September 25, 2008, specifies to contact Boeing for appropriate action: Before further flight, repair the crack using a method approved in accordance with the procedures specified in paragraph (p) of this AD.

(m) Where Boeing Alert Service Bulletin 747–53A2749, dated September 25, 2008, specifies a compliance time after the date of the service bulletin, this AD requires compliance within the specified compliance time after the effective date of this AD.

(n) Where Boeing Alert Service Bulletin 747–53A2749, dated September 25, 2008, specifies a compliance time related to accomplishing an action ''as given in Boeing Service Bulletin 747–53A2259,'' this AD requires compliance within the specified compliance time after the applicable compliance time required by paragraph (h) of this AD.

Terminating Action

(o) Accomplishing the repetitive frame inspections required by AD 2006–05–02, amendment 39–14499; or AD 2005–20–30, amendment 39–14327; terminates the inspections required by paragraphs (g), (h), and (k) of this AD.

Alternative Methods of Compliance (AMOCs)

(p)(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. Send information to ATTN: Ivan Li, Aerospace Engineer, Airframe Branch, ANM–120S, FAA, Seattle Aircraft Certification Office, 1601 Lind Avenue, SW., Renton, Washington 98057–3356; telephone (425) 917–6437; fax (425) 917–6590; or, e-mail information to *9-ANM-Seattle-ACO-AMOC-Requests@faa.gov.*

(2) To request a different method of compliance or a different compliance time for this AD, follow the procedures in 14 CFR 39.19. Before using any approved AMOC on any airplane to which the AMOC applies, notify your principal maintenance inspector (PMI) or principal avionics inspector (PAI), as appropriate, or lacking a principal inspector, your local Flight Standards District Office. The AMOC approval letter must specifically reference this AD.

(3) AMOCs approved previously in accordance with paragraph (A) of AD 86–18–01, are approved as alternative methods of compliance with the corresponding requirements of paragraph (g) of this AD.

(4) AMOCs approved previously in accordance with paragraph (B) of AD 86–18–01, are approved as alternative methods of compliance with the corresponding requirements of paragraph (h) of this AD.

(5) An AMOC that provides an acceptable level of safety may be used for any repair required by this AD, if it is approved by an Authorized Representative for the Boeing Commercial Airplanes Delegation Option Authorization Organization who has been authorized by the Manager, Seattle ACO, to make those findings. For a repair method to be approved, the repair must meet the certification basis of the airplane and the approval must specifically refer to this AD.

Material Incorporated by Reference

(q) You must use the service information contained in Table 1 of this AD, as applicable, to do the actions required by this AD, unless the AD specifies otherwise.

TABLE 1—MATERIAL INCORPORATED BY REFERENCE

Document	Revision	Date
Boeing Alert Service Bulletin 747–53A2237	1	March 28, 1986.
Boeing Alert Service Bulletin 747–53A2259	1	April 18, 1986.
Boeing Alert Service Bulletin 747–53A2749	Original	September 25, 2008.

Boeing Alert Service Bulletin 747–53A2259, Revision 1, dated April 18, 1986, contains the following effective pages:

Page Nos.	Revision level shown on page	Date shown on page
2, 3, 5, 6, 9–11, 15, 16, 18–24	Original	March 28, 1986.
1, 4, 7, 8, 12–14, 17, 25, 26	Revision 1	April 18, 1986.

(1) The Director of the Federal Register approved the incorporation by reference of the service information under 5 U.S.C. 552(a) and 1 CFR part 51.

(2) For service information identified in this AD, contact Boeing Commercial Airplanes, Attention: Data & Services Management, P.O. Box 3707, MC 2H–65, Seattle, Washington 98124–2207; telephone 206–544–5000, extension 1, fax 206–766–5680; e-mail *me.boecom@boeing.com*; Internet *https://www.myboeingfleet.com.*

(3) You may review copies of the service information at the FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington. For information on the availability of this material at the FAA, call 425–227–1221 or 425–227–1152.

(4) You may also review copies of the service information that is incorporated by reference at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.*

Issued in Renton, Washington, on December 1, 2009.

Michael J. Kaszycki,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. E9–29222 Filed 12–9–09; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2009–1112; Directorate Identifier 2009–NM–237–AD; Amendment 39–16132; AD 2009–25–12]

RIN 2120–AA64

Airworthiness Directives; Airbus Model A330–200 and –300 Series Airplanes; Model A340–200 and –300 Series Airplanes; and Model A340–500 and –600 Series Airplanes

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

ACTION: Final rule; request for comments.

SUMMARY: We are adopting a new airworthiness directive (AD) for the products listed above. This AD results

from mandatory continuing airworthiness information (MCAI) originated by an aviation authority of another country to identify and correct an unsafe condition on an aviation product. The MCAI describes the unsafe condition as:

> In-Service experience has shown cases where several oxygen containers could not fully open.
>
> Investigations have revealed that these events are due to an insufficient clearance between the oxygen container and the adjacent panels (Passenger Service Unit (PSU), spacers or filler panels).
>
> Incorrect opening of the oxygen containers could lead to non deployment of oxygen masks.
>
> This condition, if not detected and corrected, could prevent passengers from being supplied with oxygen in case of in flight cabin depressurization * * *.

This AD requires actions that are intended to address the unsafe condition described in the MCAI.

DATES: This AD becomes effective December 28, 2009.

The Director of the Federal Register approved the incorporation by reference of certain publications listed in the AD as of December 28, 2009.

We must receive comments on this AD by January 25, 2010.

ADDRESSES: You may send comments 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:* U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue, SE., Washington, DC, 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;* or in person at the Docket Operations office between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this AD, the regulatory evaluation, any comments received, and other information. The street address for the Docket Operations office (telephone (800) 647–5527) is in the **ADDRESSES** section. Comments will be available in the AD docket shortly after receipt.

FOR FURTHER INFORMATION CONTACT: Vladimir Ulyanov, Aerospace Engineer, International Branch, ANM–116, Transport Airplane Directorate, FAA, 1601 Lind Avenue, SW., Renton, Washington 98057–3356; telephone (425) 227–1138; fax (425) 227–1149.

SUPPLEMENTARY INFORMATION:

Discussion

The European Aviation Safety Agency (EASA), which is the Technical Agent for the Member States of the European Community, has issued EASA Airworthiness Directive 2009–0237–E, dated October 30, 2009 (referred to after this as ''the MCAI''), to correct an unsafe condition for the specified products. The MCAI states:

> In-Service experience has shown cases where several oxygen containers could not fully open.
>
> Investigations have revealed that these events are due to an insufficient clearance between the oxygen container and the adjacent panels (Passenger Service Unit (PSU), spacers or filler panels).
>
> Incorrect opening of the oxygen containers could lead to non deployment of oxygen masks.
>
> This condition, if not detected and corrected, could prevent passengers from being supplied with oxygen in case of in flight cabin depressurization, which would constitute an unsafe condition.
>
> To prevent such condition, this AD requires a one-time [general visual] inspection of the oxygen containers and adjacent panels installation and corrective actions, as necessary, to ensure an adequate clearance between these components.

Corrective actions include adjusting oxygen containers and tightening locking devices. You may obtain further information by examining the MCAI in the AD docket.

Relevant Service Information

Airbus has issued All Operators Telexes A330–35A3026, A340–35A4027, and A340–35A5019, all dated October 26, 2009. The actions described in this service information are intended to correct the unsafe condition identified in the MCAI.

FAA's Determination and Requirements of This AD

This product has been approved by the aviation authority of another country, and is approved for operation in the United States. Pursuant to our bilateral agreement with the State of Design Authority, we have been notified of the unsafe condition described in the MCAI and service information referenced above. We are issuing this AD because we evaluated all pertinent information and determined the unsafe condition exists and is likely to exist or develop on other products of the same type design.

Differences Between the AD and the MCAI or Service Information

We have reviewed the MCAI and related service information and, in general, agree with their substance. But we might have found it necessary to use different words from those in the MCAI to ensure the AD is clear for U.S. operators and is enforceable. In making these changes, we do not intend to differ substantively from the information provided in the MCAI and related service information.

We might also have required different actions in this AD from those in the MCAI in order to follow FAA policies. Any such differences are highlighted in a Note within the AD.

FAA's Determination of the Effective Date

An unsafe condition exists that requires the immediate adoption of this AD. The FAA has found that the risk to the flying public justifies waiving notice and comment prior to adoption of this rule because the compliance time defined in the MCAI is 150 flight hours for accomplishing the initial inspection for insufficient clearance between the oxygen container and the adjacent panels. Incorrect opening of the oxygen containers could lead to non-deployment of the oxygen masks, which could prevent passengers from being supplied with oxygen in case of in-flight cabin depressurization. Therefore, we determined that notice and opportunity for public comment before issuing this AD are impracticable and that good cause exists for making this amendment effective in fewer than 30 days.

Comments Invited

This AD is a final rule that involves requirements affecting flight safety, and we did not precede it by notice and opportunity for public comment. We invite you to send any written relevant data, views, or arguments about this AD. Send your comments to an address listed under the **ADDRESSES** section. Include ''Docket No. FAA–2009–1112; Directorate Identifier 2009–NM–237–AD'' at the beginning of your comments. We specifically invite comments on the overall regulatory, economic, environmental, and energy aspects of this AD. We will consider all comments received by the closing date and may amend this 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 AD.

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 AD will not have federalism implications under Executive Order 13132. This AD will 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 AD:

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 AD and placed it in the AD docket.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Incorporation by reference, Safety.

Adoption of the Amendment

■ Accordingly, under the authority delegated to me by the Administrator, the FAA amends 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 AD:

2009–25–12 Airbus: Amendment 39–16132. Docket No. FAA–2009–1112; Directorate Identifier 2009–NM–237–AD.

Effective Date

(a) This airworthiness directive (AD) becomes effective December 28, 2009.

Affected ADs

(b) None.

Applicability

(c) This AD applies to the airplanes identified in paragraphs (c)(1), (c)(2), and (c)(3) of this AD, all serial numbers, certificated in any category, if delivered before October 26, 2009.

(1) Airbus Model A330–201, –202, –203, –223, –243, –301, –302, –303, –321, –322, –323, –341, –342, and –343 series airplanes, on which Airbus modification 48809 has been embodied in production.

(2) Airbus Model A340–211, –212, –213, –311, –312, and –313 series airplanes, on which Airbus modification 48809 has been embodied in production.

(3) Airbus Model A340–541 and –642 airplanes.

Subject

(d) Air Transport Association (ATA) of America Code 35: Oxygen.

Reason

(e) The mandatory continued airworthiness information (MCAI) states:

In-Service experience has shown cases where several oxygen containers could not fully open.

Investigations have revealed that these events are due to an insufficient clearance between the oxygen container and the adjacent panels (Passenger Service Unit (PSU), spacers or filler panels).

Incorrect opening of the oxygen containers could lead to nondeployment of oxygen masks.

This condition, if not detected and corrected, could prevent passengers from being supplied with oxygen in case of in-flight cabin depressurization, which would constitute an unsafe condition.

To prevent such condition, this AD requires a one-time [general visual] inspection of the oxygen containers and adjacent panels installation and corrective actions, as necessary, to ensure an adequate clearance between these components.

Corrective actions include adjusting oxygen containers and tightening locking devices.

Compliance

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

Actions

(g) Unless already done, do the following actions:

(1) Within 150 flight hours after the effective date of this AD: Do a general visual inspection of the clearance between the oxygen container door lid and the adjacent panel/component of each cabin oxygen container located in the passenger service channel, in accordance with paragraph 4.2 of the applicable all operators telex (AOT) identified in Table 1 of this AD.

TABLE 1—SERVICE INFORMATION

For model—	Airbus AOT—	Dated—
A330–200 and –300 series airplanes	A330–35A3026	October 26, 2009.
A340–200 and –300 series airplanes	A340–35A4027	October 26, 2009.
A340–500 and –600 series airplanes	A340–35A5019	October 26, 2009.

(2) If any clearance is determined to be less than 2.0 millimeters during any inspection required by paragraph (g)(1) of this AD: Before further flight, do all corrective actions in accordance with paragraph 4.2 of the applicable AOT identified in Table 1 of this AD.

FAA AD Differences

Note 1: This AD differs from the MCAI and/or service information as follows: No differences.

Other FAA AD Provisions

(h) The following provisions also apply to this AD:

(1) *Alternative Methods of Compliance (AMOCs):* The Manager, International Branch, ANM–116, Transport Airplane Directorate, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. Send information to ATTN: Vladimir Ulyanov, Aerospace Engineer, International Branch, ANM–116, Transport Airplane Directorate, FAA, 1601 Lind Avenue, SW., Renton, Washington 98057–3356; telephone (425) 227–1138; fax (425) 227–1149. Before using any approved AMOC on any airplane to which the AMOC applies, notify your principal maintenance inspector (PMI) or principal avionics inspector (PAI), as appropriate, or lacking a principal inspector, your local Flight Standards District Office. The AMOC approval letter must specifically reference this AD.

(2) *Airworthy Product:* For any requirement in this AD to obtain corrective actions from a manufacturer or other source, use these actions if they are FAA-approved. Corrective actions are considered FAA-approved if they are approved by the State of Design Authority (or their delegated agent). You are required to assure the product is airworthy before it is returned to service.

(3) *Reporting Requirements:* For any reporting requirement in this AD, under the provisions of the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*), the Office of Management and Budget (OMB) has approved the information collection requirements and has assigned OMB Control Number 2120–0056.

Related Information

(i) Refer to MCAI European Aviation Safety Agency Airworthiness Directive 2009–0237–E, dated October 30, 2009; and the service information specified in Table 2 of this AD; for related information.

TABLE 2—RELATED SERVICE INFORMATION

Airbus AOT—	Dated—
A330–35A3026	October 26, 2009.
A340–35A4027	October 26, 2009.
A340–35A5019	October 26, 2009.

Material Incorporated by Reference

(j) You must use the applicable service information contained in Table 3 of this AD to do the actions required by this AD, unless the AD specifies otherwise. (Only the first page of these documents contains the document number, revision level, and date; no other page of these documents contains this information.)

TABLE 3—MATERIAL INCORPORATED BY REFERENCE

Airbus AOT—	Dated—
A330–35A3026	October 26, 2009.
A340–35A4027	October 26, 2009.
A340–35A5019	October 26, 2009.

(1) The Director of the Federal Register approved the incorporation by reference of this service information under 5 U.S.C. 552(a) and 1 CFR part 51.

(2) For service information identified in this AD, contact Airbus SAS—Airworthiness Office—EAL, 1 Rond Point Maurice Bellonte, 31707 Blagnac Cedex, France; telephone +33 5 61 93 36 96; fax +33 5 61 93 45 80; e-mail: *airworthiness.A330-A340@airbus.com*; Internet *http://www.airbus.com*.

(3) You may review copies of the service information at the FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington. For information on the availability of this material at the FAA, call 425–227–1221 or 425–227–1152.

(4) You may also review copies of the service information that is incorporated by reference at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html*.

Issued in Renton, Washington, on November 30, 2009.

Michael J. Kaszycki,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. E9–29378 Filed 12–9–09; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 210, 211, and 212

[Docket No. FDA–2004–N–0449] (formerly Docket No. 2004N–0439)

Current Good Manufacturing Practice for Positron Emission Tomography Drugs

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing regulations on current good manufacturing practice (CGMP) for positron emission tomography (PET) drugs. The regulations are intended to ensure that PET drugs meet the requirements of the Federal Food, Drug, and Cosmetic Act (the act) regarding safety, identity, strength, quality, and purity. In this final rule, we are establishing CGMP regulations for approved PET drugs. For investigational and research PET drugs, the final rule states that the requirement to follow CGMP may be met by complying with these regulations or by producing PET drugs in accordance with the United States Pharmacopeia (USP) general chapter on compounding PET radiopharmaceuticals. We are establishing these CGMP requirements for PET drugs under the provisions of the Food and Drug Administration Modernization Act of 1997 (the Modernization Act). Elsewhere in this issue of the **Federal Register**, we are announcing the availability of a guidance entitled ''PET Drugs—Current Good Manufacturing Practice (CGMP).''

DATES: This regulation is effective December 12, 2011. The incorporation by reference of a certain publication listed in the rule is approved by the Director of the Federal Register as of December 12, 2011.

FOR FURTHER INFORMATION CONTACT: Brenda Uratani, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002, 1–240–328–7621, e-mail: *Brenda.Uratani@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION:

Table of Contents

I. Introduction

We are adding to our regulations new part 212 (21 CFR part 212) to establish CGMP requirements for PET drugs in accordance with section 121 of the Modernization Act (Public Law 105–115).

A. Background

In the **Federal Register** of September 20, 2005 (70 FR 55038) (2005 proposed