

# Rules and Regulations

Federal Register

Vol. 83, No. 86

Thursday, May 3, 2018

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## DEPARTMENT OF TRANSPORTATION

### Federal Aviation Administration

#### 14 CFR Part 23

[Docket No. FAA-2018-0374; Special Conditions No. 23-288-SC]

#### Special Conditions: St. Louis Helicopter, LLC; Textron Aviation B300, B300C, B300C (MC-12W), and B300C (UC-12W) Airplanes; Installation of Rechargeable Lithium Batteries

**AGENCY:** Federal Aviation Administration (FAA), DOT.

**ACTION:** Final special conditions; request for comments.

**SUMMARY:** These special conditions are issued for the Textron Aviation models B300, B300C, B300C (MC-12W), and B300C (UC-12W) series airplanes. The airplane, as modified by St. Louis Helicopter LLC, will have a novel or unusual design feature associated with the installation of a rechargeable lithium battery. The applicable airworthiness regulations do not contain adequate or appropriate safety standards for this design feature. These special conditions contain the additional safety standards the Administrator considers necessary to establish a level of safety equivalent to that established by the existing airworthiness standards.

**DATES:** The effective date of these special conditions is May 3, 2018.

We must receive your comments by June 18, 2018.

**ADDRESSES:** Send comments identified by docket number FAA-2018-0374 using any of the following methods:

- **Federal eRegulations Portal:** Go to <http://www.regulations.gov> and follow the online instructions for sending your comments electronically.

- **Mail:** Send comments to Docket Operations, M-30, U.S. Department of Transportation (DOT), 1200 New Jersey Avenue SE, Room W12-140, West

Building Ground Floor, Washington, DC, 20590-0001.

- **Hand Delivery of Courier:** Take comments to Docket Operations in Room W12-140 of the West Building Ground Floor at 1200 New Jersey Avenue SE, Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

- **Fax:** Fax comments to Docket Operations at 202-493-2251.

**Privacy:** The FAA will post all comments it receives, without change, to <http://regulations.gov>, including any personal information the commenter provides. Using the search function of the docket website, anyone can find and read the electronic form of all comments received into any FAA docket, including the name of the individual sending the comment (or signing the comment for an association, business, labor union, etc.). DOT's complete Privacy Act Statement can be found in the **Federal Register** published on April 11, 2000 (65 FR 19477-19478), as well as at <http://DocketsInfo.dot.gov>.

**Docket:** Background documents or comments received may be read at <http://www.regulations.gov> at any time. Follow the online instructions for accessing the docket or go to the Docket Operations in Room W12-140 of the West Building Ground Floor at 1200 New Jersey Avenue SE, Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

**FOR FURTHER INFORMATION CONTACT:** Ruth Hirt, Federal Aviation Administration, Aircraft Certification Service, Small Airplane Directorate, AIR-694, 901 Locust, Room 301, Kansas City, MO; telephone (816) 329-4108; facsimile (816) 329-4090.

**SUPPLEMENTARY INFORMATION:** The FAA has determined that notice and opportunity for prior public comment hereon are impracticable because these procedures would significantly delay issuance of the approval design and thus delivery of the affected aircraft. In addition, the FAA has determined, in accordance with 5 U.S.C. 553(b)(3)(B) and 553(d)(3), that notice and opportunity for prior public comment hereon are unnecessary because the substance of these special conditions has been subject to the public comment process in several prior instances with no substantive comments received. The FAA therefore finds that good cause

exists for making these special conditions effective upon issuance.

Special conditions No.	Company/airplane model
23-15-01-SC <sup>1</sup> ....	Kestrel Aircraft Company/Model K-350.
23-09-02-SC <sup>2</sup> ....	Cessna Aircraft Company/Model 525C (CJ4).
23-08-05-SC <sup>3</sup> ....	Spectrum Aeronautical, LLC/Model 40.

### Comments Invited

We invite interested people to take part in this rulemaking by sending written comments, data, or views. The most helpful comments reference a specific portion of the special conditions, explain the reason for any recommended change, and include supporting data. We ask that you send us two copies of written comments.

We will consider all comments we receive on or before the closing date for comments. We will consider comments filed late if it is possible to do so without incurring expense or delay. We may change these special conditions based on the comments we receive.

### Background

On May 23, 2017, St. Louis Helicopter LLC (St. Louis Helicopter) applied for a supplemental type certificate (STC) to install a rechargeable lithium battery on the Textron Aviation, models B300, B300C, B300C (MC-12W), and B300C (UC-12W) airplanes. These are commuter category airplanes with a maximum of 17 seats (including crew), maximum operating altitude of 35,000 feet, and powered by two Pratt & Whitney Canada PT6A-60 engines or two PT6A-67 engines, with 15,000 pounds maximum takeoff weight.

The current regulatory requirements for part 23 airplanes do not contain adequate requirements for use of rechargeable lithium batteries in

<sup>1</sup> [http://rgl.faa.gov/Regulatory\\_and\\_Guidance\\_Library/rgSC.nsf/0/39B156C006EB842E86257EF3004BB13C?OpenDocument&Highlight=installation%20of%20rechargeable%20lithium%20battery](http://rgl.faa.gov/Regulatory_and_Guidance_Library/rgSC.nsf/0/39B156C006EB842E86257EF3004BB13C?OpenDocument&Highlight=installation%20of%20rechargeable%20lithium%20battery).

<sup>2</sup> [http://rgl.faa.gov/Regulatory\\_and\\_Guidance\\_Library/rgSC.nsf/0/902232309C19F0D4862575CB0045AC0D?OpenDocument&Highlight=installation%20of%20rechargeable%20lithium%20battery](http://rgl.faa.gov/Regulatory_and_Guidance_Library/rgSC.nsf/0/902232309C19F0D4862575CB0045AC0D?OpenDocument&Highlight=installation%20of%20rechargeable%20lithium%20battery).

<sup>3</sup> [http://rgl.faa.gov/Regulatory\\_and\\_Guidance\\_Library/rgSC.nsf/0/28E630294DCC27B986257513005968A3?OpenDocument&Highlight=installation%20of%20rechargeable%20lithium%20battery](http://rgl.faa.gov/Regulatory_and_Guidance_Library/rgSC.nsf/0/28E630294DCC27B986257513005968A3?OpenDocument&Highlight=installation%20of%20rechargeable%20lithium%20battery).

airborne applications. This type of battery possesses certain failure and operational characteristics with maintenance requirements that differ significantly from that of the nickel-cadmium (Ni-Cd) and lead-acid rechargeable batteries currently approved in other normal, utility, acrobatic, and commuter category airplanes. Therefore, the FAA is proposing this special condition to address—

- All characteristics of the rechargeable lithium batteries and their installation that could affect safe operation of the modified B300, B300C, B300C (MC-12W), and B300C (UC-12W) airplanes; and
- Appropriate Instructions for Continued Airworthiness (ICA) that include maintenance requirements to ensure the availability of electrical power from the batteries when needed.

#### Type Certification Basis

Under the provisions of § 21.101, St. Louis Helicopter must show that the B300, B300C, B300C (MC-12W), and B300C (UC-12W) airplanes, as changed, continue to meet the applicable provisions of the regulations incorporated by reference in Type Certificate Data Sheet No. A24CE<sup>4</sup> or the applicable regulations in effect on the date of application for the change. The regulations incorporated by reference in the type certificate are commonly referred to as the “original type certification basis.” The regulations incorporated by reference are located on pages 35 through 37 in A24CE.

If the Administrator finds that the applicable airworthiness regulations (*i.e.*, 14 CFR part 23) do not contain adequate or appropriate safety standards for the B300, B300C, B300C (MC-12W), and B300C (UC-12W) airplanes because of a novel or unusual design feature, special conditions are prescribed under the provisions of § 21.16.

The FAA issues special conditions, as defined in § 11.19, under § 11.38 and they become part of the type certification basis under § 21.101.

Special conditions are initially applicable to the models for which they are issued. Should the applicant apply for an STC to modify any other model(s) included on the same type certificate to incorporate the same novel or unusual design feature, the FAA would apply these special conditions to the other model(s) under § 21.101.

#### Novel or Unusual Design Features

The Textron Aviation B300, B300C, B300C (MC-12W), and B300C (UC-12W) airplanes will incorporate the following novel or unusual design features:

The installation of a rechargeable lithium battery as a main or engine start aircraft battery.

#### Discussion

The applicable regulations governing the installation of batteries in general aviation airplanes were derived from CAR 3 as part of the recodification that established 14 CFR part 23. The battery requirements identified in § 23.1353 were a rewording of the CAR requirements. Additional rulemaking activities—resulting from increased incidents of Ni-Cd battery fire or failures—incorporated § 23.1353(f) and (g), amendments 23-20 and 23-21, respectively. The FAA did not envision the introduction of lithium battery installations at the time these regulations were published.

The proposed use of rechargeable lithium batteries prompted the FAA to review the adequacy of these existing regulations. We determined the existing regulations do not adequately address the safety of lithium battery installations.

Current experience with rechargeable lithium batteries in commercial or general aviation is limited. However, other users of this technology—ranging from personal computers, to wireless telephone manufacturers, to the electric vehicle industry—have noted safety problems with rechargeable lithium batteries. These problems include overcharging, over-discharging, flammability of cell components, cell internal defects, and those resulting from exposure to extreme temperatures as described in the following paragraphs.

1. *Overcharging:* In general, rechargeable lithium batteries are significantly more susceptible than their Ni-Cd or lead-acid counterparts to thermal runaway, which is an internal failure that can result in self-sustaining increases in temperature and pressure. This is especially true for overcharging, which causes heating and destabilization of the components of the cell, leading to the formation (by plating) of highly unstable metallic lithium. The metallic lithium can ignite, resulting in a self-sustaining fire or explosion. Finally, the severity of thermal runaway due to overcharging increases with increasing battery capacity due to the higher amount of electrolyte in large batteries.

2. *Over-discharging:* Discharge of some types of rechargeable lithium battery cells beyond the manufacturer's recommended specification can cause corrosion of the electrodes of the cell, resulting in loss of battery capacity that cannot be reversed by recharging. This loss of capacity may not be detected by the simple voltage measurements commonly available to flight crews as a means of checking battery status—a problem shared with Ni-Cd batteries. In addition, over-discharging has the potential to lead to an unsafe condition (creation of dendrites that could result in internal short circuit during the recharging cycle).

3. *Flammability of Cell Components:* Unlike Ni-Cd and lead-acid batteries, some types of rechargeable lithium batteries use liquid electrolytes that are flammable. The electrolyte can serve as a source of fuel for an external fire, if there is a breach of the battery container.

4. *Cell Internal Defects:* The rechargeable lithium batteries and rechargeable battery systems have a history of undetected cell internal defects. These defects may or may not be detected during normal operational evaluation, test, and validation. This may lead to an unsafe condition during in service operation.

5. *Extreme Temperatures:* Exposure to an extreme temperature environment has the potential to create major hazards. Care must be taken to ensure that the lithium battery remains within the manufacturer's recommended specification.

#### Applicability

As discussed above, these special conditions are applicable to the B300, B300C, B300C (MC-12W), and B300C (UC-12W) airplanes. Should St. Louis Helicopter apply at a later date for an STC to modify any other model included on the same type certificate to incorporate the same novel or unusual design feature, the FAA would apply these special conditions to that model as well.

#### Conclusion

This action affects only certain novel or unusual design features on the B300, B300C, B300C (MC-12W), and B300C (UC-12W) airplanes. It is not a rule of general applicability and affects only the applicant who applied to the FAA for approval of these features on the airplane.

The substance of these special conditions has been subjected to the notice and comment period in several prior instances and has been derived without substantive change from those

<sup>4</sup> [http://rgl.faa.gov/Regulatory\\_and\\_Guidance\\_Library/rgMakeModel.nsf/0/c76fc5b6f3cf8a82862582560060751e/\\$FILE/A24CE\\_Rev\\_119.pdf](http://rgl.faa.gov/Regulatory_and_Guidance_Library/rgMakeModel.nsf/0/c76fc5b6f3cf8a82862582560060751e/$FILE/A24CE_Rev_119.pdf).

previously issued. It is unlikely that prior public comment would result in a significant change from the subject contained herein. Therefore, notice and opportunity for prior public comment hereon are unnecessary and the FAA finds good cause, in accordance with 5 U.S.C. 553(b)(3)(B) and 553(d)(3), making these special conditions effective upon issuance. The FAA is requesting comments to allow interested persons to submit views that may not have been submitted in response to the prior opportunities for comment described above.

#### List of Subjects in 14 CFR Part 23

Aircraft, Aviation safety, Signs and symbols.

#### Citation

■ The authority citation for these special conditions is as follows:

**Authority:** 49 U.S.C. 106(f), 106(g), 40113, 44701–44702, 44704; Pub. L. 113–53, 127 Stat 584 (49 U.S.C. 44704) note; 14 CFR 21.16 and 21.101; and 14 CFR 11.38 and 11.19.

#### The Special Conditions

■ Accordingly, pursuant to the authority delegated to me by the Administrator, the following special conditions are issued as part of the type certification basis for Textron Aviation B300, B300C, B300C (MC–12W), and B300C (UC–12W) airplanes modified by St. Louis Helicopter, LLC.

##### 1. Installation of Lithium Battery

The FAA adopts that the following special conditions be applied to lithium battery installations on the Textron Aviation models B300, B300C, B300C (MC–12W), and B300C (UC–12W) airplanes in lieu of the requirements § 23.1353 (a), (b), (c), (d), and (e), amendment 23–49.

Lithium battery installations on the models B300, B300C, B300C (MC–12W), and B300C (UC–12W) airplanes must be designed and installed as follows:

(1) Safe cell temperatures and pressures must be maintained during—

- Normal operations;
- Any probable failure conditions of charging or discharging or battery monitoring system; and
- Any failure of the charging or battery monitoring system not shown to be extremely remote.

(2) The rechargeable lithium battery installation must be designed to preclude explosion or fire in the event of 1(1)ii and 1(1)iii failures.

(3) Design of the rechargeable lithium batteries must preclude the occurrence of self-sustaining, uncontrolled increases in temperature or pressure.

(4) No explosive or toxic gases emitted by any rechargeable lithium battery in normal operation or as the result of any failure of the battery charging system, monitoring system, or battery installation, which is not shown to be extremely remote, may accumulate in hazardous quantities within the airplane.

(5) Installations of rechargeable lithium batteries must meet the requirements of § 23.863(a) through (d), amendment 23–34.

(6) No corrosive fluids or gases that may escape from any rechargeable lithium battery, may damage surrounding structure or any adjacent systems, equipment, electrical wiring, or the airplane in such a way as to cause a major or more severe failure condition, in accordance with § 23.1309, amendment 23–49, and applicable regulatory guidance.

(7) Each rechargeable lithium battery installation must have provisions to prevent any hazardous effect on structure or essential systems that may be caused by the maximum amount of heat the battery can generate during a short circuit of the battery or of its individual cells.

(8) Rechargeable lithium battery installations must have—

- A system to automatically control the charging rate of the battery to prevent battery overheating and overcharging; and either
- A battery temperature sensing and over-temperature warning system with a means for automatically disconnecting the battery from its charging source in the event of an over-temperature condition; or
- A battery failure sensing and warning system with a means for automatically disconnecting the battery from its charging source in the event of battery failure.

(9) Any rechargeable lithium battery installation, the function of which is required for safe operation of the aircraft, must incorporate a monitoring and warning feature that will provide an indication to the appropriate flight crewmembers whenever the state of charge of the batteries has fallen below levels considered acceptable for dispatch (see note 1) of the aircraft.

**Note 1:** Reference § 23.1353(h) for dispatch consideration.

(10) The Instructions for Continued Airworthiness (ICA) required by § 23.1529 must contain maintenance requirements (see note 2) to assure that the battery has been sufficiently charged (see note 3) at appropriate intervals specified by the battery manufacturer and the equipment manufacturer that

contain the rechargeable lithium battery or rechargeable lithium battery system. The lithium rechargeable batteries and lithium rechargeable battery systems must not degrade below specified ampere-hour levels sufficient to power the aircraft system. The ICA must also contain procedures for the maintenance of replacement batteries (see note 4) to prevent the installation of batteries that have degraded charge retention ability or other damage due to prolonged storage at a low state of charge. Replacement batteries must be of the same manufacturer and part number as approved by the FAA.

**Note 2:** Maintenance requirements include procedures that—

(a) Check battery capacity, charge degradation at manufacturers recommended inspection intervals; and

(b) Replace batteries at manufacturers recommended replacement schedule/time to prevent age related degradation.

**Note 3:** The term “sufficiently charged” means that the battery must retain enough charge, expressed in ampere-hours, to ensure that the battery cells will not be damaged.

A battery cell may be damaged by low charge (*i.e.*, below certain level), resulting in a reduction in the ability to charge and retain a full charge. This reduction would be greater than the reduction that may result from normal operational degradation.

**Note 4:** Replacement battery in spares storage may be subject to prolonged storage at a low state of charge.

Issued in Kansas City, Missouri on April 23, 2018.

**Pat Mullen,**

*Manager, Small Airplane Standards Branch, Aircraft Certification Service.*

[FR Doc. 2018–09350 Filed 5–2–18; 8:45 am]

**BILLING CODE 4910–13–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

#### 21 CFR Part 102

[Docket No. FDA–2018–N–1438]

RIN 0910–AI04

#### Crabmeat; Amendment of Common or Usual Name Regulation

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Final rule; technical amendment.

**SUMMARY:** The Food and Drug Administration (FDA or we) is amending the common or usual name