

the inspection required by paragraph (t) of this AD thereafter at the applicable interval specified in paragraphs (u)(1), (u)(2), and (u)(3) of this AD.

(1) For airplanes fitted with twin wheel MLG that have been equipped with EMM BSCU standard L4.8: At intervals not to exceed 20 months, or 6,000 flight hours, or 4,500 flight cycles, whichever occurs first.

(2) For airplanes fitted with twin wheel MLG that have been equipped with EMM BSCU standard L4.1 or L4.5: At intervals not to exceed 6 months, or 1,800 flight hours, or 1,350 flight cycles, whichever occurs first.

(3) For airplanes fitted with bogie MLG: At intervals not to exceed 20 months, or 6,000 flight hours, or 4,500 flight cycles, whichever occurs first.

#### (v) Modification

For airplanes fitted with twin wheel MLG: Within 6 months after the effective date of this AD, modify the airplane by installing EMM BSCU standard L4.9B, in accordance with the Accomplishment Instructions of Airbus Service Bulletin A320–32–1350, dated July 3, 2008.

#### (w) Optional Method of Modification

Doing a modification specified in paragraph (w)(1), (w)(2), or (w)(3) of this AD, is acceptable for compliance with the requirements of paragraph (v) of this AD.

(1) Modification of the airplane by installing EMM BSCU standard L4.9B, in accordance with the Accomplishment Instructions of Airbus Service Bulletin A320–32–1387, dated April 7, 2011.

(2) Modification of the airplane by installing conventional EMM BSCU standard 10, in accordance with the Accomplishment Instructions of Airbus Service Bulletin A320–32–1360, dated March 18, 2009; or Airbus Mandatory Service Bulletin A320–32–1336, Revision 01, dated January 10, 2008.

(3) Modification of the airplane by installing conventional EMM BSCU standard 10.1 in accordance with the Accomplishment Instructions of Airbus Service Bulletin A320–32–1369, Revision 01, dated March 31, 2010.

#### (x) Terminating Action

In-service modification of an airplane fitted with twin wheel MLG as required by paragraph (v) of this AD constitutes terminating action for the initial and repetitive inspections required by paragraph (t) of this AD. In addition, the AFM changes required by paragraph (r) of this AD may be removed from the AFM; and the requirements of paragraph (s) of this AD are no longer required.

#### (y) Exemption From Certain Actions

Except for paragraph (y) of this AD, airplanes that have been delivered with Airbus modification 38973 and/or Airbus modification 151575 that install EMM BSCU standard L4.9B are not affected by the requirements of this AD, provided that no installation of previous EMM BSCU standards L4.1, L4.5, or L4.8 has been performed since the airplane first flight.

#### (z) Parts Installation

For airplanes that do not have EMM BSCU L4.1, or EMM BSCU L4.5, or EMM BSCU

L4.8 installed: As of the effective date of this AD, no person may modify an airplane by installing EMM BSCU standards L4.1, L4.5, or L4.8 on any airplane.

#### (aa) Credit for Previous Actions

(1) This paragraph restates the requirements of paragraph (n) of AD 2007–18–09, Amendment 39–15189 (72 FR 51164, September 6, 2007). This paragraph provides credit for the inspections required by paragraph (j) of this AD, if those inspections were performed before October 11, 2007 (the effective date of AD 2007–18–09, Amendment 39–15189 (72 FR 51164, September 6, 2007)) using Chapter 12, Subject 12–14–32 of the Airbus A318/A319/A320/A321 AMM, as revised by Airbus A318/A319/A320/A321 AMM Temporary Revision 12–001, dated November 13, 2005.

(2) This paragraph provides credit for the inspections and related investigative/corrective actions required by paragraphs (j), (k), and (l) of this AD, if those inspections were performed before the effective date of this AD using Airbus Service Bulletin A320–32–1310, dated February 8, 2006.

(3) This paragraph provides credit for the modifications specified in paragraph (w)(2) of this AD, if those modifications were performed before the effective date of this AD using Airbus Mandatory Service Bulletin A320–32–1336, dated September 19, 2007.

(4) This paragraph provides credit for the modifications required by paragraph (w)(3) of this AD, if those modifications were performed before the effective date of this AD using Airbus Service Bulletin A320–32–1369, dated March 22, 2009.

#### (bb) Other FAA AD Provisions

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. 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 International Branch, send it to ATTN: Sanjay Ralhan, Aerospace Engineer, International Branch, ANM–116, Transport Airplane Directorate, FAA, 1601 Lind Avenue SW., Renton, WA 98057–3356; telephone (425) 227–1405; fax (425) 227–1149. Information may be emailed to: 9-ANM-116-AMOC-REQUESTS@faa.gov. 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. The AMOC approval letter must specifically reference this AD. AMOCs approved previously in accordance with AD 2007–18–09, Amendment 39–15189 (72 FR 51164, September 6, 2007), are not approved as AMOCs with 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.

#### (cc) Related Information

(1) Refer to MCAI EASA Airworthiness Directive 2011–0201, dated October 13, 2011, and the service information service information identified in paragraphs (cc)(1)(i) through (cc)(1)(viii) for related information.

(i) Airbus A318/A319/A320/A321, Task 12–12–32–610–001–A Check NLG Shock Absorber Fluid Level and Charge Pressure (“Two-Point Check”—Aircraft on Jacks to start), Revision August 1, 2012.

(ii) Airbus Mandatory Service Bulletin A320–32–1310, Revision 01, dated June 23, 2011.

(iii) Airbus Mandatory Service Bulletin A320–32–1336, Revision 01, dated January 10, 2008.

(iv) Airbus Service Bulletin A320–32–1350, dated July 31, 2008.

(v) Airbus Service Bulletin A320–32–1360, dated March 18, 2009.

(vi) Airbus Service Bulletin A320–32–1369, Revision 01, dated March 31, 2010.

(vii) Airbus Service Bulletin A320–32–1387, dated April 7, 2011.

(viii) Airbus Technical Note 957.1901/05, dated October 18, 2005.

(2) For service information identified in this AD, contact Airbus, Airworthiness Office—EAS, 1 Rond Point Maurice Bellonte, 31707 Blagnac Cedex, France; telephone +33 5 61 93 36 96; fax +33 5 61 93 44 51; email [account.airworth-eas@airbus.com](mailto:account.airworth-eas@airbus.com); Internet <http://www.airbus.com>. You may review copies of the referenced service information at the FAA, Transport Airplane Directorate, 1601 Lind Avenue SW., Renton, WA. For information on the availability of this material at the FAA, call 425–227–1221.

Issued in Renton, Washington, on January 31, 2013.

Ali Bahrami,

Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 2013–02898 Filed 2–7–13; 8:45 am]

BILLING CODE 4910–13–P

## DEPARTMENT OF TRANSPORTATION

### Federal Aviation Administration

#### 14 CFR Part 39

[Docket No. FAA–2013–0090; Directorate Identifier 2012–NM–149–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 747–100, 747–100B, 747–100B SUD, 747–200B, 747–200C, 747–300, 747–400, 747–400D, and 747SP series airplanes. This proposed AD was prompted by reports of worn or incorrectly assembled latches on main deck escape slides installed on airplane doors. This proposed AD would require determining if the latches are correctly assembled; and corrective actions if necessary. This proposed AD also would require, for certain airplanes, modifications to the escape slide/rafts and escape slides. We are proposing this AD to prevent a latch hook moving from closed to open in an escape slide/raft or escape slide, which could result in the escape slide/raft or escape slide not deploying correctly in an emergency, or releasing/inflating into the passenger cabin and causing injury to passengers and crew.

**DATES:** We must receive comments on this proposed AD by March 25, 2013.

**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.

For Boeing service information identified in this proposed AD, contact Boeing Commercial Airplanes, Attention: Data & Services Management, P. O. Box 3707, MC 2H–65, Seattle, WA 98124–2207; telephone 206–544–5000, extension 1; fax 206–766–5680; Internet <https://www.myboeingfleet.com>. For Goodrich service information identified in this proposed AD, contact Goodrich Corporation, Aircraft Interior Products, ATTN: Technical Publications, 3414 South Fifth Street, Phoenix, AZ 85040–1169; telephone 602–243–2200; Internet <http://www.goodrich.com/TechPubs>. You may review copies of the referenced service information at the FAA, Transport Airplane Directorate, 1601 Lind Avenue SW., Renton, WA. For information on the availability of this material at the FAA, call 425–227–1221.

### Examining the AD Docket

You may examine the AD docket on the Internet at <http://www.regulations.gov>; 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:

Sarah Piccola, Aerospace Engineer, Cabin Safety and Environmental Systems Branch, ANM–150S, FAA, Seattle Aircraft Certification Office, 1601 Lind Avenue SW., Renton, WA 98057–3356; phone: 425–917–6483; fax: 425–917–6590; email: [sarah.piccola@faa.gov](mailto:sarah.piccola@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–2013–0090; Directorate Identifier 2012–NM–149–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

We received reports that, in service, latches in the main deck escape slide/rafts and escape slides installed on airplane doors were not fully closed. The current latch design uses friction to keep the latch hook closed. Corrosion and worn parts reduce friction between the parts of the latch that keep it closed. The new latch design has a retention feature to make sure the latch stays closed. A latch hook moving from the closed to the open position in an escape

slide/raft or escape slide, if not corrected, could result in an escape slide/raft or escape slide not deploying correctly in an emergency, or releasing/inflating into the passenger cabin and causing injury to passengers and crew.

### Relevant Service Information

We reviewed Boeing Special Attention Service Bulletin 747–25–3428, Revision 3, dated June 14, 2012. For information on the procedures and compliance times, see this service information at <http://www.regulations.gov> by searching for Docket No. FAA–2013–0090.

### Concurrent Service Information

Boeing Special Attention Service Bulletin 747–25–3428, Revision 3, dated June 14, 2012, specifies concurrent or prior accomplishment of Boeing Service Bulletin 747–25–2425, Revision 1, dated September 7, 1979. For information on the procedures, see this service information at <http://www.regulations.gov> by searching for Docket No. FAA 2013 0090.

### 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 accomplishing the actions specified in the service information described previously.

The phrase “related investigative actions” might be used in this proposed AD. “Related investigative actions” are follow-on actions that (1) are related to the primary action, and (2) are actions that further investigate the nature of any condition found. Related investigative actions in an AD could include, for example, inspections.

In addition, the phrase “corrective actions” might be used in this proposed AD. “Corrective actions” are actions that correct or address any condition found. Corrective actions in an AD could include, for example, repairs.

### Costs of Compliance

We estimate that this proposed AD affects 121 airplanes of U.S. registry.

We estimate the following costs to comply with this proposed AD:

## ESTIMATED COSTS

Action	Labor cost	Parts cost	Cost per product	Cost on U.S. operators
Determine if latches are correctly assembled.	1 work-hour × \$85 per hour = \$85.	\$0 .....	\$85 .....	\$10,285.
Option to rework/replace latches instead of determining if latches are correctly assembled.	Between 3 and 24 work-hours × \$85 per hour = Between \$255 and \$2,040.	\$286 per latch .....	Between \$541 and \$2,326 .....	Between \$65,461 and \$281,446.

We estimate the following costs to do any necessary replacements that would be required based on the results of the

proposed latch assembly determination. We have no way of determining the

number of aircraft that might need this replacement:

## ON-CONDITION COSTS

Action	Labor cost	Parts cost	Cost per product
Corrective action .....	Between 3 and 24 work-hours × \$85 per hour = Between \$255 and \$ 2,040.	\$286 per latch .....	Between \$541 and \$2,326.

According to the manufacturer, all of the costs of this proposed AD may be covered under warranty, thereby reducing the cost impact on affected individuals. We do not control warranty coverage for affected individuals. As a result, we have included all costs in our cost estimate.

**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–2013–0090; Directorate Identifier 2012–NM–149–AD.

**(a) Comments Due Date**

We must receive comments by March 25, 2013.

**(b) Affected ADs**

None.

**(c) Applicability**

This AD applies to The Boeing Company Model 747–100, 747–100B, 747–100B SUD, 747–200B, 747–200C, 747–300, 747–400, 747–400D, and 747SP series airplanes; certificated in any category; as identified in Boeing Special Attention Service Bulletin 747–25–3428, Revision 3, dated June 14, 2012; except for Groups 3–4, Configuration 2, and Group 9, Configuration 2, airplanes.

**(d) Subject**

Joint Aircraft System Component (JASC)/Air Transport Association (ATA) of America Code 25, Equipment/furnishings.

**(e) Unsafe Condition**

This AD was prompted by reports of worn or incorrectly assembled latches on main deck escape slides installed on airplane doors. We are issuing this AD to prevent a latch hook moving from closed to open in an escape slide/raft or escape slide, which could result in the escape slide/raft or escape slide not deploying correctly in an emergency, or releasing/inflating into the passenger cabin and causing injury to passengers and crew.

**(f) Compliance**

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

**(g) Replacement or Rework of Escape Slide Latch Assembly**

Within 48 months after the effective date of this AD: Determine if the latches in the main deck escape slide/rafts and the escape slides installed on the airplane doors are correctly assembled, and do all applicable corrective actions, in accordance with the

Accomplishment Instructions of Boeing Special Attention Service Bulletin 747-25-3428, Revision 3, dated June 14, 2012. Do all applicable corrective actions before further flight. Options provided in Boeing Special Attention Service Bulletin 747-25-3428, Revision 3, dated June 14, 2012, for determining the correct assembly of the latches are acceptable for the corresponding requirement of this paragraph.

#### (h) Concurrent Requirements

For Groups 1, 5, 10, and 13 airplanes, as identified in Boeing Special Attention Service Bulletin 747-25-3428, Revision 3, dated June 14, 2012: Prior to or concurrently with accomplishing the actions required by paragraph (g) of this AD, replace the packboard cap nuts with flush-type inserts, reinforce the lower packboard support bracket attachments, install hooks, modify the lower liner of the main entry door and packboard, and remove the "Press to Test" circuit panel and associated circuitry, in accordance with the Accomplishment Instructions of Boeing Service Bulletin 747-25-2425, Revision 1, dated September 7, 1979.

#### (i) Credit for Previous Actions

This paragraph provides credit for the applicable concurrent actions required by paragraph (h) of this AD, if those actions were performed before the effective date of this AD using Boeing Service Bulletin 747-25-2425, dated August 25, 1978, which is not incorporated by reference in this AD.

#### (j) 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 the Related Information section 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 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. 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.

#### (k) Related Information

(1) For more information about this AD, contact Sarah Piccola, Aerospace Engineer, Cabin Safety and Environmental Systems Branch, ANM-150S, FAA, Seattle Aircraft Certification Office, 1601 Lind Avenue SW., Renton, WA 98057-3356; phone: 425-917-

6483; fax: 425-917-6590; email: [sarah.piccola@faa.gov](mailto:sarah.piccola@faa.gov).

(2) For Boeing service information identified in this AD, contact Boeing Commercial Airplanes, Attention: Data & Services Management, P. O. Box 3707, MC 2H-65, Seattle, WA 98124-2207; telephone 206-544-5000, extension 1; fax 206-766-5680; Internet <https://www.myboeingfleet.com>. For Goodrich service information identified in this AD, contact Goodrich Corporation, Aircraft Interior Products, ATTN: Technical Publications, 3414 South Fifth Street, Phoenix, AZ 85040-1169; telephone 602-243-2200; Internet <http://www.goodrich.com/TechPubs>. You may also review copies of the referenced service information at the FAA, Transport Airplane Directorate, 1601 Lind Avenue SW., Renton, WA. For information on the availability of this material at the FAA, call 425-227-1221.

Issued in Renton, Washington, on February 1, 2013.

**Ali Bahrami,**

Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 2013-02896 Filed 2-7-13; 8:45 am]

**BILLING CODE 4910-13-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

#### 21 CFR Part 886

[Docket No. FDA-2013-N-0069]

#### Medical Devices; Ophthalmic Devices; Classification of the Eyelid Weight

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

**ACTION:** Proposed rule.

**SUMMARY:** The Food and Drug Administration (FDA) is proposing to classify the eyelid weight into class II (special controls). The eyelid weight may be adhered to the outer skin of the upper eyelid (external eyelid weight) or implanted into the upper eyelid (implantable eyelid weight), and is intended for the gravity assisted treatment of lagophthalmos (incomplete eyelid closure). FDA is also giving notice of its intent to exempt the external eyelid weight device from the premarket notification requirements of the Federal Food, Drug, and Cosmetic Act (FD&C Act). After considering public comments on the proposed classification, FDA will publish a final regulation classifying this device type.

**DATES:** Submit either electronic or written comments by May 9, 2013. See section IV of this document for the proposed effective date of a final rule that may issue based on this proposal.

**ADDRESSES:** You may submit comments, identified by Docket No. FDA-2013-N-0069, by any of the following methods:

#### Electronic Submissions

Submit electronic comments in the following way:

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

#### Written Submissions

Submit written submissions in the following way:

- *Mail/Hand delivery/Courier (for paper or CD-ROM submissions):* Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

**Instructions:** All submissions received must include the Agency name and Docket No. FDA-2013-N-0069 for this rulemaking. All comments received may be posted without change to <http://www.regulations.gov>, including any personal information provided. For additional information on submitting comments, see the "Comments" heading of the **SUPPLEMENTARY INFORMATION** section of this document.

**Docket:** For access to the docket to read background documents or comments received, go to <http://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

**FOR FURTHER INFORMATION CONTACT:** Tina Kiang, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 2414, Silver Spring, MD 20993-0002, 301-796-6860, [Tina.Kiang@fda.hhs.gov](mailto:Tina.Kiang@fda.hhs.gov).

#### SUPPLEMENTARY INFORMATION:

##### I. Background

##### A. Statutory and Regulatory Authorities

The FD&C Act (21 U.S.C. 301 *et seq.*), as amended by the Medical Device Amendments of 1976 (Pub. L. 94-295), the Safe Medical Devices Act of 1990 (Pub. L. 101-629), and the Food and Drug Administration Modernization Act of 1997 (Pub. L. 105-115), among other amendments, established a comprehensive system for the regulation of medical devices intended for human use. Section 513 of the FD&C Act (21 U.S.C. 360c) established three categories (classes) of devices, depending on the regulatory controls needed to provide reasonable assurance of their safety and effectiveness. The three categories of