Actions	Compliance	Procedures
(2) If a switch cover (insulator) is not installed or is damaged in any way, install a new insulator (part number 0511080–1).	Before further flight after the inspection where any damage is found or the cover is found missing.	Do this action following the ACCOMPLISH- MENT INSTRUCTIONS section of Cessna Service Bulletin SEB00–1, dated January 17, 2000, and the Cessna Manufacturer's Maintenance Manual.
(3) If the fuel line is damaged in any way, install a new fuel line. The replacement fuel line part number varies with aircraft model.	Before further flight after the inspection where any damage is found.	Do this action following the ACCOMPLISH- MENT INSTRUCTIONS section of Cessna Service Bulletin SEB00–1, dated January 17, 2000, and the Cessna Manufacturer's Maintenance Manual.

Note 1: The compliance times specified in Cessna Service Bulletin SEB00–1, dated January 17, 2000, are different from those required by this AD. The compliance times in this AD take precedence over those in the service bulletin.

- (e) Can I comply with this AD in any other way?
- (1) You may use an alternative method of compliance or adjust the compliance time if:

(i) Your alternative method of compliance provides an equivalent level of safety; and

- (ii) The Manager, Wichita Aircraft Certification Office (ACO), approves your alternative. Submit your request through an FAA Principal Maintenance Inspector, who may add comments and then send it to the Manager, Wichita ACO.
- (2) Alternative methods of compliance approved in accordance with AD 80–04–08, which is superseded by this AD, are not approved as alternative methods of compliance with this AD.

Note 2: This AD applies to each airplane identified in paragraph (a) of this AD, 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 request approval for an alternative method of compliance in accordance with paragraph (e) of this AD. The request should include an assessment of the effect of the modification, alteration, or repair on the unsafe condition addressed by this AD; and, if you have not eliminated the unsafe condition, specific actions you propose to address it.

- (f) Where can I get information about any already-approved alternative methods of compliance? Contact Mr. Clyde Erwin, Aerospace Engineer, FAA, Wichita Aircraft Certification Office, 1801 Airport Road, Room 100, Mid-Continent Airport, Wichita, Kansas 67209, telephone: (316) 946–4149; facsimile: (316) 946–4407.
- (g) What if I need to fly the airplane to another location to comply with this AD? The FAA can issue a special flight permit under sections 21.197 and 21.199 of the Federal Aviation Regulations (14 CFR 21.197 and 21.199) to operate your airplane to a location where you can accomplish the requirements of this AD.
- (h) Are any service bulletins incorporated into this AD by reference? Actions required by this AD must be done in accordance with Cessna Service Bulletin SEB00–1 and Accomplishment Instructions, dated January 17, 2000. The Director of the Federal Register

approved this incorporation by reference under 5 U.S.C. 552(a) and 1 CFR part 51. You can get copies from the Cessna Aircraft Company, PO Box 7706, Wichita, Kansas 67277. You can look at copies at the FAA, Central Region, Office of the Regional Counsel, 901 Locust, Room 506, Kansas City, Missouri, or at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC.

- (i) Does this AD action affect any existing AD actions? This amendment supersedes AD 80–04–08, Amendment 39–3696.
- (j) When does this amendment become effective? This amendment becomes effective on December 27, 2001.

Issued in Kansas City, Missouri, on November 5, 2001.

Michael Gallagher,

Manager, Small Airplane Directorate, Aircraft Certification Service.

[FR Doc. 01–28332 Filed 11–14–01; 8:45 am] BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. 99-CE-28-AD; Amendment 39-12504; AD 2001-01-07]

RIN 2120-AA64

Airworthiness Directives; Reims Aviation S.A. Model F406 Airplanes

AGENCY: Federal Aviation Administration, DOT. ACTION: Final rule.

SUMMARY: This amendment adopts a new airworthiness directive (AD) that applies to certain Reims Aviation S.A. (Reims) Model F406 airplanes. This AD requires you to repetitively inspect the canted rib upper cap in the center wing carry-through area for cracks, and, if cracks are found, immediately repair the cracks or modify this area depending on the extent of any cracks found. This AD also requires you to modify the canted rib upper cap at a certain time period as terminating action for the repetitive inspections. This AD is the result of mandatory continuing airworthiness

information (MCAI) issued by the airworthiness authority for France. The actions specified by this AD are intended to detect and correct cracks in the canted rib upper cap in the center wing carry-through area, which could result in structural failure of the wing with possible loss of control of the airplane.

DATES: This AD becomes effective on January 7, 2002.

The Director of the Federal Register approved the incorporation by reference of certain publications listed in the regulations as of January 7, 2002.

ADDRESSES: You may get the service information referenced in this AD from Cessna Aircraft Company, Product Support, PO Box 7706, Wichita, Kansas 67277; telephone: (316) 517–5800; facsimile: (316) 942–9006. You may view this information at the Federal Aviation Administration (FAA), Central Region, Office of the Regional Counsel, Attention: Rules Docket No. 99–CE–28–AD, 901 Locust, Room 506, 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: Brian A. Hancock, Aerospace Engineer, FAA, Small Airplane Directorate, 901 Locust, Room 301, Kansas City, Missouri 64106; telephone: (816) 329– 4143, facsimile: (816) 329–4090.

SUPPLEMENTARY INFORMATION:

Discussion

What events have caused this AD? The Direction Generale De L'Aviation Civile (DGAC), which is the airworthiness authority for France, notified the FAA that an unsafe condition may exist on certain Reims F406 airplanes. The DGAC reports that a crack was found in the canted rib upper cap in the center wing carrythrough area during a routine inspection of one of the affected airplanes.

What is the potential impact if FAA took no action? This condition, if not detected and corrected in a timely manner, could result in structural failure of the wing with possible loss of

control of the airplane.

Has FAA taken any action to this point? We issued a proposal to amend part 39 of the Federal Aviation Regulations (14 CFR part 39) to include an AD that would apply to certain Reims Model F406 airplanes. This proposal was published in the Federal Register as a notice of proposed rulemaking (NPRM) on August 21, 2001 (66 FR 43811). The NPRM proposed to require you to repetitively inspect the canted rib upper cap in the center wing carry-through area for cracks, and, if cracks are found, immediately repair the cracks or modify this area depending on the extent of any cracks found. The NPRM also proposed to require you to modify the canted rib upper cap at a

certain time period as terminating action for the repetitive inspections.

Was the public invited to comment? The FAA encouraged interested persons to participate in the making of this amendment. We did not receive any comments on the proposed rule or on our determination of the cost to the public.

FAA's Determination

What is FAA's final determination on this issue? After careful review of all available information related to the subject presented above, we have determined that air safety and the public interest require the adoption of the rule as proposed except for minor editorial corrections. We determined that these minor corrections:

- —Provide 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.

Cost Impact

How many airplanes does this AD impact? We estimate that this AD affects 4 airplanes in the U.S. registry.

What is the cost impact of this AD on owners/operators of the affected airplanes? We estimate the following costs to accomplish the inspections:

Labor cost	Parts cost	Total cost per airplane	Total cost on U.S. operators
4 inspections × 3 workhours × \$60 per hour = \$720	Not applicable	\$720	\$2,880

We estimate the following costs to do any necessary modifications that will be required because of the inspection:

Labor cost	Parts cost	Total cost per airplane	Total cost on U.S. operators
60 workhours × \$60 per hour = \$3,600		\$6,975	\$27,900

Regulatory Flexibility Determination and Analysis

What are the requirements of the Regulatory Flexibility Act? The Regulatory Flexibility Act of 1980 was enacted by Congress to assure that small entities are not unnecessarily or disproportionately burdened by government regulations. This Act establishes "as principle of regulatory issuance that agencies shall endeavor, consistent with the objectives of the rule and of applicable statutes, to fit regulatory and informational requirements to the scale of the businesses, organizations, and governmental jurisdictions subject to regulation." To achieve this principle, the Act requires agencies to solicit and consider flexible regulatory proposals and to explain the rationale for their actions. The Act covers a wide range of small entities, including small businesses, not-for-profit organizations, and small governmental jurisdictions.

Agencies must perform a review to determine whether a proposed or final rule will have a significant economic impact on a substantial number of small entities. If the determination is that the rule will, the Agency must prepare a regulatory flexibility analysis as described in the RFA.

However, if an agency determines that a proposed or final rule is not expected to have a significant economic impact on a substantial number of small entities, section 605(b) of the RFA provides that the head of the agency may so certify and a regulatory flexibility analysis is not required. The certification must include a statement providing the factual basis for this determination, and the reasoning should be clear.

What is FAA's determination? The FAA has determined that this AD will not have a significant economic impact on a substantial number of small entities. Reims Aviation Model F406 aircraft are produced in France and only 4 airplanes are owned by U.S. entities. Of these 4 airplanes, Cessna Finance Corporation owns 2. Cessna Finance Corporation is part of a larger corporation with more than 1,500 employees and is not considered a small entity. We do not believe that the two remaining entities owning the F406 aircraft constitute a substantial number. Therefore, we have determined that this AD will not have a significant economic impact on a substantial number of small entities.

Regulatory Impact

Does this AD impact various entities? 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.

Does this AD involve a significant rule or regulatory action? 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 copy of the final evaluation prepared for this action is contained in the Rules Docket. A copy of it may be obtained by contacting 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, under 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. FAA amends § 39.13 by adding a new AD to read as follows:

2001-01-07 Reims Aviation S.A.:

Amendment 39–12504; Docket No. 99–CE–28–AD.

- (a) What airplanes are affected by this AD? This AD affects Model F406 airplanes, serial numbers F406–0001 through F406–0083, certificated in any category.
- (b) Who must comply with this AD? Anyone who wishes to operate any of the above airplanes must comply with this AD.
- (c) What problem does this AD address? The actions specified by this AD are intended to detect and correct cracks in the canted rib upper cap in the center wing carry-through area, which could result in structural failure of the wing with possible loss of control of the airplane.
- (d) What actions must I accomplish to address this problem? To address this problem, unless already done, you must accomplish the following:

Actions	Compliance	Procedures
(1) Inspect the canted rib upper cap in the center wing carry-through area for cracks.	Within the next 75 hours time-in-service (TIS) after January 7, 2002 (the effective date of this AD), and thereafter at 200-hour TIS intervals, but not to exceed three 200-hour interval inspections (675 hours TIS: 75-hour TIS initial inspection plus three additional 200-hour TIS repetitive inspections).	Following the ACCOMPLISHMENT IN- STRUCTIONS section of REIMS/CESSNA Service Bulletin CAB98–16, dated Novem- ber 2, 1998.
 (2) If, during any inspection required by this AD, cracks are found, accomplish the following:. (i) If the cracks are less than 2 inches in length, modify the canted rib upper cap in the center wing carry-through area. (ii) If the cracks are 2 inches in length or more, obtain a repair scheme from the manufacturer through FAA at the address specified in paragraph (f) of this AD and incorporate this repair scheme. 	Before further flight after the inspection where the crack is found.	Following the ACCOMPLISHMENT IN- STRUCTIONS section of REIMS-CESSNA Service Bulletin CAB98–16, dated Novem- ber 2, 1998.
 (3) Modify the canted rib upper cap in the center wing carry-through area. (4) Accomplishing the repair or modification required in paragraphs (d)(2)(i), (d)(2)(ii), or (d)(3) of this AD is considered terminating action for the inspection requirements of this AD. 	Within 600 hours TIS after the initial inspection required by paragraph (d)(1) of this AD, unless already accomplished through paragraphs (d)(2)(i) or (d)(2)(ii) of this AD. Not applicable	Following the ACCOMPLISHMENT IN- STRUCTIONS section of REIMS-CESSNA Service Bulletin CAB98–16, dated Novem- ber 2, 1998. Not applicable.

- (e) Can I comply with this AD in any other way? You may use an alternative method of compliance or adjust the compliance time if:
- (1) Your alternative method of compliance provides an equivalent level of safety; and
- (2) The Manager, Small Airplane
 Directorate, approves your alternative.
 Submit your request through an FAA
 Principal Maintenance Inspector, who may
 add comments and then send it to the
 Manager, Small Airplane Directorate.

Note 1: This AD applies to each airplane identified in paragraph (a) of this AD, 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 request approval for an alternative method of compliance in accordance with paragraph (e) of this AD. The request should include an assessment of the effect of the modification, alteration, or repair on the unsafe condition addressed by this AD; and, if you have not eliminated the unsafe condition, specific actions you propose to address it.

(f) Where can I get information about any already-approved alternative methods of compliance? Contact Brian A. Hancock, Aerospace Engineer, FAA, Small Airplane Directorate, 901 Locust, Room 301, Kansas City, Missouri 64106; telephone: (816) 329–4143, facsimile: (816) 329–4090.

- (g) What if I need to fly the airplane to another location to comply with this AD? The FAA can issue a special flight permit under sections 21.197 and 21.199 of the Federal Aviation Regulations (14 CFR 21.197 and 21.199) to operate your airplane to a location where you can accomplish the requirements of this AD.
- (h) Are any service bulletins incorporated into this AD by reference? Actions required by this AD must be done in accordance with REIMS/CESSNA Service Bulletin CAB98–16, dated November 2, 1998. The Director of the Federal Register approved this incorporation by reference under 5 U.S.C. 552(a) and 1 CFR part 51. You can get copies from Cessna Aircraft Company, Product Support, PO Box 7706, Wichita, Kansas 67277. You can look at copies at the FAA, Central Region, Office of the Regional Counsel, 901 Locust, Room 506, Kansas City, Missouri, or at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC.
- (i) When does this amendment become effective? This amendment becomes effective on January 7, 2002.

Note 2: The subject of this AD is addressed in French AD 1999–087(A), dated February 24, 1999.

Issued in Kansas City, Missouri, on November 6, 2001.

Michael Gallagher,

Manager, Small Airplane Directorate, Aircraft Certification Service.

[FR Doc. 01–28571 Filed 11–14–01; 8:45 am] BILLING CODE 4910–13–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 868

[Docket No. 99N-0035]

Medical Devices; Reclassification of Three Anesthesiology Preamendments Class III Devices into Class II

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is reclassifying three anesthesiology preamendments devices from class III (premarket