

# Proposed Rules

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This section of the FEDERAL REGISTER contains notices to the public of the proposed issuance of rules and regulations. The purpose of these notices is to give interested persons an opportunity to participate in the rule making prior to the adoption of the final rules.

## DEPARTMENT OF TRANSPORTATION

### Federal Aviation Administration

#### 14 CFR Part 39

[Docket No. FAA-2006-26120; Directorate Identifier 2006-NM-184-AD]

RIN 2120-AA64

#### Airworthiness Directives; Airbus Model A300 B4-600, B4-600R, and F4-600R Series Airplanes and Model C4-605R Variant F Airplanes (Collectively Called A300-600 Series Airplanes)

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

**ACTION:** Notice of proposed rulemaking (NPRM).

**SUMMARY:** The FAA proposes to adopt a new airworthiness directive (AD) for all Airbus Model A300-600 series airplanes. This proposed AD would require revising the Airworthiness Limitations Section of the Instructions for Continued Airworthiness to incorporate new limitations for fuel tank systems. This proposed AD results from fuel system reviews conducted by the manufacturer. We are proposing this AD to prevent the potential of ignition sources inside fuel tanks, which, in combination with flammable fuel vapors caused by latent failures, alterations, repairs, or maintenance actions, could result in fuel tank explosions and consequent loss of the airplane.

**DATES:** We must receive comments on this proposed AD by January 16, 2007.

**ADDRESSES:** Use one of the following addresses to submit comments on this proposed AD.

- **DOT Docket Web site:** Go to <http://dms.dot.gov> and follow the instructions for sending your comments electronically.

- **Government-wide rulemaking Web site:** Go to <http://www.regulations.gov> and follow the instructions for sending your comments electronically.

- **Mail:** Docket Management Facility, U.S. Department of Transportation, 400

Seventh Street, SW., Nassif Building, Room PL-401, Washington, DC 20590.

- **Fax:** (202) 493-2251.

- **Hand Delivery:** Room PL-401 on the plaza level of the Nassif Building, 400 Seventh Street, SW., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

Contact Airbus, 1 Rond Point Maurice Bellonte, 31707 Blagnac Cedex, France, for service information identified in this proposed AD.

**FOR FURTHER INFORMATION CONTACT:** Tom Stafford, Aerospace Engineer, International Branch, ANM-116, FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington 98057-3356; telephone (425) 227-1622; fax (425) 227-1149.

#### SUPPLEMENTARY INFORMATION:

##### Comments Invited

We invite you to submit any relevant written data, views, or arguments regarding this proposed AD. Send your comments to an address listed in the **ADDRESSES** section. Include the docket number "FAA-2006-26120; Directorate Identifier 2006-NM-184-AD" at the beginning of your comments. We specifically invite comments on the overall regulatory, economic, environmental, and energy aspects of the proposed AD. We will consider all comments received by the closing date and may amend the proposed AD in light of those comments.

We will post all comments we receive, without change, to <http://dms.dot.gov>, including any personal information you provide. We will also post a report summarizing each substantive verbal contact with FAA personnel concerning this proposed AD. Using the search function of that web site, anyone can find and read the comments in any of our dockets, including the name of the individual who sent the comment (or signed the comment on behalf of an association, business, labor union, etc.). You may review the DOT's complete Privacy Act Statement in the **Federal Register** published on April 11, 2000 (65 FR 19477-78), or you may visit <http://dms.dot.gov>.

#### Examining the Docket

You may examine the AD docket on the Internet at <http://dms.dot.gov>, or in person at the Docket Management Facility office between 9 a.m. and 5

p.m., Monday through Friday, except Federal holidays. The Docket Management Facility office (telephone (800) 647-5227) is located on the plaza level of the Nassif Building at the DOT street address stated in the **ADDRESSES** section. Comments will be available in the AD docket shortly after the Docket Management System receives them.

#### Discussion

The FAA has examined the underlying safety issues involved in fuel tank explosions on several large transport airplanes, including the adequacy of existing regulations, the service history of airplanes subject to those regulations, and existing maintenance practices for fuel tank systems. As a result of those findings, we issued a regulation titled "Transport Airplane Fuel Tank System Design Review, Flammability Reduction and Maintenance and Inspection Requirements" (66 FR 23086, May 7, 2001). In addition to new airworthiness standards for transport airplanes and new maintenance requirements, this rule included Special Federal Aviation Regulation No. 88 ("SFAR 88," Amendment 21-78, and subsequent Amendments 21-82 and 21-83).

Among other actions, SFAR 88 requires certain type design (*i.e.*, type certificate (TC) and supplemental type certificate (STC)) holders to substantiate that their fuel tank systems can prevent ignition sources in the fuel tanks. This requirement applies to type design holders for large turbine-powered transport airplanes and for subsequent modifications to those airplanes. It requires them to perform design reviews and to develop design changes and maintenance procedures if their designs do not meet the new fuel tank safety standards. As explained in the preamble to the rule, we intended to adopt airworthiness directives to mandate any changes found necessary to address unsafe conditions identified as a result of these reviews.

In evaluating these design reviews, we have established four criteria intended to define the unsafe conditions associated with fuel tank systems that require corrective actions. The percentage of operating time during which fuel tanks are exposed to flammable conditions is one of these criteria. The other three criteria address the failure types under evaluation:

single failures, single failures in combination with a latent condition(s), and in-service failure experience. For all four criteria, the evaluations included consideration of previous actions taken that may mitigate the need for further action.

The Joint Aviation Authorities (JAA) has issued a regulation that is similar to SFAR 88. (The JAA is an associated body of the European Civil Aviation Conference (ECAC) representing the civil aviation regulatory authorities of a number of European States who have agreed to co-operate in developing and implementing common safety regulatory standards and procedures.) Under this regulation, the JAA stated that all members of the ECAC that hold type certificates for transport category airplanes are required to conduct a design review against explosion risks.

We have determined that the actions identified in this AD are necessary to reduce the potential of ignition sources inside fuel tanks, which, in combination with flammable fuel vapors, could result in fuel tank explosions and consequent loss of the airplane.

The European Aviation Safety Agency (EASA), which is the airworthiness authority for the European Union, notified us that an unsafe condition may exist on all Airbus Model A300 B4–600, B4–600R, and F4–600R series airplanes and Model C4–605R Variant F airplanes (collectively called A300–600 series airplanes). The EASA advises that Airbus has issued new fuel airworthiness limitations (FALs) to address failure conditions for which an unacceptable probability of ignition risk could exist if specific tasks or practices or both are not performed in accordance with the manufacturer's requirements. The new FALs are intended to satisfy the JAA's Interim Policy of Fuel Tank Safety and SFAR 88 requirements.

#### Relevant Service Information

Airbus has issued A300–600 ALS—Airworthiness Limitations Section, dated May 31, 2006, which is a repository for stand-alone documents that are approved independently from each other. The Airbus A300–600 ALS comprises the following documents:

- ALS Part 1—Safe Life Airworthiness Limitation Items
- ALS Part 2—Damage-Tolerant Airworthiness Limitation Items
- ALS Part 3—Certification Maintenance Requirements
- ALS Part 4—Aging Systems Maintenance
- ALS Part 5—Fuel Airworthiness Limitations

ALS Part 5—Fuel Airworthiness Limitations, dated May 31, 2006, refers

to Airbus A300–600 Fuel Airworthiness Limitations, Document 95A.1929/05, Issue 1, dated December 19, 2005 (approved by the EASA on March 13, 2006). Section 1, “Maintenance/Inspection Tasks,” of Document 95A.1929/05 describes certain FAL inspections, which are periodic inspections of certain features for latent failures that could contribute to an ignition source. Section 2, “Critical Design Configuration Control Limitations,” of Document 95A.1929/05 identifies critical design configuration control limitations (CDCCLs). A CDCCL is a limitation requirement to preserve a critical ignition source prevention feature of the fuel tank system design that is necessary to prevent the occurrence of an unsafe condition. The purpose of a CDCCL is to provide instruction to retain the critical ignition source prevention feature during configuration change that may be caused by alterations, repairs, or maintenance actions. A CDCCL is not a periodic inspection.

Accomplishing the actions specified in the service information is intended to adequately address the unsafe condition. The EASA mandated the service information and issued airworthiness directive 2006–0201, dated July 11, 2006, to ensure the continued airworthiness of these airplanes in the European Union.

#### FAA's Determination and Requirements of the Proposed AD

These airplane models are manufactured in France and are type certificated for operation in the United States under the provisions of section 21.29 of the Federal Aviation Regulations (14 CFR 21.29) and the applicable bilateral airworthiness agreement. As described in FAA Order 8100.14A, “Interim Procedures for Working with the European Community on Airworthiness Certification and Continued Airworthiness,” dated August 12, 2005, the EASA has kept the FAA informed of the situation described above. We have examined the EASA's findings, evaluated all pertinent information, and determined that we need to issue an AD for airplanes of this type design that are certificated for operation in the United States.

Therefore, we are proposing this AD, which would require revising the Airworthiness Limitations Section of the Instructions for Continued Airworthiness to incorporate new limitations for fuel tank systems.

#### Costs of Compliance

This proposed AD would affect about 138 airplanes of U.S. registry. The

proposed actions would take about 2 work hours per airplane, at an average labor rate of \$80 per work hour. Based on these figures, the estimated cost of the proposed AD for U.S. operators is \$22,080, or \$160 per airplane.

#### Authority for This Rulemaking

Title 49 of the United States Code specifies the FAA's authority to issue rules on aviation safety. Subtitle I, Section 106, describes the authority of the FAA Administrator. Subtitle VII, Aviation Programs, describes in more detail the scope of the Agency's authority.

We are issuing this rulemaking under the authority described in Subtitle VII, Part A, Subpart III, Section 44701, “General requirements.” Under that section, Congress charges the FAA with promoting safe flight of civil aircraft in air commerce by prescribing regulations for practices, methods, and procedures the Administrator finds necessary for safety in air commerce. This regulation is within the scope of that authority because it addresses an unsafe condition that is likely to exist or develop on products identified in this rulemaking action.

#### Regulatory Findings

We have determined that this proposed AD would not have federalism implications under Executive Order 13132. This proposed AD would not have a substantial direct effect on the States, on the relationship between the national Government and the States, or on the distribution of power and responsibilities among the various levels of government.

For the reasons discussed above, I certify that the proposed regulation:

1. Is not a “significant regulatory action” under Executive Order 12866;
2. Is not a “significant rule” under the DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979); and
3. Will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

We prepared a regulatory evaluation of the estimated costs to comply with this proposed AD and placed it in the AD docket. See the **ADDRESSES** section for a location to examine the regulatory evaluation.

#### List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Safety.

#### The Proposed Amendment

Accordingly, under the authority delegated to me by the Administrator,

the FAA proposes to amend 14 CFR part 39 as follows:

## **PART 39—AIRWORTHINESS DIRECTIVES**

1. The authority citation for part 39 continues to read as follows:

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

### **§ 39.13 [Amended]**

2. The Federal Aviation Administration (FAA) amends § 39.13 by adding the following new airworthiness directive (AD):

**Airbus:** Docket No. FAA–2006–26120; Directorate Identifier 2006–NM–184–AD.

### **Comments Due Date**

(a) The FAA must receive comments on this AD action by January 16, 2007.

### **Affected ADs**

(b) None.

### **Applicability**

(c) This AD applies to all Airbus Model A300 B4–601, B4–603, B4–620, and B4–622 airplanes; Model A300 B4–605R and B4–622R airplanes; Model A300 F4–605R and F4–622R airplanes; and Model A300 C4–605R Variant F airplanes; certificated in any category.

**Note 1:** This AD requires revisions to certain operator maintenance documents to include new inspections and critical design configuration control limitations (CDCCLs). Compliance with the operator maintenance documents is required by 14 CFR 91.403(c). For airplanes that have been previously modified, altered, or repaired in the areas addressed by these inspections and CDCCLs, the operator may not be able to accomplish the inspections and CDCCLs described in the revisions. In this situation, to comply with 14 CFR 91.403(c), the operator must request approval for an alternative method of compliance according to paragraph (j) of this AD. The request should include a description of changes to the required inspections and CDCCLs that will preserve the critical ignition source prevention feature of the affected fuel system.

### **Unsafe Condition**

(d) This AD results from fuel system reviews conducted by the manufacturer. We are issuing this AD to prevent the potential of ignition sources inside fuel tanks, which, in combination with flammable fuel vapors caused by latent failures, alterations, repairs, or maintenance actions, could result in fuel tank explosions and consequent loss of the airplane.

### **Compliance**

(e) You are responsible for having the actions required by this AD performed within the compliance times specified, unless the actions have already been done.

## **Revise Airworthiness Limitations Section (ALS) To Incorporate Fuel Maintenance and Inspection Tasks**

(f) Within 3 months after the effective date of this AD, revise the ALS of the Instructions for Continued Airworthiness to incorporate Airbus A300–600 ALS Part 5—Fuel Airworthiness Limitations, dated May 31, 2006, as defined in Airbus A300–600 Fuel Airworthiness Limitations, Document 95A.1929/05, Issue 1, dated December 19, 2005 (approved by the European Aviation Safety Agency (EASA) on March 13, 2006), Section 1, “Maintenance/Inspection Tasks.” For all tasks identified in Section 1 of Document 95A.1929/05, the initial compliance times start from the effective date of this AD and must be accomplished within the repetitive interval specified in Section 1 of Document 95A.1929/05, except as provided by paragraph (g) of this AD.

### **Initial Compliance Time for Task 28–18–00–03–1**

(g) For Task 28–18–00–03–1, “Operational check of lo-level/underfull/calibration sensors,” identified in Section 1, “Maintenance/Inspection Tasks,” of Airbus A300–600 Fuel Airworthiness Limitations, Document 95A.1929/05, Issue 1, dated December 19, 2005: The initial compliance time is the later of the times specified in paragraphs (g)(1) and (g)(2) of this AD. Thereafter, Task 28–18–00–03–1 must be accomplished within the repetitive interval specified in Section 1 of Document 95A.1929/05.

(1) Prior to the accumulation of 34,000 total flight hours.

(2) Within 72 months or 20,000 flight hours after the effective date of this AD, whichever occurs first.

## **Revise ALS To Incorporate CDCCLs**

(h) Within 12 months after the effective date of this AD, revise the ALS of the Instructions for Continued Airworthiness to incorporate Airbus A300–600 ALS Part 5—Fuel Airworthiness Limitations, Document 95A.1929/05, Issue 1, dated December 19, 2005 (approved by the EASA on March 13, 2006), Section 2, “Critical Design Configuration Control Limitations.”

## **No Alternative Inspections, Inspection Intervals, or CDCCLs**

(i) Except as provided by paragraph (j) of this AD: After accomplishing the actions specified in paragraphs (f) and (h) of this AD, no alternative inspections, inspection intervals, or CDCCLs may be used.

## **Alternative Methods of Compliance (AMOCs)**

(j)(1) The Manager, International Branch, ANM–116, Transport Airplane Directorate, FAA, has the authority to approve AMOCs for this AD, if requested in accordance with the procedures found in 14 CFR 39.19.

(2) Before using any AMOC approved in accordance with § 39.19 on any airplane to which the AMOC applies, notify the appropriate principal inspector in the FAA Flight Standards Certificate Holding District Office.

## **Related Information**

(k) EASA airworthiness directive 2006–0201, dated July 11, 2006, also addresses the subject of this AD.

Issued in Renton, Washington, on October 17, 2006.

**Jeffrey E. Duven,**

*Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.*

[FR Doc. E6–21262 Filed 12–13–06; 8:45 am]

**BILLING CODE 4910–13–P**

## **DEPARTMENT OF HEALTH AND HUMAN SERVICES**

### **Food and Drug Administration**

### **21 CFR Part 312**

[Docket No. 2006N–0062]

RIN 0910–AF14

## **Expanded Access to Investigational Drugs for Treatment Use**

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

**ACTION:** Proposed rule.

**SUMMARY:** The Food and Drug Administration (FDA) is proposing to amend its regulations on access to investigational new drugs for the treatment of patients. The proposed rule would clarify existing regulations and add new types of expanded access for treatment use. Under the proposal, expanded access to investigational drugs for treatment use would be available to individual patients, including in emergencies; intermediate-size patient populations; and larger populations under a treatment protocol or treatment investigational new drug application (IND). The proposed rule is intended to improve access to investigational drugs for patients with serious or immediately life-threatening diseases or conditions, who lack other therapeutic options and who may benefit from such therapies.

**DATES:** Submit written or electronic comments by March 14, 2007. Submit written comments on the information collection requirements by January 16, 2007.

**ADDRESSES:** You may submit comments, identified by Docket No. 2006N–0062 and RIN 0910–AF14, by any of the following methods:  
*Electronic Submissions*

Submit electronic comments in the following ways:

- Federal eRulemaking Portal: <http://www.regulations.gov>. Follow the instructions for submitting comments.
- Agency Web site: <http://www.fda.gov/dockets/ecomments>.