(2) Thereafter, at 400-hour TIS intervals, (plus or minus 10 hours TIS), perform repetitive inspections and component replacements, as specified in Part 3 of TCM MSB No. MSB94–4G, dated October 31, 2005, and replace components as necessary.

# Installation of TCM Service Kit, EQ6642 or EQ6642R

- (l) At the next engine overhaul or starter adapter replacement after the effective date of this AD, whichever occurs first, do the following:
- (1) Install TCM service kit, P/N EQ6642 (new) or EQ6642R (rebuilt). Use the service kit installation procedures specified in Part 5 of TCM MSB No. MSB94–4G, dated October 31, 2005.
- (2) Continue performing the inspections and component replacements specified in paragraphs (g), (h), (i), (j) and (k) of this AD.

# Prohibition of Special Flight Permits for Rough-Running Engines

(m) Special flight permits are prohibited for rough-running engines described in paragraph (g)(2) of this AD.

# Alternative Methods of Compliance (AMOCs)

(n) The Manager, Atlanta Aircraft Certification Office, FAA, 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

(o) None.

# Material Incorporated by Reference

(p) You must use TCM MSB No. MSB94-4G, dated October 31, 2005, to perform the actions required by this AD. 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. Contact Teledyne Continental Motors, Inc., PO Box 90, Mobile, AL 36601; telephone (251) 438-3411 for a copy of this service information. For the Teledyne Continental Motors Web site: Go to http://www.TCMLINK.com. You may review copies at the FAA, New England Region, Office of the Regional Counsel, 12 New England Executive Park, Burlington, MA; or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or go to: http:// www.archives.gov/federal-register/cfr/ibrlocations.html.

Issued in Burlington, Massachusetts, on February 26, 2007.

### Peter A. White,

Acting Manager, Engine and Propeller Directorate, Aircraft Certification Service. [FR Doc. E7–3832 Filed 3–9–07; 8:45 am]

BILLING CODE 4910-13-P

# **DEPARTMENT OF TRANSPORTATION**

#### **Federal Aviation Administration**

### 14 CFR Part 39

[Docket No. FAA-2006-24846; Directorate Identifier 2006-NE-21-AD; Amendment 39-14981; AD 2007-05-20]

### RIN 2120-AA64

# Airworthiness Directives; Microturbo Saphir 20 Models 095 Auxiliary Power Units (APU)

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

**ACTION:** Final rule.

**SUMMARY:** We are adopting a new airworthiness directive (AD) for the products listed above. This AD results from mandatory continuing airworthiness information (MCAI) issued by an aviation authority of another country to identify and correct an unsafe condition on an aviation product. The MCAI describes the unsafe condition as:

It has been reported that with the existing configuration, a certain failure could cause overspeed of the gas generator rotor resulting in uncontained burst of the turbine liberating high-energy fragments.

We are issuing this AD to require actions to correct the unsafe condition on these products.

**DATES:** This AD becomes effective April 16, 2007. The Director of the Federal Register approved the incorporation by reference of certain publications listed in this AD as of April 16, 2007.

ADDRESSES: You may examine the AD docket on the Internet at http://dms.dot.gov or in person at the Docket Management Facility, U.S. Department of Transportation, 400 Seventh Street, SW., Nassif Building, Room PL-401, Washington, DC.

# FOR FURTHER INFORMATION CONTACT:

Tracy Murphy, Aerospace Engineer, Boston Aircraft Certification Office, FAA, Engine and Propeller Directorate; 12 New England Executive Park, Burlington, MA 01803; telephone 781– 238–7172; fax 781–238–7170.

# SUPPLEMENTARY INFORMATION:

# Streamlined Issuance of AD

The FAA is implementing a new process for streamlining the issuance of ADs related to MCAI. This streamlined process will allow us to adopt MCAI safety requirements in a more efficient manner and will reduce safety risks to the public. This process continues to follow all FAA AD issuance processes to

meet legal, economic, Administrative Procedure Act, and **Federal Register** requirements. We also continue to meet our technical decision-making responsibilities to identify and correct unsafe conditions on U.S.-certificated products.

This AD references the MCAI and related service information that we considered in forming the engineering basis to correct the unsafe condition. The AD contains text copied from the MCAI and for this reason might not follow our plain language principles.

#### Discussion

We issued a notice of proposed rulemaking (NPRM) to amend 14 CFR part 39 to include an AD that would apply to the specified products. That NPRM was published in the **Federal Register** on December 18, 2006 (71 FR 75684). That NPRM proposed to correct an unsafe condition for the specified products. The MCAI states that:

It has been reported that with the existing configuration, a certain failure could cause overspeed of the gas generator rotor resulting in uncontained burst of the turbine liberating high-energy fragments. The occurrence that the high-energy fragments would be uncontained is considered a potentially dangerous situation which requires imperative corrective action. The purpose of the modification, which has been made mandatory, is to limit gas generator speed during an acceleration towards overspeed by installation of a modified Electronic Control Unit (ECU) and Drain Valve. In addition, the modification also renders the exhaust gas temperature (EGT) control function compliant with the certificated specifications. In operation, if EGT exceeds the certificated limit value, turbine blade shedding could occur.

### Comments

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

### Conclusion

We reviewed the available data and determined that air safety and the public interest require adopting the AD as proposed.

# Differences Between This AD and the MCAI or Service Information

We have reviewed the MCAI and related service information and, in general, agree with their substance. But we might have found it necessary to use different words from those in the MCAI to ensure the AD is clear for U.S. operators and is enforceable. In making these changes, we do not intend to differ substantively from the information

provided in the MCAI and related service information.

We might also have required different actions in this AD from those in the MCAI in order to follow our FAA policies. Any such differences are described in a separate paragraph of the AD, and take precedence over the actions copied from the MCAI.

### **Costs of Compliance**

Based on the service information, we estimate that this AD will affect about 3 products of U.S. registry. We also estimate that it will take about 10 workhours per product to comply with this AD. The average labor rate is \$80 per work-hour. Required parts will cost about \$1,000 per product. Where the service information lists required parts costs that are covered under warranty, we have assumed that there will be no charge for these costs. As we do not control warranty coverage for affected parties, some parties may incur costs higher than estimated here. Based on these figures, we estimate the cost of the AD on U.S. operators to be \$5,400 or \$1,800 per product.

### 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 rulemaking action.

### **Regulatory Findings**

We 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 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 regulatory evaluation of the estimated costs to comply with this AD and placed it in the AD docket.

### **Examining the AD Docket**

You may examine the AD docket on the Internet at http://dms.dot.gov; or in person at the Docket Management Facility between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains the NPRM, the regulatory evaluation, any comments received, and other information. The street address for the Docket Office (telephone (800) 647–5227) is in the ADDRESSES section. Comments will be available in the AD docket shortly after receipt.

# 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 FAA amends 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 adding the following new AD:

**2007–05–20** Microturbo: Amendment 39–14981. Docket No. FAA–2006–24846; Directorate Identifier 2006–NE–21–AD.

# Effective Date

(a) This airworthiness directive (AD) becomes effective April 16, 2007.

### Affected ADs

(b) None.

# Applicability

(c) This AD applies to Microturbo Saphir 20 Models 095 Auxiliary Power Units (APU) installed on, but not limited to, Eurocopter AS 332C, AS 332L, AS 332L1, and AS 332L2 helicopters.

#### Reason

(d) Direction Generale De l'Aviation Civile Airworthiness Directive F–2005–146, dated August 17, 2005, states:

It has been reported that with the existing configuration, a certain failure could cause overspeed of the gas generator rotor resulting in uncontained burst of the turbine liberating high-energy fragments. The occurrence that the high-energy fragments would be uncontained is considered a potentially dangerous situation which requires imperative corrective action. The purpose of the modification, which has been made mandatory, is to limit gas generator speed during an acceleration towards overspeed by installation of a modified Electronic Control Unit (ECU) and Drain Valve. In addition, the modification also renders the exhaust gas temperature (EGT) control function compliant with the certificated specifications. In operation, if EGT exceeds the certificated limit value, turbine blade shedding could occur.

### **Actions and Compliance**

- (e) Unless already done, do the following actions except as stated in paragraph (f) below.
- (1) Within 60 days after the effective date of this AD, replace the existing ECU and drain valve.
- (2) Follow paragraph 2. of Accomplishment Instructions of Microturbo Alert Service Bulletin (ASB) No. 095–49A11, Edition 2, dated October 7, 2005, to do these actions.

# **FAA AD Differences**

- (f) This AD differs from the mandatory continuing airworthiness information (MCAI) and/ or service information as follows:
- (1) The MCAI issued by an airworthiness authority of another country refers to Microturbo ASB No. 095–49A11, dated July 27, 2005.
- (2) This AD refers to Edition 2 of that ASB, dated October 7, 2005, which contains revised torque values.

# Other FAA AD Provisions

- (g) The following provisions also apply to this AD:
- (1) Alternative Methods of Compliance (AMOCs): The Manager, Boston Aircraft Certification Office, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19.
- (2) Airworthy Product: For any requirement in this AD to obtain corrective actions from a manufacturer or other source, use these actions if they are FAA-approved. Corrective actions are considered FAA-approved if they are approved by the State of Design Authority (or their delegated agent). You are required to assure the product is airworthy before it is returned to service.
  - (3) Reporting Requirements: None.

#### **Related Information**

- (h) France AD No. F–2005–146, dated August 17, 2005, also pertains to the subject of this AD.
- (i) Contact Tracy Murphy, Aerospace Engineer, Boston Aircraft Certification Office, FAA, Engine & Propeller Directorate, 12 New England Executive Park, Burlington, MA 01803; telephone (781) 238–7172; fax (781) 238–7170, for more information about this AD.

# Material Incorporated by Reference

- (j) You must use Microturbo Alert Service Bulletin No. 095–49A11, Edition 2, dated October 7, 2005 to do the actions required by this AD, unless the AD specifies otherwise.
- (1) The Director of the Federal Register approved the incorporation by reference of this service information under 5 U.S.C. 552(a) and 1 CFR part 51.
- (2) For service information identified in this AD, contact Microturbo SA; Technical Publications Department; 8 Chemin du pont de Rupe, BP 62089; 31019 Toulouse Cedex 2, France; telephone 33 0 5 61 37 55 00; fax 33 0 5 61 70 74 45.
- (3) You may review copies at the FAA, New England Region, Office of the Regional Counsel, 12 New England Executive Park, Burlington, MA; or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call (202) 741–6030, or go to: http://www.archives.gov/federal-register/cfr/ibr-locations.html.

Issued in Burlington, Massachusetts, on March 2, 2007.

### Robert J. Ganley,

Acting Manager, Engine and Propeller Directorate, Aircraft Certification Service. [FR Doc. E7–4140 Filed 3–9–07; 8:45 am]

BILLING CODE 4910-13-P

# DEPARTMENT OF HEALTH AND HUMAN SERVICES

# **Food and Drug Administration**

#### 21 CFR Part 1271

[Docket No. 2006N-0051]

RIN 0910-AF65

# Health Resources and Services Administration

#### 42 CFR Part 121

# Blood Vessels Recovered With Organs and Intended for Use in Organ Transplantation

**AGENCIES:** Food and Drug Administration, Health Resources and Services Administration, HHS.

**ACTION:** Final rule.

**SUMMARY:** The Food and Drug Administration (FDA) and the Health Resources and Services Administration (HRSA) are amending their regulations to include as part of an organ those blood vessels recovered with the organ that are intended for use in organ transplantation (HRSA regulation); and to exclude such blood vessels from the definition of human cells, tissues, or cellular or tissue-based products (HCT/ Ps) (FDA regulation). The purpose of this final rule is to amend the regulations so that blood vessels recovered with organs and intended for use in organ transplantation, and labeled as such, are governed by the regulations pertaining to organs. The regulation of other recovered blood vessels remains unchanged. We (HRSA and FDA) believe that this change will eliminate the burden resulting from an organ procurement organization's efforts to comply with both FDA and HRSA rules with respect to blood vessels (FDA jurisdiction) and organs (HRSA jurisdiction).

**DATES:** This rule is effective on April 11, 2007

# FOR FURTHER INFORMATION CONTACT:

For information regarding FDA's rule:
Denise Sánchez, Center for
Biologics Evaluation and Research
(HFM-17), Food and Drug
Administration, 1401 Rockville
Pike, suite 200N, Rockville, MD
20852-1448, 301-827-6210.

For information regarding HRSA's rule: Jim Burdick, Division of Transplantation, Healthcare Systems Bureau, Health Resources and Services Administration (HRSA), 5600 Fishers Lane, rm. 12C–06, Rockville, MD 20857, 301–443–7577.

#### SUPPLEMENTARY INFORMATION:

### I. Introduction

HRSA oversees transplantation of organs through the Organ Procurement and Transplantation Network (OPTN), which sets policies related to the procurement, transplantation, and allocation of human organs (see 42 CFR part 121). FDA currently regulates blood vessels. However, FDA does not regulate vascularized human organs (see 21 CFR 1270.3(j)(4) and 1271.3(d)(1)). FDA's jurisdiction over blood vessels intended for use in organ transplantation overlaps with HRSA's oversight of the OPTN.

There is a routine practice of recovering blood vessels intended for use in organ transplantation during organ procurement and using such blood vessels to connect donor organ and recipient vessels. Blood vessels intended for use in organ transplantation are recovered with human organs by Organ Procurement Organizations (OPOs) and stored for use at transplant centers. Both OPOs and transplant centers are already subject to HRSA oversight because of their organ procurement and transplantation activities. The application of both HRSA and FDA regulatory requirements to these facilities in relation to organs and blood vessels procured for use in organ transplantation is not supported by a need for such dual oversight. In order to avoid the duplication of efforts and reduce the burden on affected facilities, this final rule transfers from FDA to HRSA jurisdiction over blood vessels intended and labeled for use in organ transplantation. This final rule does not affect the regulation of blood vessels intended for transplantation that do not involve organ transplantation. Jurisdiction over such blood vessels remains with FDA.

Under this final rule, blood vessels labeled and intended solely for use in organ transplantation will be subject to HRSA requirements in 42 CFR part 121 and any enforceable OPTN policies established under 42 CFR part 121. To be regulated under HRSA requirements, such blood vessels intended for use in organ transplantation must be labeled "For use in organ transplantation only." However, they are not required to be attached to the organ(s), transplanted simultaneously with such organ(s) to the same recipient, or transplanted with the organ(s) from the same donor. For example, occasionally blood vessels not used immediately for the transplantation of a donated organ are stored for a number of days and subsequently used to modify the organ transplant in the same recipient or to accomplish transplantation in the