#### (b) Affected ADs

This AD affects AD 2019–11–06, Amendment 39–19652 (84 FR 27193, June 12, 2019) (AD 2019–11–06).

#### (c) Applicability

This AD applies to The Boeing Company Model 737–800 series airplanes, certificated in any category, that have been converted to a freighter configuration using Boeing Drawing 800A0003 before April 1, 2021, and are identified as Group A in Section 5.2.1, "Effectivity," of Boeing 737–800BCF Airworthiness Limitations, D140A006, Revision L, dated April 1, 2021.

**Note 1 to paragraph (c):** Airplanes with a 737–800BCF designation are Model 737–800 series airplanes that have been converted to a freighter configuration using Boeing Drawing 800A0003.

#### (d) Subject

Air Transport Association (ATA) of America Code 53, Fuselage.

#### (e) Unsafe Condition

This AD was prompted by a determination that the compliance time for the initial ultrasonic inspection of the skin under the drag link assembly required by AD 2019–11– 06 must be reduced for certain airplanes. The FAA is issuing this AD to address cracking found in the station (STA) 540 bulkhead chord and skin, which could result in the inability of a primary structural element to sustain limit load. The unsafe condition, if not addressed, could result in possible rapid decompression and loss of structural integrity of the airplane.

#### (f) Compliance

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

#### (g) Required Actions

(1) For airplanes identified as Group 1, Configuration 2, 3, 4, or 5, or as Group 5 in Boeing Alert Service Bulletin 737-53A1368, dated February 27, 2018: At the compliance time specified in paragraph (g)(1)(i), (ii), (iii), or (iv) of this AD, whichever occurs last, perform an ultrasonic inspection of the skin under the drag link assembly in accordance with the Accomplishment Instructions, Part 2, of Boeing Alert Service Bulletin 737-53A1368, dated February 27, 2018. Do all applicable on-condition actions for the Part 2 inspection at the times specified in paragraph 1.E., "Compliance," of Boeing Alert Service Bulletin 737-53A1368, dated February 27, 2018, except where Boeing Alert Service Bulletin 737–53A1368, dated February 27, 2018, specifies contacting Boeing for repair instructions, this AD requires doing the repair using a method approved in accordance with paragraph (j) of this AD.

(i) Before the airplane accumulates 17,000 total flight cycles.

(ii) Within 5,000 flight cycles after July 17, 2019 (the effective date of AD 2019–11–06).

(iii) Within 12 months after the effective date of this AD.

(iv) Within 1,000 flight cycles after the effective date of this AD.

(2) For airplanes identified as Group 1, Configuration 1, 3, or 4 in Boeing Alert Service Bulletin 737-53A1368, dated February 27, 2018: At the compliance time specified in paragraph (g)(2)(i), (ii), (iii), or (iv) of this AD, whichever occurs last, perform an ultrasonic inspection of the repair tripler under the drag link assembly in accordance with the Accomplishment Instructions, Part 6, of Boeing Alert Service Bulletin 737-53A1368, dated February 27, 2018. Do all applicable on-condition actions for the Part 6 inspection at the times specified in paragraph 1.E., "Compliance," of Boeing Alert Service Bulletin 737-53A1368, dated February 27, 2018, except where Boeing Alert Service Bulletin 737–53A1368, dated February 27, 2018, specifies contacting Boeing for repair instructions, this AD requires doing the repair using a method approved in accordance with paragraph (j) of this AD.

(i) Before the airplane accumulates 30,000 total flight cycles.

(ii) Within 5,000 flight cycles after July 17, 2019 (the effective date of AD 2019–11–06).

(iii) Within 12 months after the effective date of this AD.

(iv) Within 1,000 flight cycles after the effective date of this AD.

#### (i) Terminating Action for Certain Requirements of AD 2019–11–06

Accomplishing the actions required by this AD replaces the corresponding initial ultrasonic inspections and on-condition actions required by paragraph (g) of AD 2019–11–06 for Model 737–800 airplanes converted to a freighter configuration using Boeing Drawing 800A0003 only.

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

(1) The Manager, AIR-520, Continued Operational Safety Branch, 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 responsible Flight Standards Office, as appropriate. If sending information directly to the manager of the certification office, send it to the attention of the person identified in paragraph (k) of this AD. Information may be emailed to: AMOC@ faa.gov.

(2) Before using any approved AMOC, notify your appropriate principal inspector, or lacking a principal inspector, the manager of the responsible Flight Standards Office.

(3) An ÂMOC 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 Company Organization Designation Authorization (ODA) that has been authorized by the Manager, AIR–520, Continued Operational Safety Branch, FAA, 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.

## (k) Related Information

For more information about this AD, contact Owen Bley-Male, Aviation Safety

Engineer, FAA, 2200 South 216th St., Des Moines, WA 98198; phone: 206–231–3992; email: *owen.f.bley-male@faa.gov.* 

#### (l) Material Incorporated by Reference

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

(2) You must use this material as applicable to do the actions required by this AD, unless the AD specifies otherwise.

(i) Boeing 737–800BCF Airworthiness Limitations, D140A006, Revision L, dated April 1, 2021.

(ii) Boeing Alert Service Bulletin 737– 53A1368, dated February 27, 2018.

(3) For Boeing material identified in this AD, contact Boeing Commercial Airplanes, Attention: Contractual & Data Services (C&DS), 2600 Westminster Blvd., MC 110– SK57, Seal Beach, CA 90740–5600; telephone 562–797–1717; website *myboeingfleet.com*.

(4) You may view this material at the FAA, Airworthiness Products Section, Operational Safety Branch, 2200 South 216th St., Des Moines, WA. For information on the availability of this material at the FAA, call 206–231–3195.

(5) You may view this material at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, visit www.archives.gov/federal-register/cfr/ ibr-locations or email fr.inspection@nara.gov.

Issued on September 19, 2024.

#### Peter A. White,

Deputy Director, Integrated Certificate Management Division, Aircraft Certification Service.

[FR Doc. 2024–21813 Filed 9–24–24; 8:45 am] BILLING CODE 4910–13–P

## DEPARTMENT OF TRANSPORTATION

#### Federal Aviation Administration

#### 14 CFR Part 39

[Docket No. FAA-2024-2314; Project Identifier MCAI-2024-00312-T]

#### RIN 2120-AA64

# Airworthiness Directives; Airbus SAS Airplanes

**AGENCY:** Federal Aviation Administration (FAA), DOT. **ACTION:** Notice of proposed rulemaking (NPRM).

**SUMMARY:** The FAA proposes to adopt a new airworthiness directive (AD) for all Airbus SAS Model A319–111, –112, –113, –114, –115, –131, –132, –133, –151N, and –153N airplanes; A320 series airplanes; and A321–211, –212, –213, –231, –232, –251N, –252N, –253N, –271N, –272N, –251NX, –252NX, –253NX, –271NX, and –272NX airplanes. This proposed AD was prompted by a determination that a

damage-tolerance and fatigue reassessment of nose landing gear (NLG) repairs is necessary for certain parts fitted on airplanes approved for operation in the Commonwealth of Independent States (CIS). This proposed AD would require repair and replacement of all affected parts, and introduces restrictions for the installation of affected parts, as specified in a European Union Aviation Safety Agency (EASA) AD, which is proposed for incorporation by reference (IBR). The FAA is proposing this AD to address the unsafe condition on these products.

**DATES:** The FAA must receive comments on this proposed AD by November 12, 2024.

**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 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.

*AD Docket:* You may examine the AD docket at *regulations.gov* under Docket No. FAA–2024–2314; or in person at Docket Operations between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this NPRM, the mandatory continuing airworthiness information (MCAI), any comments received, and other information. The street address for Docket Operations is listed above.

Material Incorporated by Reference: • For EASA material identified in this AD, contact EASA, Konrad-Adenauer-Ufer 3, 50668 Cologne, Germany; telephone +49 221 8999 000; email ADs@easa.europa.eu; website easa.europa.eu. You may find this material on the EASA website at ad.easa.europa.eu. It is also available at regulations.gov under Docket No. FAA– 2024–2314.

• You may view this material at the FAA, Airworthiness Products Section, Operational Safety Branch, 2200 South 216th St., Des Moines, WA. For information on the availability of this material at the FAA, call 206–231–3195.

FOR FURTHER INFORMATION CONTACT: Timothy Dowling, Aviation Safety Engineer, FAA, 1600 Stewart Avenue, Suite 410, Westbury, NY 11590; phone

## 206–231–3667; email *Timothy.P.Dowling@faa.gov.* **SUPPLEMENTARY INFORMATION:**

#### **Comments Invited**

The FAA invites you to send any written relevant data, views, or arguments about this proposal. Send your comments to an address listed under **ADDRESSES**. Include "Docket No. FAA-2024-2314; Project Identifier MCAI-2024-00312-T" at the beginning of your comments. The most helpful comments reference a specific portion of the proposal, explain the reason for any recommended change, and include supporting data. The FAA will consider all comments received by the closing date and may amend this proposal because of those comments.

Except for Confidential Business Information (CBI) as described in the following paragraph, and other information as described in 14 CFR 11.35, the FAA will post all comments received, without change, to *regulations.gov*, including any personal information you provide. The agency will also post a report summarizing each substantive verbal contact received about this NPRM.

## **Confidential Business Information**

CBI is commercial or financial information that is both customarily and actually treated as private by its owner. Under the Freedom of Information Act (FOIA) (5 U.S.C. 552), CBI is exempt from public disclosure. If your comments responsive to this NPRM contain commercial or financial information that is customarily treated as private, that you actually treat as private, and that is relevant or responsive to this NPRM, it is important that you clearly designate the submitted comments as CBI. Please mark each page of your submission containing CBI as "PROPIN." The FAA will treat such marked submissions as confidential under the FOIA, and they will not be placed in the public docket of this NPRM. Submissions containing CBI should be sent to Timothy Dowling, Aviation Safety Engineer, FAA, 1600 Stewart Avenue, Suite 410, Westbury, NY 11590; phone 206-231-3667; email Timothy.P.Dowling@faa.gov. Any commentary that the FAA receives that is not specifically designated as CBI will be placed in the public docket for this rulemaking.

#### Background

EASA, which is the Technical Agent for the Member States of the European Union, has issued EASA AD 2024–0022, dated January 23, 2024 (EASA AD 2024–0022) (also referred to as the

MCAI), to correct an unsafe condition for all Airbus SAS Model A319-111, A319-112, A319-113, A319-114, A319-115, A319-131, A319-132, A319-133, A319-151N, A319-153N, A320-211, A320-212, A320-214, A320-215, A320-216, A320-231, A320-232, A320-233, A320-251N, A320-252N, A320-253N, A320-271N, A320-272N, A320-273N, A321-211, A321-212, A321-213, A321-231, A321-232, A321-251N, A321-251NX, A321-252N, A321-252NX, A321-253N, A321-253NX, A321-271N, A321-271NX, A321-272N, and A321-272NX airplanes. Model A320–215 airplanes are not certificated by the FAA and are not included on the U.S. type certificate data sheet; this proposed AD therefore does not include those airplanes in the applicability.

The MCAI states that a design review led to a determination that a damagetolerance and fatigue reassessment of NLG repairs is required for certain parts fitted on airplanes approved for CIS operation. The EASA AD addresses the reassessment of these repairs. The unsafe condition, if not addressed, could lead to damage or failure of the affected parts and the NLG, and possible damage to the airplane and injury to occupants, following modifications for CIS operations.

Different runway standards in CIS countries have resulted in the need for specific landing gear modifications or repairs on those modified landing gears. The landing gear components modified for CIS runway conditions may be inadequate for continued operation. While it is possible there are few or no U.S. airplanes subject to the repair and replacement requirements of this AD, the FAA has determined that this AD is necessary to identify airplanes with affected parts and confirm the need for any follow-on actions.

The FAA is proposing this AD to address the unsafe condition on these products.

You may examine the MCAI in the AD docket at *regulations.gov* under Docket No. FAA–2024–2314.

## Material Incorporated by Reference Under 1 CFR Part 51

EASA AD 2024–0022 specifies procedures for repair and replacement, as applicable, of the affected parts. EASA AD 2024–0022 also limits the installation of affected parts under certain conditions. This material is reasonably available because the interested parties have access to it through their normal course of business or by the means identified in **ADDRESSES**.

## **FAA's Determination**

This product has been approved by the aviation authority of another country and is approved for operation in the United States. Pursuant to the FAA's bilateral agreement with this State of Design Authority, it has notified the FAA of the unsafe condition described in the MCAI referenced above. The FAA is issuing this NPRM after determining that the unsafe condition described previously is likely to exist or develop in other products of the same type design.

## Proposed AD Requirements in This NPRM

This proposed AD would require accomplishing the actions specified in EASA AD 2024–0022 described previously, except for any differences identified as exceptions in the regulatory text of this proposed AD.

## Explanation of Required Compliance Information

In the FAA's ongoing efforts to improve the efficiency of the AD process, the FAA developed a process to use some civil aviation authority (CAA) ADs as the primary source of information for compliance with requirements for corresponding FAA ADs. The FAA has been coordinating this process with manufacturers and CAAs. As a result, the FAA proposes to incorporate EASA AD 2024-0022 by reference in the FAA final rule. This proposed AD would, therefore, require compliance with EASA AD 2024–0022 in its entirety through that incorporation, except for any differences identified as exceptions in the regulatory text of this proposed AD.

Using common terms that are the same as the heading of a particular section in EASA AD 2024–0022 does not mean that operators need comply only with that section. For example, where the AD requirement refers to "all required actions and compliance times," compliance with this AD requirement is not limited to the section titled "Required Action(s) and Compliance Time(s)" in EASA AD 2024–0022. Service information required by EASA AD 2024–0022 for compliance will be available at regulations.gov under Docket No. FAA-2024-2314 after the FAA final rule is published.

## **Costs of Compliance**

The FAA estimates that this AD, if adopted as proposed, would affect 1,680 airplanes of U.S. registry. The FAA estimates the following costs to comply with this proposed AD:

## ESTIMATED COSTS FOR REQUIRED ACTIONS

Labor cost	Parts cost	Cost per product	Cost on U.S. operators
1 work-hour × \$85 per hour = \$85	\$0	\$85	Up to \$142,800.

The FAA has received no definitive data on which to base the cost estimates for the repairs or replacements specified in this proposed AD. The cost of parts could be as high as \$5,620 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.

The FAA is 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**

The FAA 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) Would not affect intrastate aviation in Alaska, and

(3) Would 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:

Airbus SAS: Docket No. FAA–2024–2314; Project Identifier MCAI–2024–00312–T.

## (a) Comments Due Date

The FAA must receive comments on this airworthiness directive (AD) by November 12, 2024.

#### (b) Affected ADs

None.

#### (c) Applicability

This AD applies to all Airbus SAS airplanes identified in paragraphs (c)(1) through (3) of this AD, certificated in any category.

- (1) Model A319–111, –112, –113, –114, –115, –131, –132, –133, –151N, and –153N airplanes.
- (2) Model A320–211, –212, –214, –216,
- -231, -232, -233, -251N, -252N, -253N,
- –271N, –272N, and –273N airplanes.
- (3) Model A321–211, –212, –213, –231,
- -232, -251N, -251NX, -252N, -252NX,
- –253N, –253NX, –271N, –271NX, –272N, and –272NX airplanes.

#### (d) Subject

Air Transport Association (ATA) of America Code 32, Landing gear.

#### (e) Unsafe Condition

This AD was prompted by a determination that a damage-tolerance and fatigue reassessment of nose landing gear (NLG) repairs is necessary for certain parts fitted on airplanes approved for operation in the Commonwealth of Independent States (CIS). The FAA is issuing this AD to address the reassessment of these repairs. The unsafe condition, if not addressed, could lead to damage or failure of the affected parts and the NLG, and possible damage to the airplane and injury to occupants.

## (f) Compliance

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

#### (g) Requirements

Except as specified in paragraph (h) of this AD: Comply with all required actions and compliance times specified in, and in accordance with, EASA AD 2024-0022, dated January 23, 2024 (EASA AD 2024-0022).

## (h) Exceptions to EASA AD 2024-0022

(1) Where EASA AD 2024-0022 refers to its effective date, this AD requires using the effective date of this AD.

(2) This AD does not adopt the "Remarks" section of EASA AD 2024-0022.

## (i) Additional AD Provisions

The following provisions also apply to this AD:

(1) Alternative Methods of Compliance (AMOCs): The Manager, International Validation Branch, 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 responsible Flight Standards Office, as appropriate. If sending information directly to the manager of the International Validation Branch, mail it to the address identified in paragraph (j) of this AD. Information may be emailed to: 9-AVS-AIR-730-AMOC@faa.gov. Before using any approved AMOC, notify your appropriate principal inspector, or lacking a principal inspector, the manager of the responsible Flight Standards Office.

(2) Contacting the Manufacturer: For any requirement in this AD to obtain instructions from a manufacturer, the instructions must be accomplished using a method approved by the Manager. International Validation Branch, FAA; or EASA; or Airbus SAS's EASA Design Organization Approval (DOA). If approved by the DOA, the approval must include the DOA-authorized signature.

(3) Required for Compliance (RC): Except as required by paragraph (i)(2) of this AD, if any material contains procedures or tests that are identified as RC, those procedures and tests must be done to comply with this AD; any procedures or tests that are not identified as RC are recommended. Those procedures and tests that are not identified 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 procedures and tests identified as RC can be done and the airplane can be put back in an airworthy condition. Any substitutions or changes to procedures or tests identified as RC require approval of an AMOC.

## (j) Additional Information

For more information about this AD, contact Timothy Dowling, Aviation Safety Engineer, FAA, 1600 Stewart Avenue, Suite 410, Westbury, NY 11590; phone 206-231-3667; email Timothy.P.Dowling@faa.gov.

## (k) Material Incorporated by Reference

(1) The Director of the Federal Register approved the incorporation by reference (IBR) of the material listed in this paragraph under 5 U.S.C. 552(a) and 1 CFR part 51.

(2) You must use this material as applicable to do the actions required by this AD, unless this AD specifies otherwise.

(i) European Union Aviation Safety Agency (EASA) AD 2024-0022, dated January 23, 2024.

(ii) [Reserved]

(3) For EASA AD 2024–0022 identified in this AD, contact EASA, Konrad-Adenauer-Ufer 3, 50668 Cologne, Germany; telephone +49 221 8999 000; email ADs@ easa.europa.eu; website easa.europa.eu. You may find this EASA AD on the EASA website at ad.easa.europa.eu.

(4) You may view this material at the FAA, Airworthiness Products Section, Operational Safety Branch, 2200 South 216th St., Des Moines, WA. For information on the availability of this material at the FAA, call 206-231-3195.

(5) You may view this material at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, visit www.archives.gov/federal-register/cfr/ ibr-locations, or email fr.inspection@ nara.gov.

Issued on September 19, 2024.

## Peter A. White,

Deputy Director, Integrated Certificate Management Division, Aircraft Certification Service.

[FR Doc. 2024-21811 Filed 9-24-24; 8:45 am] BILLING CODE 4910-13-P

## DEPARTMENT OF HEALTH AND

## HUMAN SERVICES

#### Food and Drug Administration

## 21 CFR Part 866

[Docket No. FDA-2024-N-3533]

## **Microbiology Devices; Reclassification** of Antigen, Antibody, and Nucleic Acid-Based Hepatitis B Virus Assay Devices

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

**ACTION:** Proposed amendment; proposed order; request for comments.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is proposing to reclassify qualitative hepatitis B virus (HBV) antigen assays, qualitative HBV antibody assays and quantitative assays that detect anti-HBs

(antibodies to HBV surface antigen (HBsAg)), and quantitative HBV nucleic acid-based assays, all of which are postamendments class III devices, into class II (general controls and special controls), subject to premarket notification. FDA is also proposing three new device classification regulations along with the special controls that the Agency believes are necessary to provide a reasonable assurance of safety and effectiveness for each device.

DATES: Either electronic or written comments on the proposed order must be submitted by November 25, 2024. Please see section X of this document for the proposed effective date when the new requirements apply and for the proposed effective date of a final order based on this proposed order.

**ADDRESSES:** You may submit comments as follows. Please note that late, untimely filed comments will not be considered. The https:// www.regulations.gov electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of November 25, 2024. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are received on or before that date.

#### Electronic Submissions

Submit electronic comments in the following way:

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

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

## Written/Paper Submissions

Submit written/paper submissions as follows: