Federal Aviation Administration

Memorandum

Date: October 25, 2012

To: See Distribution List

From: FOR David W. Hempe, Manager, Aircraft Engineering Division, AIR-100 SignCahlen
James D. Seipel, Acting Manager, Production and Airworthiness Division, AIR-200

Prepared by: Terry Fahr, Engineering Procedures Branch, AIR-110

Subject: Approval of Temperature Controlled Shipping Containers (Non-ULD), Revision 2.1

Memo No.: AIR-100-12-110-002

Regulatory Reference: Title 14 of the Code of Federal Regulations (14 CFR) § 21.8(d)

Policy References: FAA Orders 8110.4C, 8110.42C, 8120.2G, 8150.4, and 8900.1

This memorandum provides guidance on issuing a design and production approval for temperature controlled shipping containers, hereafter referred to as 'device(s).' This policy does not apply to unit load devices (ULD) covered by Technical Standard Order (TSO)-C90c, *Cargo Pallets, Nets, and Containers.*

This memorandum, the second revision, supersedes the memoranda issued on January 8, 2010 and, the first revision, dated February 27, 2012, on the same subject. This includes technical corrections to revision 1, and adds criteria for permitting the co-loading of the device with other cargo.

Transportation of high-value medicines, vaccines, and other biomedical materials requires a temperature stable environment. There are several commercially available battery-powered devices in use today. However, these devices must be deactivated to be carried as cargo on aircraft. Device manufacturers have approached the FAA seeking approval for aircraft-specific devices that can be carried in active mode.

We authorize you to proceed with such projects in accordance with the attached procedures. This memorandum constitutes an approved deviation from FAA Orders 8110.42C, *Parts Manufacturer Approval Procedur*es, and 8120.2G, *Production Approval and Certificate Management Procedures*. Carriage of a device in active mode, as cargo on an air carrier, requires design and production approval from the Aircraft Certification Service and operational authorization from the Flight Standards Service. Although a TSO authorization (TSOA) would provide a design and production approval, we do not have an applicable TSO.

There is a compelling public interest in air transportation of biomedical materials. Therefore, we have developed an interim approval process using 14 CFR 21.8(d) for the design and a PMA for production. Though TSO-C90c cannot be used, the technical criteria published in FAA Order 8150.4, *Certification of Cargo Containers with Self-Contained Temperature Control Systems (Active ULDs)*, Appendix 1, may apply to the evaluation of these devices.

The attached procedure will be in effect until an appropriate TSO is available. After that time, a TSOA should be used for approval of any new devices. PMA holders' existing approved devices may continue to be produced under the PMA or they may apply for a TSOA.

PMAs and FAA Letters of Design Approval previously issued under 14 CFR 21.305(d) for these devices will be amended in accordance with paragraph 6 of the attached procedure at the next amendment or revision.

Points of contact are: Bruce Kaplan, AIR-110, at 202-385-6318, and Angelia Collier, AIR-220, at 202-385-6389.

Attachments:

A Procedure for Approving Temperature Controlled non-ULD Shipping Containers, Revision 2

Authorization for carriage of temperature controlled non-ULD shipping containers in active mode (hereafter referred to as a *'device'*) requires three steps (see the flow chart on page 4):

1. A design approval - based on appropriate technical criteria.
2. An approval for production of the d*evice*.
3. Aircraft operator authorization to carry the d*evice* in active mode on specific aircraft.

Below is guidance on issuing the design and production approvals. The Flight Standards Service (AFS-300) provides guidance to operators on revising their operations manual in FAA Order 8900.1, volume 3, chapter 47, section 1.

To summarize the approach below: For the design approval, the ACO will specify technical requirements in a G-1 Issue Paper that will establish the approval basis for issuing an FAA Letter of Design Approval under 14 CFR 21.8(d). Though the input and output are different, the ACO can use the basic procedures for 'Test & Computation - General Analysis' contained in FAA Order 8110.42C. For the production approval, Parts Manufacturer Approval (PMA) will be used. The basic processes for issuing PMA based on a supplemental type certificate (STC) will be followed. However, the 'Approval Basis' will be the FAA Letter of Design Approval under 14 CFR 21.8(d). The procedure below constitutes an approved deviation to FAA Orders 8110.42C and 8120.2G.

Design Approval

1. The applicant should apply to the Aircraft Certification office (ACO) for a design approval under 14 CFR 21.8(d). The ACOs are required to coordinate with the Transport Airplane Directorate Standards Staff on developing and approving specific methods of compliance (MOC) for assessing the effect of the *device* on aircraft fire detection/suppression systems, and MOC for lithium batteries, if used.

2. The ACO should develop a G-1 Issue Paper, in accordance with Order 8110.112 *Standardized Procedures for Usage of Issue Papers and Development of Equivalent Levels of Safety Memorandums,* that contains the technical requirements that establish the approval basis for issuing an FAA Letter of Design Approval under 14 CFR 21.8(d). Those technical requirements should include the applicable technical requirements from FAA Order 8150.4, Appendix 1 and any other requirements the FAA finds necessary to establish a minimum level of safety consistent with the regulations. The G-1 Issue Paper must be coordinated with the Aircraft Engineer Division (AIR-100) in accordance with Order 8110.4C Change 4, paragraph 6-10.

3. The G-1 Issue Paper should also require that the applicant submit the following items:

a. The specific pallet/cargo-net combinations for which it seeks carriage approval for the *Device*. The applicant must conduct a compatibility demonstration (and/or analysis) for each proposed pallet/cargo-net combinations. These approved pallet/cargo-net combinations will become part of the limitations sections of the Instructions for Continued Airworthiness (ICA) and operating instructions.

b. Required markings, placards, and labeling, including:

i. Marking required by 14 CFR 45.15.

ii. Any other placards or labeling required for the safe handling, operation, and carriage of the *Device* in active mode.

c. Instructions for Continued Airworthiness (ICA) containing:

i. A complete set of instructions for maintenance, inspection, and return-to-service after maintenance, and who is authorized to perform these functions.

ii. All proposed limitations and restrictions necessary to safely carry the *Device* on an aircraft. This includes the list of approved pallet/cargo-net combinations, the number of *Devices* allowed for each of these combinations, and a statement that no other cargo is allowed under the cargo-net. Co-loading of the *device* with other cargo is permitted, however, when the applicant provides instructions for the co-loading, and data showing:

(1) Sufficient venting of the *device* in the co-loading configuration.

(2) Incorporation of adequate measures to prevent damage to the *device* due to shifting of the co-loaded cargo.

(3) Sufficient air circulation around the *device* in the co-loading configuration to permit proper interface of any smoke with the aircraft smoke detectors.

d. Operating Instructions for the *device*, which include:

i. Procedures for pre-flight preparation and inspection, including identification of any serviceable tags or other instruments required to certify airworthiness prior to carriage.

ii. Instructions to ensure air carrier and ground handling personnel can identify that the unit is operating properly and ensure that the unit is removed from service in case of failure;

iii. Procedures for normal and emergency operations;

iv. Procedures for handling of the *device*;

v. Instructions for the proper loading of the *device* for each approved pallet/cargo-net combination;

vi. All limitations (as approved in the ICA); and

vii. Training requirements for the above.

e. A certifying statement from the applicant as follows: “I certify that we have complied with all the technical requirements identified in the G-1 Issue Paper”.

4. The ACO should use the basic processes for 'Test & Computation – General Analysis' contained in FAA Order 8110.42. Upon showing compliance with all the G-1 Issue Paper technical requirements, the ACO may issue an 'FAA Letter of Design Approval under 14 CFR 21.8(d).' The ACO should review and approve the limitations section of the applicant's ICA.

5. The ACO should request that the Aircraft Evaluation Group (AEG) review the applicant's ICA and Operating Instructions.

6. Applicants may apply to their geographic Manufacturing Inspection District Office (MIDO) for PMA by following the procedure in FAA Order 8120.2G, paragraph 2-44. The application letter may follow the example in FAA Order 8120.2G with a reference to the FAA Letter of Design Approval under 14 CFR 21.8(d) in lieu of an STC. The PMA supplement can be prepared using the example in FAA Order 8120.2G, figure 2-9, with the following deviations:

Approved Replacement for Part Number:	Not Applicable.
Approval Basis and Approved Design Data:	FAA Letter of Design Approval under 14 CFR 21.8(d). *All other data should follow figure 2-9.*
Make Eligibility:	See Model Eligibility.
Model Eligibility:	This device may be carried on any aircraft for which the following pallet/cargo-net combinations are approved in the aircraft weight and balance manual. *(See Note below.)*

Note: *List the pallet/cargo-net combinations approval in the limitations section of the ICA. The following statement should also be included in this section:* "This device may only be carried in aircraft in accordance with the aircraft operator's manual procedures & limitations for carriage of this specific Device."

7. A *device* produced in pursuit of an FAA design approval should be considered a prototype or test article. If the applicant adequately controls the article, it may subsequently be approved upon issuance of a PMA.

8. After issuance of the FAA Letter of Design Approval, all design changes must be submitted for approval to the ACO, unless an alternate procedure has been authorized by the ACO.

Production Approval

1. Upon receipt of the application, the MIDO will follow the process described in FAA Order 8120.2G.

2. The applicant will establish a quality system. Upon meeting the requirements of 14 CFR part 21 subpart K, the MIDO will issue the PMA letter and supplement.

3. The applicant marks the *device* in accordance with 14 CFR 45.15(a).

Flow Chart of Approval Process for Temperature Controlled non-ULD Shipping Containers, Revision 3.