

## 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 FAA amends § 39.13 by adding the following new airworthiness directive (AD):

**The Boeing Company:** Docket No. FAA–2016–6141; Directorate Identifier 2015–NM–048–AD.

#### (a) Comments Due Date

We must receive comments by June 20, 2016.

#### (b) Affected ADs

None.

#### (c) Applicability

This AD applies to The Boeing Company Model 767–200, –300, –300F, and –400ER series airplanes, certificated in any category, excluding airplanes identified in paragraphs (c)(1) and (c)(2) of this AD.

(1) Airplanes on which the center auxiliary tank consists only of the spaces between the side of body rib 0 and rib 3 of the left and right wings (*i.e.*, the wing center structural box is a dry bay and is not part of the fuel tank).

(2) Airplanes equipped with a flammability reduction means (FRM) approved by the FAA as compliant with the Fuel Tank Flammability Reduction (FTFR) rule (73 FR 42444, July 21, 2008) requirements of section 25.981(b) or section 26.33(c)(1) of the Federal Aviation Regulations (14 CFR 25.981(b) or 14 CFR 26.33(c)(1)).

#### (d) Subject

Air Transport Association (ATA) of America Code 28, Fuel.

#### (e) Unsafe Condition

This AD was prompted by fuel system reviews conducted by the manufacturer. We are issuing this AD to prevent ignition sources inside the center fuel tank, which, in combination with flammable fuel vapors, could result in a fuel tank explosion and consequent loss of the airplane.

#### (f) Compliance

Comply with this AD within the compliance times specified, unless already done.

#### (g) Modification

Within 60 months after the effective date of this AD, modify the fuel quantity indicating system (FQIS) to prevent development of an ignition source inside the center fuel tank due to electrical fault conditions, using a method approved in accordance with the procedures specified in paragraph (i) of this AD.

#### (h) Alternative Actions for Cargo Airplanes

For airplanes used exclusively for cargo operations: As an alternative to the requirements of paragraph (g) of this AD, do

the actions specified in paragraphs (h)(1) and (h)(2) of this AD. To exercise this option, operators must perform the first inspection required under paragraph (h)(1) of this AD within 6 months after the effective date of this AD. To exercise this option for airplanes returned to service after conversion of the airplane from a passenger configuration to an all-cargo configuration more than 6 months after the effective date of this AD, operators must perform the first inspection required under paragraph (h)(1) of this AD prior to further flight after the conversion.

(1) Within 6 months after the effective date of this AD, record the existing fault codes stored in the FQIS processor and then do a BITE check (check of built-in test equipment) of the FQIS, in accordance with the Accomplishment Instructions of Boeing Service Bulletin 767–28–0118, dated July 15, 2014. If any nondispatchable fault code is recorded prior to the BITE check or as a result of the BITE check, before further flight, do all applicable repairs and repeat the BITE check until a successful test is performed with no nondispatchable faults found, in accordance with Boeing Service Bulletin 767–28–0118, dated July 15, 2014. Repeat these actions thereafter at intervals not to exceed 650 flight hours. Modification as specified in paragraph (h)(2) of this AD does not terminate the repetitive BITE check requirement of this paragraph.

(2) Within 60 months after the effective date of this AD, modify the airplane by separating FQIS wiring that runs between the FQIS processor and the center tank wing spar penetrations, including any circuits that might pass through a main fuel tank, from other airplane wiring that is not intrinsically safe, using methods approved in accordance with the procedures specified in paragraph (i) of this AD.

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

(1) The Manager, Seattle Aircraft Certification Office (ACO), FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or local Flight Standards District Office, as appropriate. If sending information directly to the manager of the ACO, send it to the attention of the person identified in paragraph (j) of this AD. Information may be emailed to: [9-ANM-Seattle-ACO-AMOC-Requests@faa.gov](mailto:9-ANM-Seattle-ACO-AMOC-Requests@faa.gov).

(2) Before using any approved AMOC, notify your appropriate principal inspector, or lacking a principal inspector, the manager of the local flight standards district office/certificate holding district office.

(3) An AMOC that provides an acceptable level of safety may be used for any repair, modification, or alteration required by this AD if it is approved by the Boeing Commercial Airplanes Organization Designation Authorization (ODA) that has been authorized by the Manager, Seattle ACO, to make those findings. To be approved, the repair method, modification deviation, or alteration deviation must meet the certification basis of the airplane, and the approval must specifically refer to this AD.

(4) For service information that contains steps that are labeled as Required for Compliance (RC), the provisions of paragraphs (i)(4)(i) and (i)(4)(ii) apply.

(i) The steps labeled as RC, including substeps under an RC step and any figures identified in an RC step, must be done to comply with the AD. An AMOC is required for any deviations to RC steps, including substeps and identified figures.

(ii) Steps not labeled as RC may be deviated from using accepted methods in accordance with the operator's maintenance or inspection program without obtaining approval of an AMOC, provided the RC steps, including substeps and identified figures, can still be done as specified, and the airplane can be put back in an airworthy condition.

#### (j) Related Information

For more information about this AD, contact Jon Regimbal, Aerospace Engineer, Propulsion Branch, ANM–140S, FAA, Seattle Aircraft Certification Office (ACO), 1601 Lind Avenue SW., Renton, WA 98057–3356; phone: 425–917–6506; fax: 425–917–6590; email: [Jon.Regimbal@faa.gov](mailto:Jon.Regimbal@faa.gov).

Issued in Renton, Washington, on April 15, 2016.

**Victor Wicklund,**

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

[FR Doc. 2016–09795 Filed 5–3–16; 8:45 am]

**BILLING CODE 4910–13–P**

## DEPARTMENT OF TRANSPORTATION

### Federal Aviation Administration

#### 14 CFR Part 39

[Docket No. FAA–2016–6140; Directorate Identifier 2015–NM–059–AD]

**RIN 2120–AA64**

#### Airworthiness Directives; The Boeing Company Airplanes

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

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

**SUMMARY:** We propose to adopt a new airworthiness directive (AD) for certain The Boeing Company Model 777 airplanes. This proposed AD was prompted by fuel system reviews conducted by the manufacturer. This proposed AD would require modifying the fuel quantity indicating system (FQIS) to prevent development of an ignition source inside the center fuel tank due to electrical fault conditions. This proposed AD would also provide alternative actions for cargo airplanes. We are proposing this AD to prevent ignition sources inside the center fuel tank, which, in combination with flammable fuel vapors, could result in a

fuel tank explosion and consequent loss of the airplane.

**DATES:** We must receive comments on this proposed AD by June 20, 2016.

**ADDRESSES:** You may send comments, using the procedures found in 14 CFR 11.43 and 11.45, by any of the following methods:

- *Federal eRulemaking Portal:* Go to <http://www.regulations.gov>. Follow the instructions for submitting comments.
- *Fax:* 202-493-2251.
- *Mail:* U.S. Department of Transportation, Docket Operations, M-30, West Building Ground Floor, Room W12-140, 1200 New Jersey Avenue SE., Washington, DC 20590.
- *Hand Delivery:* Deliver to Mail address above between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

#### Examining the AD Docket

You may examine the AD docket on the Internet at <http://www.regulations.gov> by searching for and locating Docket No. FAA-2016-6140; or in person at the Docket Management Facility between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this proposed AD, the regulatory evaluation, any comments received, and other information. The street address for the Docket Office (phone: 800-647-5527) is in the **ADDRESSES** section. Comments will be available in the AD docket shortly after receipt.

**FOR FURTHER INFORMATION CONTACT:** Jon Regimbal, Aerospace Engineer, Propulsion Branch, ANM-140S, FAA, Seattle Aircraft Certification Office (ACO), 1601 Lind Avenue SW., Renton, WA 98057-3356; phone: 425-917-6506; fax: 425-917-6590; email: [Jon.Regimbal@faa.gov](mailto:Jon.Regimbal@faa.gov).

#### SUPPLEMENTARY INFORMATION:

##### Comments Invited

We invite you to send any written relevant data, views, or arguments about this proposal. Send your comments to an address listed under the **ADDRESSES** section. Include “Docket No. FAA-2016-6140; Directorate Identifier 2015-NM-059-AD” at the beginning of your comments. We specifically invite comments on the overall regulatory, economic, environmental, and energy aspects of this proposed AD. We will consider all comments received by the closing date and may amend this proposed AD because of those comments.

We will post all comments we receive, without change, to <http://www.regulations.gov>, including any

personal information you provide. We will also post a report summarizing each substantive verbal contact we receive about this proposed AD.

#### 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. Subsequently, SFAR 88 was amended by: Amendment 21-82 (67 FR 57490, September 10, 2002; corrected at 67 FR 70809, November 26, 2002) and Amendment 21-83 (67 FR 72830, December 9, 2002; corrected at 68 FR 37735, June 25, 2003, to change “21-82” to “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, combination of failures, and unacceptable (failure) experience. For all three failure criteria, the evaluations included consideration of previous actions taken that may mitigate the need for further action.

We have determined that the actions identified in this proposed 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.

#### Model 777 FQIS Design

The design of the in-tank FQIS components and wiring has the potential for latent faults that could cause arcs, sparks, or resistive heating in the event of a hot short of an FQIS tank circuit to power wiring. The wiring of the FQIS is in some areas cobundled or closely adjacent to power wiring. An ignition source combined with flammable conditions in a center fuel tank could result in ignition of flammable vapor in the fuel tank, causing a structural failure of the wing and inflight breakup of the airplane.

Under the policy contained in FAA Policy Memo PS-ANM100-2003-112-15 ([http://rgl.faa.gov/Regulatory\\_and\\_Guidance\\_Library/rgPolicy.nsf/0/DC94C3A46396950386256D5E006AED11?OpenDocument&Highlight=sfar](http://rgl.faa.gov/Regulatory_and_Guidance_Library/rgPolicy.nsf/0/DC94C3A46396950386256D5E006AED11?OpenDocument&Highlight=sfar)), the FAA determined that this ignition source risk combined with the fleet average flammability for the center wing tank on Model 777 airplanes created an unsafe condition for the center fuel tank. Applying that same policy, the FAA determined that, due to a lower fleet average flammability, that same unsafe condition does not exist in the main (wing) tanks of Model 777 airplanes, in the center auxiliary fuel tank of Model 777-200 series airplanes with a center auxiliary fuel tank capacity of less than 12,500 U.S. gallons (*i.e.*, airplanes on which the wing center structural box is a dry bay and is not part of the center fuel tank), or in the body auxiliary tank of Model 777-200LR series airplanes.

#### Related Rulemaking

On March 21, 2016, we issued AD 2016-07-07, Amendment 39-18452 (81 FR 19472, April 5, 2016), for certain Boeing Model 757-200, -200PF, -200CB, and -300 series airplanes. AD 2016-07-07 requires similar actions to those proposed in this NPRM. AD 2016-07-07 addressed the numerous public comments that were submitted on the proposal.

#### FAA's Determination

We are proposing this AD because we evaluated all the relevant information and determined the unsafe condition described previously is likely to exist or develop in other products of the same type design.

### Proposed AD Requirements

This proposed AD would require modifying the FQIS to prevent development of an ignition source inside the center fuel tank due to electrical fault conditions. As an alternative for cargo airplanes, this proposed AD would provide the alternative to modify the airplane by separating FQIS wiring routed between the FQIS processor and the center fuel tank, provided repetitive BITE checks

(checks of built-in test equipment) of the FQIS are also performed.

### Costs of Compliance

We estimate that this proposed AD affects 187 airplanes of U.S. registry. This estimate includes 29 cargo airplanes. Currently, there are no experimental, private, business/corporate/executive, or government aircraft registered in the United States that would be affected by the proposed airworthiness directive. The 158

affected U.S. air-carrier passenger airplanes are already required by applicable FAA operating regulations to be modified to include flammability reduction measures (FRM), so the proposed AD would not apply to those airplanes. However, to address the potential for those airplanes to be converted to cargo airplanes before the compliance deadline for the operating rule FRM requirement, we provide the following cost estimates to comply with this proposed AD:

### ESTIMATED COSTS—REQUIRED ACTIONS

Action	Labor cost	Parts cost	Cost per product
Modification .....	600 work-hours × \$85 per hour = \$51,000 .....	\$150,000	\$201,000

### ESTIMATED COSTS—ALTERNATIVE ACTIONS

Action	Labor cost	Parts cost	Cost per product
BITE check .....	1 work-hours × \$85 per hour = \$85 per check .....	\$0	\$85 per check.
Wire separation .....	230 work-hours × \$85 per hour = \$19,550 .....	\$10,000	\$29,550.

### 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 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 this 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),

(3) Will not affect intrastate aviation in Alaska, and

(4) 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.

### List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Incorporation by reference, 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 FAA amends § 39.13 by adding the following new airworthiness directive (AD):

**The Boeing Company:** Docket No. FAA–2016–6140; Directorate Identifier 2015–NM–059–AD.

#### (a) Comments Due Date

We must receive comments by June 20, 2016.

#### (b) Affected ADs

None.

#### (c) Applicability

This AD applies to The Boeing Company Model 777–200, 777–200LR, 777–300, 777–300ER, and 777F series airplanes, certificated in any category, excluding airplanes identified in paragraphs (c)(1) and (c)(2) of this AD.

(1) Airplanes on which the center tank consists only of the inboard structural box of the left and right wings (*i.e.*, the wing center structural box is a dry bay and is not part of the fuel tank).

(2) Airplanes equipped with a flammability reduction means (FRM) approved by the FAA as compliant with the Fuel Tank Flammability Reduction (FTFR) rule (73 FR 42444, July 21, 2008) requirements of section 25.981(b) or section 26.33(c)(1) of the Federal Aviation Regulations (14 CFR 25.981(b) or 14 CFR 26.33(c)(1)).

#### (d) Subject

Air Transport Association (ATA) of America Code 28, Fuel.

#### (e) Unsafe Condition

This AD was prompted by fuel system reviews conducted by the manufacturer. We are issuing this AD to prevent ignition sources inside the center fuel tank, which, in combination with flammable fuel vapors, could result in a fuel tank explosion and consequent loss of the airplane.

#### (f) Compliance

Comply with this AD within the compliance times specified, unless already done.

#### (g) Modification

Within 60 months after the effective date of this AD, modify the fuel quantity

indicating system (FQIS) to prevent development of an ignition source inside the center fuel tank due to electrical fault conditions, using a method approved in accordance with the procedures specified in paragraph (i) of this AD.

#### (h) Alternative Actions for Cargo Airplanes

For airplanes used exclusively for cargo operations: As an alternative to the requirements of paragraph (g) of this AD, do the actions specified in paragraphs (h)(1) and (h)(2) of this AD, using methods approved in accordance with the procedures specified in paragraph (i) of this AD. To exercise this alternative, operators must perform the first inspection required under paragraph (h)(1) of this AD within 6 months after the effective date of this AD. To exercise this alternative for airplanes returned to service after conversion of the airplane from a passenger configuration to an all-cargo configuration more than 6 months after the effective date of this AD, operators must perform the first inspection required under paragraph (h)(1) of this AD prior to further flight after the conversion.

(1) Within 6 months after the effective date of this AD, record the existing fault codes stored in the FQIS processor and then do a BITE check (check of built-in test equipment) of the FQIS. If any nondispatchable fault code is recorded prior to the BITE check or as a result of the BITE check, before further flight, do all applicable repairs and repeat the BITE check until a successful test is performed with no nondispatchable faults found, using a method approved in accordance with the procedures specified in paragraph (i) of this AD. Repeat these actions thereafter at intervals not to exceed 650 flight hours. Modification as specified in paragraph (h)(2) of this AD does not terminate the repetitive BITE check requirement of this paragraph.

(2) Within 60 months after the effective date of this AD, modify the airplane by separating FQIS wiring that runs between the FQIS processor and the center tank wing spar penetrations, including any circuits that might pass through a main fuel tank, from other airplane wiring that is not intrinsically safe, using methods approved in accordance with the procedures specified in paragraph (i) of this AD.

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

(1) The Manager, Seattle Aircraft Certification Office (ACO), FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or local Flight Standards District Office, as appropriate. If sending information directly to the manager of the ACO, send it to the attention of the person identified in paragraph (j) of this AD. Information may be emailed to: [9-ANM-Seattle-ACO-AMOC-Requests@faa.gov](mailto:9-ANM-Seattle-ACO-AMOC-Requests@faa.gov).

(2) Before using any approved AMOC, notify your appropriate principal inspector, or lacking a principal inspector, the manager of the local flight standards district office/certificate holding district office.

(3) An AMOC that provides an acceptable level of safety may be used for any repair, modification, or alteration required by this AD if it is approved by the Boeing Commercial Airplanes Organization Designation Authorization (ODA) that has been authorized by the Manager, Seattle ACO, to make those findings. To be approved, the repair method, modification deviation, or alteration deviation must meet the certification basis of the airplane, and the approval must specifically refer to this AD.

#### (j) Related Information

For more information about this AD, contact Jon Regimbal, Aerospace Engineer, Propulsion Branch, ANM-140S, FAA, Seattle Aircraft Certification Office (ACO), 1601 Lind Avenue SW., Renton, WA 98057-3356; phone: 425-917-6506; fax: 425-917-6590; email: [Jon.Regimbal@faa.gov](mailto:Jon.Regimbal@faa.gov).

Issued in Renton, Washington, on April 15, 2016.

**Victor Wicklund,**

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

[FR Doc. 2016-09801 Filed 5-3-16; 8:45 am]

**BILLING CODE 4910-13-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

#### 21 CFR Part 610

[Docket No. FDA-2016-N-1170]

#### Standard Preparations, Limits of Potency, and Dating Period Limitations for Biological Products; Companion to Direct Final Rule

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

**ACTION:** Proposed rule.

**SUMMARY:** The Food and Drug Administration (FDA or Agency or we) is proposing to amend the general biological products standards relating to dating periods and also to remove certain standards relating to standard preparations and limits of potency. FDA is proposing this action to update outdated requirements, and accommodate new and evolving technology and testing capabilities, without diminishing public health protections. This proposed action is part of FDA's retrospective review of its regulations in response to an Executive order.

**DATES:** Submit either electronic or written comments on this proposed rule or its companion direct final rule by July 18, 2016. If FDA receives any timely significant adverse comments on the direct final rule with which this proposed rule is associated, the Agency

will publish a document withdrawing the direct final rule within 30 days after the comment period ends. FDA will apply any significant adverse comments received on the direct final rule to the proposed rule in developing the final rule. FDA will then proceed to respond to comments under this proposed rule using the usual notice and comment procedures.

**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 instructions for submitting comments. Comments submitted electronically, including attachments, to <http://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 <http://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):** Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

- For written/paper comments submitted to the Division of Dockets Management, 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-2016-N-1170 for "Standard Preparations, Limits of Potency, and Dating Period Limitations for Biological Products." Received comments will be placed in the docket and, except for