

Proposed Rules

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This section of the FEDERAL REGISTER contains notices to the public of the proposed issuance of rules and regulations. The purpose of these notices is to give interested persons an opportunity to participate in the rule making prior to the adoption of the final rules.

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. 2004-SW-04-AD]

RIN 2120-AA64

Airworthiness Directives; Bell Helicopter Textron Canada Model 222, 222B, 222U, and 230 Helicopters

AGENCY: Federal Aviation Administration, DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: This document proposes adopting a new airworthiness directive (AD) for the specified Bell Helicopter Textron Canada (BHTC) model helicopters. The AD would require certain inspections of the main rotor yoke (yoke) for a crack, fretting, or buffer deterioration. If a crack is found, the AD would require replacing the yoke with an airworthy yoke before further flight. If fretting or buffer deterioration are found, the AD would require further inspecting the main rotor hub assembly (hub assembly) and repairing or replacing any unairworthy parts. Also, the AD would require a torque inspection of the flapping bearing retaining nuts at specified intervals. This proposal is prompted by the discovery of a crack in a yoke. The actions specified by the proposed AD are intended to prevent failure of the yoke and subsequent loss of control of the helicopter.

DATES: Comments must be received on or before August 23, 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-04-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. Comments may be inspected at the

Office of the Regional Counsel between 9 a.m. and 3 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT:

Charles Harrison, Aviation Safety Engineer, FAA, Rotorcraft Directorate, Safety Management Group, Fort Worth, Texas 76193-0110, telephone (817) 222-5128, fax (817) 222-5961.

SUPPLEMENTARY INFORMATION:

Comments Invited

Interested persons are invited to participate in the making of the proposed 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 above. All communications received on or before the closing date for comments will be considered before taking action on the proposed rule. The proposals contained in this document may be changed in light of the comments received.

Comments are specifically invited on the overall regulatory, economic, environmental, and energy aspects of the proposed 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 summarizing each FAA-public contact concerned with the substance of this proposal will be filed in the Rules Docket.

Commenters wishing the FAA to acknowledge receipt of their mailed comments submitted in response to this proposal must submit a self-addressed, stamped postcard on which the following statement is made: "Comments to Docket No. 2004-SW-04-AD." The postcard will be date stamped and returned to the commenter.

Discussion

Transport Canada, the airworthiness authority for Canada, notified the FAA that an unsafe condition may exist on BHTC Model 222, 222B, 222U, and 230 helicopters. Transport Canada advises of a fatigue crack being found in a yoke in the area of the flapping bearing bushings.

BHTC has issued Alert Service Bulletin (ASB) Nos. 222-03-97 for the Model 222 and 222B helicopters, 222U-03-68 for the Model 222U helicopters,

and 230-03-28 for the Model 230 helicopters, all dated September 23, 2003. The ASB's specify a recurring visual inspection of the yoke for a crack, fretting, or buffer deterioration in the four (4) areas around the flapping bearing attachment bushings and verifying the torque of the main rotor flapping bearing retaining bolts/nuts. Transport Canada classified these service bulletins as mandatory and issued AD No. CF-2003-27, dated November 17, 2003, to ensure the continued airworthiness of these helicopters in Canada.

These helicopter models are type certificated in Canada 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, Transport Canada has kept the FAA informed of the situation described above. The FAA has examined the findings of Transport Canada, reviewed all available information, and determined that AD action is necessary for products of these type designs that are certificated for operation in the United States.

This previously described unsafe condition is likely to exist or develop on other helicopters of the same type design registered in the United States. Therefore, the proposed AD would require:

- Initial and recurring visual inspections, using a 10X or higher magnifying glass, of the yoke for a crack, fretting, or buffer deterioration in the four areas around the flapping bearing attachment bushings. If a crack is found, before further flight, replace the yoke with an airworthy yoke. If fretting or buffer deterioration is found, the hub assembly must be further inspected.

- Initially and at specified intervals, assure that there is no movement while torquing the main rotor flapping bearing retaining nuts to 100 ft-lbs. While holding the bolt head, apply 100 foot-pounds (135Nm) of torque to the nut in the tightening direction. If 100 foot-pounds (135Nm) of torque is reached without movement of the nut, before further flight, torque the bolt to 125 foot-pounds. If any nut moves before reaching 100 foot-pounds (135Nm) of torque, remove both flapping bearings from the hub assembly. Repair or replace any unairworthy part with an airworthy part.

The FAA estimates that this proposed AD would affect 105 helicopters of U.S. registry. The FAA also estimates that this proposed AD would:

- Take ½ work hour to inspect the yoke every 25 hours time-in-service (TIS), assuming 8 inspections a year that would equal 4 work hours per year;
 - Take ½ work hour to inspect the flapping bearing retaining bolts torque every 50 hours TIS, assuming 4 inspections a year that would equal 2 work hours per year;
 - Take 4 work hours to remove, inspect, and replace the yoke if required.
 - The average labor rate is \$65 per work hour.
 - Required parts would cost approximately \$32,675.
 - Based on these figures, we estimate the total cost impact of the proposed AD on U.S. operators to be \$3,499,125, assuming all yokes are replaced near the end of the first year.
- The regulations proposed herein would 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 proposal would not have federalism implications under Executive Order 13132.

For the reasons discussed above, I certify that this proposed regulation (1) is not a “significant regulatory action” under Executive Order 12866; (2) is not a “significant rule” under the DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979); and (3) if promulgated, 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 draft economic 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, Safety.

The Proposed Amendment
Accordingly, pursuant to the authority delegated to me by the Administrator, the Federal Aviation Administration proposes to amend 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:
Bell Helicopter Textron Canada: Docket No. 2004–SW–04–AD.
Applicability: The following helicopter models, certificated in any category:

Model	Serial number (S/N)	With main rotor hub (hub) assembly part number (P/N), installed
(1) 222	47006–47089	222–011–101–ALL or 222–012–101–ALL.
(2) 222B	47131–47156	222–011–101–ALL or 222–012–101–ALL.
(3) 222U	47501–47574	222–011–101–ALL or 222–012–101–ALL.
(4) 230	23001–23038	222–012–101–ALL.

Compliance: Required as indicated, unless accomplished previously.
To prevent failure of the yoke and subsequent loss of control of the helicopter, accomplish the following:

- (a) Within 50 hours time-in-service (TIS) or by the next scheduled inspection for the hub assembly, whichever occurs first, and thereafter at intervals not to exceed 25 hours TIS, using a 10X or higher magnifying glass, visually inspect the main rotor yoke (yoke)

for a crack, fretting or buffer deterioration in the four areas around the flapping bearing attachment bushings as shown in the following Figure 1 of this AD:
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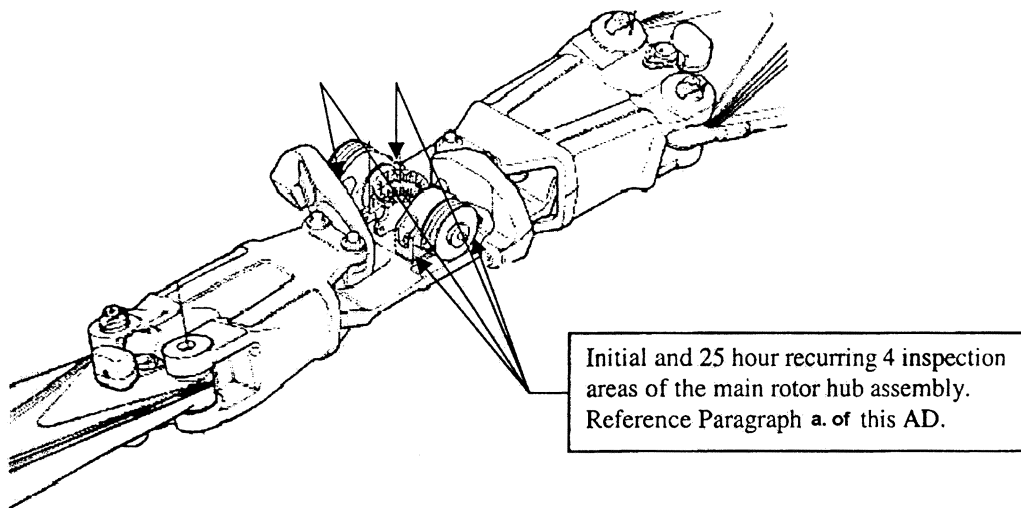


Figure 1. Main Rotor Hub Assembly

Note 1: Bell Helicopter Textron Alert Service Bulletin (ASB) Nos. 222-03-97 for the Model 222 and 222B, 222U-03-68 for the Model 222U, and 230-03-28 for the Model 230, all dated September 23, 2003, pertain to the subject of this AD.

(1) If a crack is found, before further flight, replace the yoke with an airworthy yoke.

(2) If fretting or buffer deterioration is found on the yoke in the areas shown in Figure 1 of this AD, before further flight, disassemble the hub assembly and further inspect the yoke with a 10X or higher magnifying glass in the four areas shown in Figures 2 and 3 of this AD.

(i) If a crack is found on any part, before further flight, replace the part with an airworthy part.

(ii) If fretting or buffer deterioration is found on any part, before further flight, repair any unairworthy part or replace the part with an airworthy part.

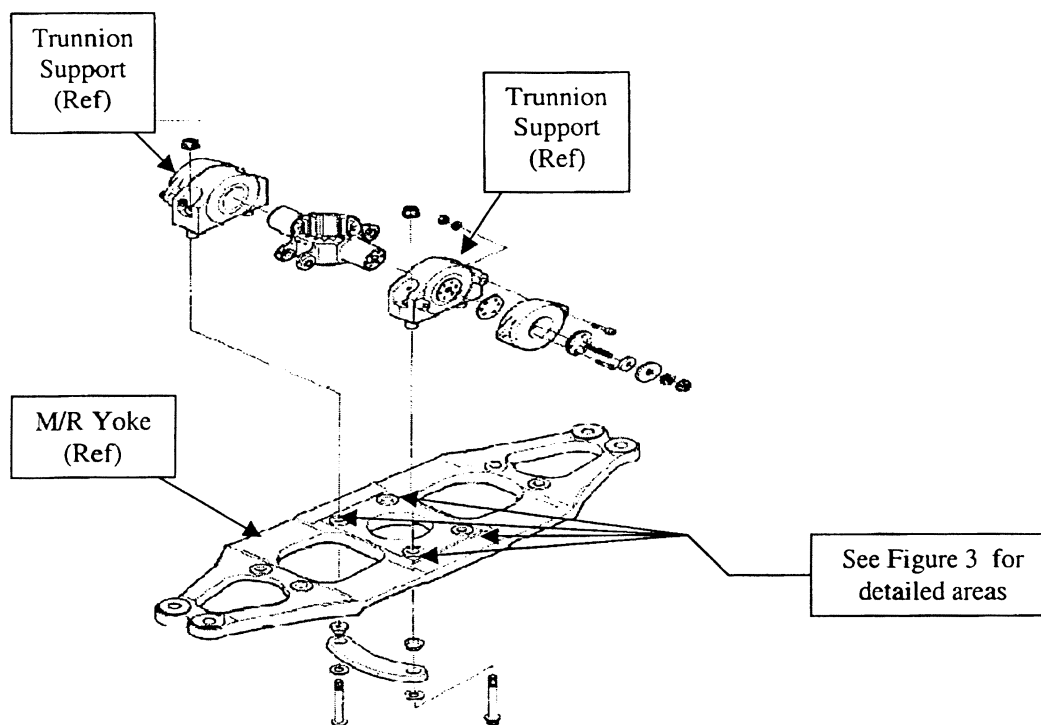


Figure 2. Main Rotor Yoke

Shown with trunnion supports removed.

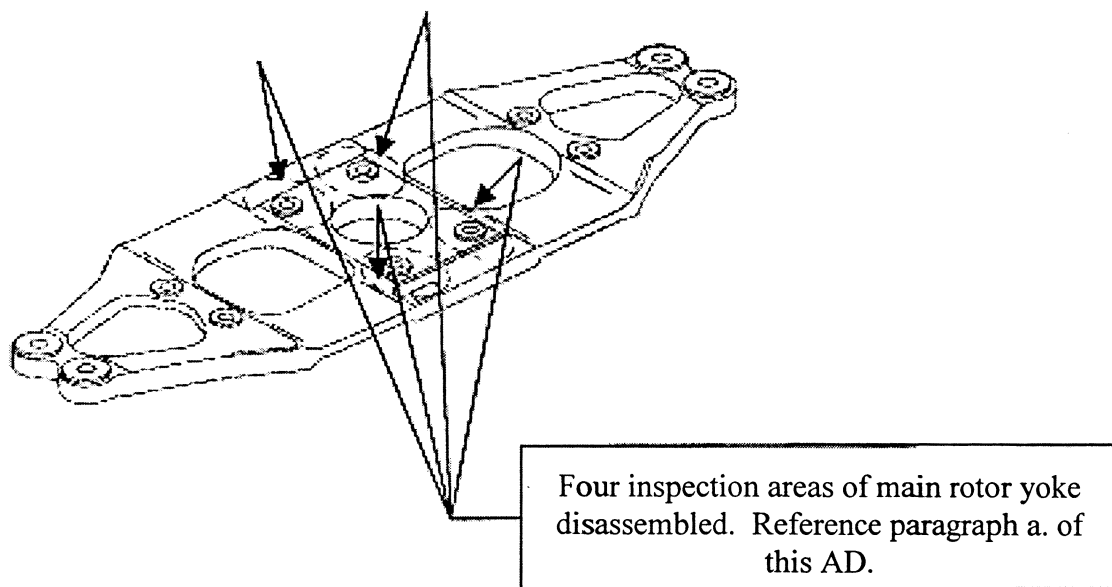


Figure 3. Main Rotor Yoke Inspection Areas

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(b) Within 50 hours TIS or by the next scheduled inspection for each hub assembly, whichever occurs first, and thereafter at intervals not to exceed 50 hours TIS, determine the torque of the four main rotor flapping bearing retaining bolts or nuts. While holding the bolt head, apply 100 foot-pounds (135Nm) of torque to the nut in the tightening direction.

(1) If 100 foot-pounds (135Nm) of torque is reached without movement of the nut, before further flight, torque the nut to 125 foot-pounds.

(2) If any nut moves before reaching 100 foot-pounds (135Nm) of torque, before further flight, remove both flapping bearings from the hub assembly. Inspect the yoke, the bolt and nut, and the trunnion supports with a 10X or higher magnifying glass, for a crack, fretting, or buffer deterioration.

(i) If a crack is found on any part, before further flight, replace the part with an airworthy part.

(ii) If fretting or buffer deterioration is found on any part, before further flight, repair any unairworthy part or replace the part with an airworthy part.

(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, FAA, for information about previously approved alternative methods of compliance.

Note 2: The subject of this AD is addressed in Transport Canada (Canada) AD CF-2003-27, dated November 17, 2003.

Issued in Fort Worth, Texas, on June 16, 2004.

David A. Downey,
Manager, Rotorcraft Directorate, Aircraft Certification Service.

[FR Doc. 04-14315 Filed 6-23-04; 8:45 am]

BILLING CODE 4910-13-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 3

[Docket No. 2004N-0194]

Definition of Primary Mode of Action of a Combination Product

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule; extension of comment period.

SUMMARY: The Food and Drug Administration (FDA) is extending until August 20, 2004, the comment period on the primary mode of action proposed rule that appeared in the **Federal Register** of May 7, 2004 (69 FR 25527). In the primary mode of action proposed rule, the agency states its intentions to amend the product jurisdiction

regulations to define “mode of action” and “primary mode of action” (PMOA). Along with these definitions, the proposed rule sets forth an algorithm the agency would use to assign combination products to an agency component for regulatory oversight when the agency cannot determine with reasonable certainty which mode of action provides the most important therapeutic action of the combination product. Finally, the proposed rule would also require a sponsor to base its recommendation of the agency component with primary jurisdiction for regulatory oversight of its combination product on the PMOA definition and, if appropriate, the assignment algorithm. The proposed rule is intended to promote the public health by codifying the agency’s criteria for the assignment of combination products in transparent, consistent, and predictable terms.

DATES: Submit written or electronic comments no later than August 20, 2004.

ADDRESSES: You may submit comments, identified by Docket 2004N-0194, by any of the following methods:

- Federal eRulemaking Portal: <http://www.regulations.gov>. Follow the instructions for submitting comments.
- Agency Web site: <http://www.fda.gov/dockets/ecomments>.