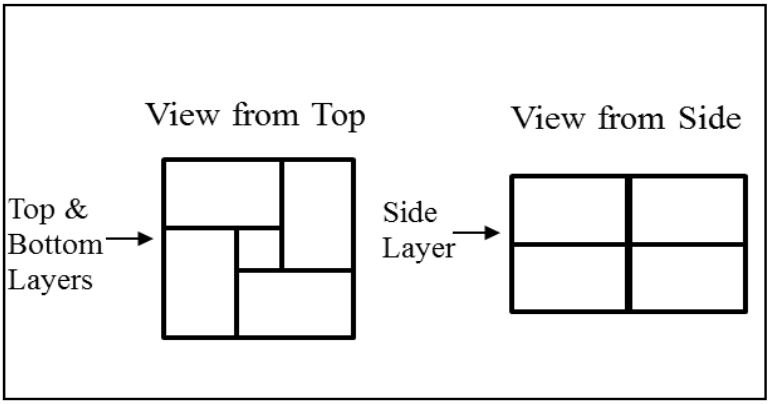
o Finally, insert the foam plug to seal the contents of the box.

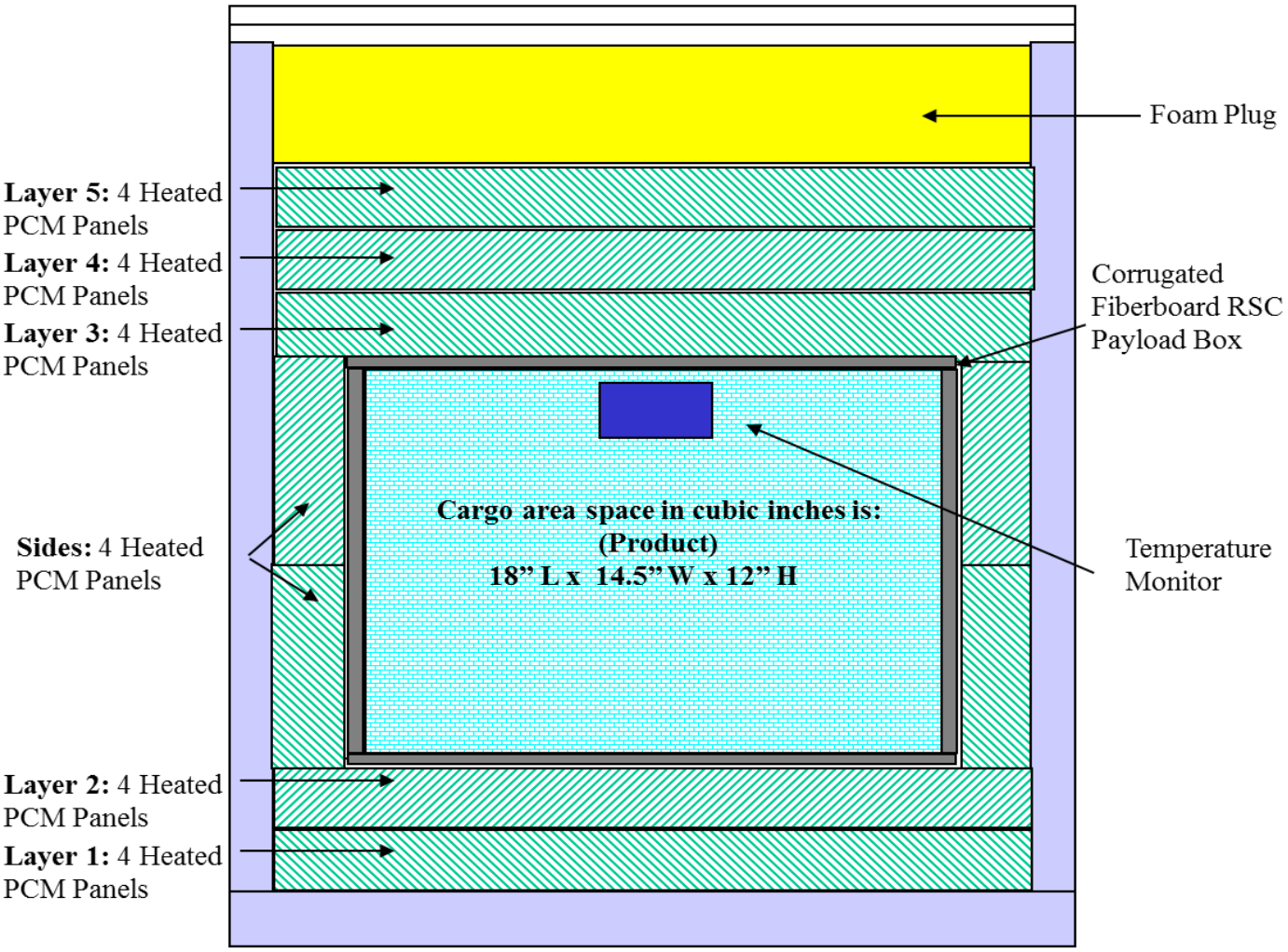
Notes:
o Follow procedures according to each protocol diagram of box used.

o To precondition the Phase Change Panels, store them in a layer (no more than two high) at 30°C for at least 24 hours, or until fully melted, prior use.

Extra Large – Cold Weather Packing Protocol Diagrams

Total amount of heated PCM Panels = 28

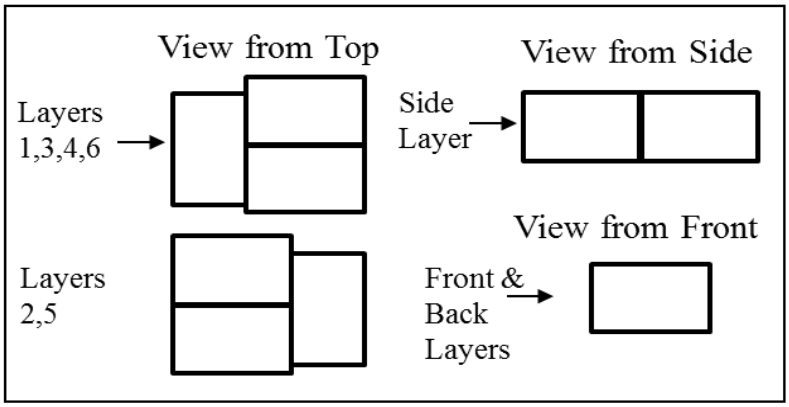


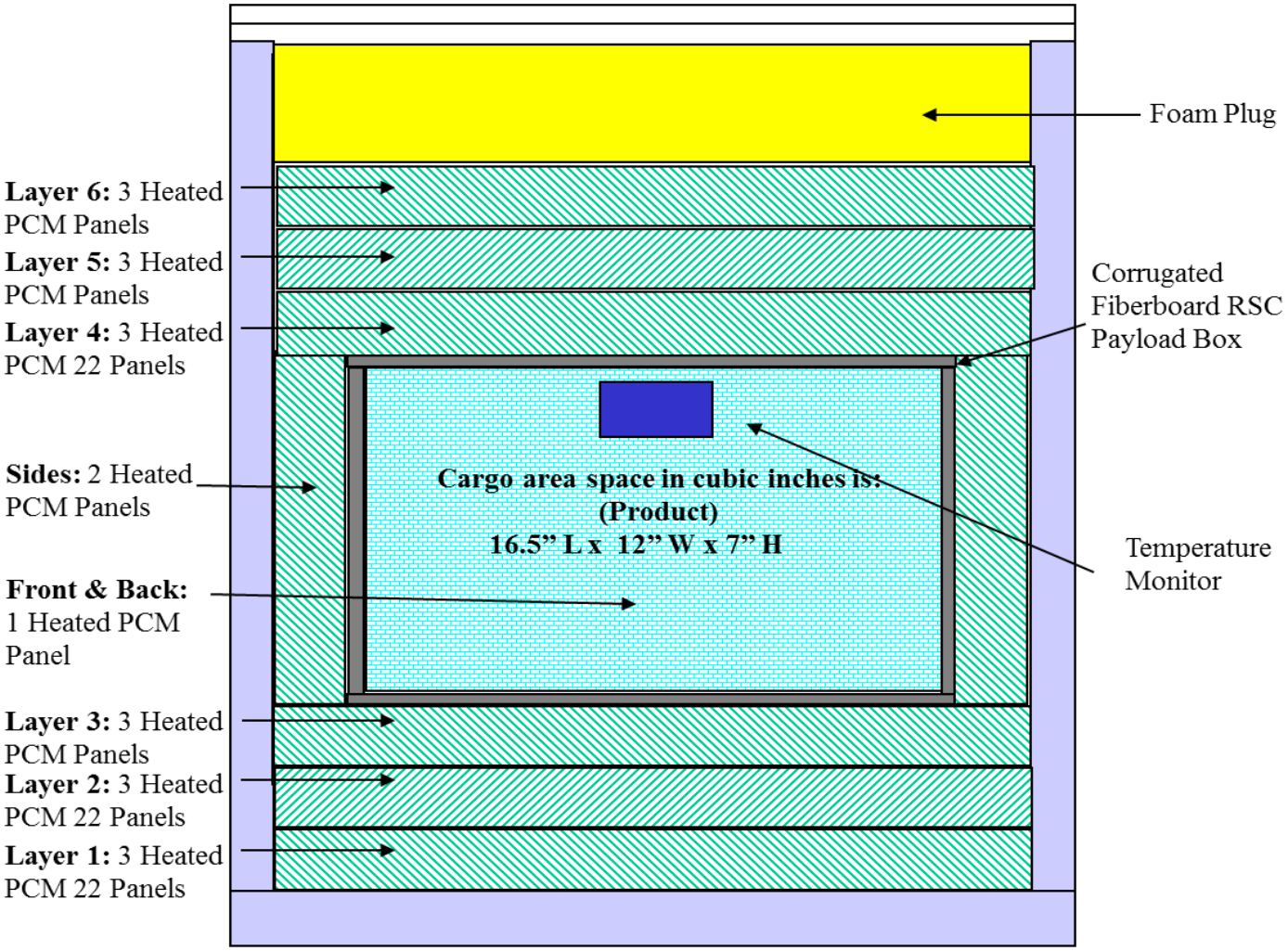


Side View

Large – Cold Weather Packing Protocol Diagrams

Total amount of heated PCM Panels = 24

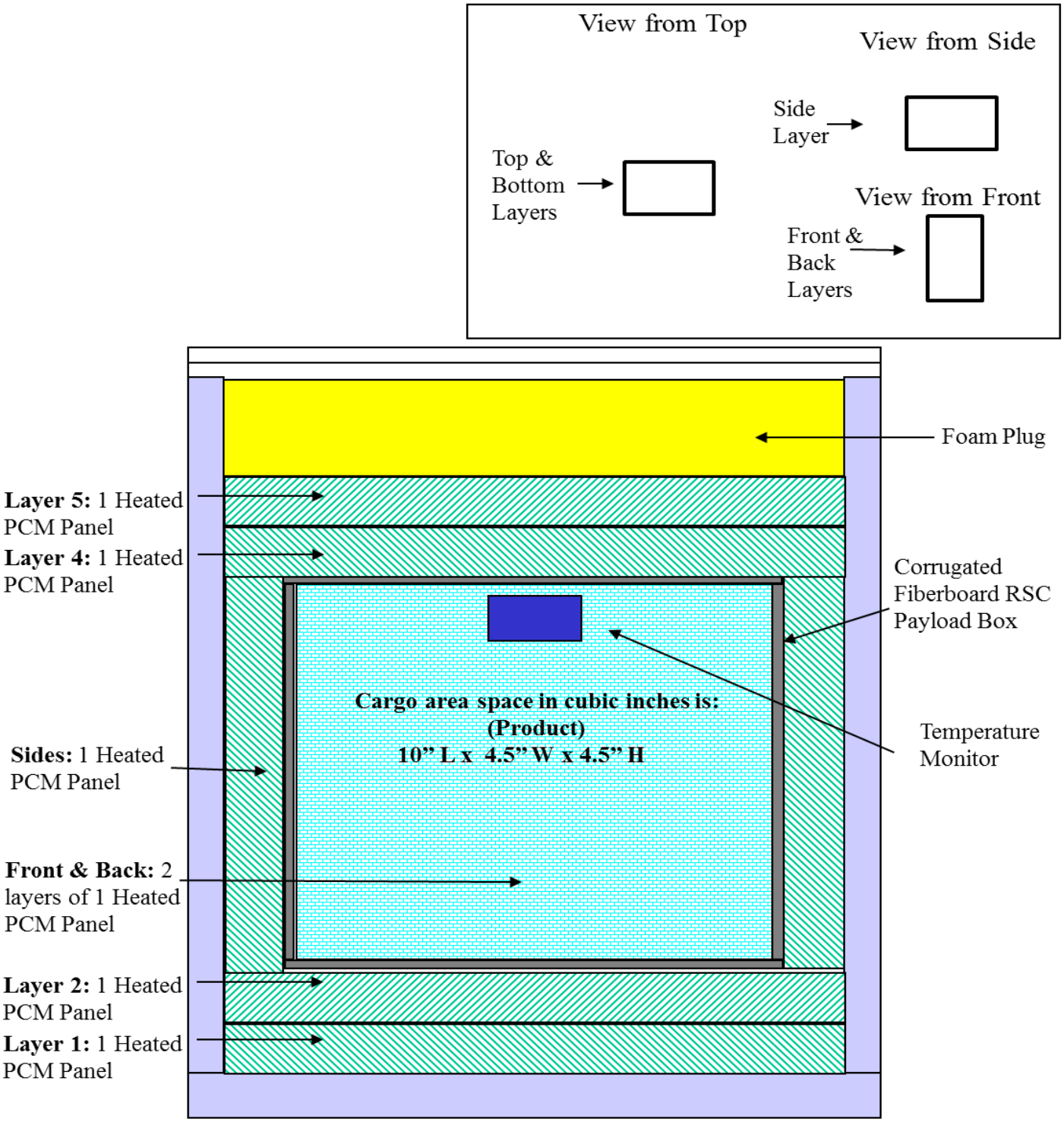




Side View

Medium – Cold Weather Packing Protocol Diagrams

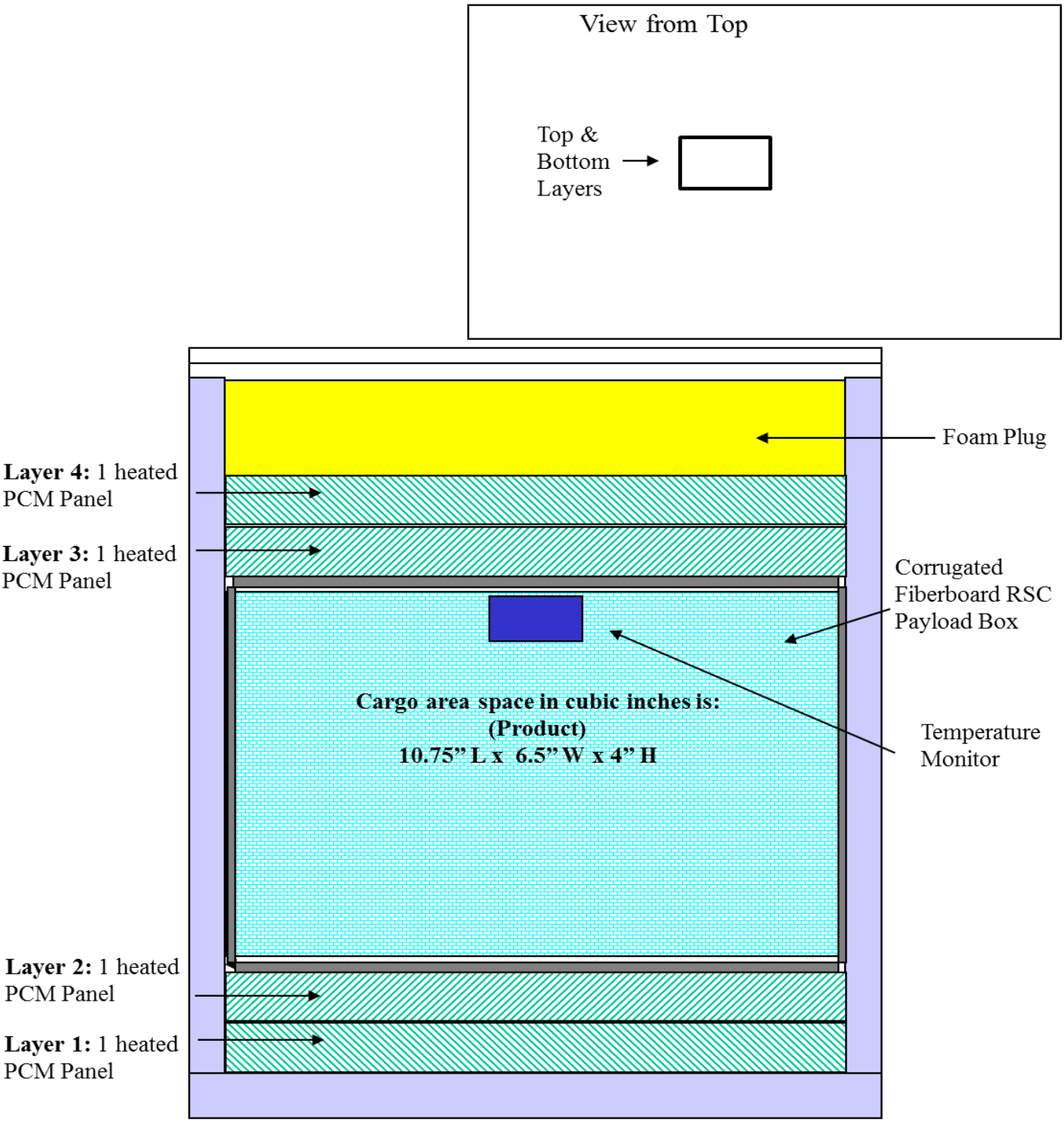
Total amount of heated PCM Panels = 10



Side View

Small – Cold Weather Packing Protocol Diagrams

Total amount of heated PCM Panels = 4



Side View

Moderate Weather Packing Protocol

- Moderate Weather Configuration is used when the ambient temperature at the **receiving site** is between 55°F and 77°F.
- Protocols are designed to keep temperature sensitive products requiring Controlled Room Temperature between 15°C and 30°C during transportation, for a minimum 72 hours.
- 48oz. and 24oz. gel packs are used in all boxes for layering.
- Inert packing material (i.e. peanuts and paper) can be used as void space filler in the cargo area space (avoid bubble wrap).
- Gel packs must be placed in layers according to attached diagrams. Note that all gel packs are at **Room Temperature** (See moderate weather packing configuration diagrams.)

Moderate Weather Packing Protocol Procedures

The Moderate Weather Packing Protocol is used whenever the ambient or outside temperature at the receiving site is between 55 degrees Fahrenheit and 77 degrees Fahrenheit. Begin the Moderate Weather packing protocol by:

o Placing a layer of room temperature gel packs at the bottom of the box.

o Next item will be the product.

o Place room temperature gel packs around the product's side(s) to fill in gap between product and the insulated walls of the box.

o This is followed by placing an activated temperature monitor inside the cargo area space. Activate the temperature monitor and adhere it to the underside of the cargo area space box lid, centered over the top of the product (avoid adhering the temperature monitor to the product directly)

o Follow with another layer of room temperature gel packs.

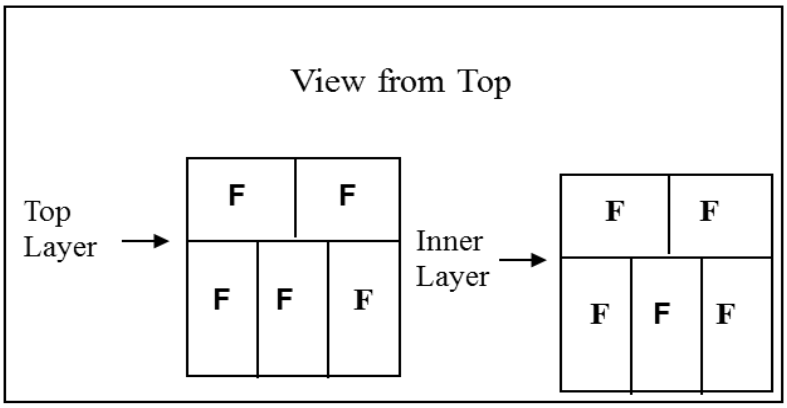
o Finally, insert the foam plug to seal the contents of the box.

Notes:
o Follow procedures according to each protocol diagram of box used.

o To precondition the Gel Packs, store them in a layer (no more than two high) at 18°C to 22°C, until fully stabilized with the environment.

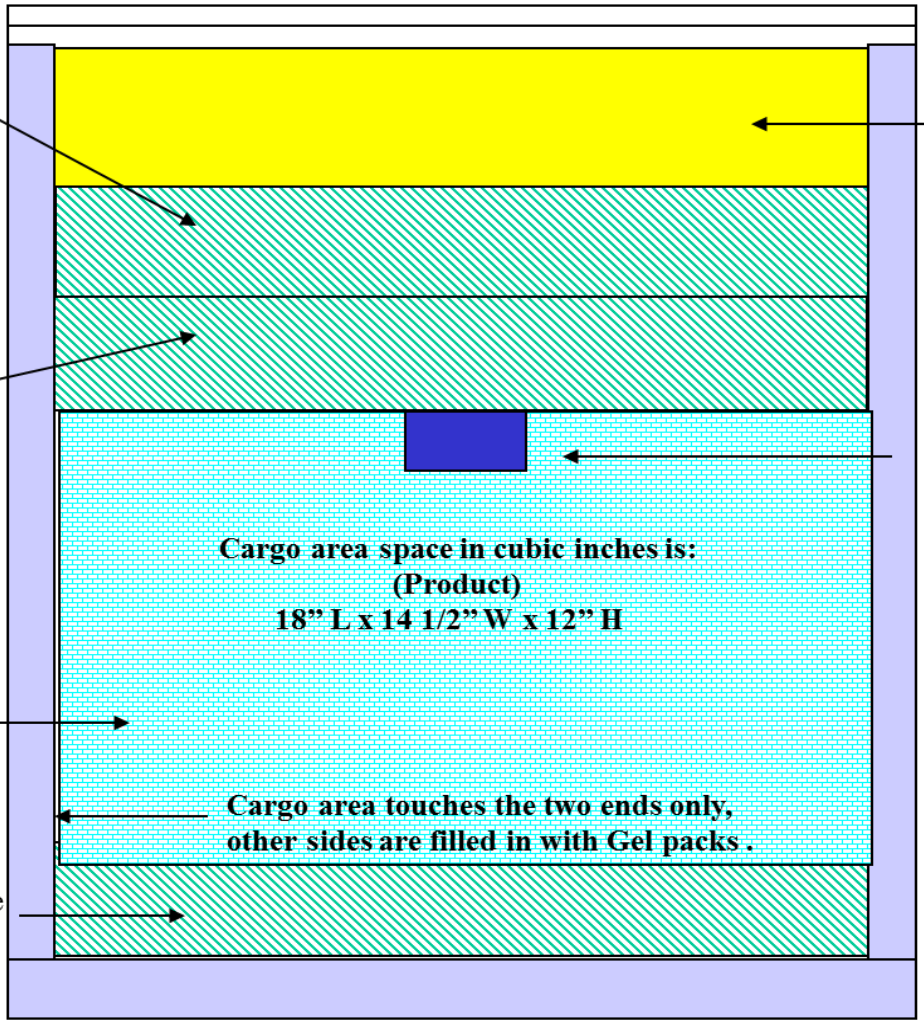
Extra Large Protocol Diagrams

Total amount of Room Temp 48 oz. Gel Packs = 27



Layer 3:

5 Large Room Temp Gel Packs (48 oz. each)



Layer 2:

5 Large Room Temp Gel Packs (48 oz. each)

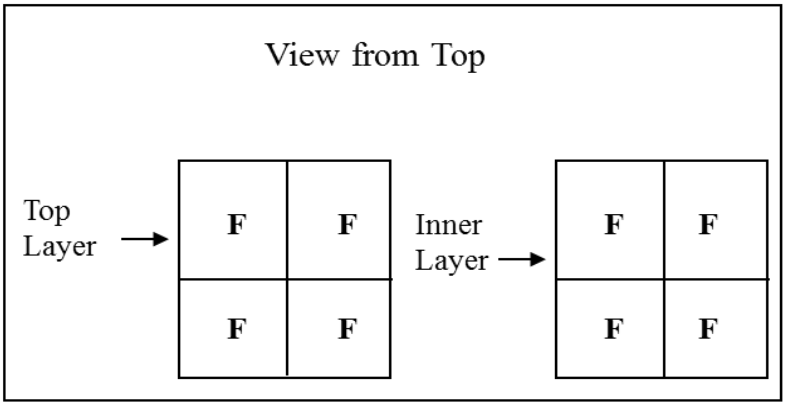
Use a total of 12 Large Room Temp Gel Packs (6 on each long side 48 oz. Each)

Layer 1: 5 Large Room Temp Gel Packs (48 oz. each)

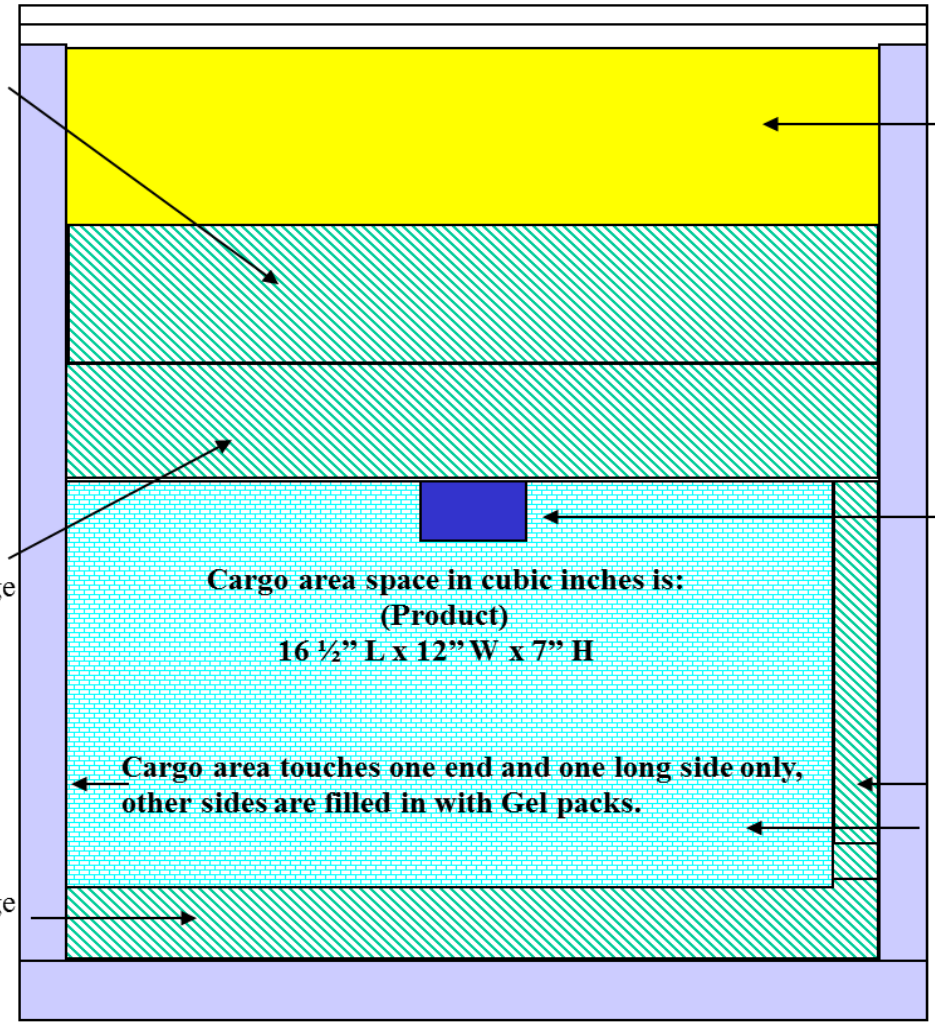
Side View

Large Packing Protocol Diagrams

Total amount of Room Temp 48 oz. Gel Packs = 17



Layer 3:
4 Large Room Temp Gel Packs (48 oz. each)



Layer 2: 4 Large Room Temp Gel Packs (48 oz. each)

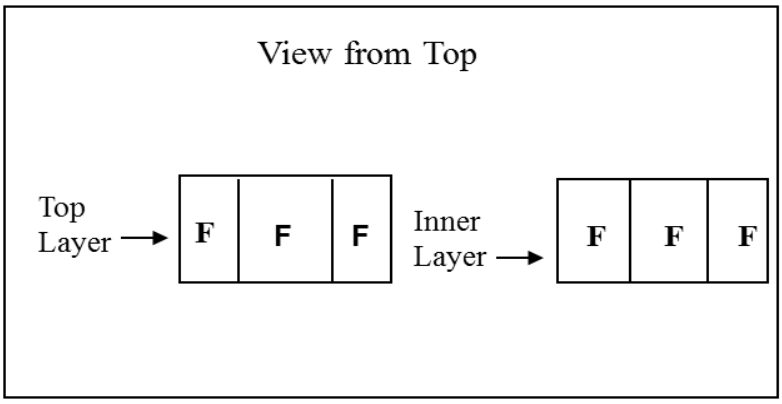
Use a total of 5 Large Room Temp Gel Packs (2 in one end and 3 in one long side 48 oz each)

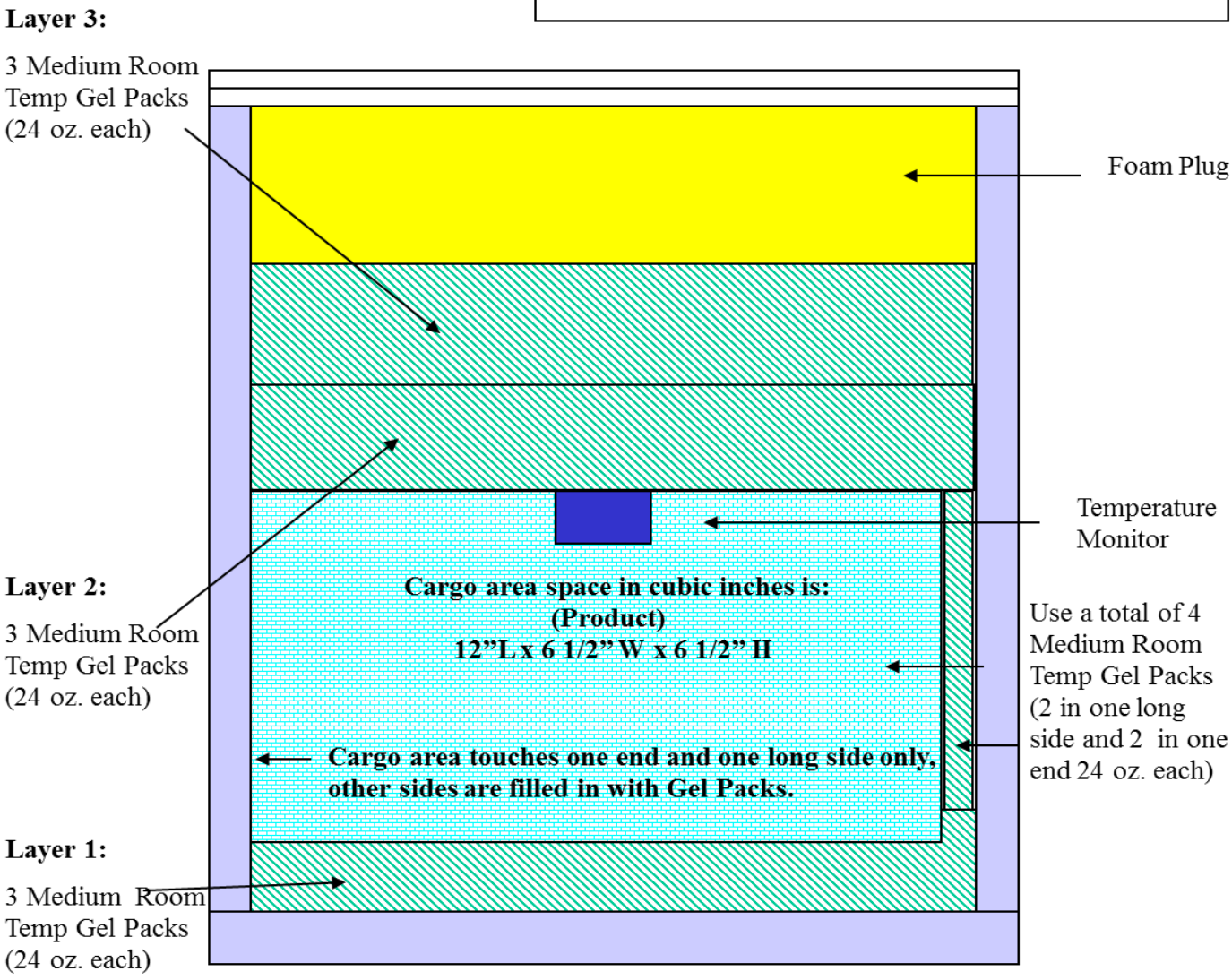
Layer 1: 4 Large Room Temp Gel Packs (48 oz. each)

Side View

Medium Packing Protocol Diagrams

Total amount of Room Temp 24 oz. Gel Packs = 13

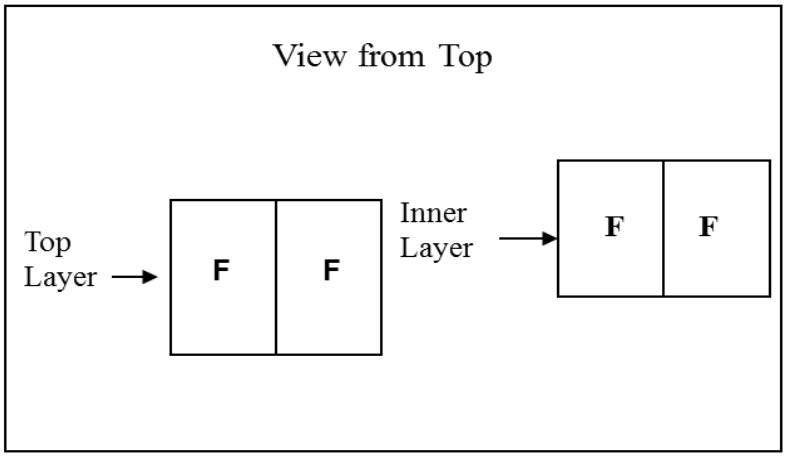




Side View

Small Packing Protocol Diagrams

Total amount of Room Temp 24 oz. Gel Packs = 8



Layer 3:

2 Medium Room Temp Gel Packs (24 oz. each)

Foam Plug

Temperature Monitor

Layer 2:

2 Medium Room Temp Gel Packs (24 oz. each)

Cargo area space in cubic inches is:
(Product)
10 3/4" L x 6 1/2" W x 4" H

2 Medium Room Temp Gel Packs in one long side only (24 oz each).

Cargo area touches the two ends and one long side only, other side is filled in with Gel Packs.

Layer 1:

2 Medium Room Temp Gel Packs (24 oz. each)

Side View

Warm Weather Packing Protocol

- Warm Weather Configuration is used when the ambient temperature **at the receiving site** is consistently above 77°F.
- Protocols are designed to keep temperature sensitive products requiring Controlled Room Temperature between 15°C and 30°C during transportation, for a minimum of 72 hours.
- 48oz. and 24oz. gel packs are used in all boxes for layering.
- Inert packing material (i.e. peanuts and paper) can be used as void space filler in the cargo area space (avoid bubble wrap).
- Gel packs must be placed in layers according to attached diagrams. Note that all gel packs are at **Room Temperature** (See warm weather packing configuration diagrams.)

Warm Weather Packing Protocol Procedures

The Warm Weather Packing Protocol is used whenever the ambient or outside temperature at the receiving site is consistently above 77 degrees Fahrenheit. Begin the Warm Weather packing protocol by:

o Placing a layer of room temperature gel packs at the bottom of the box.

o Next item will be the product.

o Place room temperature gel packs around the product's side(s) to fill in gap between product and the insulated walls of the box.

o This is followed by placing an activated temperature monitor inside the cargo area space. Activate the temperature monitor and adhere it to the underside of the cargo area space box lid, centered over the top of the product (avoid adhering the temperature monitor to the product directly)

o Follow with additional layers of room temperature gel packs.

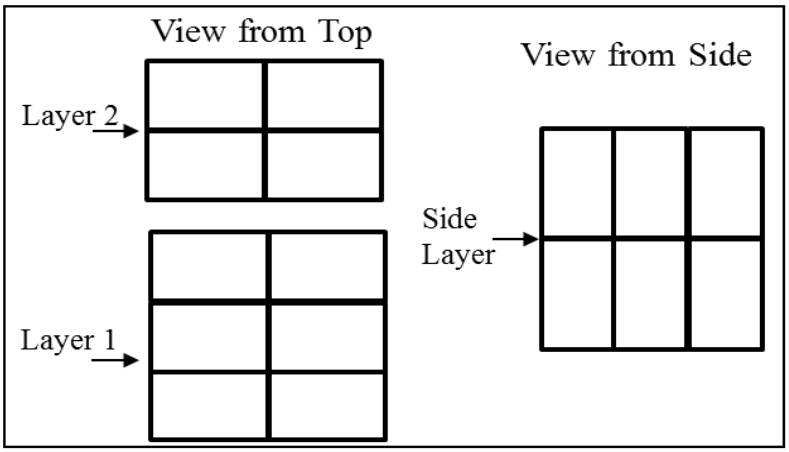
o Finally, insert the foam plug to seal the contents of the box.

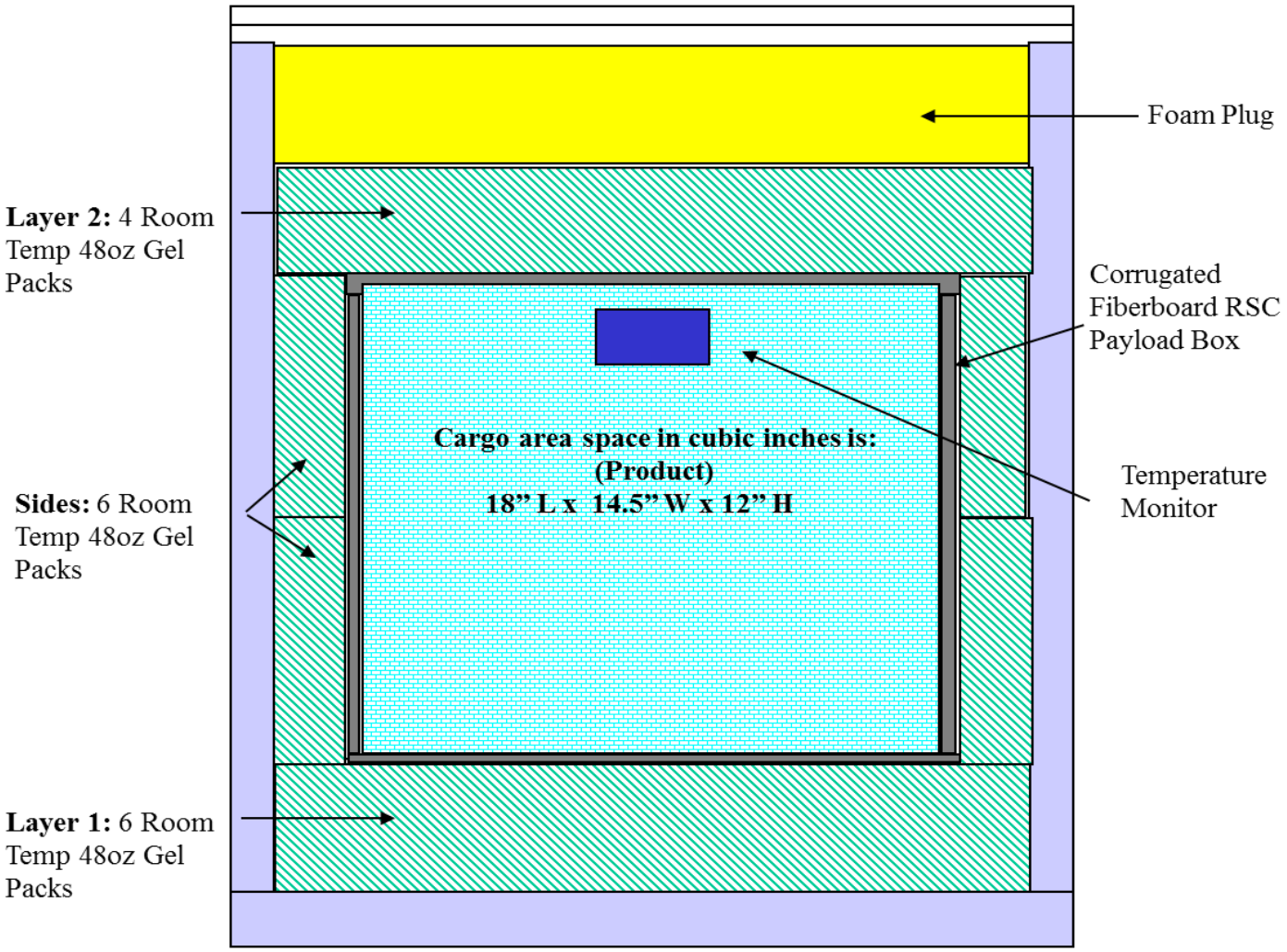
Notes:
o Follow procedures according to each protocol diagram of box used.

o To precondition the Gel Packs, store them in a layer (no more than two high) at 18°C to 22°C, until fully stabilized with the environment.

Extra Large – Warm Weather Packing Protocol Diagrams

Total amount of Room Temp 48oz Gel Packs = 22

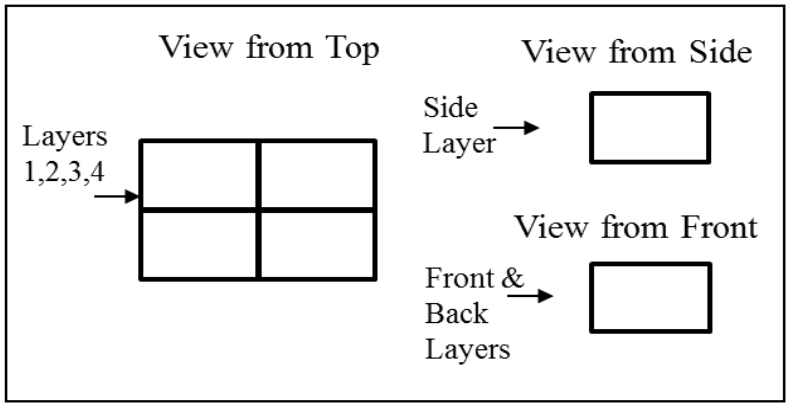


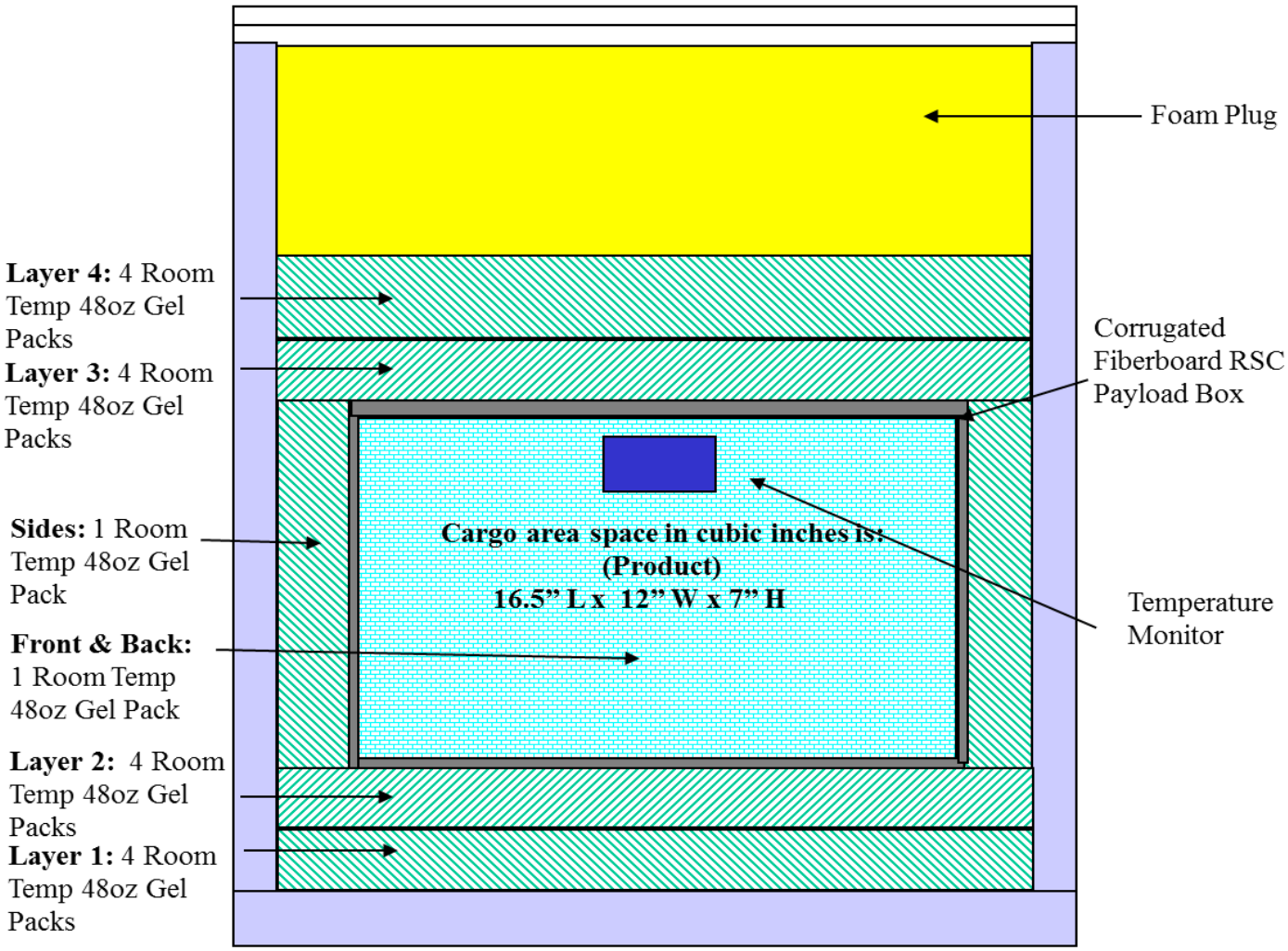


Side View

Large – Warm Weather Packing Protocol Diagrams

Total amount of Room Temp 48oz Gel Packs = 20

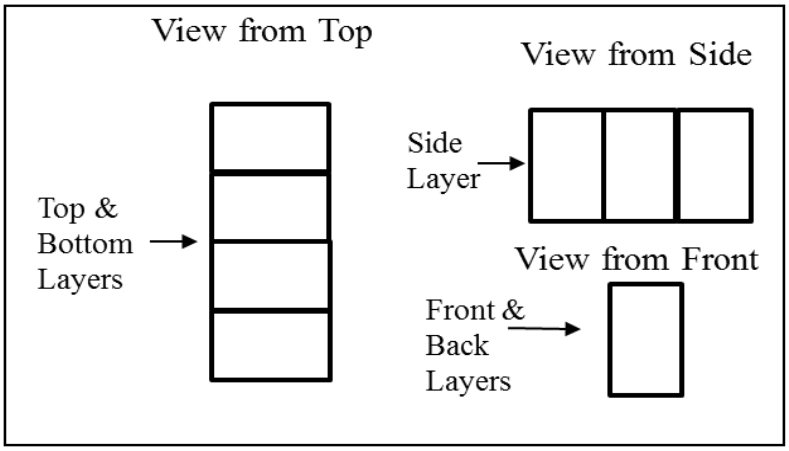


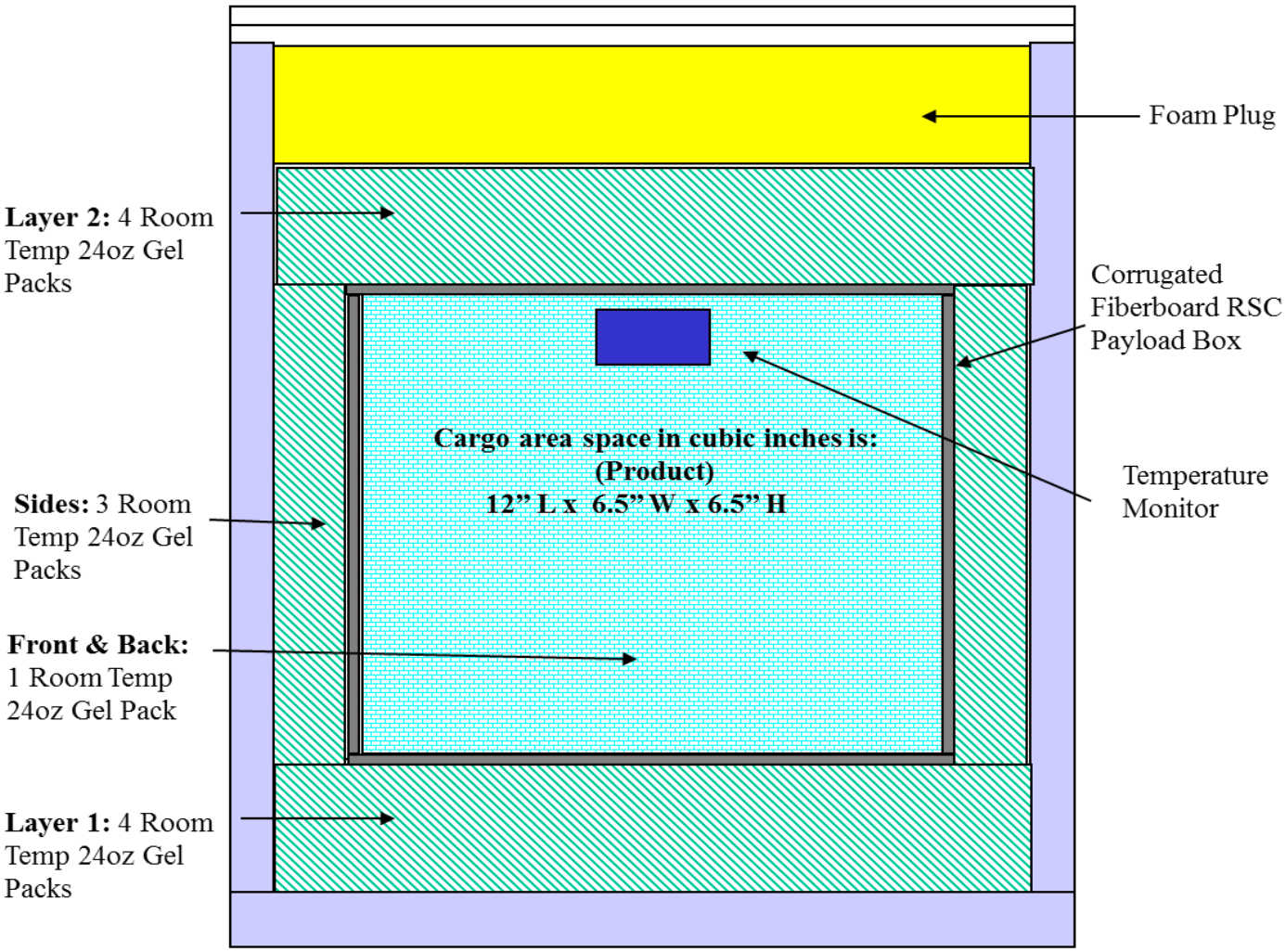


Side View

Medium – Warm Weather Packing Protocol Diagrams

Total amount of Room Temp 24oz Gel Packs = 16

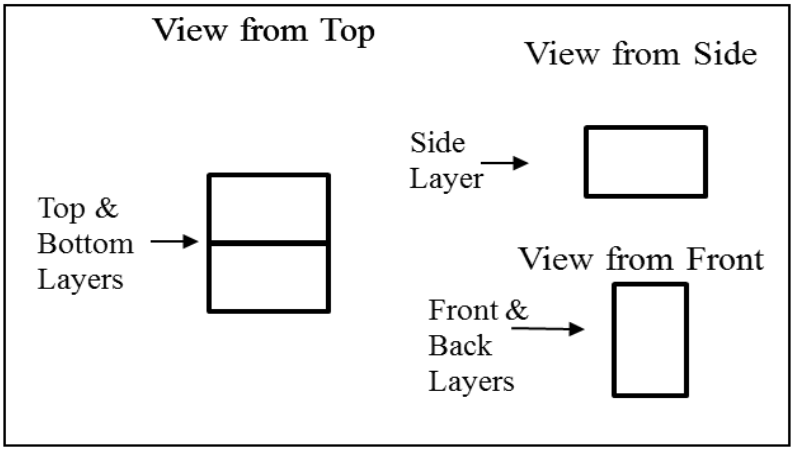


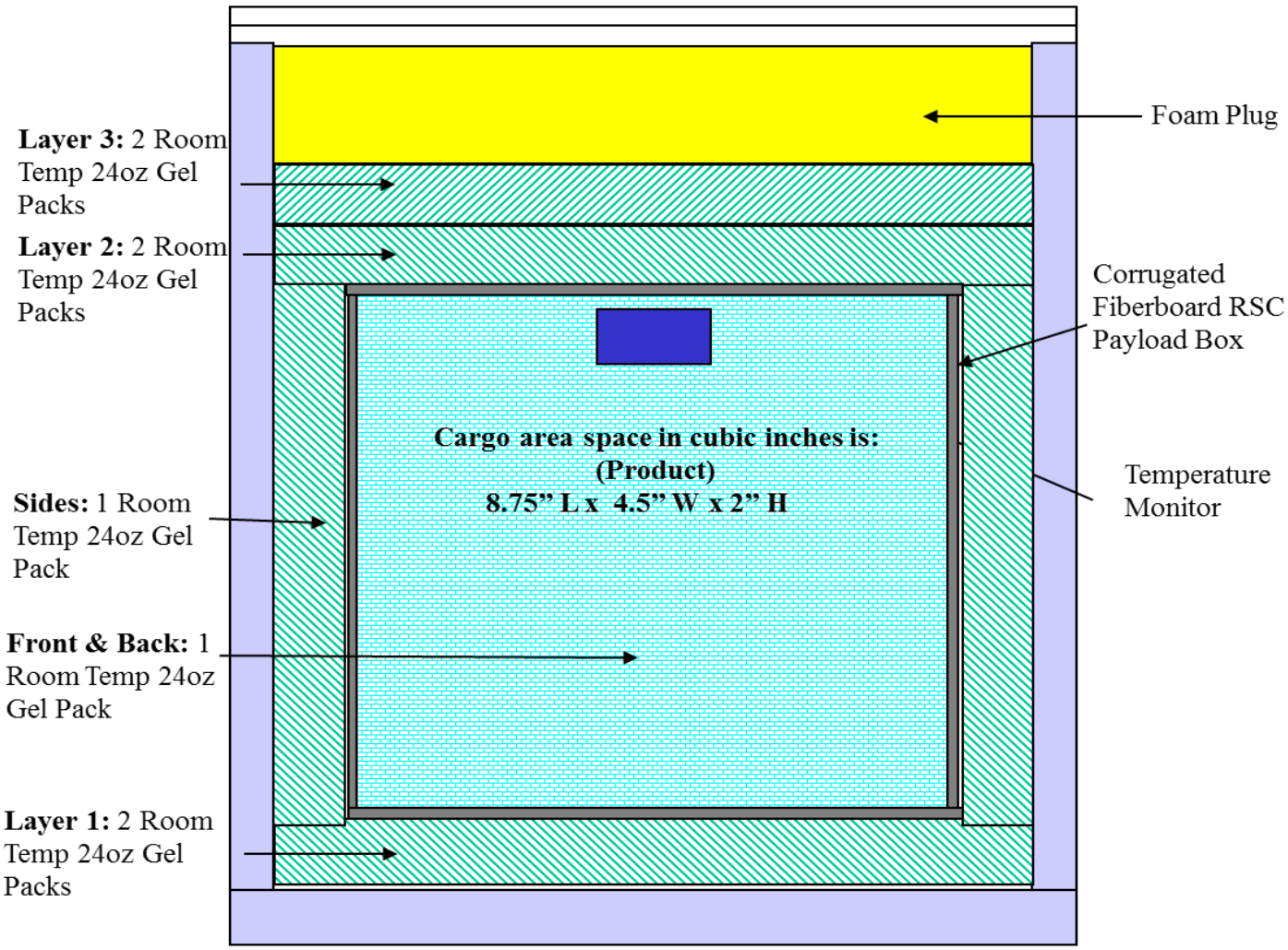


Side View

Small – Warm Weather Packing Protocol Diagrams

Total amount of Room Temp 24oz Gel Packs = 10



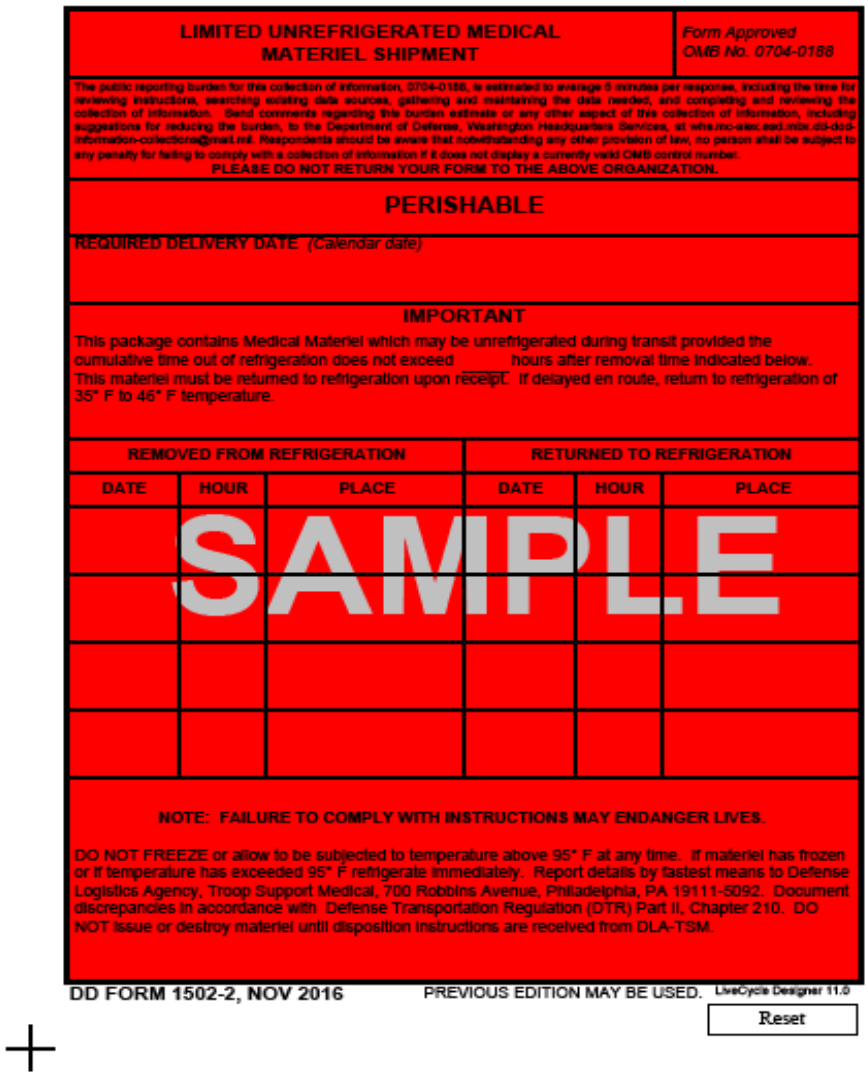


Side View

ENCLOSURE 4

LABELS AND FORMS

DD Form 1502-2 – Limited Unrefrigerated Material Shipment Bright Red Pressure-Sensitive Label



LIMITED UNREFRIGERATED MEDICAL MATERIEL SHIPMENT

Form Approved OMB No. 0704-0188

The public reporting burden for this collection of information, 0704-0188, is estimated to average 5 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden, to the Department of Defense, Washington Headquarters Services, at whs.mc-alex.esd.mbx.dd-dod-information-collections@mail.mil. Respondents should be aware that notwithstanding any other provision of law, no person shall be subject to any penalty for failing to comply with a collection of information if it does not display a currently valid OMB control number.

PLEASE DO NOT RETURN YOUR FORM TO THE ABOVE ORGANIZATION.

PERISHABLE

REQUIRED DELIVERY DATE *(Calendar date)*

IMPORTANT

This package contains Medical Materiel which may be unrefrigerated during transit provided the cumulative time out of refrigeration does not exceed _____ hours after removal time indicated below. This materiel must be returned to refrigeration upon receipt. If delayed en route, return to refrigeration of 35° F to 46° F temperature.

REMOVED FROM REFRIGERATION			RETURNED TO REFRIGERATION		
DATE	HOUR	PLACE	DATE	HOUR	PLACE

SAMPLE

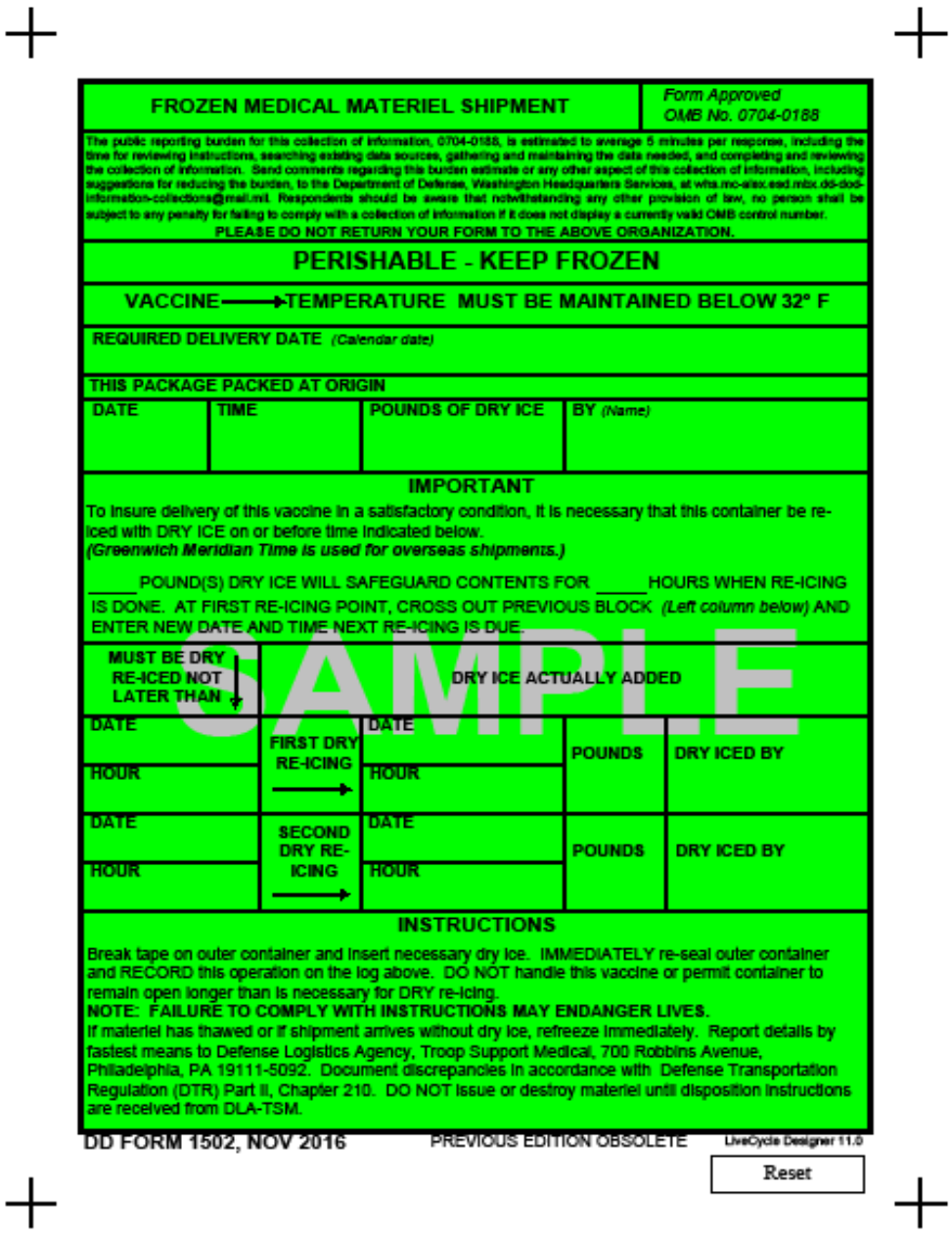
NOTE: FAILURE TO COMPLY WITH INSTRUCTIONS MAY ENDANGER LIVES.

DO NOT FREEZE or allow to be subjected to temperature above 95° F at any time. If materiel has frozen or if temperature has exceeded 95° F refrigerate immediately. Report details by fastest means to Defense Logistics Agency, Troop Support Medical, 700 Robbins Avenue, Philadelphia, PA 19111-5092. Document discrepancies in accordance with Defense Transportation Regulation (DTR) Part II, Chapter 210. DO NOT issue or destroy materiel until disposition instructions are received from DLA-TSM.

DD FORM 1502-2, NOV 2016 PREVIOUS EDITION MAY BE USED. LiveCycle Designer 11.0

Reset

DD Form 1502 – Frozen Medical Material Shipment
Bright Green Pressure-Sensitive Label



FROZEN MEDICAL MATERIEL SHIPMENT | *Form Approved OMB No. 0704-0188*

The public reporting burden for this collection of information, 0704-0188, is estimated to average 5 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden, to the Department of Defense, Washington Headquarters Services, at whs.mc-alex.esd.mbx.dd-dod-information-collections@mail.mil. Respondents should be aware that notwithstanding any other provision of law, no person shall be subject to any penalty for failing to comply with a collection of information if it does not display a currently valid OMB control number.

PLEASE DO NOT RETURN YOUR FORM TO THE ABOVE ORGANIZATION.

PERISHABLE - KEEP FROZEN

VACCINE ⟶ TEMPERATURE MUST BE MAINTAINED BELOW 32° F

REQUIRED DELIVERY DATE *(Calendar date)*

THIS PACKAGE PACKED AT ORIGIN

DATE	TIME	POUNDS OF DRY ICE	BY *(Name)*

IMPORTANT

To insure delivery of this vaccine in a satisfactory condition, it is necessary that this container be re-iced with DRY ICE on or before time indicated below.
(Greenwich Meridian Time is used for overseas shipments.)

_____ POUND(S) DRY ICE WILL SAFEGUARD CONTENTS FOR _____ HOURS WHEN RE-ICING IS DONE. AT FIRST RE-ICING POINT, CROSS OUT PREVIOUS BLOCK *(Left column below)* AND ENTER NEW DATE AND TIME NEXT RE-ICING IS DUE.

MUST BE DRY RE-ICED NOT LATER THAN ↓		DRY ICE ACTUALLY ADDED			
DATE / HOUR	FIRST DRY RE-ICING ⟶	DATE / HOUR	POUNDS	DRY ICED BY	
DATE / HOUR	SECOND DRY RE-ICING ⟶	DATE / HOUR	POUNDS	DRY ICED BY	

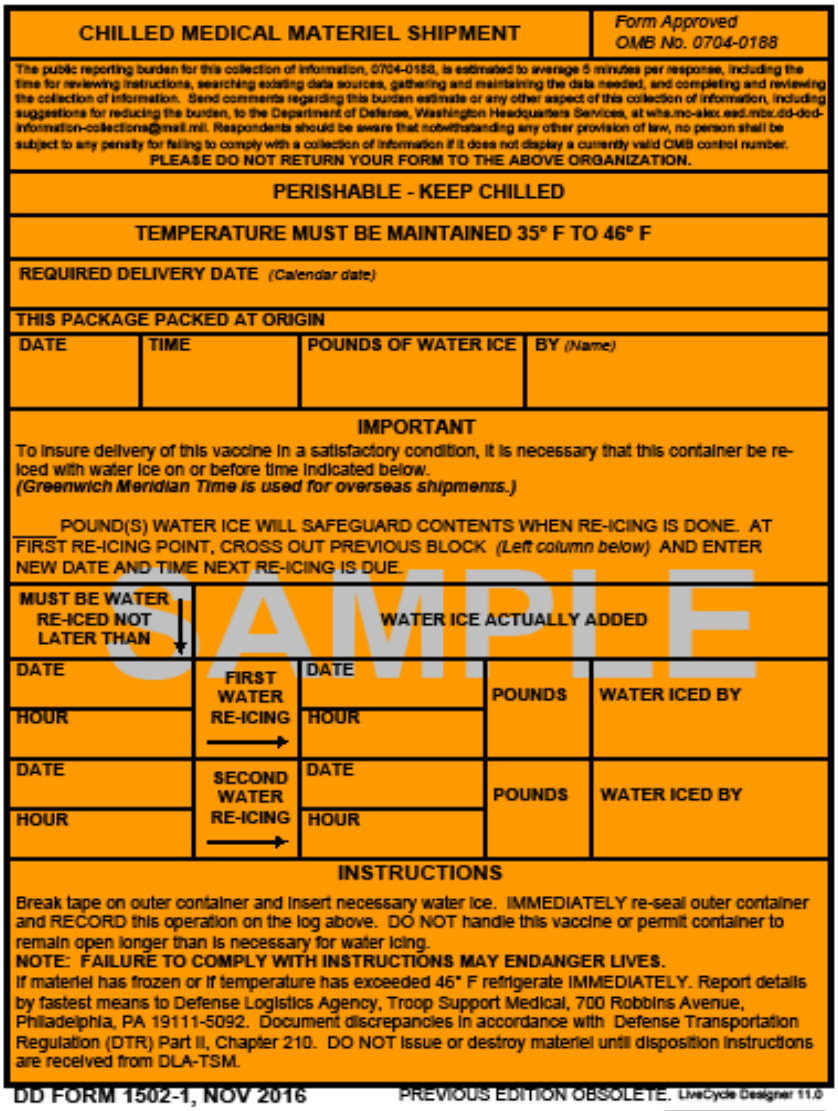
INSTRUCTIONS

Break tape on outer container and insert necessary dry ice. IMMEDIATELY re-seal outer container and RECORD this operation on the log above. DO NOT handle this vaccine or permit container to remain open longer than is necessary for DRY re-icing.
NOTE: FAILURE TO COMPLY WITH INSTRUCTIONS MAY ENDANGER LIVES.
If materiel has thawed or if shipment arrives without dry ice, refreeze immediately. Report details by fastest means to Defense Logistics Agency, Troop Support Medical, 700 Robbins Avenue, Philadelphia, PA 19111-5092. Document discrepancies in accordance with Defense Transportation Regulation (DTR) Part II, Chapter 210. DO NOT issue or destroy materiel until disposition instructions are received from DLA-TSM.

DD FORM 1502, NOV 2016 PREVIOUS EDITION OBSOLETE LiveCycle Designer 11.0

Reset

DD Form 1502-1 – Chilled Medical Material Shipment
Bright Orange Pressure-Sensitive Label



CHILLED MEDICAL MATERIEL SHIPMENT | *Form Approved OMB No. 0704-0188*

The public reporting burden for this collection of information, 0704-0188, is estimated to average 5 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden, to the Department of Defense, Washington Headquarters Services, at whs.mc-alex.esd.mbx.dd-ded-information-collections@mail.mil. Respondents should be aware that notwithstanding any other provision of law, no person shall be subject to any penalty for failing to comply with a collection of information if it does not display a currently valid OMB control number.
PLEASE DO NOT RETURN YOUR FORM TO THE ABOVE ORGANIZATION.

PERISHABLE - KEEP CHILLED

TEMPERATURE MUST BE MAINTAINED 35° F TO 46° F

REQUIRED DELIVERY DATE *(Calendar date)*

THIS PACKAGE PACKED AT ORIGIN

DATE	TIME	POUNDS OF WATER ICE	BY *(Name)*

IMPORTANT

To insure delivery of this vaccine in a satisfactory condition, it is necessary that this container be re-iced with water ice on or before time indicated below.
(Greenwich Meridian Time is used for overseas shipments.)

____ POUND(S) WATER ICE WILL SAFEGUARD CONTENTS WHEN RE-ICING IS DONE. AT FIRST RE-ICING POINT, CROSS OUT PREVIOUS BLOCK *(Left column below)* AND ENTER NEW DATE AND TIME NEXT RE-ICING IS DUE.

MUST BE WATER RE-ICED NOT LATER THAN ↓		WATER ICE ACTUALLY ADDED		
DATE / HOUR	FIRST WATER RE-ICING →	DATE / HOUR	POUNDS	WATER ICED BY
DATE / HOUR	SECOND WATER RE-ICING →	DATE / HOUR	POUNDS	WATER ICED BY

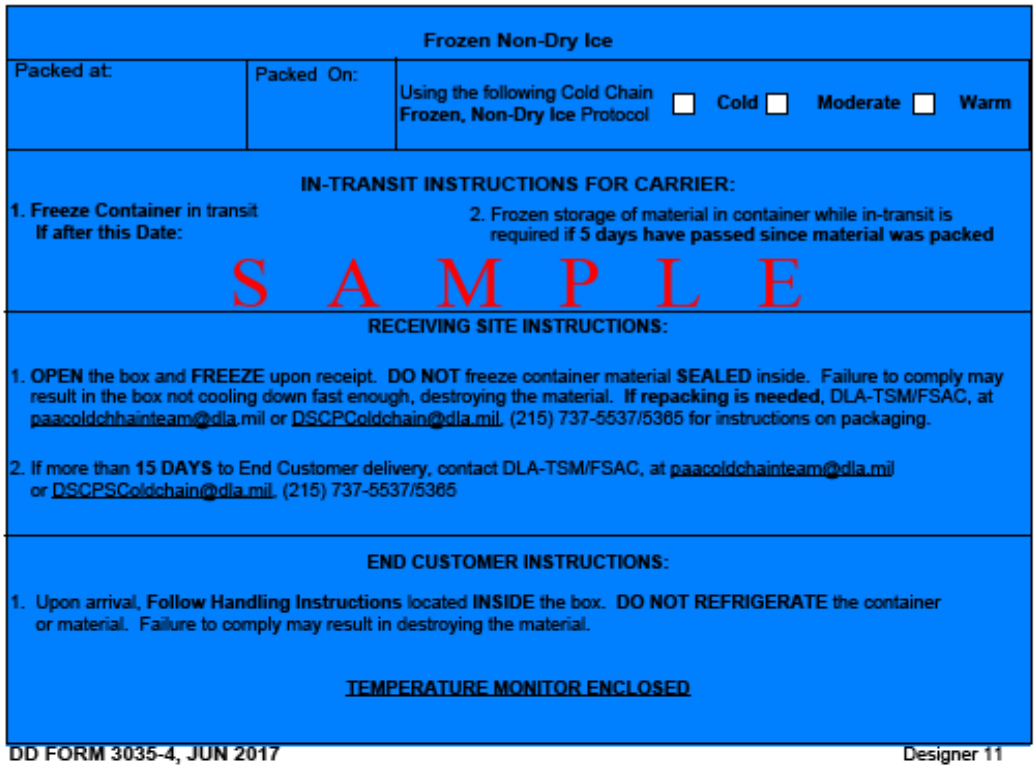
INSTRUCTIONS

Break tape on outer container and insert necessary water ice. IMMEDIATELY re-seal outer container and RECORD this operation on the log above. DO NOT handle this vaccine or permit container to remain open longer than is necessary for water icing.
NOTE: FAILURE TO COMPLY WITH INSTRUCTIONS MAY ENDANGER LIVES.
If materiel has frozen or if temperature has exceeded 46° F refrigerate IMMEDIATELY. Report details by fastest means to Defense Logistics Agency, Troop Support Medical, 700 Robbins Avenue, Philadelphia, PA 19111-5092. Document discrepancies in accordance with Defense Transportation Regulation (DTR) Part II, Chapter 210. DO NOT issue or destroy materiel until disposition instructions are received from DLA-TSM.

DD FORM 1502-1, NOV 2016 PREVIOUS EDITION OBSOLETE. LiveCycle Designer 11.0

Reset

DD Form 3035-4 - Cold Chain Management Shipping Label for Freezer Items



Frozen Non-Dry Ice

Packed at:	Packed On:	Using the following Cold Chain **Frozen, Non-Dry Ice** Protocol ☐ **Cold** ☐ **Moderate** ☐ **Warm**

IN-TRANSIT INSTRUCTIONS FOR CARRIER:

1. **Freeze Container** in transit **If after this Date:**
2. Frozen storage of material in container while in-transit is required if **5 days have passed since material was packed**

S A M P L E

RECEIVING SITE INSTRUCTIONS:

1. **OPEN** the box and **FREEZE** upon receipt. **DO NOT** freeze container material **SEALED** inside. Failure to comply may result in the box not cooling down fast enough, destroying the material. **If repacking is needed,** DLA-TSM/FSAC, at paacoldchhainteam@dla.mil or DSCPColdchain@dla.mil, (215) 737-5537/5365 for instructions on packaging.

2. If more than **15 DAYS** to End Customer delivery, contact DLA-TSM/FSAC, at paacoldchainteam@dla.mil or DSCPSColdchain@dla.mil, (215) 737-5537/5365

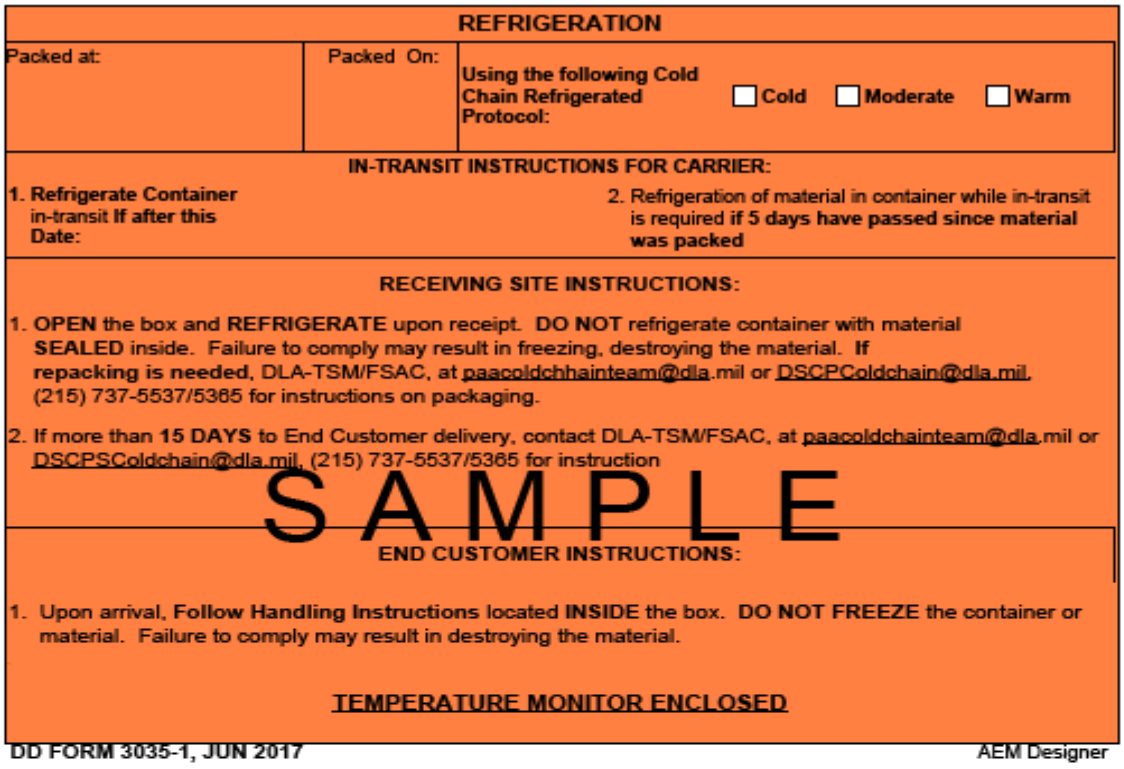
END CUSTOMER INSTRUCTIONS:

1. Upon arrival, **Follow Handling Instructions** located **INSIDE** the box. **DO NOT REFRIGERATE** the container or material. Failure to comply may result in destroying the material.

TEMPERATURE MONITOR ENCLOSED

DD FORM 3035-4, JUN 2017 **Designer 11**

DD Form 3035-1 - Cold Chain Management Shipping Label for Refrigerated Items



REFRIGERATION

Packed at:	Packed On:	Using the following Cold Chain Refrigerated Protocol: ☐ Cold ☐ Moderate ☐ Warm

IN-TRANSIT INSTRUCTIONS FOR CARRIER:

1. **Refrigerate Container in-transit If after this Date:**
2. Refrigeration of material in container while in-transit is required **if 5 days have passed since material was packed**

RECEIVING SITE INSTRUCTIONS:

1. **OPEN** the box and **REFRIGERATE** upon receipt. **DO NOT** refrigerate container with material **SEALED** inside. Failure to comply may result in freezing, destroying the material. **If repacking is needed**, DLA-TSM/FSAC, at paacoldchhainteam@dla.mil or DSCPColdchain@dla.mil, (215) 737-5537/5365 for instructions on packaging.
2. If more than **15 DAYS** to End Customer delivery, contact DLA-TSM/FSAC, at paacoldchainteam@dla.mil or DSCPSColdchain@dla.mil, (215) 737-5537/5365 for instruction

SAMPLE

END CUSTOMER INSTRUCTIONS:

1. Upon arrival, **Follow Handling Instructions** located **INSIDE** the box. **DO NOT FREEZE** the container or material. Failure to comply may result in destroying the material.

TEMPERATURE MONITOR ENCLOSED

DD FORM 3035-1, JUN 2017 AEM Designer

DD Form 3035-2 - Cold Chain Management Shipping Label for Hybrid Items

HYBRID

Packed at:	Packed On:	Using the following Cold Chain Hybrid Protocol ☐ Cold ☐ Moderate ☐ Warm

IN-TRANSIT INSTRUCTIONS FOR CARRIER:

1. Refrigerate Container in transit. If after this Date:		2. Refrigeration of material in container while in-transit is required if 5 days have passed since material was packed

RECEIVING SITE INSTRUCTIONS:

1. **OPEN** the box and **REFRIGERATE** upon receipt. **DO NOT** refrigerate the container **SEALED**. Failure to comply may result in the container getting too warm, destroying the material. **If repacking is needed,** DLA-TSM/FSAC, at paacoldchhainteam@dla.mil or DSCPColdchain@dla.mil, (215) 737-5537/5365 for instructions on packaging.

2. If more than **15 DAYS** to End Customer delivery, contact DLA-TSM/FSAC, at paacoldchainteam@dla.mil or DSCPSColdchain@dla.mil, (215) 737-5537/5365

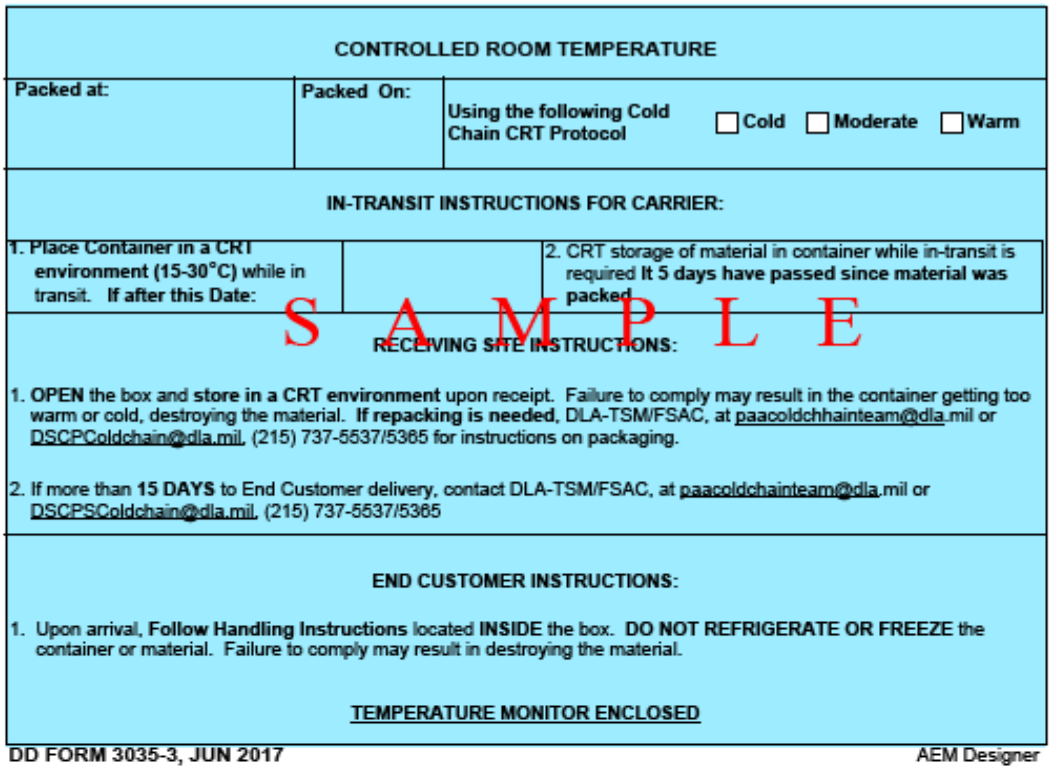
END CUSTOMER INSTRUCTIONS:

1. Upon arrival, **Follow Handling Instructions** located **INSIDE** the box. **DO NOT FREEZE** the container or material. Failure to comply may result in destroying the material.

TEMPERATURE MONITOR ENCLOSED

DD FORM 3035-2, JUN 2017 AEM Designer

DD Form 3052-3 - Cold Chain Management Shipping Label for Controlled Room Temperature Items



CONTROLLED ROOM TEMPERATURE

Packed at:	Packed On:	Using the following Cold Chain CRT Protocol ☐ Cold ☐ Moderate ☐ Warm

IN-TRANSIT INSTRUCTIONS FOR CARRIER:

1. Place Container in a CRT environment (15-30°C) while in transit. If after this Date:		2. CRT storage of material in container while in-transit is required **It 5 days have passed since material was packed**

S A M P L E

RECEIVING SITE INSTRUCTIONS:

1. **OPEN** the box and **store in a CRT environment** upon receipt. Failure to comply may result in the container getting too warm or cold, destroying the material. **If repacking is needed**, DLA-TSM/FSAC, at paacoldchhainteam@dla.mil or DSCPColdchain@dla.mil, (215) 737-5537/5365 for instructions on packaging.

2. If more than **15 DAYS** to End Customer delivery, contact DLA-TSM/FSAC, at paacoldchainteam@dla.mil or DSCPSColdchain@dla.mil, (215) 737-5537/5365

END CUSTOMER INSTRUCTIONS:

1. Upon arrival, **Follow Handling Instructions** located **INSIDE** the box. **DO NOT REFRIGERATE OR FREEZE** the container or material. Failure to comply may result in destroying the material.

TEMPERATURE MONITOR ENCLOSED

DD FORM 3035-3, JUN 2017 AEM Designer

DD Form 1502N – NOTICE FOR FROZEN MEDICAL SHIPMENTS

NOTICE FOR FROZEN MEDICAL MATERIEL SHIPMENTS

IF THIS SHIPMENT IS RECEIVED WITH NO DRY ICE IN THE CONTAINER, OR IF THE FROZEN GEL PACKS ARE WARM TO THE TOUCH, TAKE THE FOLLOWING ACTIONS:

1. Place the materiel in freeze below 32° F.

2. Suspend the material from issue and use and report discrepancy on DD-361," Transportation Discrepancy Report (TDR)," or SF-364, "Report of Discrepancy (ROD)," as appropriate, to:

DLA Troop Support
Directorate of Medical Materiel
ATTN: FSAC
700 Robbins Avenue, Bldg 6A
Philadelphia, PA 19111-5092

3. As an alternate, report discrepancy electronically through Web SDR: https://www2.transactionservices.dla.mil/websdr/home.asp.

4. Include the following data in the report: (Use separate report for each item)

(a) National Stock Number, National Drug Code, or Product/ Part Number

(b) Complete Nomenclature

(c) Name of manufacturer

(d) Lot (control) numbers

(e) Contract and/or requisition numbers

(f) Total dollar value

(g) Quantity

(h) Present storage condition

(i) Temperature or adverse storage condition existing during shipment; also furnish environmental temperature at time of receipt

(j) Nature of the complaint

(k) Name of last known carrier from which material was received and final destination for shipment

(l) TCN or GBL numbers

(m) Date and hour material delivered by carrier

(n) Date and hour material returned to refrigeration

(o) Other details concerning condition of material identify origin of shipment *(Depot or contractor's name)*, and all entries recorded on DD Form 1502-1

(p) Name, location, telephone number (DSN and commercial with area code), and work email address of person most familiar with this situation

5. **DO NOT** issue or destroy material until disposition instructions are received from DLA-TSM/FSAC.

6. Attach the following to the DD-361 or SF364 (unless submitting electronically):

a. DD Form 1502 label *(remove from the package)*.
b. Copy of GBL and/or copy of carrier's delivery document.
c. Copy of the Report of Shipment (REPSHIP) if received electronically (or information furnished if REPSHIP received by telephone).

DD FORM 1502N, JUN 2017 PREVIOUS EDITION IS OBSOLETE. Page 1 of 1
AEM LiveCycle Designer

DD Form 1502-N1 – NOTICE FOR CHILLED MEDICAL SHIPMENTS

NOTICE FOR CHILLED MEDICAL MATERIEL SHIPMENTS

IF THIS SHIPMENT IS RECEIVED WITH THE CHILLED AND/OR FROZEN GEL PACKS WARM TO THE TOUCH, TAKE THE FOLLOWING ACTIONS:

1. Place the materiel in chill space. (Refrigeration temperature 36° to 46° F)

2. Suspend the material from issue and use and report discrepancy on DD-361," Transportation Discrepancy Report (TDR)," or SF-364, "Report of Discrepancy (ROD)," as appropriate, to:

   DLA Troop Support
   Directorate of Medical Materiel
   ATTN: FSAC
   700 Robbins Avenue, Bldg 6A
   Philadelphia, PA 19111-5092

3. As an alternate, report discrepancy electronically through WebSDR: https://www2.transactionservices.dla.mil/websdr/home.asp.

4. Include the following data in the report: (Use separate report for each item)

   (a) National Stock Number, National Drug Code, or Product/ Part Number

   (b) Complete Nomenclature

   (c) Name of manufacturer

   (d) Lot (control) numbers

   (e) Contract and/or requisition numbers

   (f) Total dollar value

   (g) Quantity

   (h) Present storage condition

   (i) Temperature or adverse storage condition existing during shipment; also furnish environmental temperature at time of receipt

   (j) Nature of the complaint

   (k) Name of last known carrier from which material was received and final destination for shipment

   (l) TCN or GBL numbers

   (m) Date and hour material delivered by carrier

   (n) Date and hour material returned to refrigeration

   (o) Other details concerning condition of material identify origin of shipment *(Depot or contractor's name), and all* entries recorded on DD Form 1502-1

   (p) Name, location, telephone number (DSN and commercial with area code), and work email address of person most familiar with this situation

5. **DO NOT** issue or destroy material until disposition instructions are received from DLA-TSM/FSAC.

6. Attach the following to the DD-361 or SF 364 (unless submitting electronically):

   a. DD Form 1502-1 label *(remove from the package)*.
   b. Copy of GBL and/or copy of carrier's delivery document.
   c. Copy of the Report of Shipment (REPSHIP) if received electronically (or information furnished if REPSHIP received by telephone).

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DD Form 1502-2N – NOTICE FOR LIMITED UNREFRIGERATED MEDICAL SHIPMENTS

NOTICE FOR LIMITED UNREFRIGERATED MEDICAL MATERIEL SHIPMENTS

IF THIS SHIPMENT IS RECEIVED BEYOND THE REQUIRED DELIVERY DATE, OR IF THE MATERIAL MAY HAVE BEEN EXPOSED TO TEMPERATURES OVER 95ºF OR BELOW 32ºF, TAKE THE FOLLOWING ACTIONS:

1. Place the materiel in chill space. (Refrigeration temperature 35º to 46º F)

2. Suspend the material from issue and use and report discrepancy on DD-361," Transportation Discrepancy Report (TDR)," or SF-364, "Report of Discrepancy (ROD)," as appropriate, to:

   DLA Troop Support
   Directorate of Medical Materiel
   ATTN: FSAC
   700 Robbins Avenue, Bldg 6A
   Philadelphia, PA 19111-5092

3. As an alternate, report discrepancy electronically through WebSDR: https://www2.transactionservices.dla.mil/websdr/home.asp.

4. Include the following data in the report: (Use separate report for each item)

   (a) National Stock Number, National Drug Code, or Product/ Part Number

   (b) Complete Nomenclature

   (c) Name of manufacturer

   (d) Lot (control) numbers

   (e) Contract and/or requisition numbers

   (f) Total dollar value

   (g) Quantity

   (h) Present storage condition

   (i) Temperature or adverse storage condition existing during shipment; also furnish environmental temperature at time of receipt

   (j) Nature of the complaint

   (k) Name of last known carrier from which material was received and final destination for shipment

   (l) TCN or GBL numbers

   (m) Date and hour material delivered by carrier

   (n) Date and hour material returned to refrigeration

   (o) Other details concerning condition of material identify origin of shipment *(Depot or contractor's name), and all* entries recorded on DD Form 1502-1

   (p) Name, location, telephone number (DSN and commercial with area code), and work email address of person most familiar with this situation

5. **DO NOT** issue or destroy material until disposition instructions are received from DLA-TSM/FSAC.

6. Attach the following to the DD-361 or SF 364 (unless submitting electronically):

   a. DD Form 1502-2 label *(remove from the package)*.
   b. Copy of GBL and/or copy of carrier's delivery document.
   c. Copy of the Report of Shipment (REPSHIP) if received electronically (or information furnished if REPSHIP received by telephone).

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GLOSSARY

PART I. ABBREVIATIONS AND ACRONYMS

ASTM	American Society for Testing Materials
AFI	Air Force Instruction
AFMAN	Air Force Manual
CGA	Compressed Gas Association
DLA	Defense Logistics Agency
DLAI	Defense Logistics Agency Issuance
DLAR	Defense Logistics Agency Regulation
DOD	Department of Defense
DSCP	Defense Supply Center Philadelphia
DSS	Distribution Standard System
DTR	Defense Transportation Regulation
EDA	Electronic Document Access
FLIS	Federal Logistics Information System
FSC	Federal Supply Class
ITSC	Item Type Storage Code
MCO	Marine Corps Order
MMC	Medical Master Catalog
NAVMEDPUB	Naval Medical Publication
NAVSUPINST	Naval Supply Instruction
NAVSUPPUB	Naval Supply Publication
TB	Technical Bulletin
TM	Technical Manual
TQ	Technical Quality

PART II. DEFINITIONS

Unless otherwise noted, these terms and their definitions are for the purpose of this regulation.

Cold Chain Management. The process of preparing temperature-sensitive medical products for shipment utilizing standardized systems and procedures, ensuring that required temperatures are maintained throughout the supply chain, and the validation that those conditions are met during all phases of distribution until delivery. Items are identified in the FLIS, the DOD repository for item data, by the ITSC.

Controlled Room Temperature. Items that are thermostatically controlled between 20°C and 25°C (68°F and 77°F), with excursions allowed down to 15°C (59°F) and up to 30°C (86°F).

Closures. A device that closes an opening in a receptacle.

Freezer Items. Items that are thermostatically controlled between -25°C and -10°C (-13°F and 14°F)

Hazardous and Refrigerated (Chill) Items. Hazardous material items that require refrigeration; must be stored with compatible hazardous materials.

Hybrid Items. Items that can be thermostatically controlled between -20°C and 8°C (-4°F and 46°F); frozen or refrigerated.

Non-Stringent. Desired temperature ranges per manufacturer input.

Phase Change Materials. Packaging materials used for applications that need to maintain a controlled room temperature. When used as a liquid, they act as a heat source (keeping the contents warm). When used as a solid, they act as a heat sink (protecting the contents from heat).

Refrigerant Pack. A non-toxic, non-hazardous coolant material with a freezing/melting point of 0°C (32°F).

Stringent. Exact temperature requirements as determined by the item's federal licensure. Excursions outside of the required temperature range warrant materiel quality analysis.

Suppressed Temperature Gel Packs. Gel packs containing a suppressed temperature freezing point formula. This ice gel formulation is best for the shipment of products that need to stay below freezing temperatures.