

PART 78—BRUCELLOSIS

■ Accordingly, we are adopting as a final rule, without change, the interim rule that amended 9 CFR part 78 and that was published at 71 FR 2991–2993 on January 19, 2006.

Done in Washington, DC, this 23rd day of June 2006.

Kevin Shea,  
*Acting Administrator, Animal and Plant Health Inspection Service.*

[FR Doc. 06–5800 Filed 6–28–06; 8:45 am]

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DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2006–23578; Directorate Identifier 2006–CE–01–AD; Amendment 39–14668; AD 2006–13–15]

RIN 2120–AA64

Airworthiness Directives; Mitsubishi Heavy Industries MU–2B Series Airplanes

AGENCY: Federal Aviation Administration (FAA), Department of Transportation (DOT).

ACTION: Final rule.

**SUMMARY:** We are adopting a new airworthiness directive (AD) for all Mitsubishi Heavy Industries MU–2B series airplanes. This AD requires you to do the following: Remove and visually inspect the wing attach barrel nuts, bolts, and retainers for cracks, corrosion, and fractures; replace any cracked, corroded, or fractured parts; inspect reusable wing attach barrel nuts and bolts for deformation and irregularities in the threads; check the minimum breakaway torque of reused wing attach barrel nuts; replace any deformed or irregular parts; and install new or reusable parts and torque to the correct value. This AD results from a recent safety evaluation that used a data-driven approach to evaluate the design, operation, and maintenance of the MU–2B series airplanes in order to determine

their safety and define what steps, if any, are necessary for their safe operation. Part of that evaluation was the identification of unsafe conditions that exist or could develop on the affected type design airplanes. We are issuing this AD to detect and correct cracks, corrosion, fractures, and incorrect torque values in the wing attach barrel nuts, which could result in failure of the wing barrel nuts and/or associated wing attachment hardware. This failure could lead to in-flight separation of the outer wing from the center wing section and result in loss of controlled flight.

**DATES:** This AD becomes effective on August 11, 2006.

As of August 11, 2006, the Director of the Federal Register approved the incorporation by reference of certain publications listed in the regulation.

**ADDRESSES:** For service information identified in this AD, contact Mitsubishi Heavy Industries America, Inc., 4951 Airport Parkway, Suite 800, Addison, Texas 95001; telephone: (972) 934–5480; fax: (972) 934–5488, or Turbine Aircraft Services, Inc., 4550 Jimmy Doolittle Drive, Addison, Texas 75001; telephone: (972) 248–3108; facsimile: (972) 248–3321.

To view the AD docket, go to the Docket Management Facility, U.S. Department of Transportation, 400 Seventh Street, SW., Nassif Building, Room PL–401, Washington, DC 20590–0001, or on the Internet at <http://dms.dot.gov>. The docket number is FAA–2006–23578; Directorate Identifier 2006–CE–01–AD.

**FOR FURTHER INFORMATION CONTACT:** Andrew McAnaul, Aerospace Engineer, ASW–150 (c/o MIDO–43), 10100 Reunion Place, Suite 650, San Antonio, Texas 78216; telephone: (210) 308–3365; facsimile: (210) 308–3370.

**SUPPLEMENTARY INFORMATION:**

**Discussion**

On April 18, 2006, 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 all Mitsubishi Heavy Industries MU–2B series airplanes. This proposal was published in the **Federal Register** as a

supplemental notice of proposed rulemaking (NPRM) on April 24, 2006 (71 FR 20915). We issued the supplemental NPRM to incorporate revised manufacturer service information that adds airplanes to the applicability, revises the serial numbers of the affected airplanes, and updates the manufacturer’s contact information. The supplemental NPRM proposed to require you to do the following:

- Remove and visually inspect the wing attach barrel nuts, bolts, and retainers for cracks, corrosion, and fractures;
- Replace any cracked, corroded, or fractured wing attach barrel nuts, bolts, and retainers with new parts;
- Inspect reusable wing attach barrel nuts and bolts for deformation and irregularities in the threads;
- Check the minimum breakaway torque of reused wing attach barrel nuts;
- Replace any deformed or irregular wing attach barrel nuts or bolts with new parts; and
- Install new or reusable parts and torque to the correct value.

**Comments**

We provided the public the opportunity to participate in developing this AD. We received no comments on the proposal or on the determination of the cost to the public.

**Conclusion**

We have carefully reviewed the available data and determined that air safety and the public interest require adopting the AD as proposed except for minor editorial corrections. We have determined that these minor corrections:

- are consistent with 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.

**Costs of Compliance**

We estimate that this AD affects 399 airplanes in the U.S. registry.

We estimate the following costs to do the inspection:

Labor cost	Parts cost	Total cost for each airplane	Total cost on U.S. operators
12 work-hours × \$80 an hour = \$960 .....	Not applicable ....	\$960	\$960 × 399 = \$383,040

We estimate the following costs to do any necessary replacements that will be

required based on the results of the inspection. We have no way of

determining the number of airplanes that may need this replacement:

Labor cost	Parts cost	Total cost for each airplane to replace all 8 wing attach barrel nuts
No additional labor cost. Any necessary replacements will be done at the time of inspection.	\$60 for each barrel nut. There are 8 barrel nuts on each airplane. Possible total cost of: $\$60 \times 8 = \$480$ .	\$480

The FAA is committed to updating the aviation community of expected costs associated with the MU-2B series airplane safety evaluation conducted in 2005. As a result of that commitment, the accumulating expected costs of all ADs related to the MU-2B series airplane safety evaluation may be found in the Final Report section at the following Web site: [http://www.faa.gov/aircraft/air\\_cert/design\\_approvals/small\\_airplanes/cos/mu2\\_foia\\_reading\\_library/](http://www.faa.gov/aircraft/air_cert/design_approvals/small_airplanes/cos/mu2_foia_reading_library/).

#### Authority for This Rulemaking

Title 49 of the United States Code specifies the FAA's authority to issue rules on aviation safety. Subtitle I, Section 106 describes the authority of the FAA Administrator. Subtitle VII, Aviation Programs, describes in more detail the scope of the agency's authority.

We are issuing this rulemaking under the authority described in Subtitle VII, Part A, Subpart III, Section 44701, "General requirements." Under that section, Congress charges the FAA with promoting safe flight of civil aircraft in air commerce by prescribing regulations for practices, methods, and procedures the Administrator finds necessary for safety in air commerce. This regulation is within the scope of that authority because it addresses an unsafe condition that is likely to exist or develop on products identified in this AD.

#### Regulatory Findings

We have determined that this AD will not have federalism implications under Executive Order 13132. This AD 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.

For the reasons discussed above, I certify that this 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 AD (and other information as included in the Regulatory Evaluation) 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 "Docket No. FAA-2006-23578; Directorate Identifier 2006-CE-01-AD" in your request.

#### 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 the following new AD:

**2006-13-15 Mitsubishi Heavy Industries, Ltd.:** Amendment 39-14668; Docket No. FAA-2006-23578; Directorate Identifier 2006-CE-01-AD.

#### Effective Date

(a) This AD becomes effective on August 11, 2006.

#### Affected ADs

(b) None.

#### Applicability

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

Model	Serial Nos.
MU-2B-10 .....	101 through 120 (Except 102, 114, 115, and 118).
MU-2B-15 .....	114, 115, and 118.
MU-2B-20 .....	102, and 121 through 238.
MU-2B-25 .....	239 through 318 (Except 313), and 313SA.
MU-2B-26 .....	319 through 347 (Except 321), and 349SA.
MU-2B-26A .....	321SA, 348SA, and 350SA through 394SA (Except 365SA).
MU-2B-30 .....	502 through 547.
MU-2B-35 .....	548 through 654 (Except 652), and 652SA.
MU-2B-36 .....	501, and 655 through 696 (Except 661).
MU-2B-36A .....	661SA, and 697SA through 730SA (Except 700SA).
MU-2B-40 .....	365SA.
MU-2B-60 .....	700SA.

#### Unsafe Condition

(d) This AD results from a recent safety evaluation that used a data-driven approach to evaluate the design, operation, and maintenance of the MU-2B series airplanes in order to determine their safety and define what steps, if any, are necessary for their safe operation. Part of that evaluation was to

identify unsafe conditions that exist or could develop on the affected type design airplanes. The actions specified in this AD are intended to detect and correct cracks, corrosion, fractures, and incorrect torque values in the wing attach barrel nuts, which could result in failure of the wing attach barrel nuts and/or associated wing

attachment hardware. This failure could lead to in-flight separation of the outer wing from the center wing section and result in loss of controlled flight.

#### Compliance

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

Actions	Compliance	Procedures
<p>(1) Remove each wing attach barrel nut, bolt, and retainer and do a visual inspection for cracks, corrosion, and fractures.</p> <p>(2) If any signs of cracks, corrosion, or fractures are found on any wing attach barrel nut during the inspection required in paragraph (e)(1) of this AD, replace that wing attach barrel nut, bolt, and retainer with new parts and install to the correct torque value.</p> <p>(3) If no signs of cracks, corrosion, or fractures are found during the inspection required in paragraph (e)(1) of this AD, you may reuse the wing attach barrel nuts and bolts if they have been inspected and are free of deformation and irregularities in the threads and meet the minimum breakaway torque requirement. Reinstall inspected parts to the correct torque value. If the wing attach barrel nuts and bolts are not free of deformation and irregularities in the threads or do not meet the minimum breakaway torque requirement, install new parts to the correct torque value.</p>	<p>Within the next 200 hours time-in-service or 12 months after August 11, 2006 (the effective detailed date of this AD), whichever occurs first, unless already done.</p> <p>Before further flight after the inspection required in paragraph (e)(1) of this AD, unless already done.</p> <p>Before further flight after the inspection required in paragraph (e)(1) of this AD, unless already done.</p>	<p>Follow Mitsubishi Heavy Industries, Ltd. MU-2 Service Bulletins referenced as JCAB T.C.: No. 241, dated July 14, 2004, and FAA T.C.: No. 103/57-004A, dated March 10, 2006, as applicable.</p> <p>Follow Mitsubishi Heavy Industries, Ltd. MU-2 Service Bulletins referenced as JCAB T.C.: No. 241, dated July 14, 2004, and FAA T.C.: No. 103/57-004A, dated March 10, 2006, as applicable, and the appropriate maintenance manual.</p> <p>Follow Mitsubishi Heavy Industries, Ltd. MU-2 Service Bulletins referenced as JCAB T.C.: No. 241, dated July 14, 2004, and FAA T.C.: No. 103/57-004A, dated March 10, 2006, as applicable, and the appropriate maintenance manual.</p>

#### Alternative Methods of Compliance (AMOCs)

(f) The Manager, Fort Worth Airplane Certification Office, FAA, ATTN: Andrew McAnaul, Aerospace Engineer, ASW-150 (c/o MIDO-43), 10100 Reunion Place, Suite 650, San Antonio, Texas 78216; telephone: (210) 308-3365; facsimile: (210) 308-3370, has the authority to approve alternative methods of compliance for this AD, if requested using the procedures found in 14 CFR 39.19.

#### Related Information

(g) Mitsubishi Heavy Industries, Ltd. MU-2 Service Bulletins JCAB T.C.: No. 241, dated July 14, 2004, and FAA T.C.: No. 103/57-004A, dated March 10, 2006, pertain to the subject of this AD.

#### Material Incorporated by Reference

(h) You must do the actions required by this AD following Mitsubishi Heavy Industries, Ltd. MU-2 Service Bulletins referenced as JCAB T.C.: No. 241, dated July 14, 2004, and FAA T.C.: No. 103/57-004A, pages 1 and 4 dated March 10, 2006, pages 2, 3, 5, 6, and 7 dated August 2, 2004. The Director of the Federal Register approved the incorporation by reference of this service bulletin in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. To get a copy of this service information, contact Mitsubishi Heavy Industries America, Inc., 4951 Airport Parkway, Suite 800, Addison, Texas 75001; telephone: (972) 934-5480; fax: (972) 934-5488, or Turbine Aircraft Services, Inc., 4550 Jimmy Doolittle Drive, Addison, Texas 75001; telephone: (972) 248-3108; facsimile: (972) 248-3321. To review copies of this service information, go to the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, go to: [http://www.archives.gov/federal\\_register/code\\_of\\_federal\\_regulations/ibr\\_locations.html](http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html) or call (202) 741-6030. To

view the AD docket, go to the Docket Management Facility; U.S. Department of Transportation, 400 Seventh Street, SW., Nassif Building, Room PL-401, Washington, DC 20590-001 or on the Internet at <http://dms.dot.gov>. The docket number is FAA-2006-23578; Directorate Identifier 2006-CE-01-AD.

Issued in Kansas City, Missouri, on June 19, 2006.

**James E. Jackson,**

*Acting Manager, Small Airplane Directorate, Aircraft Certification Service.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

#### 21 CFR Parts 1 and 11

[Docket No. 2005D-0356]

#### Guidance for Industry: Questions and Answers Regarding the Final Rule on Establishment and Maintenance of Records (Edition 3); Availability

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice of availability of guidance.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of a guidance entitled "Questions and Answers Regarding Establishment and Maintenance of Records (Edition 3)." The guidance responds to various questions raised about section 306 of the Public Health

Security and Bioterrorism Preparedness and Response Act of 2002 (the Bioterrorism Act) and the agency's implementing regulation, which requires the establishment and maintenance of records by persons who manufacture, process, pack, transport, distribute, receive, hold, or import food in the United States. Such records are to allow for the identification of the immediate previous sources and the immediate subsequent recipients of food. Persons covered by the regulation who employ 500 or more full-time equivalent employees (FTEs) had to be in compliance by December 9, 2005, and those who employ 11-499 FTEs had to be in compliance by June 9, 2006. Persons who employ 10 or fewer FTEs have until December 11, 2006 to be in compliance. "Person" includes an individual, partnership, corporation, and association.

**DATES:** Submit written or electronic comments on the agency guidance at any time.

**ADDRESSES:** You may submit comments, identified by Docket No. 2005D-0356, by any of the following methods:

#### Electronic Submissions

Submit electronic comments in the following ways:

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

#### Written Submissions

Submit written submissions in the following ways: