

Service Bulletin F28/53-151, dated June 4, 2001, excluding Manual Change Notification—Maintenance Documentation MCNM F28-025, dated June 4, 2001. 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 Fokker Services B.V., P.O. Box 231, 2150 AE Nieuw-Vennep, the Netherlands. 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.

Note 4: The subject of this AD is addressed in Dutch airworthiness directive 2001-093, dated July 31, 2001.

Effective Date

(h) This amendment becomes effective on April 8, 2003.

Issued in Renton, Washington, on February 13, 2003.

Ali Bahrami,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 03-4165 Filed 3-3-03; 8:45 am]

BILLING CODE 4910-13-P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. 2002-NM-93-AD; Amendment 39-13076; AD 2003-04-27]

RIN 2120-AA64

Airworthiness Directives; Bombardier Model CL-600-2C10 Series Airplanes

AGENCY: Federal Aviation Administration, DOT.

ACTION: Final rule.

SUMMARY: This amendment adopts a new airworthiness directive (AD), applicable to all Bombardier CL-600-2C10 series airplanes, that requires revising the Airworthiness Limitations Section of the Instructions for Continued Airworthiness to incorporate functional and operational checks of the active and standby actuators of the rudder travel limiter (RTL) system. The actions specified by this AD are intended to prevent a significant latent failure in the RTL, which could lead to a critical loss of RTL function under certain conditions, and consequent loss of controllability of the airplane or structural damage. This action is intended to address the identified unsafe condition.

DATES: Effective April 8, 2003.

The incorporation by reference of certain publications listed in the regulations is approved by the Director

of the Federal Register as of April 8, 2003.

ADDRESSES: The service information referenced in this AD may be obtained from Bombardier, Inc., Canadair, Aerospace Group, P.O. Box 6087, Station Centre-ville, Montreal, Quebec H3C 3G9, Canada. This information may be examined at the Federal Aviation Administration (FAA), Transport Airplane Directorate, Rules Docket, 1601 Lind Avenue, SW., Renton, Washington; or at the FAA, New York Aircraft Certification Office, 10 Fifth Street, Third Floor, Valley Stream, New York; or at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC.

FOR FURTHER INFORMATION CONTACT: Dan Parrillo, Aerospace Engineer, Systems and Flight Test Branch, ANE-172, FAA, New York Aircraft Certification Office, 10 Fifth Street, Third Floor, Valley Stream, New York 11581; telephone (516) 256-7505; fax (516) 568-2716.

SUPPLEMENTARY INFORMATION: A proposal to amend part 39 of the Federal Aviation Regulations (14 CFR part 39) to include an airworthiness directive (AD) that is applicable to all Bombardier CL-600-2C10 series airplanes was published in the **Federal Register** on September 25, 2002 (67 FR 60187). That action proposed to require revising the Airworthiness Limitations Section of the Instructions for Continued Airworthiness to incorporate functional and operational checks of the active and standby actuators of the rudder travel limiter (RTL) system.

Comments

Interested persons have been afforded an opportunity to participate in the making of this amendment. No comments were submitted in response to the proposal or the FAA's determination of the cost to the public.

Explanation of Change to Final Rule

We have revised this final rule to specify that the accountable Aircraft Certification Office (ACO) is the New York ACO, 10 Fifth Street, Third Floor, Valley Stream, New York, not the Atlanta ACO.

Conclusion

The FAA has determined that air safety and the public interest require the adoption of the rule with the change described previously. The FAA has determined that this change will neither increase the economic burden on any operator nor increase the scope of the AD.

Cost Impact

The FAA estimates that 15 Model CL-600-2C10 series airplanes of U.S. registry will be affected by this AD, that it will take approximately 1 work hour per airplane to accomplish the required actions, and that the average labor rate is \$60 per work hour. Based on these figures, the cost impact of the AD on U.S. operators is estimated to be \$900, or \$60 per airplane.

The cost impact figure discussed above is based on assumptions that no operator has yet accomplished any of the requirements of this AD action, and that no operator would accomplish those actions in the future if this AD were not adopted. The cost impact figures discussed in AD rulemaking actions represent only the time necessary to perform the specific actions actually required by the AD. These figures typically do not include incidental costs, such as the time required to gain access and close up, planning time, or time necessitated by other administrative actions.

Regulatory Impact

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 the following new airworthiness directive:

2003-04-27 Bombardier, Inc. (Formerly Canadair): Amendment 39-13076. Docket 2002-NM-93-AD.

Applicability: All Model CL-600-2C10 series airplanes, certificated in any category.

Note 1: This AD requires revisions to certain operator maintenance documents to include new inspections. Compliance with these inspections is required by 14 CFR part 91.403(c). For airplanes that have been previously modified, altered, or repaired in the areas addressed by these inspections, the operator may not be able to accomplish the inspections described in the revisions. In this situation, to comply with 14 CFR part 91.403(c), the operator must request approval for an alternative method of compliance in accordance with paragraph (c) of this AD. The request should include a description of changes to the required inspections that will ensure the continued damage tolerance of the affected structure. The FAA has provided guidance for this determination in Advisory Circular (AC) 25-1529.

Compliance: Required as indicated, unless accomplished previously.

To prevent a significant latent failure in the rudder travel limiter (RTL), which

could lead to a critical loss of RTL function under certain conditions, and consequent loss of controllability of the airplane or structural damage, accomplish the following:

Revise Airworthiness Limitations Section

(a) Within 30 days of the effective date of this AD, revise the Airworthiness Limitations Section of the Instructions for Continued Airworthiness by incorporating the tasks of the Temporary Revisions of Part 2 of the Maintenance Requirements Manual (MRM), Section 1, Appendix A, Certification Maintenance Requirements; as listed in the following table; into the Airworthiness Limitations Section:

CRJ 700 regional jet temporary revision	Task number	Task description
MRM2-41, dated September 28, 2001	27-20-00-108	RTL standby actuator (with SSCU part number (P/N) C13045BA01): Operational check of the RTL standby actuator.
MRM2-42, dated September 28, 2001	27-20-00-107	RTL active and standby actuators (with SSCU P/N C13045BA02): Functional check of the RTL active and standby actuators.
MRM2-43, dated September 28, 2001	27-20-00-102	RTL active and standby actuators (with SSCU P/N C13045BA02): Operational check of the RTL active and standby actuators.

(b) Thereafter, except as provided by paragraph (c) of this AD, no alternative operational and functional checks or check intervals may be approved for the task numbers specified in the temporary revisions listed in paragraph (a) of this AD.

Alternative Methods of Compliance

(c) 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, New York Aircraft Certification Office (ACO), FAA. Operators shall submit their requests through an appropriate FAA Principal Maintenance Inspector, who may add comments and then send it to the Manager, New York ACO.

Note 2: Information concerning the existence of approved alternative methods of compliance with this AD, if any, may be obtained from the New York ACO.

Special Flight Permits

(d) Special flight permits may be issued in accordance with §§ 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.

Incorporation by Reference

(e) The action shall be done in accordance with CRJ 700 Regional Jet, Temporary Revision MRM2-41, dated

September 28, 2001; CRJ 700 Regional Jet, Temporary Revision MRM2-42, dated September 28, 2001; and CRJ 700 Regional Jet, Temporary Revision MRM2-43, dated September 28, 2001. 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 Bombardier, Inc., Canadair, Aerospace Group, P.O. Box 6087, Station Centre-ville, Montreal, Quebec H3C 3G9, Canada. Copies may be inspected at the FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington; or at the FAA, New York Aircraft Certification Office, 10 Fifth Street, Third Floor, Valley Stream, New York; or at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC.

Note 3: The subject of this AD is addressed in Canadian airworthiness directive CF-2002-06, dated January 21, 2002.

Effective Date

(f) This amendment becomes effective on April 8, 2003.

Issued in Renton, Washington, on February 24, 2003.

Ali Bahrami,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 03-4852 Filed 3-3-03; 8:45 am]

BILLING CODE 4910-13-U

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 610

[Docket No. 97N-0449]

RIN 0910-AB51

Revision to the General Safety Requirements for Biological Products

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the biologics regulations regarding general biological products standards by adding an administrative procedure for obtaining exemptions from the general safety test (GST) requirements. We are taking this action because the GST may not be relevant or necessary for certain biological products. The rule will permit manufacturers of biological products to apply for an exemption from the GST requirement provided they submit information to demonstrate that they use appropriate production controls and quality assurance safeguards.

DATES: This rule is effective May 5, 2003.

FOR FURTHER INFORMATION CONTACT: Stephen M. Ripley, Center for Biologics