

Area of Application. Survey area plus:

Michigan:
Alpena
Calhoun
Crawford
Grand Traverse
Huron
Iosco
Kent
Leelanau
Ottawa
Saginaw
Washtenaw
Wayne
Ohio:
Ottawa

* * * * *

TEXAS

* * * * *

Nueces
Survey Area

Texas:
Nueces

Area of Application. Survey area plus:

* * * * *

Texas:
Bee
Calhoun
Cameron
Kleberg
San Patricio
Webb

* * * * *

[FR Doc. 2016-20179 Filed 8-23-16; 8:45 am]

BILLING CODE 6325-39-P

DEPARTMENT OF TRANSPORTATION**Federal Aviation Administration****14 CFR Part 23**

[Docket No. FAA-2016-9001; Notice No. 23-16-02-SC]

Special Conditions: Pilatus Aircraft, Ltd., Model PC-12, PC-12/45, and PC-12/47 Airplanes, Lithium Batteries

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed special conditions.

SUMMARY: This action proposes special conditions for the Pilatus Aircraft, Ltd., Model PC-12, PC-12/45, and PC-12/47 airplanes. This airplane as modified by Finnoff Aviation 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 proposed special conditions contain the additional safety standards that the Administrator considers necessary to establish a level

of safety equivalent to that established by the existing airworthiness standards.

DATES: Send your comments on or before October 11, 2016.

ADDRESSES: Send comments identified by docket number FAA-2016-9001 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 Web site, 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, Programs and Procedures, ACE-114, Small Airplane Directorate, Aircraft Certification Service, 901 Locust; Kansas City, Missouri 64106; telephone (816) 329-4108; facsimile (816) 329-4090.

SUPPLEMENTARY INFORMATION:**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 September 28, 2015, Finnoff Aviation applied for a supplemental type certificate for installation of a rechargeable lithium battery in the Model PC-12, PC-12/45, PC-12/47 airplanes. The Model PC-12, PC-12/45, PC-12/47 airplanes are single-engine turboprop-powered business aircraft that can accommodate up to nine passengers with a take-off weight up to 10,450 lbs.

The current regulatory requirements for part 23 airplanes do not contain adequate requirements for the application of rechargeable lithium batteries in 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 (1) all characteristics of the rechargeable lithium batteries and their installation that could affect safe operation of the modified Model PC-12, PC-12/45, and PC-12/47 airplanes, and (2) appropriate Instructions for Continued Airworthiness (ICAW) 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, Finnoff Aviation must show that the Model PC-12, PC-12/45, and PC-12/47, as changed, continue to meet the applicable provisions of the regulations incorporated by reference in Type Certificate No. A78EU¹ or the applicable regulations in effect on the date of application for the change.

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 Model PC-12, PC-12/45, and

¹ http://rgl.faa.gov/Regulatory_and_Guidance_Library/rgMakeModel.nsf/0/6BCB00B1F3CA4EF886257FED0069EF2D?OpenDocument.

PC-12/47 airplanes because of a novel or unusual design feature, special conditions are prescribed under the provisions of § 21.16.

Special conditions are initially applicable to the model for which they are issued. Should the applicant apply for a supplemental type certificate to modify any other model included on the same type certificate to incorporate the same or similar novel or unusual design feature, the special conditions would also apply to the other model under § 21.101.

In addition to the applicable airworthiness regulations and special conditions, the Model PC-12, PC-12/45, and PC-12/47 airplanes must comply with the fuel vent and exhaust emission requirements of 14 CFR part 34 and the noise certification requirements of 14 CFR part 36.

The FAA issues special conditions, as defined in 14 CFR 11.19, in accordance with § 11.38, and they become part of the type-certification basis under § 21.101.

Novel or Unusual Design Features

The Model PC-12, PC-12/45, and PC-12/47 airplanes will incorporate the following novel or unusual design feature: Installation of a rechargeable lithium battery as the main or engine start aircraft battery.

Discussion

Presently, there is limited experience with use of rechargeable lithium batteries and rechargeable lithium battery systems in applications involving commercial aviation. However, other users of this technology, ranging from personal computers, wireless telephone manufacturers to the electric vehicle industry, have noted safety problems with lithium batteries. These problems include overcharging, over-discharging, flammability of cell components, and cell internal defects described in the following paragraphs:

1. Overcharging: In general, lithium batteries are significantly more susceptible to internal failures that can result in self-sustaining increases in temperature and pressure (*i.e.*, thermal runaway) than the Ni-Cd or lead-acid counterparts. 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 may ignite, resulting in a fire or explosion. Finally, the severity of thermal runaway due to overcharging increases with increasing battery capacity and due to a higher amount of electrolyte in large batteries.

2. Over-discharging: Discharge of some types of lithium battery cells beyond a certain voltage (typically 2.4 volts) 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, which is a problem shared with Ni-Cd batteries.

3. Flammability of Cell Components: Unlike Ni-Cd and lead-acid batteries, some types of lithium batteries use liquid electrolytes that are flammable. The electrolyte may 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 unsafe conditions when operating in service.

These problems experienced by users of lithium batteries raise concern about the use of these batteries in commercial aviation. The intent of the special condition is to establish appropriate airworthiness standards for lithium battery installations in the Model PC-12, PC-12/45, and PC-12/47 airplanes and to ensure, as required by §§ 23.1309 and 23.601, that these battery installations are neither hazardous nor unreliable.

In summary, the lithium battery installation will consider the following items:

(a) The flammable fluid fire protection requirement is § 23.863. In the past, this rule was not applied to batteries of normal, utility, acrobatic, and commuter category airplanes since the electrolytes utilized in Ni-Cd and lead-acid batteries are not flammable.

(b) New Instructions for Continuous Airworthiness that include maintenance requirements to ensure that batteries used as spares have been maintained in an appropriate state of charge and installed lithium batteries have been sufficiently charged at appropriate intervals. These instructions must also describe proper repairs, if allowed, and battery part number configuration control.

(c) The applicant must conduct a system safety assessment for the failure condition classification of a failure of the battery charging and monitoring functionality (per Advisory Circular AC

23.1309-1E²), and develop mitigation to preclude any adverse safety effects. Mitigation may include software, Airborne Electronic Hardware (AEH) or a combination of software and hardware, which should be developed to the appropriate Design Assurance Level(s) (DALs), respectively (per Advisory Circular AC 20-115C³ and Advisory Circular AC 20-152⁴).

(d) New requirements, in the proposed special conditions section, address the hazards of overcharging and over-discharging that are unique to lithium batteries, which should be applied to all rechargeable lithium battery and battery installations on the Model PC-12, PC-12/45, and PC-12/47 airplanes in lieu of the requirements of § 23.1353(a)(b)(c)(d)(e), amendment 23-49.

Note 1: These special conditions are not intended to replace § 23.1353(a)(b)(c)(d)(e) at amendment 23-49 in the certification basis of Model PC-12, PC-12/45, and PC-12/47 airplanes. These special conditions apply only to rechargeable lithium batteries and lithium battery systems and their installations. The requirements of § 25.1353 at amendment 23-49 remains in effect for batteries and battery installations on Model PC-12, PC-12/45, and PC-12/47 airplanes that do not use rechargeable lithium batteries.

Applicability

As discussed above, these special conditions are applicable to the Model PC-12, PC-12/45, and PC-12/47 airplanes. Should Finnoff Aviation apply at a later date for a supplemental type certificate to modify any other model included on Type Certificate No. A78EU⁵ to incorporate the same novel or unusual design feature, the special conditions would apply to that model as well.

Conclusion

This action affects only certain novel or unusual design features on one model series of airplanes. It is not a rule of general applicability and it affects only the applicant who applied to the FAA for approval of these features on the airplane.

² [http://rgl.faa.gov/Regulatory_and_Guidance_Library/rgAdvisoryCircular.nsf/0/719e41e1d26099108625795d005d5302/\\$FILE/23.1309-1E.pdf](http://rgl.faa.gov/Regulatory_and_Guidance_Library/rgAdvisoryCircular.nsf/0/719e41e1d26099108625795d005d5302/$FILE/23.1309-1E.pdf).

³ [http://rgl.faa.gov/Regulatory_and_Guidance_Library/rgAdvisoryCircular.nsf/0/e35fbc0060e2159186257bbe00719fb3/\\$FILE/AC20-115C.pdf](http://rgl.faa.gov/Regulatory_and_Guidance_Library/rgAdvisoryCircular.nsf/0/e35fbc0060e2159186257bbe00719fb3/$FILE/AC20-115C.pdf).

⁴ [http://rgl.faa.gov/Regulatory_and_Guidance_Library/rgAdvisoryCircular.nsf/0/6d4ae0bf1bde3579862570360055d119/\\$FILE/AC%2020-152.pdf](http://rgl.faa.gov/Regulatory_and_Guidance_Library/rgAdvisoryCircular.nsf/0/6d4ae0bf1bde3579862570360055d119/$FILE/AC%2020-152.pdf).

⁵ http://rgl.faa.gov/Regulatory_and_Guidance_Library/rgMakeModel.nsf/0/6BCB00B1F3CA4EF886257FED0069EF2D?OpenDocument.

List of Subjects in 14 CFR Part 23

Aircraft, Aviation safety, Signs and symbols.

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

Authority: 49 U.S.C. 106(g), 40113, 44701, 44702, 44704.

The Proposed Special Conditions

■ Accordingly, the Federal Aviation Administration (FAA) proposes the following special conditions as part of the type certification basis for Pilatus Aircraft, Ltd., Model PC-12, PC-12/45, and PC-12/47 airplanes modified by Finnoff Aviation.

1. Installation of Lithium Batteries must show compliance to the following requirements:

- (1) Safe cell temperatures and pressures must be maintained during—
 - i. Normal operations;
 - ii. Any probable failure conditions of charging or discharging or battery monitoring system;
 - iii. 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)(ii) and (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 gasses 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) at 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(c) at amendment 23-62 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—

i. A system to automatically control the charging rate of the battery to prevent battery overheating and overcharging, or;

ii. 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;

iii. 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 functionally required for safe operation of the airplane must incorporate a monitoring and warning feature that will provide an indication to the appropriate flight crewmembers whenever the State of Charge (SOC) of the batteries has fallen below levels considered acceptable for dispatch of the airplane.

(10) The Instructions for Continued Airworthiness required by § 23.1529 at amendment 23-26 must contain maintenance requirements to assure that the battery has been sufficiently charged at appropriate intervals specified by the battery manufacturer and the equipment manufacturer that contain the rechargeable lithium battery or rechargeable lithium battery system. This is required to ensure that lithium rechargeable batteries and lithium rechargeable battery systems will not degrade below specified ampere-hour levels sufficient to power the aircraft system. The Instructions for Continued Airworthiness must also contain procedures for the maintenance of replacement batteries in spares storage 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: The term “sufficiently charged” means that the battery will retain enough of a charge, expressed in ampere-hours, to ensure that the battery cells will not be damaged. A battery cell may be damaged by lowering the charge below a point where there is 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.

(11) In showing compliance with the proposed special conditions herein, paragraphs (1) through (8), and the RTCA document, Minimum Operational Performance Standards for Rechargeable Lithium Battery Systems, DO-311, may be used. The list of planned DO-311 tests should be documented in the certification or compliance plan and agreed to by the Denver ACO. Alternate methods of compliance other than DO-

311 tests must be coordinated with the directorate and Denver ACO.

Issued in Kansas City, Missouri, on August 18, 2016.

Pat Mullen,

Acting Manager, Small Airplane Directorate, Aircraft Certification Service.

[FR Doc. 2016-20273 Filed 8-23-16; 8:45 am]

BILLING CODE 4910-13-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 16 and 511

[Docket No. FDA-2011-N-0079]

Disqualification of a Clinical Investigator

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing to amend the regulations for new animal drugs for investigational use to expand the scope of clinical investigator disqualification to include ineligibility to conduct nonclinical laboratory studies. Currently, when the Commissioner of Food and Drugs (the Commissioner) determines that an investigator is ineligible to receive a new animal drug for investigational use, the investigator also is ineligible to conduct any clinical investigation that supports an application for a research or marketing permit for products regulated by FDA. Under this proposal, when the Commissioner determines that an investigator is ineligible to receive a new animal drug for investigational use, the investigator also will be ineligible to conduct any nonclinical study intended to support an application for a research or marketing permit for a new animal drug. This proposal is intended to help ensure adequate protection of animal research subjects and the quality and integrity of data submitted to FDA.

DATES: Submit either electronic or written comments on the proposed rule by November 22, 2016. See section VII of this document for the proposed effective date of a final rule based on this document.

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal:* <http://www.regulations.gov>. Follow the