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. 2003–CE–51–AD]

RIN 2120–AA64

Airworthiness Directives; Raytheon Aircraft Company 65, 90, 99, 100, 200, and 1900 Series Airplanes, and Models 70 and 300 Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: The FAA proposes to supersede Airworthiness Directive (AD) 87–22–01 R1, which applies to certain Raytheon Aircraft Company (Raytheon) 65, 90, 99, 100, 200, and 1900 series airplanes, and Models 70 and 300 airplanes. AD 87–22–01 R1 currently requires you to repetitively inspect the nose landing gear (NLG) fork for cracks. If cracks are found that exceed certain limits, AD 87–22–01 R1 requires you to replace the NLG fork with a serviceable part or an improved NLG fork (Kit No. 101–8030–1 S or Kit No. 114–8015–1 S, as applicable). Installing an improved NLG fork kit is terminating action for the repetitive inspection requirements. This proposed AD is the result of FAA's current policy to disallow airplane operation when known cracks exist in primary structure. This proposed AD would retain the inspection requirements of AD 87–22–01 R1 and would require you to incorporate an improved NLG fork kit anytime a crack is found. We are issuing this proposed AD to detect and correct cracks in the NLG fork, which could result in reduced structural integrity and inability of the NLG fork to carry design limit and ultimate loads. The reduced residual strength may cause separation failure of the NLG fork, which could result in loss of control of the airplane during take off, landing, and taxi operations.

DATES: We must receive any comments on this proposed AD by May 18, 2004.

ADDRESSES: Use one of the following to submit comments on this proposed AD:

- *By mail:* FAA, Central Region, Office of the Regional Counsel, Attention: Rules Docket No. 2003–CE–51–AD, 901 Locust, Room 506, Kansas City, Missouri 64106.
- *By fax:* (816) 329–3771.
- *By e-mail: 9-ACE–7-Docket@faa.gov*. Comments sent electronically must contain ''Docket No. 2003–CE–51–AD'' in the subject line. If you send comments electronically as attached electronic files, the files must be formatted in Microsoft Word 97 for Windows or ASCII.

You may get the service information identified in this proposed AD from Raytheon Aircraft Company, 9709 E. Central, Wichita, Kansas 67201–0085; telephone: (800) 429–5372 or (316) 676–3140.

You may view the AD docket at FAA, Central Region, Office of the Regional Counsel, Attention: Rules Docket No. 2003–CE–51–AD, 901 Locust, Room 506, Kansas City, Missouri 64106. Office hours are 8 a.m. to 4 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: Steven E. Potter, Aerospace Engineer, Wichita Aircraft Certification Office (ACO), FAA, 1801 Airport Road, Wichita, Kansas 67209; telephone: (316) 946–4124; facsimile: (316) 946–4407.

SUPPLEMENTARY INFORMATION:

Comments Invited

How do I comment on this proposed AD? We invite you to submit any written relevant data, views, or arguments regarding this proposal. Send your comments to an address listed under **ADDRESSES.** Include ''AD Docket No. 2003–CE–51–AD'' in the subject line of your comments. If you want us to acknowledge receipt of your mailed comments, send us a self-addressed, stamped postcard with the docket number written on it. We will date-stamp your postcard and mail it back to you.

Are there any specific portions of this proposed AD I should pay attention to? We specifically invite comments on the overall regulatory, economic, environmental, and energy aspects of this proposed AD. If you contact us through a nonwritten communication and that contact relates to a substantive part of this proposed AD, we will summarize the contact and place the summary in the docket. We will consider all comments received by the closing date and may amend this proposed AD in light of those comments and contacts.

Discussion

Has FAA taken any action to this point? Reports of cracks in the nose landing gear (NLG) fork on several Raytheon airplanes caused us to issue AD 87–22–01, Amendment 39–5748 and AD 87–22–01 R1, Amendment 39–6312 against certain Raytheon 65, 90, 99, 100, 200, and 1900 series airplanes, and Models 70 and 300 airplanes.

AD 87–22–01 required you to repetitively inspect the nose landing gear (NLG) fork for cracks. If cracks were found during any inspection that exceeded certain limits, you were required to replace the NLG fork with a serviceable part.

AD 87–22–01 R1 retained the repetitive inspection and replacement requirements from AD 87–22–01. AD 87–22–01 R1 also introduced incorporating an improved NLG fork (Kit No. 101–8030–1 S or Kit No. 114–8015–1 S, as applicable) as a terminating action for the repetitive inspection requirements.

What has happened since AD 87–22–01 R1 to initiate this proposed action? As currently written, AD 87–22–01 R1 allows continued flight if cracks are found in the NLG fork that do not exceed certain limits. AD 87–22–01 R1 contradicts the FAA's current policy to disallow airplane operation when known cracks exist in primary structure, unless the ability to sustain limit and ultimate load with these cracks is proven. The NLG fork is considered primary structure, and the FAA has not received any analysis to prove that limit and ultimate loads can be sustained with cracks in this area. For this reason, the FAA has determined that the crack limits contained in AD 87–22–01 R1 should be eliminated and that AD action should be taken to require immediate incorporation of Kit No. 101–8030–1 S or Kit No. 114–8015–1 S, as applicable, anytime a crack is found.

This policy did not exist when we issued AD 87–22–01 and AD 87–22–01 R1.

What is the potential impact if FAA took no action? This condition, if not detected and corrected, could cause

failure of the NLG fork to carry design limit and ultimate loads. Failure of the NLG fork could result in loss of control of the airplane during take off, landing, and taxi operations.

Is there service information that applies to this subject? Raytheon has issued Mandatory Service Bulletin SB 32–2102, Revision 7, Revised: July, 2003, to remove flight with allowable crack limits.

What are the provisions of this service information? The service bulletin includes procedures for:

—inspecting the nose landing gear (NLG) fork assembly for cracks; and

—replacing the NLG fork assembly anytime cracks are found.

FAA's Determination and Requirements of this Proposed AD

What has FAA decided? We have evaluated all pertinent information and identified an unsafe condition that is likely to exist or develop on other products of this same type design. Therefore, we are proposing AD action.

What would this proposed AD require? This proposed AD would supersede AD 87–22–01 R1 with a new AD that would incorporate the actions in the previously-referenced service bulletin.

How does the revision to 14 CFR part 39 affect this proposed AD? On July 10, 2002, we published a new version of 14 CFR part 39 (67 FR 47997, July 22, 2002), which governs FAA's AD system. This regulation now includes material that relates to altered products, special flight permits, and alternative methods of compliance. This material previously was included in each individual AD. Since this material is included in 14 CFR part 39, we will not include it in future AD actions.

Costs of Compliance

How many airplanes would this proposed AD impact? We estimate that this proposed AD affects approximately 5,296 airplanes in the U.S. registry.

What would be the cost impact of this proposed AD on owners/operators of the affected airplanes? We estimate the following costs to accomplish this proposed inspection:

Labor cost	Parts cost	Total cost per airplane	Total cost on U.S. operators
2 workhours × $65 per hour = $130	Not applicable	$130	$130 × 5,296 = $688,480.

We estimate the following costs to accomplish any necessary replacements that would be required based on the results of this proposed inspection. We have no way of determining the number of airplanes that may need this repair/replacement:

Labor cost	Parts cost	Total cost per kit
4 workhours × $65 per hour = $260	Kit No. 101–8030–1 S = $4,152 Kit No. 114–8015–1 S = $4,210	Kit No. 101–8030–1 S: $260 + $4,152 = $4,412. Kit No. 114–8015–1 S: $60 + $4,210 = $4,470.

Regulatory Findings

Would this proposed AD impact various entities? We have determined that this proposed AD would not have federalism implications under Executive Order 13132. This proposed AD 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.

Would this proposed AD involve a significant rule or regulatory action? For the reasons discussed above, I certify that this proposed AD:

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. 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.

We prepared a summary of the costs to comply with this proposed AD and placed it in the AD Docket. You may get a copy of this summary by sending a request to us at the address listed under **ADDRESSES**. Include ''AD Docket No. 2003–CE–51–AD'' in your request.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Safety.

The Proposed Amendment

Accordingly, under the authority delegated to me by the Administrator, the Federal Aviation Administration proposes to amend 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. The FAA amends § 39.13 by removing Airworthiness Directive (AD) 87–22–01 R1, Amendment 39–6312 and by adding a new AD to read as follows:

Raytheon Aircraft Company: Docket No. 2003–CE–51–AD

When Is the Last Date I Can Submit Comments on This Proposed AD?

(a) We must receive comments on this proposed airworthiness directive (AD) by May 18, 2004.

What Other ADs Are Affected by This Action?

(b) This AD supersedes AD 87–22–01 R1, Amendment 39–6312.

What Airplanes Are Affected by This AD?

(c) This AD affects the following airplane models and serial numbers that are certificated in any category:

Model	Serial Nos.
(1) A65 and A65–8200	LC–240 through LC–335.
(2) 70	LB–1 through LB–35.
(3) 65–A80, 65–A80–8800, and 65–B80	LD–151 through LD–511.
(4) 65–88	LP–1 through LP–26, LP–28, and LP–30 through LP–47.
(5) 65–90, 65–A90, B90, C90, and C90A	LJ–1 through LJ–1190.

Model	Serial Nos.
(6) 65–A90–1 (U–21A, JU–21A, U–21G, RU–21A, RU–21D, and RU–21H).	LM–1 through LM–141.
(7) 65–A90–2 (RU–21B)	LS–1 through LS–3.
(8) 65–A90–3 (RU–21C)	LT–1 and LT–2.
(9) 65–A90–4 (RU–21E and RU–21H)	LU–1 through LU–15.
(10) E90	LW–1 through LW–347.
(11) F90	LA–2 through LA–236.
(12) H90 (T–44A)	LL–1 through LL–61.
(13) 99, 99A, A99, A99A, B99, and C99	U–1 through U–239.
(14) 100 and A100	B–2 through B–93, and B–100 through B–247.
(15) A100 (U–21F)	B–95 through B–99.
(16) A100–1 (U–21J)	BB–3 through BB–5.
(17) B100	BE–1 through BE–137.
(18) 200 and B200	BB–2, and BB–6 through BB–1314.
(19) 200C and B200C	BL–1 through BL–72, and BL–124 through BL–131.
(20) 200CT and B200CT	BN–1 through BN–4.
(21) 200T and B200T	BT–1 through BT–33.
(22) A200 (C–12A and C–12C)	BC–1 through BC–75 and BD–1 through BD–30.
(23) A200C (UC–12B)	BJ–1 through BJ–66.
(24) A200CT (C–12D, FWC–12D, and C–12F)	BP–1, BP–7 through BP–11, BP–19, and BP–24 through BP–63.
(25) A200CT (RC–12D and RC–12H)	GR–1 through GR–19.
(26) A200CT (RC–12G)	FC–1 through FC–3.
(27) A200CT (RC–12K)	FE–1 through FE–9.
(28) B200C (C–12F)	BL–73 through BL–112, BL–118 through BL–123, and BP–64 through BP–71.
(29) B200C (UC–12F)	BU–1 through BU–10.
(30) B200C (UC–12M)	BV–1 through BV–10.
(31) 300	FA–1 through FA–168, and FF–1 through FF–19.
(32) 1900	UA–1 through UA–3.
(33) 1900C	UB–1 through UB–74, and UC–1 through UC–78.
(34) 1900C (C–12J)	UD–1 through UD–6.

What Is the Unsafe Condition Presented in This AD?

(d) The actions specified in this AD are intended to detect and correct cracks in the nose landing gear (NLG) fork, which could result in reduced structural integrity and failure of the NLG fork to carry design ultimate load. This failure could result in loss of control of the airplane during take off, landing, and taxi operations.

What Must I do To Address This Problem?

(e) To address this problem, you must do the following:

Actions	Compliance	Procedures
(1) Inspect, using fluorescent liquid penetrant or magnetic particle method, the nose landing gear (NLG) fork assembly for any signs of cracks.	*For airplanes affected by AD 87–22–01 R1:* Initially inspect within 200 hours time-in-service (TIS) after the last inspection required by AD 87–22–01 R1. *For airplanes not affected by AD 87–22–01 R1:* Initially inspect within the next 200 hours TIS after the effective date of this AD, unless already done.	Follow the instructions in Part II of Raytheon Aircraft Company Mandatory Service Bulletin SB 32–2102, Revision 7, Revised: July, 2003.
(2) If cracks are found during the inspection required in paragraph (e)(1) of this AD, incorporate Kit No. 101–8030–1 S or Kit No. 114–8015–1 S (as applicable).	Before further flight after the effective date of this AD.	Follow the instructions in Part III of Raytheon Aircraft Company Mandatory Service Bulletin SB 32–2102, Revision 7, Revised: July, 2003.
(3) If no cracks are found during the inspection required in paragraph (e)(1) of this AD, repetitively inspect until Kit No. 101–8030–1 S or Kit No. 114–8015–1 S (as applicable) is incorporated. When Kit No. 101–8030–1 S or Kit No. 114–8015–1 S is incorporated, no further action is required.	Repetitively inspect at intervals not to exceed 200 hours TIS after the initial inspection. Incorporate Kit No. 101–8030–1 S or Kit No. 114–8015–1 S (as applicable) prior to further flight after any inspection in which cracks are found.	Follow the instructions in Part III of Raytheon Aircraft Company Mandatory Service Bulletin SB 32–2102, Revision 7, Revised: July, 2003.
(4) Incorporating Kit No. 101–8030–1 S or Kit No. 114–8015–1 S (as applicable) is the terminating action for the repetitive inspection requirements specified in paragraph (e)(3) of this AD.	Kit No. 101–8030–1 S or Kit No. 114–8015–1 S (as applicable) can be incorporated at any time. When incorporated, no further action is required.	Follow Raytheon Aircraft Company Mandatory Service Bulletin SB 32–2102, Revision 7, Revised: July, 2003.

May I Request an Alternative Method of Compliance?

(f) You may request a different method of compliance or a different compliance time for this AD by following the procedures in 14 CFR 39.19. Unless FAA authorizes otherwise, send your request to your principal inspector. The principal inspector may add comments and will send your request to the Manager, Wichita Aircraft Certification Office (ACO), FAA. For information on any already approved alternative methods of compliance, contact Steven E. Potter, Aerospace Engineer, Wichita ACO, FAA, 1801 Airport Road,

Wichita, Kansas 67209; telephone: (316) 946–4124; facsimile: (316) 946–4407.

May I Get Copies of the Documents Referenced in This AD?

(g) You may get copies of the documents referenced in this AD from Raytheon Aircraft Company, 9709 E. Central, Wichita, Kansas 67201–0085; telephone: (800) 429–5372 or (316) 676–3140. You may view these documents at FAA, Central Region, Office of the Regional Counsel, 901 Locust, Room 506, Kansas City, Missouri 64106.

Issued in Kansas City, Missouri, on March 12, 2004.

Scott L. Sedgwick,

Acting Manager, Small Airplane Directorate, Aircraft Certification Service.

[FR Doc. 04–6113 Filed 3–17–04; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Chapter I

[Docket No. 2004N–0115]

Prescription Drug Importation; Public Meeting and Establishment of Docket

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public meeting and establishment of docket.

The Food and Drug Administration (FDA), on behalf of the U.S. Department of Health and Human Services' (HHS) Task Force on Drug Importation, is announcing that it is establishing a docket to receive information and comments on certain issues related to the importation of prescription drugs. FDA is also announcing a public meeting to enable interested individuals, organizations, and other stakeholders to present information to the Task Force for consideration in the study on importation mandated by the Medicare Prescription Drug, Improvement and Modernization Act of 2003. The Task Force is particularly interested in information related to whether and under what circumstances drug importation could be conducted safely, and what its likely consequences would be for the health, medical costs, and development of new medicines for American patients.

Date and Time: The public meeting will be held on April 14, 2004, from 9 a.m. to 5 p.m.

Location: The public meeting will be held at the Natcher Auditorium, Building 45, National Institutes of Health (NIH), 9000 Rockville Pike, Bethesda, MD 20892. Parking will be limited and there may be delays entering the NIH campus due to increased security. We recommend arriving by Metro if possible. NIH is accessible from the Metro's red line at the Medical Center/NIH stop.

Contact Person: Karen Strambler, Office of Policy, Office of the Commissioner, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–3360, e-mail: *Karen.Strambler@fda.gov*.

Registration and Requests for Oral Presentation: No registration is required to attend the public meeting. Seating will be on a first-come, first-serve basis. If you wish to present at the public meeting, please submit your request and a summary of your presentation to Karen Strambler the contact person listed in this document. Requests should be identified with the docket number listed in brackets in the heading of this document. (To ensure timely handling, the outer envelope should be clearly marked with the docket number listed in brackets in the heading of this document and the statement ''Prescription Drug Importation Public Meeting.'')

Speakers must submit requests for presentations along with a short summary of their presentation by close of business on March 30, 2004. Presenters must send final electronic presentations, if any, in PowerPoint, Microsoft Word, or Adobe Portable Document Format (PDF) to Karen Strambler the contact person listed in this document by close of business on April 7, 2004.

The public docket will formally remain open until June 1, 2004, and we encourage commenters to submit written and electronic comments before that date. However, FDA recognizes that there may be a need for further public input, and will be prepared to accept additional comments beyond this date as necessary. Submit electronic comments to *http://www.fda.gov/dockets/ecomments*. Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

Requests to present should contain the following information:

- Presenter's name;
- Address;
- Telephone number;
- E-mail address;
- Fax number;
- Affiliation, if any;
- Summary of the presentation; and
- Approximate amount of time requested for the presentation.

FDA encourages persons and groups having similar interests to consolidate their information and present it through a single representative, if possible, to enable a broad range of views to be presented. After reviewing the requests to present, the agency will schedule each appearance and notify each participant by e-mail or telephone of the time allotted to the participant and the approximate time the participant's presentation is scheduled to begin.

Presenters must send final electronic presentations, if any, in Microsoft PowerPoint, Microsoft Word, or PDF to Karen Strambler the contact person listed in this document by close of business on April 7, 2004.

If you need special accommodations due to disability, please inform Elizabeth French, Office of Policy (HF–11), Office of the Commissioner, Food and Drug Administration, 5600 Fishers Lane, rm. 14–101, Rockville, MD 20857, 301–827–3360, FAX: 301–594–6777, e-mail: *efrench@oc.fda.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

On December 8, 2003, President Bush signed the Medicare Prescription Drug, Improvement and Modernization Act of 2003 (Medicare Modernization Act) (Public Law 108–173). Section 1121 of this legislation gives the Secretary of HHS (the Secretary) the authority to implement a system in the United States for the importation of Canadian prescription drugs. However, the Secretary is permitted to implement such a system only if he is first able to certify to the Congress that it would be safe and cost-effective. Section 1122 of this legislation also directs the Secretary to conduct a study that examines whether and under what circumstances drug importation could be conducted safely, and what its likely consequences would be for the health, medical costs, and development of new medicines for American patients. To comply with the Congressional mandate, the Secretary has formed the Task Force on Drug Importation to advise and assist HHS in this study. The Task Force plans to consider several issues in the study, including several that Congress specifically asked HHS to consider. To assist in this effort we are asking for public comment on the following issues, which the Conference Report to the Medicare Modernization Act directs us to address in the study:

- *Impact of Unapproved Drugs*: What is the scope and volume of unapproved drugs entering the United States through mail shipments and at border crossings? What are the safety concerns posed by these products? What evidence exists to substantiate these concerns? Can they be quantified? What is the scope and