

experiences these early stages of deterioration.

The same commenter states the cost impact estimate stated in the NPRM is inaccurate. The commenter states the cost of parts is \$2,600, resulting in a cost-per-helicopter of \$7,897, or a total fleet cost of \$165,847.

The FAA agrees with the revised costs and we have changed the economic analysis accordingly.

After careful review of the available data, including the comments noted above, the FAA has determined that air safety and the public interest require the adoption of the rule with the changes described previously. The FAA has determined that these changes will not increase the scope of the AD. Also, we have determined that an increase in estimated costs of \$659 per helicopter does not constitute a substantial increase of the economic burden on any operator.

The FAA estimates that this AD will affect 21 helicopters of U.S. registry, and the required actions will take approximately 81.5 work hours per helicopter to accomplish at an average labor rate of \$65 per work hour. Required parts will cost approximately \$2,600 per helicopter. Based on these figures, the total estimated cost impact of the AD on U.S. operators is \$7,897 per helicopter, or \$165,847 for the entire fleet.

The regulations adopted herein 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. Therefore, it is determined that this final rule does not have federalism implications under Executive Order 13132.

For the reasons discussed above, I certify that this action (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); and (3) will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act. A final evaluation has been prepared for this action and it is contained in the Rules Docket. A copy of it may be obtained from the Rules Docket at the location provided under the caption **ADDRESSES**.

List of Subjects in 14 CFR Part 39

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

Adoption of the Amendment

■ Accordingly, pursuant to the authority delegated to me by the Administrator, the Federal Aviation Administration amends part 39 of the Federal Aviation Regulations (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. Section 39.13 is amended by adding a new airworthiness directive to read as follows:

2004-15-22 Sikorsky Aircraft Corporation: Amendment 39-13756. Docket No. 2003-SW-35-AD.

Applicability: Model S-61L, S-61N, S-61NM, and S-61R helicopters, certificated in any category.

Compliance: Required within 60 days, unless accomplished previously.

To detect an impending engine bearing (bearing) failure, which, if undetected and not addressed by appropriate crew action, may result in oil leakage, severing of the shaft housing, an uncontained in-flight fire, and a subsequent emergency landing, accomplish the following:

(a) Install an engine chip detector, part number 3049T42P01 or 3018T72P01, in the engine power turbine accessory drive assembly using the Accomplishment Instructions, paragraphs 3.A. and 3.B., in General Electric Aircraft Engines CT58 Service Bulletin Number 72-0195, dated May 1, 2003.

(b) Install an on-board engine chip detector annunciation system using Sikorsky Aircraft Corporation Alert Service Bulletin No. 61B30-15, Revision A, dated October 20, 2003 (ASB). For helicopters with a master warning caution panel (MWCP) manufactured by United Controls or Sundstrand Data, install in accordance with paragraph 3.B. of the ASB. For helicopters with a MWCP manufactured by Grimes Mfg., install in accordance with paragraph 3.C. of the ASB.

(c) After accomplishing paragraph (b) of this AD, before further flight, perform a functional test of the engine chip detector system and repeat the functional test at intervals not to exceed 150 hours TIS using the Accomplishment Instructions, paragraph 3.D., of the ASB.

(d) Insert the emergency procedures for an on-board engine chip detector warning light illumination into the Emergency Procedures section of the applicable Rotorcraft Flight Manual using the Accomplishment Instructions, paragraph 3.E., of the ASB.

(e) To request a different method of compliance or a different compliance time for this AD, follow the procedures in 14 CFR 39.19. Contact the Boston Aircraft Certification Office, Engine and Propeller Directorate, FAA, for information about previously approved alternative methods of compliance.

(f) The actions, including installations, testing, and inserting information into the Rotorcraft Flight Manual, shall be done in accordance with General Electric Aircraft Engines CT58 Service Bulletin Number 72-0195, dated May 1, 2003; and Sikorsky Aircraft Corporation Alert Service Bulletin No. 61B30-15, Revision A, dated October 20, 2003. The Director of the Federal Register approved this incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies may be obtained from Sikorsky Aircraft Corporation, Attn: Manager, Commercial Tech Support, 6900 Main Street, Stratford, Connecticut 06614, phone (203) 386-3001, fax (203) 386-5983; and from GE Aircraft Engines Customer Support Center, M/D 285, 1 Neumann Way, Evendale, OH 45215, telephone (513) 552-3272; fax (513) 552-3329, e-mail GEAE.csc@ae.ge.com. Copies may be inspected at the FAA, Office of the Regional Counsel, Southwest Region, 2601 Meacham Blvd., Room 663, Fort Worth, Texas; or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or go to: http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.

(g) This amendment becomes effective on September 7, 2004.

Issued in Fort Worth, Texas, on July 22, 2004.

David A. Downey,

Manager, Rotorcraft Directorate, Aircraft Certification Service.

[FR Doc. 04-17370 Filed 7-30-04; 8:45 am]

BILLING CODE 4910-13-P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. 2004-SW-14-AD; Amendment 39-13755; AD 2004-15-21]

RIN 2120-AA64

Airworthiness Directives; Agusta S.p.A. Model A109K2 Helicopters

AGENCY: Federal Aviation Administration, DOT.

ACTION: Final rule; request for comments.

SUMMARY: This amendment adopts a new airworthiness directive (AD) for Agusta S.p.A. (Agusta) Model A109K2 helicopters. This action requires dye-penetrant inspecting the tail rotor trunnion (trunnion) assembly for a crack at specified intervals, replacing any cracked trunnion with an airworthy trunnion, and reporting any failed trunnion. This amendment is prompted by the report of an accident involving a tail rotor hub and blade assembly separating from the helicopter due to

fatigue failure of the trunnion. The cause for the crack in the trunnion has not been determined and is still under investigation. This condition, if not detected, could result in failure of the trunnion, loss of the tail rotor hub and blade assembly, and subsequent loss of control of the helicopter.

DATES: Effective August 17, 2004.

The incorporation by reference of certain publications listed in the regulations is approved by the Director of the Federal Register as of August 17, 2004.

Comments for inclusion in the Rules Docket must be received on or before October 1, 2004.

ADDRESSES: Submit comments in triplicate to the Federal Aviation Administration (FAA), Office of the Regional Counsel, Southwest Region, Attention: Rules Docket No. 2004-SW-14-AD, 2601 Meacham Blvd., Room 663, Fort Worth, Texas 76137. You may also send comments electronically to the Rules Docket at the following address: 9-asw-adcomments@faa.gov.

The service information referenced in this AD may be obtained from Agusta, 21017 Cascina Costa di Samarate (VA) Italy, Via Giovanni Agusta 520, telephone 39 (0331) 229111, fax 39 (0331) 229605-222595. This information may be examined at the FAA, Office of the Regional Counsel, Southwest Region, 2601 Meacham Blvd., Room 663, Fort Worth, Texas; or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or go to: http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html

FOR FURTHER INFORMATION CONTACT:

Richard Monschke, Aviation Safety Engineer, FAA, Rotorcraft Directorate, Rotorcraft Standards Staff, Fort Worth, Texas 76193-0110, telephone (817) 222-5116, fax (817) 222-5961.

SUPPLEMENTARY INFORMATION: This amendment adopts a new AD for Agusta Model A109K2 helicopters. This action requires dye-penetrant inspecting the trunnion assembly for a crack at specified intervals, replacing any cracked trunnion with an airworthy trunnion, and reporting any cracked trunnion. This amendment is prompted by the report of an accident involving a tail rotor hub and blade assembly separating from the helicopter due to fatigue failure of the trunnion. This condition, if not detected, could result in failure of the trunnion, loss of the tail rotor hub and blade assembly, and

subsequent loss of control of the helicopter.

Ente Nazionale per l'Aviazione Civile (ENAC), the airworthiness authority for Italy, notified the FAA that an unsafe condition may exist on Agusta Model A109K2 helicopters with trunnion assembly, part number (P/N) 109-0131-05 (all dashes), installed. ENAC advises of the need to carry out checks and inspections of the cracked trunnion assembly as specified in the manufacturer's technical bulletin.

Agusta issued Alert Bollettino Tecnico No. 109K-37, dated February 13, 2004 (ABT). The ABT specifies inspecting the trunnion assembly, P/N 109-0131-05 (all dashes), for a crack within either 10 or 150 operating hours depending on the accumulated operating hours and subsequently every 150 operating hours. ENAC classified this ABT as mandatory and issued AD No 2004-068, dated February 18, 2004, to ensure the continued airworthiness of these helicopters in Italy.

This helicopter model is manufactured in Italy and is type certificated for operation in the United States under the provisions of 14 CFR 21.29 and the applicable bilateral agreement. Pursuant to the applicable bilateral agreement, ENAC has kept the FAA informed of the situation described above. The FAA has examined the findings of ENAC, reviewed all available information, and determined that AD action is necessary for products of this type design that are certificated for operation in the United States.

This unsafe condition is likely to exist or develop on other helicopters of the same type design registered in the United States. Therefore, this AD is being issued to prevent failure of the trunnion and subsequent loss of control of the helicopter. This AD requires:

- Dye-penetrant inspecting the trunnion, P/N 109-0131-05 (all dash numbers):
 - With 150 or more hours time-in-service (TIS), within the next 10 hours TIS; and
 - With less than 150 hours TIS, at 150 hours TIS; and
 - Thereafter, at intervals not to exceed 150 hours TIS.
 - Replacing any cracked trunnion with an airworthy trunnion before further flight.
 - Reporting information about any cracked trunnion to Richard Monschke, Aviation Safety Engineer, FAA, Rotorcraft Directorate, Rotorcraft Standards Staff, Fort Worth, Texas 76193-0110, telephone (817) 222-5116, fax (817) 222-5961.

The cause for the crack in the trunnion has not been determined and

is still under investigation. Therefore, the initial dye-penetrant inspection of the trunnion for a crack is required within the next 10 hours TIS, a very short compliance time interval. Additionally, based on the TIS utilization rate of these model helicopters, the 150-hour constitutes a very short compliance time. Therefore, the initial and repetitive inspections are deemed necessary as an emergency action to control the hazard until the cause of the cracks are identified because the previously described critical unsafe condition can adversely affect the controllability and structural integrity of the helicopter. Hence, this AD must be issued immediately.

Since a situation exists that requires the immediate adoption of this regulation, it is found that notice and opportunity for prior public comment hereon are impracticable, and that good cause exists for making this amendment effective in less than 30 days.

The FAA estimates that this AD will:

- Affect 4 helicopters;
 - Take about 8 work hours at an average labor rate of \$65 per work hour for 4 inspections yearly;
 - Cost about \$200 for consumable materials per helicopter; and
 - Cost about \$2320 for a trunnion assembly and \$23 for a lock washer, assuming a one-time replacement.
- However, the manufacturer states in the ABT that it will replace one trunnion if the trunnion is scrapped.

Based on these figures, the total estimated cost impact of the AD on U.S. operators will be \$18,492 or 9,212, assuming the manufacturer replaces the trunnion free as stated in the ABT.

Comments Invited

Although this action is in the form of a final rule that involves requirements affecting flight safety and, thus, was not preceded by notice and an opportunity for public comment, comments are invited on this rule. Interested persons are invited to comment on this rule by submitting such written data, views, or arguments as they may desire. Communications should identify the Rules Docket number and be submitted in triplicate to the address specified under the caption **ADDRESSES**. All communications received on or before the closing date for comments will be considered, and this rule may be amended in light of the comments received. Factual information that supports the commenter's ideas and suggestions is extremely helpful in evaluating the effectiveness of the AD action and determining whether additional rulemaking action would be needed.

Comments are specifically invited on the overall regulatory, economic, environmental, and energy aspects of the rule that might suggest a need to modify the rule. All comments submitted will be available in the Rules Docket for examination by interested persons. A report that summarizes each FAA-public contact concerned with the substance of this AD will be filed in the Rules Docket.

Commenters wishing the FAA to acknowledge receipt of their mailed comments submitted in response to this rule must submit a self-addressed, stamped postcard on which the following statement is made: "Comments to Docket No. 2004-SW-14-AD. The postcard will be date stamped and returned to the commenter.

The regulations adopted herein 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. Therefore, it is determined that this final rule does not have federalism implications under Executive Order 13132.

The FAA has determined that this regulation is an emergency regulation that must be issued immediately to correct an unsafe condition in aircraft, and that it is not a "significant regulatory action" under Executive Order 12866. It has been determined further that this action involves an emergency regulation under DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979). If it is determined that this emergency regulation otherwise would be significant under DOT Regulatory Policies and Procedures, a final regulatory evaluation will be prepared and placed in the Rules Docket. A copy of it, if filed, may be obtained from the Rules Docket at the location provided under the caption **ADDRESSES**.

List of Subjects in 14 CFR Part 39

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

Adoption of the Amendment

■ Accordingly, pursuant to the authority delegated to me by the Administrator, the Federal Aviation Administration amends part 39 of the Federal Aviation Regulations (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. Section 39.13 is amended by adding a new airworthiness directive to read as follows:

2004-15-21 **Agusta S.p.A.:** Amendment 39-13755. Docket No. 2004-SW-14-AD.

Applicability: Model A109K2 helicopters, with tail rotor trunnion assembly (trunnion), part number 109-0131-05 (all dash numbers), installed, certificated in any category.

Compliance: Required as indicated.

To detect a crack and prevent fatigue failure of the trunnion, loss of the tail rotor hub and blade assembly, and subsequent loss of control of the helicopter, do the following:

(a) Using a qualified Level II Inspector and following the Compliance Instructions, paragraphs 1. through 8., of Agusta Bollettino Tecnico No. 109K-37, dated February 13, 2004, dye penetrant inspect the trunnion for a crack as follows:

(1) Unless accomplished previously, within 10 hours time-in-service (TIS) for trunnions with 150 or more hours TIS;

(2) Unless accomplished previously, on or before accumulating 150 hours TIS for trunnions with less than 150 hours TIS; and

(3) Thereafter, at intervals not to exceed 150 hours TIS.

(b) If a crack is found, before further flight, replace the cracked trunnion with an airworthy trunnion before further flight.

(1) Within 5 days, report the part number, serial number, total hours TIS, and a description of the crack to Richard Monschke, Aviation Safety Engineer, FAA, Rotorcraft Directorate, Rotorcraft Standards Staff, Fort Worth, Texas 76193-0110, telephone (817) 222-5116, fax (817) 222-5961.

(2) Information collection requirements contained in this AD have been approved by the Office of Management and Budget (OMB) under the provisions of the Paperwork Reduction Act of 1980 (44 U.S.C. 3501 *et seq.*) and have been assigned OMB Control Number 2120-0056.

(c) To request a different method of compliance or a different compliance time for this AD, follow the procedures in 14 CFR 39.19. Contact the Safety Management Group, Rotorcraft Directorate, FAA, for information about previously approved alternative methods of compliance.

(d) Do the inspection following Agusta Bollettino Tecnico No. 109K-37, dated February 13, 2004. This incorporation by reference was approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies may be obtained from Agusta, 21017 Cascina Costa di Samarate (VA) Italy, Via Giovanni Agusta 520, telephone 39 (0331) 229111, fax 39 (0331) 229605-222595. Copies may be inspected at the FAA, Office of the Regional Counsel, Southwest Region, 2601 Meacham Blvd., Room 663, Fort Worth, Texas; or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or go to: http://www.archives.gov/federal_register/

[code_of_federal_regulations/ibr_locations.html](#).

(e) This amendment becomes effective on August 17, 2004.

Note: The subject of this AD is addressed in Ente Nazionale per l'Aviazione Civile (Italy) AD No. 2004-068, dated February 18, 2004.

Issued in Fort Worth, Texas, on July 22, 2004.

David A. Downey,

Manager, Rotorcraft Directorate, Aircraft Certification Service.

[FR Doc. 04-17369 Filed 7-30-04; 8:45 am]

BILLING CODE 4910-13-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 14

Advisory Committee; Pediatric Advisory Committee; Establishment

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is announcing the establishment of a Pediatric Advisory Committee in the Office of the Commissioner. Elsewhere in this issue of the **Federal Register**, FDA is publishing a document requesting nominations for the membership on this committee. This document adds the Pediatric Advisory Committee to the agency's list of standing advisory committees in 21 CFR 14.100.

DATES: This rule is effective August 2, 2004. Authority for the committee being established will end on June 18, 2006, unless the Commissioner formally determines that renewal is in the public interest.

FOR FURTHER INFORMATION CONTACT: Jan Johannessen, Office of Science and Health Coordination (HF-33), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-6687.

SUPPLEMENTARY INFORMATION: Under the Federal Advisory Committee Act of October 6, 1972 (Public Law 92-463) (5 U.S.C. app. 2); section 904 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 394), as amended by the Food and Drug Administration Revitalization Act (Public Law 101-635); section 14 of the Best Pharmaceuticals for Children Act (Public Law 107-109), as amended by section 3(b)(2) of the Pediatric Research Equity Act of 2003 (Public Law 108-155), and 21 CFR 14.40(b),