

**DEPARTMENT OF TRANSPORTATION****Federal Aviation Administration****14 CFR Part 39**

[Docket No. FAA-2017-0648; Product Identifier 2017-CE-012-AD; Amendment 39-19070; AD 2017-20-13]

RIN 2120-AA64

**Airworthiness Directives; PIAGGIO AERO INDUSTRIES S.p.A. Airplanes**

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

**ACTION:** Final rule.

**SUMMARY:** We are adopting a new airworthiness directive (AD) for PIAGGIO AERO INDUSTRIES S.p.A. Model P-180 airplanes. 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 disbonding of the upper and lower metal skin from the honeycomb core on the elevator assembly and other flight control surfaces. We are issuing this AD to require actions to address the unsafe condition on these products.

**DATES:** This AD is effective November 16, 2017.

The Director of the Federal Register approved the incorporation by reference of a certain publication listed in this AD as of November 16, 2017.

**ADDRESSES:** You may examine the AD docket on the Internet at <http://www.regulations.gov> by searching for and locating Docket No. FAA-2017-0638; or in person at Document Management Facility, U.S. Department of Transportation, Docket Operations, M-30, West Building Ground Floor, Room W12-140, 1200 New Jersey Avenue SE., Washington, DC 20590.

For service information identified in this AD, contact PIAGGIO AERO INDUSTRIES S.p.A.—Continued Airworthiness, Via Pionieri e Aviatori d'Italia snc—16154 Genova, Italy; Telephone: +39 010 0998046; Fax: None; email: [airworthiness@piaggioaerospace.it](mailto:airworthiness@piaggioaerospace.it); Internet: [www.piaggioaerospace.it/en/customer-support#care](http://www.piaggioaerospace.it/en/customer-support#care). You may view this referenced service information at the FAA, Policy and Innovation Division, 901 Locust, Kansas City, Missouri 64106. For information on the availability of this material at the FAA, call (816) 329-4148. It is also available on the Internet at <http://www.regulations.gov>

by searching for Docket No. FAA-2017-0648.

**FOR FURTHER INFORMATION CONTACT:**

Mike Kiesov, Aerospace Engineer, FAA, Small Airplane Standards Branch, 901 Locust, Room 301, Kansas City, Missouri 64106; telephone: (816) 329-4144; fax: (816) 329-4090; email: [mike.kiesov@faa.gov](mailto:mike.kiesov@faa.gov).

**SUPPLEMENTARY INFORMATION:****Discussion**

We issued a notice of proposed rulemaking (NPRM) to amend 14 CFR part 39 by adding an AD that would apply to certain PIAGGIO AERO INDUSTRIES S.p.A. Model P-180 airplanes. The NPRM was published in the **Federal Register** on June 29, 2017 (82 FR 29445). The NPRM proposed to correct an unsafe condition for the specified products and was based on mandatory continuing airworthiness information (MCAI) originated by an aviation authority of another country. The MCAI states:

During a post flight inspection of a right hand (RH) elevator assembly, disbonding was detected on the upper and lower metal skin from the honeycomb core. Subsequent investigation identified that a manufacturing deficiency caused the detected disbonding and that other flight control surfaces could potentially be affected by the same deficiency.

This condition, if not detected and corrected, could reduce the structural stiffness of the flight control surface and downgrade its aerodynamic characteristics, possibly resulting in reduced control of the aeroplane.

To address this potential unsafe condition, Piaggio Aero Industries (PAI) issued Service Bulletin (SB) 80-0455 to provide inspection instructions.

For the reasons described above, this [EASA] AD requires repetitive inspections of the affected flight control assemblies and, depending on findings, repair or replacement. This [EASA] AD also requires reporting of the inspection result to PAI.

The MCAI can be found in the AD docket on the Internet at <https://www.regulations.gov/document?D=FAA-2017-064-0002>.

**Comments**

We gave the public the opportunity to participate in developing this AD. We received no comments on the NPRM or on the determination of the cost to the public.

**Conclusion**

We reviewed the relevant data and determined that air safety and the public interest require adopting this AD as proposed except for minor editorial changes. We have determined that these minor changes:

- Are consistent with the intent that was proposed in the NPRM for correcting the unsafe condition; and
- Do not add any additional burden upon the public than was already proposed in the NPRM.

**Related Service Information Under 14 CFR Part 51**

We reviewed PIAGGIO AERO INDUSTRIES S.p.A. Mandatory Service Bulletin N.: 80-0455, dated: January 13, 2017. This service information describes procedures for repetitive inspections to verify the structural integrity of the flight control assemblies. This service information is reasonably available because the interested parties have access to it through their normal course of business or by the means identified in the **ADDRESSES** section of this AD.

**Costs of Compliance**

We estimate that this AD will affect 103 products of U.S. registry. We also estimate that it will take 9 work-hours per product to comply with the basic requirements of this AD. The average labor rate is \$85 per work-hour.

Based on these figures, we estimate the cost of this AD on U.S. operators to be \$78,795, or \$765 per product.

The scope of damage found in the required inspections could vary significantly from airplane to airplane. We have no way of determining how much damage may be found on each airplane or the cost to repair damaged parts on each airplane.

In addition, we have no way of knowing how many products may need replacement as a result of the required inspections. The following cost estimates were obtained directly from the manufacturer and we estimate that any necessary follow-on replacement actions would cost as follows:

- (i) Control surface repair: 10 work-hours for a cost of \$850 per product.
- (ii) Left Hand (LH) Forward Wing Flap Replacement: 4 work-hours and require parts costing \$30,079, for a total cost of \$30,419.
- (iii) Right Hand (RH) Forward Wing Flap Replacement: 4 work-hours and require parts costing \$30,079, for a total cost of \$30,419.
- (iv) LH Aileron Assembly: 7 work-hours and require parts costing \$40,715, for a total cost of \$41,310.
- (v) RH Aileron Assembly: 7 work-hours and require parts costing \$86,050, for a total cost of \$86,645.
- (vi) Main Wing LH Inboard Flap Assembly: 4 work-hours and require parts costing \$22,699, for a total cost of \$23,039.
- (vii) Main Wing RH Inboard Flap Assembly: 4 work-hours and require

parts costing \$22,699, for a total cost of \$23,039.

(viii) LH Elevator Assembly: 8 work-hours and require parts costing \$59,917, for a total cost of \$60,597.

(ix) RH Elevator Assembly: 8 work-hours and require parts costing \$59,917, for a total cost of \$60,597.

There is an additional 10 work-hours that may be required for post-repair or post-installation replacement of flight control surface adjustments and testing, for a total cost of \$850.

#### 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.

This AD is issued in accordance with authority delegated by the Executive Director, Aircraft Certification Service, as authorized by FAA Order 8000.51C. In accordance with that order, issuance of ADs is normally a function of the Compliance and Airworthiness Division, but during this transition period, the Executive Director has delegated the authority to issue ADs applicable to small airplanes and domestic business jet transport airplanes to the Director of the Policy and Innovation Division.

#### 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),

(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.

#### 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-2017-0648; 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 the NPRM, the regulatory evaluation, any comments received, and other information. The street address for the Docket Office (telephone (800) 647-5527) is in the ADDRESSES section. Comments will be available in the AD docket shortly after receipt.

#### 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:

**2017-20-13 Piaggio Aero Industries S.p.A.:**  
Amendment 39-19070; Docket No. FAA-2017-0648; Product Identifier 2017-CE-012-AD.

#### (a) Effective Date

This airworthiness directive (AD) becomes effective November 16, 2017.

#### (b) Affected ADs

None.

#### (c) Applicability

This AD applies to PIAGGIO AERO INDUSTRIES S.p.A. P-180 airplanes, serial numbers 1002, 1004 through 1220, that are:

- (1) Equipped with flight control surfaces part numbers (P/Ns) and serial numbers (S/Ns) not listed in table 1 of PIAGGIO AERO INDUSTRIES S.p.A. Mandatory Service Bulletin N.: 80-0455, dated: January 13, 2017 (PAI SB No. 80-0455); and
- (2) certificated in any category.

#### (d) Subject

Air Transport Association of America (ATA) Code 27: Flight Controls.

#### (e) Reason

This AD was prompted by 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 disbonding of the upper and lower metal skin from the honeycomb core on the elevator assembly and other flight control surfaces. We are issuing this AD to prevent structural stiffness of the flight control surface and the downgrade of its aerodynamic characteristics, resulting in reduced control.

#### (f) Actions and Compliance

Unless already done, do the actions in paragraphs (f)(1) through (8) of this AD. The parts affected by this AD are all left hand (LH) forward flaps, right hand (RH) forward flaps, main wing LH inboard flaps, main wing RH inboard flaps, LH ailerons, RH ailerons, LH elevators, and RH elevators, hereafter referred to as "affected control surface" in this AD.

(1) Within the next 50 hours time-in-service (TIS) after November 16, 2017 (the effective date of this AD) or within the next 200 hours TIS after the last coin tapping inspection of the affected control surface following PAI Non-Destructive Test Manual (NDTM) 180-MAN-0300-01107, Chapter 51-00-01; whichever occurs later, do a coin tapping inspection of each affected control surface. Repetitively thereafter inspect at the intervals specified in paragraphs (f)(3)(i) and (ii). Follow Part B of the Accomplishment Instructions in PAI SB No. 80-0455.

- (i) Do two repetitive inspections at intervals not to exceed 200 hours TIS; and
- (ii) Repetitively thereafter inspect at intervals not to exceed 600 hours TIS.

(2) If damage is found during any inspection required in paragraph (f)(1) of this AD, before further flight, repair or replace as necessary each damaged affected control surface following Part B and/or C of the Accomplishment Instructions in PAI SB No. 80-0455.

(3) Within 50 hours TIS after the repair of an affected control surface as required by paragraph (f)(2) of this AD, do a coin tapping inspection of that repaired affected control surface. Repetitively thereafter inspect at the intervals specified in paragraphs (f)(3)(i) and (ii) of this AD. Follow the instructions in PAI SB No. 80-0455.

- (i) Do two repetitive inspections at intervals not to exceed 200 hours TIS; and
- (ii) Repetitively thereafter inspect at intervals not to exceed 600 hours TIS.

(4) If damage is found during any inspection required in paragraph (f)(3) of this AD, before further flight, repair or replace as necessary each damaged affected control surface following the instructions in Part B and/or C of the Accomplishment Instructions in PAI SB No. 80-0455.

(5) Repair of an affected control surface, as required by paragraph (f)(2) or (4) of this AD, does not constitute terminating action for repetitive inspections as required by this AD

for that affected control surface, unless the FAA-approved repair instructions specify otherwise.

(6) Replacement of the affected part on an airplane with a part listed in table 1 of PAI SB No. 80–0455, constitutes terminating action for the repetitive inspections required by this AD for that part.

(7) You may incorporate the actions of PAI SB No. 80–0455, into your FAA-approved airplane inspection program (AIP) or maintenance program (instructions for continued airworthiness) to ensure the continuing airworthiness of each operated airplane.

(8) After November 16, 2017 (the effective date of this AD), you may install on an airplane an affected control surface not listed in table 1 of PAI SB No. 80–0455, provided that before further flight after installation, the affected control surface has been inspected as specified in this AD and found airworthy.

#### (g) Other FAA AD Provisions

The following provisions also apply to this AD:

(1) *Alternative Methods of Compliance (AMOCs)*: The Manager, Standards Office, 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: Mike Kiesov, Aerospace Engineer, FAA, Small Airplane Standards Branch, 901 Locust, Room 301, Kansas City, Missouri 64106; telephone: (816) 329–4144; fax: (816) 329–4090; email: [mike.kiesov@faa.gov](mailto:mike.kiesov@faa.gov).

Before using any approved AMOC on any airplane to which the AMOC applies, notify your appropriate principal inspector (PI) in the FAA Flight Standards District Office (FSDO), or lacking a PI, your local FSDO.

(2) *Contacting the Manufacturer*: For any requirement in this AD to obtain corrective actions from a manufacturer, the action must be accomplished using a method approved by the Manager, Small Airplane Standards Branch, FAA; or the European Aviation Safety Agency (EASA).

(3) *Reporting Requirements*: For any reporting requirement in this AD, a federal agency may not conduct or sponsor, and a person is not required to respond to, nor shall a person be subject to a penalty for failure to comply with a collection of information subject to the requirements of the Paperwork Reduction Act unless that collection of information displays a current valid OMB Control Number. The OMB Control Number for this information collection is 2120–0056. Public reporting for this collection of information is estimated to be approximately 5 minutes per response, including the time for reviewing instructions, completing and reviewing the collection of information. All responses to this collection of information are mandatory. Comments concerning the accuracy of this burden and suggestions for reducing the burden should be directed to the FAA at: 800 Independence Ave. SW., Washington, DC 20591, Attn: Information Collection Clearance Officer, AES–200.

#### (h) Related Information

Refer to MCAI European Aviation Safety Agency (EASA) AD No.: 2017–0045, dated

March 9, 2017 for related information. You may examine the MCAI on the Internet at <https://www.regulations.gov/document?D=FAA-2017-0648-0002>.

#### (i) Material Incorporated by Reference

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

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

(i) PIAGGIO AERO INDUSTRIES S.p.A. Mandatory Service Bulletin (SB) No.: 80–0455, dated January 13, 2017.

(ii) Reserved.

(3) For PIAGGIO AERO INDUSTRIES S.p.A. service information identified in this AD, contact PIAGGIO AERO INDUSTRIES S.p.A.—Continued Airworthiness, Via Pionieri e Aviatori d'Italia snc—16154 Genova, Italy; Telephone: +39 010 0998046; Fax: None; email: [airworthiness@piaggioaerospace.it](mailto:airworthiness@piaggioaerospace.it); Internet: [www.piaggioaerospace.it/en/customer-support#care](http://www.piaggioaerospace.it/en/customer-support#care).

(4) You may view this service information at the FAA, Policy and Innovation Division, 901 Locust, Kansas City, Missouri 64106. For information on the availability of this material at the FAA, call (816) 329–4148. In addition, you can access this service information on the Internet at <http://www.regulations.gov> by searching for and locating Docket No. FAA–2017–0648.

(5) You may view this 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/cfr/ibr-locations.html>.

Issued in Kansas City, Missouri, on September 29, 2017.

**Pat Mullen,**

*Acting Deputy Director, Policy & Innovation Division, Aircraft Certification Service.*

[FR Doc. 2017–21443 Filed 10–11–17; 8:45 am]

**BILLING CODE 4910–13–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

#### 21 CFR Part 882

[Docket No. FDA–2017–N–1608]

### Medical Devices; Neurological Devices; Classification of Cranial Motion Measurement Device; Correction

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

**ACTION:** Final order; correction.

**SUMMARY:** The Food and Drug Administration (FDA) is correcting a

final order entitled “Medical Devices; Neurological Devices; Classification of Cranial Motion Measurement Device” that appeared in the **Federal Register** of July 28, 2017. The final order was published with an incorrect statement in the preamble about whether FDA planned to exempt the device from premarket notification requirements. This document corrects that error.

**DATES:** Effective October 12, 2017.

**FOR FURTHER INFORMATION CONTACT:** Jay Gupta, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 2611, Silver Spring, MD 20993–0002, 301–796–2795, [jay.gupta@fda.hhs.gov](mailto:jay.gupta@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:** In the **Federal Register** of July 28, 2017 (82 FR 35069), FDA published the final order “Medical Devices; Neurological Devices; Classification of Cranial Motion Measurement Device.” The final order published with an incorrect statement in the preamble about whether FDA planned to exempt the device from premarket notification requirements under section 510(k) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 360(k)).

#### Correction

In the **Federal Register** of July 28, 2017, in FR Doc. 2017–15895, the following correction is made:

On page 35070, after table 1 in the third column, the last paragraph is corrected to read as follows:

“Section 510(m) of the FD&C Act provides that FDA may exempt a class II device from the premarket notification requirements under section 510(k), if FDA determines that premarket notification is not necessary to provide reasonable assurance of the safety and effectiveness of the device. For this type of device, FDA has determined that premarket notification is necessary to provide reasonable assurance of the safety and effectiveness of the device. Therefore, this device type is not exempt from premarket notification requirements. Persons who intend to market this type of device must submit to FDA a premarket notification, prior to marketing the device, which contains information about the cranial motion measurement device they intend to market.”

Dated: October 4, 2017.

**Leslie Kux,**

*Associate Commissioner for Policy.*

[FR Doc. 2017–21982 Filed 10–11–17; 8:45 am]

**BILLING CODE 4164–01–P**