

Rules and Regulations

Federal Register

Vol. 87, No. 141

Monday, July 25, 2022

This section of the FEDERAL REGISTER contains regulatory documents having general applicability and legal effect, most of which are keyed to and codified in the Code of Federal Regulations, which is published under 50 titles pursuant to 44 U.S.C. 1510.

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DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 25

[Docket No. FAA-2022-0731; Special Conditions No. 25-826-SC]

Special Conditions: StandardAero Business Aviation Services, LLC, Textron Aviation Inc. Model BAe.125 Series 800A/800B and Hawker 800/800XP Airplanes; Rechargeable Lithium Batteries and Battery Systems

AGENCY: Federal Aviation Administration (FAA), Department of Transportation (DOT).

ACTION: Final special conditions; request for comments.

SUMMARY: These special conditions are issued for the Textron Aviation Inc., (Textron) Model BAe.125 Series 800A/800B and Hawker 800/800XP airplanes. These airplanes, as modified by StandardAero Business Aviation Services, LLC, will have a novel or unusual design feature when compared to the state of technology envisioned in the airworthiness standards for transport-category airplanes. This design feature is a rechargeable lithium ion battery contained in the Standby Attitude Module (SAM). The applicable airworthiness regulations do not contain adequate or appropriate safety standards for this design feature. These 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: This action is effective on StandardAero Business Aviation Services, LLC on July 25, 2022. Send comments on or before September 8, 2022.

ADDRESSES: Send comments identified by Docket No. FAA-2022-0731 using any of the following methods:

- *Federal eRegulations Portal:* Go to <https://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 or 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: Except for Confidential Business Information (CBI) as described in the following paragraph, and other information as described in title 14, Code of Federal Regulations (14 CFR) 11.35, the FAA will post all comments received without change to <https://www.regulations.gov/>, including any personal information you provide. The FAA will also post a report summarizing each substantive verbal contact received about these special conditions.

Confidential Business Information: Confidential Business Information (CBI) is commercial or financial information that is both customarily and actually treated as private by its owner. Under the Freedom of Information Act (FOIA) (5 U.S.C. 552), CBI is exempt from public disclosure. If your comments responsive to these special conditions contain commercial or financial information that is customarily treated as private, that you actually treat as private, and that is relevant or responsive to these special conditions, it is important that you clearly designate the submitted comments as CBI. Please mark each page of your submission containing CBI as "PROPIN." The FAA will treat such marked submissions as confidential under the FOIA, and the indicated comments will not be placed in the public docket of these special conditions. Send submissions containing CBI to Nazih Khaouly, Aircraft Systems, AIR-623, Technical Innovation Policy Branch, Policy and Innovation Division, Aircraft Certification Service, Federal Aviation Administration, 2200 South 216th Street, Des Moines, Washington 98198; telephone and fax 206-231-3160; email nazih.khaouly@faa.gov. Comments the

FAA receives, which are not specifically designated as CBI, will be placed in the public docket for these special conditions.

Docket: Background documents or comments received may be read at <https://www.regulations.gov/> at any time. Follow the online instructions for accessing the docket or go 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.

FOR FURTHER INFORMATION CONTACT: Nazih Khaouly, Aircraft Systems, AIR-623, Technical Innovation Policy Branch, Policy and Innovation Division, Aircraft Certification Service, Federal Aviation Administration, 2200 South 216th Street, Des Moines, Washington 98198; telephone and fax 206-231-3160; email nazih.khaouly@faa.gov.

SUPPLEMENTARY INFORMATION: The substance of these special conditions has been published in the **Federal Register** for public comment in several prior instances with no substantive comments received. Therefore, the FAA finds, pursuant to § 11.38(b), that new comments are unlikely, and notice and comment prior to this publication are unnecessary.

Comments Invited

The FAA invites 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.

The FAA will consider all comments received by the closing date for comments. The FAA may change these special conditions based on the comments received.

Background

On March 15, 2022, StandardAero Business Aviation Services, LLC applied for a supplemental type certificate for a rechargeable lithium ion battery contained in the SAM on the Textron Model BAe.125 Series 800A/800B and Hawker 800/800XP airplanes. The SAM is a self-contained situational awareness instrument that provides aircraft attitude, altitude, airspeed, and slip indication, and contains a rechargeable lithium ion battery. The Textron Model

BAe.125 Series 800A/800B and Hawker 800/800XP airplanes are twin-engine transport category business jets, each with a maximum passenger capacity of 15 passengers and 2 crewmembers, and a maximum takeoff weight of 27,400 pounds.

Type Certification Basis

Under the provisions of title 14, Code of Federal Regulations (14 CFR) 21.101, StandardAero Business Aviation Services, LLC must show that the Textron Model BAe.125 Series 800A/800B and Hawker 800/800XP airplanes, as changed, continue to meet the applicable provisions of the regulations listed in Type Certificate No. A3EU or the applicable regulations in effect on the date of application for the change, except for earlier amendments as agreed upon by the FAA.

If the Administrator finds that the applicable airworthiness regulations (e.g., 14 CFR part 25) do not contain adequate or appropriate safety standards for the Textron Model BAe.125 Series 800A/800B and Hawker 800/800XP 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 novel or unusual design feature, these special conditions would also apply to the other model under § 21.101.

In addition to the applicable airworthiness regulations and special conditions, the Textron Model BAe.125 Series 800A/800B and Hawker 800/800XP 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 Textron Model BAe.125 Series 800A/800B and Hawker 800/800XP airplanes will incorporate the following novel or unusual design feature:

Installation of a rechargeable lithium ion battery contained in the SAM.

Discussion

Rechargeable lithium batteries are considered to be a novel or unusual design feature in transport category airplanes, with respect to the

requirements in 14 CFR 25.1353. This type of battery has certain failure, operational, and maintenance characteristics that differ significantly from those of the nickel-cadmium and lead-acid rechargeable batteries currently approved for installation on transport category airplanes. These batteries introduce higher energy levels into airplane systems through new chemical compositions in various battery-cell sizes and construction. Interconnection of these cells in battery packs introduces failure modes that require unique design considerations, such as provisions for thermal management.

Special Condition 1 requires that each individual cell within a rechargeable lithium battery be designed to maintain safe temperatures and pressures. Special Condition 2 addresses these same issues but for the entire battery. Special Condition 2 requires the battery be designed to prevent propagation of a thermal event, such as self-sustained, uncontrolled increases in temperature or pressure from one cell to adjacent cells.

Special Conditions 1 and 2 are intended to ensure that the cells and battery are designed to eliminate the potential for uncontrollable failures. However, a certain number of failures will occur due to various factors beyond the control of the designer. Therefore, other special conditions are intended to protect the airplane and its occupants if failure occurs.

Special Conditions 3, 7, and 8 are self-explanatory.

Special Condition 4 clarifies that the flammable fluid fire-protection requirements of 14 CFR 25.863 apply to rechargeable lithium battery installations. Section 25.863 is applicable to areas of the airplane that could be exposed to flammable fluid leakage from airplane systems. Rechargeable lithium batteries contain electrolyte that is a flammable fluid.

Special Condition 5 requires each rechargeable lithium battery installation to not damage surrounding structure or adjacent systems, equipment, or electrical wiring from corrosive fluids or gases that may escape in such a way as to cause a major or more severe failure condition. Special Condition 6 requires each rechargeable lithium battery installation to have provisions to prevent any hazardous effect on airplane structure or systems caused by the maximum amount of heat it can generate due to any failure of it or its individual cells. The means of meeting special conditions 5 and 6 may be the same, but they are independent requirements addressing different

hazards. Special Condition 5 addresses corrosive fluids and gases, whereas Special Condition 6 addresses heat.

Special Condition 9 requires rechargeable lithium batteries to have an “automatic” means to disconnect their charging source due to the fast acting nature of lithium battery chemical reactions. Manual intervention would not be timely or effective in mitigating the hazards associated with these batteries.

These special conditions apply to all rechargeable lithium battery installations in lieu of 14 CFR 25.1353(b)(1) through (4) at amendment 25–123, or § 25.1353(c)(1) through (4) at earlier amendments. Those regulations will remain in effect for other battery installations on these airplanes.

These 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.

Applicability

As discussed above, these special conditions are applicable to the Textron Model BAe.125 Series 800A/800B and Hawker 800/800XP airplanes. Should StandardAero Business Aviation Services, LLC apply at a later date for a supplemental type certificate to modify any other model included on Type Certificate No. A3EU to incorporate the same novel or unusual design feature, these special conditions would apply to that model as well.

Conclusion

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

List of Subjects in 14 CFR Part 25

Aircraft, Aviation safety, Reporting and recordkeeping requirements.

Authority Citation

The authority citation for these special conditions is as follows:

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

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 Model BAe.125 Series 800A/800B and Hawker 800/800XP airplanes, as modified by

StandardAero Business Aviation Services, LLC.

Rechargeable Lithium Battery Installations

In lieu of § 25.1353(b)(1) through (4) at amendment 25–123, or § 25.1353(c)(1) through (4) at earlier amendments, each rechargeable lithium battery installation must:

1. Be designed to maintain safe cell temperatures and pressures under all foreseeable operating conditions to prevent fire and explosion.
2. Be designed to prevent the occurrence of self-sustaining, uncontrollable increases in temperature or pressure, and automatically control the charge rate of each cell to protect against adverse operating conditions, such as cell imbalance, back charging, overcharging and overheating.
3. Not emit explosive or toxic gases, either in normal operation or as a result of its failure that may accumulate in hazardous quantities within the airplane.
4. Meet the requirements of § 25.863.
5. Not damage surrounding structure or adjacent systems, equipment, or electrical wiring from corrosive fluids or gases that may escape in such a way as to cause a major or more-severe failure condition.
6. Have provisions to prevent any hazardous effect on airplane structure or systems caused by the maximum amount of heat it can generate due to any failure of it or its individual cells.
7. Have a failure sensing and warning system to alert the flight crew if its failure affects safe operation of the airplane.
8. Have a monitoring and warning feature that alerts the flightcrew when its charge state falls below acceptable levels if its function is required for safe operation of the airplane.
9. Have a means to automatically disconnect from its charging source in the event of an over-temperature condition, cell failure or battery failure.

Note: A battery system consists of the battery, battery charger and any protective, monitoring and alerting circuitry or hardware inside or outside of the battery. It also includes vents (where necessary) and packaging. For the purpose of this special condition, a battery and battery system are referred to as a battery.

Issued in Kansas City, Missouri, on July 20, 2022.

Patrick R. Mullen,

Manager, Technical Innovation Policy Branch, Policy and Innovation Division, Aircraft Certification Service.

[FR Doc. 2022–15837 Filed 7–22–22; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 801

[Docket No. FDA–2017–D–6841]

Unique Device Identification: Policy Regarding Compliance Dates for Class I and Unclassified Devices, Direct Marking, and Global Unique Device Identification Database Requirements for Certain Devices; Guidance for Industry and Food and Drug Administration Staff; Availability

AGENCY: Food and Drug Administration, Department of Health and Human Services (HHS).

ACTION: Availability of guidance.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a final guidance entitled “Unique Device Identification: Policy Regarding Compliance Dates for Class I and Unclassified Devices, Direct Marking, and Global Unique Device Identification Database Requirements for Certain Devices.” This guidance updates the previous version of the guidance, “Unique Device Identification: Policy Regarding Compliance Dates for Class I and Unclassified Devices and Certain Devices Requiring Direct Marking,” issued July 1, 2020. This final guidance explains FDA’s compliance policy regarding Global Unique Device Identification Database (GUDID) submission requirements for certain class I devices considered consumer health products and describes how a labeler of a class I devices can determine if its device is one of these devices. Additionally, the guidance explains that FDA intends to extend our existing compliance policy regarding GUDID submission requirements for class I and unclassified devices, other than implantable, life-supporting, or life-sustaining (I/LS/LS) devices, for an additional 75 calendar days.

DATES: The announcement of the guidance is published in the **Federal Register** on July 25, 2022.

ADDRESSES: You may submit either electronic or written comments on Agency guidances at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

- **Federal eRulemaking Portal:** <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically,

including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else’s Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <https://www.regulations.gov>.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see “Written/Paper Submissions” and “Instructions”).

Written/Paper Submissions

Submit written/paper submissions as follows:

- **Mail/Hand Delivery/Courier (for written/paper submissions):** Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in “Instructions.”

Instructions: All submissions received must include the Docket No. FDA–2017–D–6841 for “Unique Device Identification: Policy Regarding Compliance Dates for Class I and Unclassified Devices, Direct Marking, and Global Unique Device Identification Database Requirements for Certain Devices.” Received comments will be placed in the docket and, except for those submitted as “Confidential Submissions,” publicly viewable at <https://www.regulations.gov> or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

- **Confidential Submissions—**To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states “THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.” The Agency will review this copy, including the claimed confidential information, in