Directorate, 1601 Lind Avenue, SW., Renton, Washington; or at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC.

Effective Date

(h) This amendment becomes effective on March 12, 2003.

Issued in Renton, Washington, on January 29, 2003.

Ali Bahrami,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 03–2496 Filed 2–4–03; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. 2003–CE–07–AD; Amendment 39–13043; AD 2003–03–18]

RIN 2120–AA64

Airworthiness Directives; Raytheon Aircraft Company Beech Models 1900, 1900C, and 1900D Airplanes

AGENCY: Federal Aviation Administration, DOT.

ACTION: Final rule; request for comments.

SUMMARY: This amendment adopts a new airworthiness directive (AD) that applies to all Raytheon Aircraft Company (Raytheon) Beech Models 1900, 1900C, and 1900D airplanes. This AD requires you to perform control column sweep and stop bolt inspections to verify full elevator travel to the primary up and down stops and that the stop bolt length is not excessive, re-rig the elevator control system if the airplane does not pass the control column sweep and stop inspections, and do a more detailed inspection at a later time if the airplane does pass the inspection. This AD also requires you to report the results of certain inspections. This AD is the result of recent ground testing and a review of the rigging procedures of a Raytheon Beech Model 1900D airplane, which reveals that the elevator control system could be mis-rigged to restrict elevator travel if current maintenance procedures are not properly followed. In these instances, it may appear to the crew that they have full elevator control column movement. However, the elevator may not have full travel. Such restricted travel may remain undetected until the airplane is operated in a loading condition that requires full elevator authority to control the pitch. The actions specified by this AD are intended to detect and correct any mis-rigged elevator control system, which could lead to insufficient elevator control authority and loss of control of the airplane.

DATES: The AD becomes effective February 5, 2003, to all affected persons who did not receive emergency AD 2003–03–18, issued January 27, 2003. Emergency AD 2003–03–18 contained the requirements of this amendment and became effective immediately upon receipt and required the actions 4 days after issuance (January 31, 2003).

The Federal Aviation Administration (FAA) must receive any comments on this rule on or before March 7, 2003.

ADDRESSES: Submit comments to FAA, Central Region, Office of the Regional Counsel, Attention: Rules Docket No. 2003–CE–07–AD, 901 Locust, Room 506, Kansas City, Missouri 64106. You may view any comments at this location between 8 a.m. and 4 p.m., Monday through Friday, except Federal holidays. You may also send comments electronically to the following address: *9-ACE-7-Docket@faa.gov.* Comments sent electronically must contain ''Docket No. 2003–CE–07–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 text.

You may view information related to this AD at FAA, Central Region, Office of the Regional Counsel, Attention: Rules Docket No. 2003–CE–07–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: Paul DeVore, Aerospace Engineer, FAA, Wichita Aircraft Certification Office, 1801 Airport Road, Room 100, Mid-Continent Airport, Wichita, Kansas 67209; telephone: (316) 946–4142; facsimile: (316) 946–4407.

SUPPLEMENTARY INFORMATION:

Discussion

What Has Happened so Far?

Recent ground testing and a review of the rigging procedures of a Raytheon Beech Model 1900D airplane reveals that the elevator control system could be mis-rigged to restrict elevator travel if current maintenance procedures are not properly followed. In these instances, it may appear to the crew that they have full elevator control column movement. However, the elevator may not have full travel. Such restricted travel may remain undetected until the airplane is operated in a loading condition that requires full elevator authority to control the pitch.

The Raytheon Beech Models 1900 and 1900C airplanes incorporate the same elevator control system design and are affected by this condition.

In certain loading conditions, a mis-rigged elevator control system, if not detected and corrected, could lead to insufficient elevator control authority and loss of control of the airplane.

Raytheon has not issued service information regarding this subject. Rigging procedures are included in the applicable Raytheon 1900/1900C or 1900D maintenance manual.

On January 27, 2003, FAA issued emergency AD 2003–03–18 to require you to:

—Perform control column sweep and stop bolt inspections to verify full elevator travel to the primary up and down stops and to verify that the stop bolt length is not excessive;

—If the airplane does not pass the initial control column sweep and stop bolt inspections, re-rig and/or do a more detailed inspection of the elevator control system;

—If the airplane does pass the initial control column sweep and stop bolt length inspections, do a more detailed inspection within 100 hours time-in-service (TIS); and

—Report the results of the initial inspection and the 100-hour TIS inspection (if applicable).

Why Is it Important to Publish This AD?

The FAA found that immediate corrective action was required, that notice and opportunity for prior public comment were impracticable and contrary to the public interest, and that good cause existed to make the AD effective immediately by individual letters issued on January 27, 2003, to all known U.S. operators of Raytheon Beech Models 1900, 1900C, and 1900D airplanes. These conditions still exist, and the AD is published in the **Federal Register** as an amendment to section 39.13 of the Federal Aviation Regulations (14 CFR 39.13) to make it effective to all persons.

Comments Invited

How Do I Comment on This AD?

Although this action is in the form of a final rule and was not preceded by notice and opportunity for public comment, FAA invites your comments on the rule. You may submit whatever written data, views, or arguments you choose. You need to include the rule's docket number and submit your comments to the address specified under the caption **ADDRESSES.** We will consider all comments received on or before the closing date specified above.

We may amend this rule in light of comments received. Factual information that supports your ideas and suggestions is extremely helpful in evaluating the effectiveness of the AD action and determining whether we need to take additional rulemaking action.

Are There any Specific Portions of the AD I Should pay Attention to?

We specifically invite comments on the overall regulatory, economic, environmental, and energy aspects of the rule that might suggest a need to modify the rule. You may view all comments we receive before and after the closing date of the rule in the Rules Docket. We will file a report in the Rules Docket that summarizes each FAA contact with the public that concerns the substantive parts of this AD.

How Can I Be Sure FAA Receives my Comment?

If you want us to acknowledge the receipt of your written comments, you must include a self-addressed, stamped postcard. On the postcard, write ''Comments to Docket No. 2003–CE–07–AD.'' We will date stamp and mail the postcard back to you.

Regulatory Impact

Does This AD Impact Various Entities?

These regulations 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, FAA has determined that this final rule does not have federalism implications under Executive Order 13132.

Does This AD Involve a Significant Rule or Regulatory Action?

We have determined that this regulation is an emergency regulation that must be issued immediately to correct an unsafe condition in aircraft, and is not a significant regulatory action under Executive Order 12866. It has been determined further that this action involves an emergency regulation under DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979). If it is determined that this emergency regulation otherwise would be significant under DOT Regulatory Policies and Procedures, a final regulatory evaluation will be prepared and placed in the Rules Docket (otherwise, an evaluation is not required). A copy of it, if filed, may be obtained from the Rules Docket.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, 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 airworthiness directive (AD) to read as follows:

2003–03–18 Raytheon Aircraft Company: Amendment 39–13043; Docket No. 2003–CE–07–AD.

(a) *What airplanes are affected by this AD?* This AD applies to Beech Models 1900, 1900C, and 1900D airplanes, all serial numbers, that are certificated in any category.

(b) *Who must comply with this AD?* Anyone who operates any of the airplanes identified in paragraph (a) of this AD must comply with this AD.

(c) *What problem does this AD address?* The actions specified by this AD are intended to detect and correct any mis-rigged elevator control system, which could lead to insufficient elevator control authority and loss of control of the airplane.

(d) *What must I do to address this problem?* To address this problem, you must accomplish the following actions:

Actions	Compliance	Procedures
(1) Perform a control column sweep inspection to verify full elevator travel to the primary up and down stops. Accomplish this inspection using the following procedures: (i) Remove the aft fairing from the vertical stabilizer to gain visual access to surface stop bolts on the elevator control horn support using the applicable Raytheon Aircraft Company 1900/1900C or 1900D maintenance manual. (ii) Have another appropriately-rated maintenance person perform a full pitch-down to full pitch-up control column sweep. Visually ensure that the elevator control horns contact the surface stop bolts for both the full pitch-down and full pitch-up control column positions. (iii) Measure the length of both elevator down stop bolts from the crown of the bolt head to the face of the elevator lower stop bolt support. (A) If the dimension of each stop bolt is equal to or less than 1.00 inch, the bolts are acceptable for the purposes of this inspection. (B) If the dimension of either stop bolt is greater than 1.00 inch, accomplish (prior to further flight) the travel board inspection procedures as specified in paragraph (d)(3)(i) of this AD. If it passes the procedure specified in paragraph (d)(3)(i), the bolt is acceptable even though it exceeds 1.00 inch.	Initially inspect within 4 days after February 5, 2003 (the effective date of this AD), except that this action was required no later than January 31, 2003, for those who received emergency AD 2003–03–18. If necessary, accomplish the travel board inspection prior to further flight after the inspection required by paragraph (d)(1)(iii)(B) of this AC.	In accordance with the applicable Raytheon Aircraft Company 1900/1900C or 1900D maintenance manual.

Actions	Compliance	Procedures
(2) If the airplane does not pass the control column sweep inspection or bolt length requirements of paragraphs (d)(1)(ii), (d)(1)(iii), or (d)(3)(i) of this AD. (i) Accomplish the elevator control system rigging procedure in accordance with the applicable Raytheon Aircraft Company 1900/1900C or 1900D maintenance manual. Do not reinstall the aft fairing because access to the surface stop bolts is still necessary; (ii) Perform a control column sweep inspection by accomplishing the actions in paragraphs (d)(1)(ii), (d)(3)(i), and (d)(3)(ii) of this AD. These actions are also referenced in paragraph (d)(4) of this AD; and (iii) When the airplane passes the requirements of the above inspection, replace the aft fairing.	Prior to further flight after the applicable inspection required by paragraphs (d)(1), (d)(3), and (d)(4) of this AD.	In accordance with the applicable Raytheon Aircraft Company 1900/1900C or 1900D maintenance manual.
(3) If the airplane passes the inspection of paragraph (d)(1) of this AD, replace (prior to further flight) the aft fairing; and accomplish (d)(3)(i) of this AD within 100 hours TIS and any necessary actions prior to further flight after that as specified in paragraphs (d)(3)(ii) of this AD: (i) Utilizing elevator travel boards, inspect to ensure that the surface stops on the control horn support allow the following: (A) Up elevator travel of 20 degrees, +1 degree −0 degree; and (B) Down elevator travel of 14 degrees, +1 degree −0 degree. (ii) If the airplane does not pass the inspection required by paragraph (d)(3)(i) of this AD, accomplish (prior to further flight) the elevator control system rigging procedures as specified in paragraphs (d)(2)(i), (d)(2)(ii), and (d)(3)(i) of this AD.	Replace the aft fairing prior to further flight after the applicable inspection required by paragraphs (d)(1), (d)(3), and (d)(4) of this AD. Unless accomplished per paragraph (d)(1)(iii)(B) of this AD, accomplish the travel board inspection within 100 hours TIS after the initial inspection required by paragraph (d)(1) of this AD. Accomplish any necessary re-rigging prior to further flight after the inspection required by this AD.	In accordance with the applicable Raytheon Aircraft Company 1900/1900C or 1900D maintenance manual.
(4) Perform a control column sweep inspection by accomplishing the actions of paragraphs (d)(1)(i), (d)(1)(ii), (d)(2), (d)(3)(i), and (d)(3)(ii) of this AD. If the aft fairing is already removed, the actions of paragraphs (d)(1)(i) are not required.	Prior to further flight after each time the elevator control system is re-rigged. Examples of items that require re-rigging include, but are not limited to, changing the tension on the elevator primary control cables and replacing the elevator control system components such as cables, pulleys, push-pull tubes, and bellcranks.	In accordance with the applicable Raytheon Aircraft Company 1900/1900C or 1900D maintenance manual.
(5) Report the results of the initial inspection required by paragraph (d)(1) of this AD and the initial travel board inspection required by paragraph (d)(3)(i) of this AD. Break out the results of the control column sweep inspection, bolt length measurement, and the travel board inspection. Along with the results, include the airplane model, serial number, and the number of hours TIS at the time of inspection. Label the document ''Inspection results of AD 2003–03–18''.	Within 10 days after the initial inspections required by paragraph (d)(1) or (d)(3)(i) of this AD.	Submit the results to the Raytheon Aircraft Company, 9709 E. Central, Wichita Kansas 67201–0085; telephone: (800) 429–5372 or (316) 676–3140; facsimile; (316) 676–8051; e-mail: *tom_peay@raytheon.com.*

(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, Wichita 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.

Note: 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 Paul DeVore, Aerospace Engineer, FAA, Wichita Aircraft Certification Office, 1801 Airport Road, Room 100, Mid-Continent Airport, Wichita, Kansas 67209; telephone: (316) 946–4142; 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 provided the following is adhered to:

(1) When re-rigging is required, operate the airplane with crew only and no cargo.

(2) All special flight permits must be coordinated with the Wichita ACO at the address, phone number, and facsimile number specified in paragraph (f) of this AD.

(h) *Where can I view information related to this AD?* You may view information related to this AD at FAA, Central Region, Office of the Regional Counsel, 901 Locust, Room 506, Kansas City, Missouri 64106.

(i) *When does this AD become effective?* This AD becomes effective February 5, 2003, to all affected persons who did not receive emergency AD 2003–03–18, issued January 27, 2003. Emergency AD 2003–03–18 contained the requirements of this amendment and became effective immediately upon receipt and required the actions no later than January 31, 2003 (4 days after distribution).

Issued in Kansas City, Missouri, on January 30, 2003.

Michael Gallagher,

Manager, Small Airplane Directorate, Aircraft Certification Service.

[FR Doc. 03–2784 Filed 2–4–03; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 866

[Docket No. 97P–0313]

Medical Devices; Reclassification and Codification of Fully Automated Short-Term Incubation Cycle Antimicrobial Susceptibility Devices From Class III to Class II

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is reclassifying the fully automated short-term incubation cycle antimicrobial susceptibility device for use in determining in vitro susceptibility of bacterial pathogens isolated from clinical specimens from class III to class II (special controls). The special control that will apply to this device is a guidance document entitled ''Class II Special Controls Guidance Document: Antimicrobial Susceptibility Test (AST) Systems; Guidance for Industry and FDA.'' The agency is also announcing that it has issued an order in the form of a letter to BioMerieux Vitek, Inc., reclassifying the device. The agency is classifying this device into class II because special controls, in addition to the general controls, will provide reasonable assurance of the safety and effectiveness of the device and there is sufficient information to establish special controls.

DATES: This rule is effective May 6, 2003.

FOR FURTHER INFORMATION CONTACT: Freddie M. Poole, Center for Devices and Radiological Health (HFZ–440), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–2096.

SUPPLEMENTARY INFORMATION:

I. Background (Regulatory Authorities)

The Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 301 *et seq.*), as amended by the Medical Device Amendments of 1976 (the 1976 amendments) (Public Law 94–295), the Safe Medical Devices Act of 1990 (the SMDA) (Public Law 101–629), and the Food and Drug Administration Modernization Act of 1997 (the FDAMA) (Public Law 105–115), established a comprehensive system for the regulation of medical devices intended for human use. Section 513 of the act (21 U.S.C. 360c) established three categories (classes) of devices, depending on the regulatory controls needed to provide reasonable assurance of their safety and effectiveness. The three categories of devices are class I (general controls), class II (special controls), and class III (premarket approval).

Under the 1976 amendments, class II devices were defined as devices for which there is insufficient information to show that general controls themselves will assure safety and effectiveness, but for which there is sufficient information to establish performance standards to provide such assurance. The SMDA broadened the definition of class II devices to mean devices for which there is insufficient information to show that general controls themselves will assure safety and effectiveness, but for which there is sufficient information to establish special controls to provide such assurance, including performance standards, postmarket surveillance, patient registries, development and dissemination of guidance, recommendations, and any other appropriate actions the agency deems necessary (section 513(a)(1)(B) of the act).

Under section 513 of the act, devices that were in commercial distribution before May 28, 1976 (the date of enactment of the 1976 amendments), generally referred to as preamendments devices, are classified after FDA has: (1) Received a recommendation from a device classification panel (an FDA advisory committee); (2) published the panel's recommendation for comment, along with a proposed regulation classifying the device; and (3) published a final regulation classifying the device. FDA has classified most preamendments devices under these procedures.

Devices that were not in commercial distribution prior to May 28, 1976, generally referred to as postamendments devices, are classified automatically by statute (section 513(f) of the act) into class III without any FDA rulemaking process. Those devices remain in class III and require premarket approval, unless and until: (1) The device is reclassified into class I or II; (2) FDA issues an order classifying the device into class I or II in accordance with new section 513(f)(2) of the act, as amended by the FDAMA; or (3) FDA issues an order finding the device to be substantially equivalent, under section 513(i) of the act, to a predicate device that does not require premarket approval. The agency determines whether new devices are substantially equivalent to previously offered devices by means of premarket notification procedures in section 510(k) of the act (21 U.S.C. 360(k)) and part 807 of the regulations (21 CFR part 807).

A preamendments device that has been classified into class III may be marketed, by means of premarket notification procedures, without submission of a premarket approval application (PMA) until FDA issues a final regulation under section 515(b) of the act (21 U.S.C. 360e(b)) requiring premarket approval.

Reclassification of postamendments devices is governed by section 513(f)(3) of the act, formerly section 513(f)(2) of the act. This section provides that FDA may initiate the reclassification of a device classified into class III under section 513(f)(1) of the act, or the manufacturer or importer of a device may petition the Secretary of Health and Human Services (the Secretary) for the issuance of an order classifying the device in class I or class II. FDA's regulations in § 860.134 (21 CFR 860.134) set forth the procedures for the filing and review of a petition for reclassification of such class III devices. In order to change the classification of the device, it is necessary that the proposed new class have sufficient regulatory controls to provide reasonable assurance of the safety and effectiveness of the device for its intended use.

The FDAMA added a new section 513(f)(2) to the act which addresses classification of postamendments devices. New section 513(f)(2) of the act