

medical research programs, and the licensee's disposal of radioactive material into sanitary sewerage in accordance with § 20.2003.

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PART 35—MEDICAL USE OF BYPRODUCT MATERIAL

5. The authority citation for Part 35 continues to read as follows:

Authority: Secs. 81, 161, 182, 183, 68 Stat. 935, 948, 953, 954, as amended (42 U.S.C. 2111, 2201, 2232, 2233); sec. 201, 88 Stat. 1242, as amended (42 U.S.C. 5841).

§ 35.2 [Amended]

6. In § 35.2, the definition for *misadministration* is amended in paragraphs (1)(i), (2)(i), (3)(i), (4)(i), (5)(i), (6)(i), and (6)(ii) by removing the term "patient or human research subject" and inserting the word "individual."

7. In § 35.33, paragraphs (a)(2), (a)(3), (a)(4), (b), and (c) are revised to read as follows:

§ 35.33 Notifications, reports, and records of misadministrations.

(a) * * *

(2) The licensee shall submit a written report to the appropriate NRC Regional Office listed in 10 CFR 30.6 within 15 days after discovery of the misadministration. The written report must include the licensee's name; the prescribing physician's name; a brief description of the event; why the event occurred; the effect on the individual who received the misadministration; what improvements are needed to prevent recurrence; actions taken to prevent recurrence; whether the licensee notified the individual (or the individual's responsible relative or guardian), and if not, why not; and if there was notification, what information was provided. The report must not contain the individual's name or any other information that could lead to identification of the individual. To meet the requirements of this section, the notification of the individual receiving the misadministration may be made instead to that individual's responsible relative or guardian, when appropriate.

(3) The licensee shall notify the referring physician and also notify the individual receiving the misadministration of the misadministration no later than 24 hours after its discovery, unless the referring physician personally informs the licensee either that he will inform the individual or that, based on medical judgement, telling the individual would be harmful. The licensee is not required

to notify the individual without first consulting the referring physician. If the referring physician or the individual receiving the misadministration cannot be reached within 24 hours, the licensee shall notify the individual as soon as possible thereafter. The licensee may not delay any appropriate medical care for the individual, including any necessary remedial care as a result of the misadministration, because of any delay in notification.

(4) If the individual was notified, the licensee shall also furnish, within 15 days after discovery of the misadministration, a written report to the individual by sending either:

- (i) A copy of the report that was submitted to the NRC; or
- (ii) A brief description of both the event and the consequences as they may affect the individual, provided a statement is included that the report submitted to the NRC can be obtained from the licensee.

(b) Each licensee shall retain a record of each misadministration for 5 years. The record must contain the names of all individuals involved (including the prescribing physician, allied health personnel, the individual who received the misadministration, and that individual's referring physician, if applicable), the individual's social security number or other identification number if one has been assigned, a brief description of the misadministration, why it occurred, the effect on the individual, improvements needed to prevent recurrence, and the actions taken to prevent recurrence.

(c) Aside from the notification requirement, nothing in this section affects any rights or duties of licensees and physicians in relation to each other, to individuals receiving misadministrations, or to that individual's responsible relatives or guardians.

Dated at Rockville, Maryland, this 14th day of September, 1995.

For the Nuclear Regulatory Commission.

John C. Hoyle,

Secretary of the Commission.

[FR Doc. 95-23288 Filed 9-19-95; 8:45 am]

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DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. 95-NM-148-AD; Amendment 39-9364; AD 95-19-03]

Airworthiness Directives; Aerospatiale Model ATR 42-300 and 42-320 Series Airplanes

AGENCY: Federal Aviation Administration, DOT.

ACTION: Final rule; request for comments.

SUMMARY: This amendment adopts a new airworthiness directive (AD), applicable to certain Aerospatiale Model ATR42-300 and -320 series airplanes. This action requires modification of the electrical wire bundle associated with the smoke detection system. This amendment is prompted by a report of a short circuit in this electrical wire bundle, which was caused by chafing of the wire against a smoke detection pipe. The actions specified in this AD are intended to prevent such chafing, which could result in short circuits of the electrical wire bundle and a potential fire hazard.

DATES: Effective October 5, 1995.

The incorporation by reference of certain publications listed in the regulations is approved by the Director of the Federal Register as of October 5, 1995.

Comments for inclusion in the Rules Docket must be received on or before November 20, 1995.

ADDRESSES: Submit comments in triplicate to the Federal Aviation Administration (FAA), Transport Airplane Directorate, ANM-103, Attention: Rules Docket No. 95-NM-148-AD, 1601 Lind Avenue, SW., Renton, Washington 98055-4056.

The service information referenced in this AD may be obtained from Aerospatiale, 316 Route de Bayonne, 31060 Toulouse, Cedex 03, France. This information may be examined at the FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington; or at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC.

FOR FURTHER INFORMATION CONTACT: Gary Lium, Aerospace Engineer, Standardization Branch, ANM-113, FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington 98055-4056; telephone (206) 227-1112; fax (206) 227-1149.

SUPPLEMENTARY INFORMATION: The Direction Générale de l'Aviation Civile

(DGAC), which is the airworthiness authority for France, recently notified the FAA that an unsafe condition may exist on certain Aerospatiale Model ATR42-300 and -320 series airplanes. The DGAC advises that there has been a report of a short circuit of the electrical wire bundle between frames 16 and 21 on an in-service airplane equipped with an interior modified for a container cargo compartment. The crew reported that there was an electrical smoke warning indication, which was associated with multiple system failure indications and the popping of circuit breakers. The short circuit was caused by chafing of the 1M wire bundle against a smoke detection pipe. This condition, if not corrected, could result in a fire.

Aerospatiale has issued Service Bulletin ATR42-25-0094, dated June 23, 1995, which describes procedures for modifying the smoke detection system. The modification consists of (1) replacing the smoke detection pipe in the forward cargo compartment at Frame 16, and (2) installing spacers between the electrical wire bundle (route 1M) and the smoke detection pipe from Frame 16 to Frame 21. The DGAC classified this service bulletin as mandatory and issued French airworthiness directive (CN) 95-103-059(B), dated May 24, 1995, in order to assure the continued airworthiness of these airplanes in France.

This airplane model is manufactured in France and is type certificated for operation in the United States under the provisions of section 21.29 of the Federal Aviation Regulations (14 CFR 21.19) and the applicable bilateral airworthiness agreement. Pursuant to this bilateral airworthiness agreement, the DGAC has kept the FAA informed of the situation described above. The FAA has examined the findings of the DGAC, 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.

Since an unsafe condition has been identified that is likely to exist or develop on other airplanes of the same type design registered in the United States, this AD is being issued to prevent chafing in the electrical wire bundle associated with the smoke detection system. This AD requires modification of the smoke detection system by replacing the smoke detection pipe in the forward cargo compartment, and installing spacers between the electrical wire bundle and the smoke detection pipe. The actions are required to be accomplished in accordance with

the service bulletin described previously.

None of the Model ATR42-300 or -320 series airplanes affected by this action is on the U.S. Register. All airplanes included in the applicability of this rule currently are operated by non-U.S. operators under foreign registry; therefore, they are not directly affected by this AD action. However, the FAA considers that this rule is necessary to ensure that the unsafe condition is addressed in the event that any of these subject airplanes are imported and placed on the U.S. Register in the future.

Should an affected airplane be imported and placed on the U.S. Register in the future, it would require approximately 4 work hours to accomplish the required actions, at an average labor charge of \$60 per work hour. Required parts would be provided by the manufacturer at no charge to operators. Based on these figures, the total cost impact of this AD would be \$240 per airplane.

Since this AD action does not affect any airplane that is currently on the U.S. register, it has no adverse economic impact and imposes no additional burden on any person. Therefore, notice and public procedures hereon are unnecessary and the amendment may be made effective in less than 30 days after publication in the Federal Register.

Comments Invited

Although this action is in the form of a final rule and was not preceded by notice and 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 shall 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, both before and after the closing date for comments, 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 comments submitted in response to this rule must submit a self-addressed, stamped postcard on which the following statement is made: "Comments to Docket Number 95-NM-148-AD." The postcard will be date stamped and returned to the commenter.

The regulations adopted herein will not have substantial direct effects 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, in accordance with Executive Order 12612, it is determined that this final rule does not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

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 USC 106(g), 40101, 40113, 44701.

§ 39.13 [Amended]

2. Section 39.13 is amended by adding the following new airworthiness directive:

95-19-03 Aerospatiale: Amendment 39-9364. Docket 95-NM-148-AD.

Applicability: Model ATR42-300 and -320 series airplanes; as listed and described in *Aerospatiale Service Bulletin ATR42-25-0094*, dated June 23, 1995; certificated in any category.

Note 1: This AD applies to each airplane identified in the preceding applicability provision, regardless of whether it has been modified, altered, or repaired in the area subject to the requirements of this AD. For airplanes that have been modified, altered, or repaired so that the performance of the requirements of this AD is affected, the owner/operator must use the authority provided in paragraph (b) of this AD to request approval from the FAA. This approval may address either no action, if the current configuration eliminates the unsafe condition; or different actions necessary to address the unsafe condition described in this AD. Such a request should include an assessment of the effect of the changed configuration on the unsafe condition addressed by this AD. In no case does the presence of any modification, alteration, or repair remove any airplane from the applicability of this AD.

Compliance: Required as indicated, unless accomplished previously.

To prevent chafing of the wire bundle associated with the smoke detection system, which could result in short circuits in the electrical wire bundle and a potential fire hazard, accomplish the following:

(a) Within 2,400 flight hours or 12 months after the effective date of this AD, whichever occurs later, modify the smoke detection system in accordance with *Aerospatiale Service Bulletin ATR42-25-0094*, dated June 23, 1995.

(b) An alternative method of compliance or adjustment of the compliance time that provides an acceptable level of safety may be used if approved by the Manager, Standardization Branch, ANM-113, FAA, Transport Airplane Directorate. Operators shall submit their requests through an appropriate FAA Principal Maintenance Inspector, who may add comments and then send it to the Manager, Standardization Branch, ANM-113.

Note 2: Information concerning the existence of approved alternative methods of compliance with this AD, if any, may be obtained from the Standardization Branch, ANM-113.

(c) Special flight permits may be issued in accordance with sections 21.197 and 21.199 of the Federal Aviation Regulations (14 CFR 21.197 and 21.199) to operate the airplane to a location where the requirements of this AD can be accomplished.

(d) The modification shall be done in accordance with *Aerospatiale Service Bulletin ATR42-25-0094*, dated June 23, 1995. 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 *Aerospatiale*, 316 Route de Bayonne, 31060 Toulouse, Cedex 03, France. Copies may be inspected at the FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington; or at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC.

(e) This amendment becomes effective on October 5, 1995.

Issued in Renton, Washington, on September 5, 1995.

Darrell M. Pederson,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 95-22458 Filed 9-19-95; 8:45 am]

BILLING CODE 4910-13-U

14 CFR Part 39

[Docket No. 94-CE-15-AD; Amendment 39-9377; AD 95-19-15]

Airworthiness Directives; American General Aircraft Corporation Models AA-5, AA-5A, AA-5B, and AG-5B Airplanes

AGENCY: Federal Aviation Administration, DOT.

ACTION: Final rule.

SUMMARY: This amendment adopts a new airworthiness directive (AD) that applies to American General Aircraft Corporation (American General) Models AA-5, AA-5A, AA-5B, and AG-5B airplanes. This action requires inspecting the wing attach shoulder bolts for fretting, scoring, wear, or enlarged or elongated mounting holes (known as damage from hereon), and replacing any damaged parts and repairing any damaged areas; and inspecting the wing spar at the center spar clearance gap for excessive clearance, and shimming the spar if excessive clearance is found. The actions specified by this AD are intended to prevent wing attach shoulder bolt failure, which, if not detected and corrected, could lead to structural damage to the wing/fuselage to the point of failure.

DATES: Effective November 17, 1995.

The incorporation by reference of certain publications listed in the regulations is approved by the Director of the Federal Register as of November 17, 1995.

ADDRESSES: Service information that applies to this AD may be obtained from Fletch Air, Inc., 9000 Randolph Street, Houston, Texas 77061; telephone (713) 649-8700 or (800) 329-4647; facsimile (713) 643-0070. This information may also be examined at the Federal Aviation Administration (FAA), Central Region, Office of the Assistant Chief Counsel, Room 1558, 601 E. 12th Street, Kansas City, Missouri 64106; or at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC.

FOR FURTHER INFORMATION CONTACT: Mr. Ozzie Lopez, Aerospace Engineer, FAA,

Atlanta Aircraft Certification Office, Campus Building, 1701 Columbia Avenue, suite 2-160, College Park, Georgia 30337-2748; telephone (404) 305-7359; facsimile (404) 305-7348.

SUPPLEMENTARY INFORMATION: A proposal to amend part 39 of the Federal Aviation Regulations (14 CFR part 39) to include an AD that would apply to certain American General Models AA-5, AA-5A, AA-5B, and AG-5B airplanes was published in the Federal Register on September 28, 1994 (59 FR 49359). The action proposed to require inspecting the wing attach shoulder bolts for fretting, scoring, wear, or enlarged or elongated mounting holes (known as damage from hereon), and replacing any damaged parts and repairing any damaged areas; inspecting the wing spar at the center spar clearance gap for excessive clearance, and shimming the spar if excessive clearance is found; and reporting to the FAA the results of the inspections. Accomplishment of the proposed inspections would be in accordance with American General Critical Service Bulletin SB-185, dated July 6, 1994. Accomplishment of the proposed possible repairs, replacements, and excessive clearance shimming would be in accordance with the applicable maintenance manual.

Interested persons have been afforded an opportunity to participate in the making of this amendment. Due consideration has been given to the comments received from one commenter.

The commenter states that the NPRM calls out an incorrect part number (901044-3 and 901044-2) for serial numbers AA-5-0001 through AA-5-0714 of the AA-5 series airplanes. The commenter suggests that the AD be changed to reflect wing attach bolt, part number 901044-1, for the referenced airplanes. The FAA concurs and has incorporated reference to wing attach bolt, part number 901044-1, into the applicable portion of the AD.

The commenter also explains that serial numbers AA-5-0001 through AA-5-0714 of the AA-5 series airplanes have a 38-gallon gas tank capacity, which is smaller than the 52-gallon capacity of the rest of the fleet. The commenter recommends that this action not affect these airplanes because the bolts are subjected to different loads. The FAA concurs that these earlier models of the AA-5 series airplanes contain smaller fuel tanks and that the airplanes incur different loads than the rest of the fleet. However, failure of these bolts is also attributable to excessive wing spar to center spar