(h) Subject

Joint Aircraft Service Component (JASC) Code: Engine Controls, 7600.

Issued in Fort Worth, Texas, on May 21, 2014.

Lance T. Gant,

Acting Directorate Manager, Rotorcraft Directorate, Aircraft Certification Service.

[FR Doc. 2014–12717 Filed 6–2–14; 8:45 am]

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DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2014–0336; Directorate Identifier 2013–SW–063–AD; Amendment 39–17857; AD 2014–11–07]

RIN 2120–AA64

Airworthiness Directives; Agusta S.p.A Helicopters (Type Certificate Currently Held by AgustaWestland S.p.A) (Agusta)

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 Agusta Model A109A, A109A II, A109C, A109E, A109K2, A109S, AW109SP, A119, and AW119 MKII helicopters. This AD requires inspecting and replacing certain part-numbered main rotor swashplate support nuts. This AD is prompted by a report of two cracked nuts found on an A109S helicopter. These actions are intended to detect a cracked nut and prevent failure of the main rotor system, and subsequent loss of control of the helicopter.

DATES: This AD becomes effective June 18, 2014.

We must receive comments on this AD by August 4, 2014.

ADDRESSES: You may send comments by any of the following methods:

- *Federal eRulemaking Docket:* Go to *http://www.regulations.gov.* Follow the online instructions for sending your comments electronically.
- *Fax:* 202–493–2251.
- *Mail:* Send comments to the U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE., Washington, DC 20590–0001.
- *Hand Delivery:* Deliver to the ''Mail'' address 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 foreign authority's AD, the economic 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 service information identified in this AD, contact AgustaWestland, Product Support Engineering, Via del Gregge, 100, 21015 Lonate Pozzolo (VA) Italy, ATTN: Maurizio D'Angelo; telephone 39–0331–664757; fax 39 0331–664680; or at *http://www.agustawestland.com/technical-bulletins.* You may review the referenced service information at the FAA, Office of the Regional Counsel, Southwest Region, 2601 Meacham Blvd., Room 663, Fort Worth, Texas 76137.

FOR FURTHER INFORMATION CONTACT: Robert Grant, Aviation Safety Engineer, Safety Management Group, FAA, 2601 Meacham Blvd., Fort Worth, Texas 76137; telephone (817) 222–5110; email *robert.grant@faa.gov.*

SUPPLEMENTARY INFORMATION:

Comments Invited

This AD is a final rule that involves requirements affecting flight safety, and we did not provide you with notice and an opportunity to provide your comments prior to it becoming effective. However, we invite you to participate in this rulemaking by submitting written comments, data, or views. We also invite comments relating to the economic, environmental, energy, or federalism impacts that resulted from adopting this AD. The most helpful comments reference a specific portion of the AD, explain the reason for any recommended change, and include supporting data. To ensure the docket does not contain duplicate comments, commenters should send only one copy of written comments, or if comments are filed electronically, commenters should submit them only one time. We will file in the docket all comments that we receive, as well as a report summarizing each substantive public contact with FAA personnel concerning this rulemaking during the comment period. We will consider all the comments we receive and may conduct additional rulemaking based on those comments.

Discussion

The European Aviation Safety Agency (EASA), which is the Technical Agent for the Member States of the European Union, has issued EASA Emergency AD No. 2013–0265–E, dated October 30, 2013, to correct an unsafe condition for Agusta Model A109A, A109A II, A109C, A109E, A109K2, A109LUH, A109S, AW109SP, A119, and AW119 MKII helicopters. EASA advises that during a scheduled inspection of the rotating control installation, two nuts, part number (P/N) MS21042–4, which connect the swashplate support to the upper case of the main transmission were found cracked. EASA states a subsequent investigation determined that the cracks in the nuts resulted from a production deficiency, which caused hydrogen embrittlement, at the nut manufacturer. EASA also states that this condition, if not detected and corrected, could lead to failure of the main rotor function and subsequent loss of control of the helicopter. The EASA Emergency AD requires repetitive inspections of each nut, P/N MS21042–4, for a crack, replacing any nut that has a crack with a different part-numbered nut, and, within 3 months, replacing each nut that does not have a crack with a different part-numbered nut. EASA Emergency AD 2013–0265–E also prohibits installing a nut, P/N MS21042–4, to connect the swashplate support to the upper case on any helicopter.

FAA's Determination

These helicopters have been approved by the aviation authority of Italy and are approved for operation in the United States. Pursuant to our bilateral agreement with Italy, EASA, its technical representative, has notified us of the unsafe condition described in the EASA AD. We are issuing this AD because we evaluated all information provided by EASA and determined the unsafe condition exists and is likely to exist or develop on other helicopters of these same type designs.

Related Service Information

Agusta has issued Bollettino Tecnico (BT) No. 109–137 for Model A109A, A109A II and A109C helicopters; BT No. 109EP–131 for Model A109E helicopters; BT No. 109K–59 for Model A109K2 helicopters; BT No. 109S–056 for Model A109S helicopters; BT No. 109SP–070 for Model AW109SP helicopters; and BT No. 119–062 for Model A119 and AW119 MKII helicopters. All of the BTs are Revision 0 and are dated October 29, 2013. Each BT describes procedures for inspecting

the nuts connecting the swashplate support to the upper case of the main transmission for a crack and for replacing each nut, P/N MS21042–4, with a nut, P/N NAS1805–4.

AD Requirements

This AD requires, within 10 hours time-in-service (TIS), inspecting each nut, P/N MS21042–4, which connects the swashplate support to the upper case of the main transmission, for a crack. If there is a crack on any nut, or within 25 hours TIS if there is not a crack, this AD requires replacing each nut, P/N MS21042–4, connecting the swashplate support to the upper case of the main transmission. This AD also prohibits installing a nut, P/N MS21042–4, connecting the swashplate support to the upper case of the main transmission on any helicopter.

Differences Between This AD and the EASA

The EASA AD requires replacing each nut, P/N MS21042–4, within 3 months, while this AD requires replacing the nuts within 25 hours TIS. The EASA AD also requires that each of the P/N MS21042–4 nuts be replaced with P/N NAS1805–4 nuts and this AD does not. The EASA AD also requires repetitive inspections of the P/N MS21042–4 nuts until they can be replaced and this AD does not. This AD does not apply to Model A109LUH helicopters as they are not type-certificated in the U.S.

Costs of Compliance

We estimate that this AD affects 222 helicopters of U.S. Registry. We estimate that operators may incur the following costs in order to comply with this AD. At an average labor rate of $85 per work-hour, inspecting the nuts connecting the swashplate support to the upper case of the main transmission requires about .5 work-hour, for a cost per helicopter of $43, and a total cost to U.S. operators of $9,546. Replacing the nuts requires about 1 work-hour, and required parts cost is minimal, for a cost per helicopter of $85 and a total cost to U.S. operators of $18,870.

FAA's Justification and Determination of the Effective Date

Providing an opportunity for public comments before adopting these AD requirements would delay implementing the safety actions needed to correct this known unsafe condition. Therefore, we find that the risk to the flying public justifies waiving notice and comment before adopting this rule because the required corrective actions must be done within 10 hours TIS and 25 hours TIS, a very short time period based on the average flight-hour utilization rate of these helicopters.

Since an unsafe condition exists that requires the immediate adoption of this AD, 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 less than 30 days.

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, I certify that this AD:

1. Is not a ''significant regulatory action'' under Executive Order 12866;

2. Is not a ''significant rule'' under DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979);

3. Will not affect intrastate aviation in Alaska to the extent that it justifies making a regulatory distinction; 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.

We prepared an economic 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 airworthiness directive (AD):

2014–11–07 Agusta S.p.A Helicopters (Type Certificate Currently Held By AgustaWestland S.p.A) (Agusta): Amendment 39–17857; Docket No. FAA–2014–0336; Directorate Identifier 2013–SW–063–AD.

(a) Applicability

This AD applies to Agusta Model A109A, A109A II, A109C, A109E, A109K2, A109S, AW109SP, A119, and AW119 MKII helicopters with a nut, part-number (P/N) MS21042–4, connecting the main rotor swashplate support to the upper case of the main transmission installed, certificated in any category.

(b) Unsafe Condition

This AD defines the unsafe condition as a crack on a nut connecting the main rotor swashplate support to the upper case of the main transmission. This condition could result in failure of the main rotor system and subsequent loss of control of the helicopter.

(c) Effective Date

This AD becomes effective June 18, 2014.

(d) Compliance

You are responsible for performing each action required by this AD within the specified compliance time unless it has already been accomplished prior to that time.

(e) Required Actions

(1) Within 10 hours time-in-service (TIS), using a light, visually inspect each nut, P/N MS21042–4, which connects the swashplate support to the upper case of the main transmission for a crack.

(i) If there is a crack, before further flight, remove all six nuts, P/N MS21042–4, connecting the swashplate support to the upper case.

(ii) If there are no cracks, within 25 hours TIS, remove all six nuts, P/N MS21042–4, connecting the swashplate support to the upper case.

(2) Do not install a nut, P/N MS21042–4, connecting the swashplate support to the upper case of the main transmission on any helicopter.

(f) Alternative Methods of Compliance (AMOCs)

(1) The Manager, Safety Management Group, Rotorcraft Directorate, FAA, may

approve AMOCs for this AD. Send your proposal to: Robert Grant, Aviation Safety Engineer, Safety Management Group, FAA, 2601 Meacham Blvd., Fort Worth, Texas 76137; telephone (817) 222–5110; email *robert.grant@faa.gov.*

(2) For operations conducted under a 14 CFR part 119 operating certificate or under 14 CFR part 91, subpart K, we suggest that you notify your principal inspector, or lacking a principal inspector, the manager of the local flight standards district office or certificate holding district office, before operating any aircraft complying with this AD through an AMOC.

(g) Additional Information

(1) Agusta Bollettino Tecnico (BT) No. 109–137 for Model A109A, A109A II and A109C helicopters; BT No. 109EP–131 for Model A109E helicopters; BT No. 109K–59 for Model A109K2 helicopters; BT No. 109S–056 for Model A109S helicopters; BT No. 109SP–070 for Model AW109SP helicopters; and BT No. 119–062 for Model A119 and AW119 MKII helicopters, all Revision 0 and dated October 29, 2013, which are not incorporated by reference, contain additional information about the subject of this AD. For service information identified in this AD, contact AgustaWestland, Product Support Engineering, Via del Gregge, 100, 21015 Lonate Pozzolo (VA) Italy, ATTN: Maurizio D'Angelo; telephone 39–0331–664757; fax 39–0331–664680; or at *http://www.agustawestland.com/technical-bullettins.* You may review a copy of the service information at the FAA, Office of the Regional Counsel, Southwest Region, 2601 Meacham Blvd., Room 663, Fort Worth Texas 76137.

(2) The subject of this AD is addressed in European Aviation Safety Agency (EASA) Emergency AD No. 2013–0265–E, dated October 30, 2013. You may view the EASA AD on the internet at *http://www.regulations.gov* in Docket No. FAA–2014–0336.

(h) Subject

Joint Aircraft Service Component (JASC) Code: 6200 Main Rotor System.

Issued in Fort Worth, Texas, on May 21, 2014.

Lance T. Gant,

Acting Directorate Manager, Rotorcraft Directorate, Aircraft Certification Service.

[FR Doc. 2014–12719 Filed 6–2–14; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 878

[Docket No. FDA–2014–N–0576]

Medical Devices; General and Plastic Surgery Devices; Classification of the Powered Surgical Instrument for Improvement in the Appearance of Cellulite

AGENCY: Food and Drug Administration, HHS.

ACTION: Final order.

SUMMARY: The Food and Drug Administration (FDA) is classifying the powered surgical instrument for improvement in the appearance of cellulite into class II (special controls). The Agency is classifying the device into class II (special controls) in order to provide a reasonable assurance of safety and effectiveness of the device.

DATES: This order is effective July 3, 2014. The classification was applicable on July 12, 2013.

FOR FURTHER INFORMATION CONTACT: Jitendra Virani, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. G459, Silver Spring, MD 20993–0002, 301–796–6398.

SUPPLEMENTARY INFORMATION:

I. Background

In accordance with section 513(f)(1) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 360c(f)(1)), devices that were not in commercial distribution before May 28, 1976 (the date of enactment of the Medical Device Amendments of 1976), generally referred to as postamendments devices, are classified automatically by statute into class III without any FDA rulemaking process. These devices remain in class III and require premarket approval, unless and until the device is classified or reclassified into class I or II, or FDA issues an order finding the device to be substantially equivalent, in accordance with section 513(i) of the FD&C Act, to a predicate device that does not require premarket approval. The Agency determines whether new devices are substantially equivalent to predicate devices by means of premarket notification procedures in section 510(k) of the FD&C Act (21 U.S.C. 360(k)) and part 807 (21 CFR part 807) of the regulations.

Section 513(f)(2) of the FD&C Act, as amended by section 607 of the Food and Drug Administration Safety and Innovation Act (Pub. L. 112–144, July 9, 2012, 126 Stat. 1054), provides two procedures by which a person may request FDA to classify a device under the criteria set forth in section 513(a)(1) (a de novo request). Under the first procedure, the person submits a premarket notification under section 510(k) of the FD&C Act for a device that has not previously been classified and, within 30 days of receiving an order classifying the device into class III under section 513(f)(1) of the FD&C Act, the person requests a classification under section 513(f)(2). Under the second procedure, rather than first submitting a premarket notification under section 510(k) and then a request for classification under the first procedure, the person determines that there is no legally marketed device upon which to base a determination of substantial equivalence and requests a classification under section 513(f)(2) of the FD&C Act. If the person submits a request to classify the device under this second procedure, FDA may decline to undertake the classification request if FDA identifies a legally marketed device that could provide a reasonable basis for review of substantial equivalence with the device or if FDA determines that the device submitted is not of ''low-moderate risk'' or that general controls would be inadequate to control the risks and special controls to mitigate the risks cannot be developed.

In response to a request to classify a device under either procedure provided by section 513(f)(2) of the FD&C Act, FDA will classify the device by written order within 120 days. This classification will be the initial classification of the device. In accordance with section 513(f)(1) of the FD&C Act, FDA issued an order on March 14, 2011, classifying the Cabochon System into class III, because it was not substantially equivalent to a device that was introduced or delivered for introduction into interstate commerce for commercial distribution before May 28, 1976, or a device which was subsequently reclassified into class I or class II. On October 29, 2011, Cabochon Aesthetics, Inc., submitted a request for classification of the Cabochon System under section 513(f)(2) of the FD&C Act. The manufacturer recommended that the device be classified into class II (Ref. 1).

In accordance with section 513(f)(2) of the FD&C Act, FDA reviewed the request in order to classify the device under the criteria for classification set forth in section 513(a)(1) of the FD&C Act. FDA classifies devices into class II if general controls by themselves are insufficient to provide reasonable