

# Proposed Rules

Federal Register

Vol. 81, No. 200

Monday, October 17, 2016

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.

## OFFICE OF SPECIAL COUNSEL

### 5 CFR Part 1800

#### Filing of Complaints of Prohibited Personnel Practices or other Prohibited Activities and Filing Disclosures of Information; Correction

**AGENCY:** U.S. Office of Special Counsel.

**ACTION:** Notice of proposed rulemaking and related information collection activity; Correction.

**SUMMARY:** This document corrects the Addresses section to a proposed rule published in the **Federal Register** as of September 2, 2016, regarding Filing of Complaints of Prohibited Personnel Practices or other Prohibited Activities and Filing Disclosures of Information. This correction addresses a typographical error in the email address used for submitting a comment pursuant to the notice.

**FOR FURTHER INFORMATION CONTACT:** Kenneth Hendricks, (202) 254-3600.

#### Correction

In proposed rule FR Doc. 2016-20527, on page 1 in the issue of September 2, 2016, make the following correction in the **ADDRESSES** section of the preamble. On page 1 on the last line of the second bullet, change the email address to the following: "*oira\_submission@omb.eop.gov*"

Dated: October 11, 2016.

**Bruce Gipe,**

*Chief Operating Officer.*

[FR Doc. 2016-24974 Filed 10-14-16; 8:45 am]

**BILLING CODE 7405-01-P**

## DEPARTMENT OF TRANSPORTATION

### Federal Aviation Administration

#### 14 CFR Parts 27 and 29

[Docket No.: FAA-2016-9275; Notice No. 16-07]

RIN 2120-AK91

#### Rotorcraft Pilot Compartment View

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

**ACTION:** Notice of proposed rulemaking (NPRM).

**SUMMARY:** The FAA is proposing to revise its rules for pilot compartment view to allow ground tests to demonstrate compliance for night operations. The current regulations require night flight testing to demonstrate compliance, which is not necessary in every case. The proposed rule would relieve the burden of performing a night flight test under certain conditions.

**DATES:** Send comments on or before November 16, 2016.

**ADDRESSES:** Send comments identified by docket number (Docket No.: FAA-2016-9275) using any of the following methods:

- *Federal eRulemaking Portal:* Go to <http://www.regulations.gov> and follow the online instructions for sending your comments electronically.
- *Mail:* Send comments to Docket Operations, M-30; U.S. Department of Transportation (DOT), 1200 New Jersey Avenue SE., Room W12-140, West Building Ground Floor, Washington, DC 20590-0001.
- *Hand Delivery or Courier:* Take comments to Docket Operations in Room W12-140 of the West Building Ground Floor at 1200 New Jersey Avenue SE., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.
- *Fax:* Fax comments to Docket Operations at 202-493-2251.

*Privacy:* In accordance with 5 U.S.C. 553(c), DOT solicits comments from the public to better inform its rulemaking process. DOT posts these comments, without edit, including any personal information the commenter provides, to [www.regulations.gov](http://www.regulations.gov), as described in the system of records notice (DOT/ALL-14 FDMS), which can be reviewed at [www.dot.gov/privacy](http://www.dot.gov/privacy).

*Docket:* Background documents or comments received may be read at <http://www.regulations.gov> at any time. Follow the online instructions for accessing the docket or go to the Docket Operations in Room W12-140 of the West Building Ground Floor at 1200 New Jersey Avenue SE., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. **FOR FURTHER INFORMATION CONTACT:** For technical questions concerning this action, contact Clark Davenport, Aviation Safety Engineer, Safety Management Group, Rotorcraft Directorate, FAA, 10101 Hillwood Pkwy, Fort Worth, TX 76177; telephone (817) 222-5151; email [Clark.Davenport@faa.gov](mailto:Clark.Davenport@faa.gov).

#### SUPPLEMENTARY INFORMATION:

##### Authority for This Rulemaking

The FAA's authority to issue rules on aviation safety is found in Title 49 of the United States Code. 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.

This rulemaking is issued under the authority described in Subtitle VII, Part A, Subpart III, Sections 44701 and 44704. Under that section, the FAA is charged with prescribing regulations promoting safe flight of civil aircraft in air commerce by prescribing minimum standards required in the interest of safety for the design and performance of aircraft. Under section 44704, the Administrator issues type certificates for aircraft, aircraft engines, propellers, and specified appliances when the Administrator finds the product is properly designed and manufactured, performs properly, and meets the regulations and minimum standards prescribed under section 44701(a). This regulation is within the scope of these authorities because it would promote safety by updating the existing minimum prescribed standards used during the type certification process to address an equivalent method of showing compliance.

#### I. Background

##### Statement of the Problem

The FAA's rules on airworthiness standards for the pilot compartment in rotorcraft and the requirements for each pilot's view from that compartment are located in parts 27 and 29 of title 14 of

the Code of Federal Regulations. Specifically, §§ 27.773(a) and 29.773(a) require that each pilot compartment must be free of glare and reflection that could interfere with the pilot's view. Sections 27.773(b) and 29.773(b) require a flight test to show compliance with paragraph (a) if certification for night operations is requested. While this requirement applies to all applicants for rotorcraft installations that may affect the pilot's ability to see outside the aircraft, the FAA has determined that a flight test may not be the only means available to show compliance for some modifications. As a result, the FAA has concluded that the current requirements in §§ 27.773 and 29.773 are imposing an unnecessary economic burden on applicants for certification for night operation.

## II. Discussion of the Proposal

Currently, §§ 27.773(b) and 29.773(b) require all applicants for certification for night operations to conduct a night flight test to show compliance with §§ 27.773(a) and 29.773(a). While manufacturers of newly type certificated rotorcraft will conduct night flight tests to comply with other rules and do not view this requirement as a significant additional burden, supplemental type certificate (STC) and field approval applicants have questioned the night flight test requirement for changes to the rotorcraft type design. STC and field approval applicants who add a piece of avionics equipment that minimally changes the lighting characteristics of the cockpit, for example a navigation or communication radio, have stated the requirement for a flight test is too costly compared to the scope of the modification.

As an alternative, the applicants have proposed performing a ground test simulating night conditions. In some cases, a ground test will meet the requirements of §§ 27.773(b) and 29.773(b) while significantly reducing the cost and burden to the applicant.

Upon review of the flight test requirements in §§ 27.773(b) and 29.773(b), based on the feedback received from numerous applicants, the FAA proposes to allow a ground test as an alternative to a night flight test in certain cases to show compliance for night operations. The FAA has determined that internal lighting modifications can be evaluated with a ground test, whereas external lighting modifications may require a flight test. For example, the applicant could demonstrate compliance by creating an environment where external light is blocked from entering the cockpit or where the rotorcraft is placed in a

darkened hangar, paint booth, or other environment. In such a situation, the FAA has concluded that a ground test should provide the same level of safety as the existing regulations. The conditions under which a ground test would be acceptable and an acceptable means of compliance for the ground test would be addressed in Advisory Circular (AC) 27-1B, Certification of Normal Category Rotorcraft and AC 29-2C, Certification of Transport Category Rotorcraft.<sup>1</sup>

Though the proposed rule would allow applicants to show compliance either by a flight test or ground test, it would not preclude the use of a night flight test. An applicant may conduct a flight test at night for other reasons and choose to use that flight to show compliance with §§ 27.773 or 29.773. The FAA finds that the proposed change to allow a ground test as an option would be relieving to industry.

## III. Regulatory Notices and Analyses

### A. Regulatory Evaluation

Changes to Federal regulations must undergo several economic analyses. First, Executive Order 12866 and Executive Order 13563 direct that each Federal agency shall propose or adopt a regulation only upon a reasoned determination that the benefits of the intended regulation justify its costs. Second, the Regulatory Flexibility Act of 1980 (Pub. L. 96-354) requires agencies to analyze the economic impact of regulatory changes on small entities. Third, the Trade Agreements Act (Pub. L. 96-39) prohibits agencies from setting standards that create unnecessary obstacles to the foreign commerce of the United States. In developing U.S. standards, the Trade Act requires agencies to consider international standards and, where appropriate, that they be the basis of U.S. standards. Fourth, the Unfunded Mandates Reform Act of 1995 (Pub. L. 104-4) requires agencies to prepare a written assessment of the costs, benefits, and other effects of proposed or final rules that include a Federal mandate likely to result in the expenditure by State, local, or tribal governments, in the aggregate, or by the private sector, of \$100 million or more annually (adjusted for inflation with base year of 1995). This portion of the preamble summarizes the FAA's analysis of the economic impacts of this proposed rule. Department of Transportation Order DOT 2100.5 prescribes policies and procedures for simplification, analysis,

<sup>1</sup> [http://rgl.faa.gov/Regulatory\\_and\\_Guidance\\_Library/](http://rgl.faa.gov/Regulatory_and_Guidance_Library/).

and review of regulations. If the expected cost impact is so minimal that a proposed or final rule does not warrant a full evaluation, this order permits that a statement to that effect and the basis for it to be included in the preamble if a full regulatory evaluation of the cost and benefits is not prepared. Such a determination has been made for this proposed rule. The reasoning for this determination follows. The current regulations require night flight testing to demonstrate compliance for night operations. The proposed rule provides a ground test as an alternative to a night flight test in certain cases, such as internal lighting modifications. The requirements for a ground test are less stringent than a night flight test. Thus, the proposed rule would relieve the industry from the burden of performing a night flight test under certain conditions. The expected outcome would be a minimal economic impact with positive net benefits, and a regulatory evaluation was not prepared. The FAA requests comments with supporting justification about the FAA determination of minimal economic impact. The FAA has, therefore, determined that this proposed rule is not a "significant regulatory action" as defined in section 3(f) of Executive Order 12866, and is not "significant" as defined in DOT's Regulatory Policies and Procedures.

### B. Regulatory Flexibility Determination

The Regulatory Flexibility Act of 1980 (Pub. L. 96-354) (RFA) establishes "as a principle of regulatory issuance that agencies shall endeavor, consistent with the objectives of the rule and of applicable statutes, to fit regulatory and informational requirements to the scale of the businesses, organizations, and governmental jurisdictions subject to regulation." To achieve this principle, agencies are required to solicit and consider flexible regulatory proposals and to explain the rationale for their actions to assure that such proposals are given serious consideration. The RFA covers a wide-range of small entities, including small businesses, not-for-profit organizations, and small governmental jurisdictions.

Agencies must perform a review to determine whether a rule will have a significant economic impact on a substantial number of small entities. If the agency determines that it will, the agency must prepare a regulatory flexibility analysis as described in the RFA. However, if an agency determines that a rule is not expected to have a significant economic impact on a substantial number of small entities, section 605(b) of the RFA provides that

the head of the agency may so certify and a regulatory flexibility analysis is not required. The certification must include a statement providing the factual basis for this determination, and the reasoning should be clear.

The proposed rule provides a ground test as an alternative to a night flight test in certain cases, such as internal lighting modifications. The requirements for a ground test are less stringent than a night flight test. Thus, the proposed rule would relieve the industry from the burden of performing a night flight test under certain conditions. The expected outcome would be a minimal economic impact with positive net benefits on any small entity affected by this rulemaking action.

If an agency determines that a rulemaking will not result in a significant economic impact on a substantial number of small entities, the head of the agency may so certify under section 605(b) of the RFA. Therefore, as provided in section 605(b), the head of the FAA certifies that this rulemaking will not result in a significant economic impact on a substantial number of small entities.

#### *C. International Trade Impact Assessment*

The Trade Agreements Act of 1979 (Pub. L. 96–39), as amended by the Uruguay Round Agreements Act (Pub. L. 103–465), prohibits Federal agencies from establishing standards or engaging in related activities that create unnecessary obstacles to the foreign commerce of the United States. Pursuant to these Acts, the establishment of standards is not considered an unnecessary obstacle to the foreign commerce of the United States, so long as the standard has a legitimate domestic objective, such as the protection of safety, and does not operate in a manner that excludes imports that meet this objective. The statute also requires consideration of international standards and, where appropriate, that they be the basis for U.S. standards. The FAA has assessed the potential effect of this proposed rule and determined that offers potential regulatory relief to both domestic and international entities—thus does not create unnecessary obstacles to the foreign commerce of the United States.

#### *D. Unfunded Mandates Assessment*

Title II of the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4) requires each Federal agency to prepare a written statement assessing the effects of any Federal mandate in a proposed or final agency rule that may result in an

expenditure of \$100 million or more (in 1995 dollars) in any one year by State, local, and tribal governments, in the aggregate, or by the private sector; such a mandate is deemed to be a “significant regulatory action.” The FAA currently uses an inflation-adjusted value of \$155 million in lieu of \$100 million. This proposed rule does not contain such a mandate; therefore, the requirements of Title II of the Act do not apply.

#### *E. Paperwork Reduction Act*

The Paperwork Reduction Act of 1995 (44 U.S.C. 3507(d)) requires that the FAA consider the impact of paperwork and other information collection burdens imposed on the public. The FAA has determined that there would be no new requirement for information collection associated with this proposed rule.

#### *F. International Compatibility*

In keeping with U.S. obligations under the Convention on International Civil Aviation, it is FAA policy to conform to International Civil Aviation Organization (ICAO) Standards and Recommended Practices to the maximum extent practicable. The FAA has determined that there are no ICAO Standards and Recommended Practices that correspond to these proposed regulations.

#### *G. Environmental Analysis*

FAA Order 1050.1F identifies FAA actions that are categorically excluded from preparation of an environmental assessment or environmental impact statement under the National Environmental Policy Act in the absence of extraordinary circumstances. The FAA has determined this rulemaking action qualifies for the categorical exclusion identified in paragraph 5–6.6 and involves no extraordinary circumstances.

### **IV. Executive Order Determinations**

#### *A. Executive Order 13132, Federalism*

The FAA has analyzed this proposed rule under the principles and criteria of Executive Order 13132, Federalism. The agency has determined that this action would not have a substantial direct effect on the States, or the relationship between the Federal Government and the States, or on the distribution of power and responsibilities among the various levels of government, and, therefore, would not have Federalism implications.

#### *B. Executive Order 13211, Regulations that Significantly Affect Energy Supply, Distribution, or Use*

The FAA analyzed this proposed rule under Executive Order 13211, Actions Concerning Regulations that Significantly Affect Energy Supply, Distribution, or Use (May 18, 2001). The agency has determined that it would not be a “significant energy action” under the executive order and would not be likely to have a significant adverse effect on the supply, distribution, or use of energy.

#### *C. Executive Order 13609, International Cooperation*

Executive Order 13609, Promoting International Regulatory Cooperation, promotes international regulatory cooperation to meet shared challenges involving health, safety, labor, security, environmental, and other issues and to reduce, eliminate, or prevent unnecessary differences in regulatory requirements. The FAA has analyzed this action under the policies and agency responsibilities of Executive Order 13609, and has determined that this action would have no effect on international regulatory cooperation.

### **V. Additional Information**

#### *A. Comments Invited*

The FAA invites interested persons to participate in this rulemaking by submitting written comments, data, or views. The agency also invites comments relating to the economic, environmental, energy, or federalism impacts that might result from adopting the proposals in this document. The most helpful comments reference a specific portion of the proposal, explain the reason for any recommended change, and include supporting data. To ensure the docket does not contain duplicate comments, commenters should send only one copy of written comments, or if comments are filed electronically, commenters should submit only one time.

The FAA will file in the docket all comments it receives, as well as a report summarizing each substantive public contact with FAA personnel concerning this proposed rulemaking. Before acting on this proposal, the FAA will consider all comments it receives on or before the closing date for comments. The FAA will consider comments filed after the comment period has closed if it is possible to do so without incurring expense or delay. The agency may change this proposal in light of the comments it receives.

### B. Availability of Rulemaking Documents

An electronic copy of rulemaking documents may be obtained from the Internet by—

1. Searching the Federal eRulemaking Portal (<http://www.regulations.gov>);
2. Visiting the FAA's Regulations and Policies Web page at [http://www.faa.gov/regulations\\_policies](http://www.faa.gov/regulations_policies) or
3. Accessing the Government Printing Office's Web page at <http://www.gpo.gov/fdsys/>.

Copies may also be obtained by sending a request to the Federal Aviation Administration, Office of Rulemaking, ARM-1, 800 Independence Avenue SW., Washington, DC 20591, or by calling (202) 267-9680. Commenters must identify the docket or notice number of this rulemaking.

All documents the FAA considered in developing this proposed rule, including economic analyses and technical reports, may be accessed from the Internet through the Federal eRulemaking Portal referenced in item (1) above.

### List of Subjects

#### 14 CFR Part 27

Aircraft, Aviation safety

#### 14 CFR Part 29

Aircraft, Aviation safety

### The Proposed Amendment

In consideration of the foregoing, the Federal Aviation Administration proposes to amend chapter I of title 14, Code of Federal Regulations as follows:

### PART 27—AIRWORTHINESS STANDARDS: NORMAL CATEGORY ROTORCRAFT

- 1. The authority citation for part 27 continues to read as follows:

**Authority:** 49 U.S.C. 106(g), 40113, 44701–44702, 44704.

- 2. Amend § 27.773 by revising paragraph (b) to read as follows:

#### § 27.773 Pilot Compartment View

\* \* \* \* \*

(b) If certification for night operation is requested, compliance with paragraph (a) of this section must be shown by ground or night flight tests.

### PART 29—AIRWORTHINESS STANDARDS: TRANSPORT CATEGORY ROTORCRAFT

- 1. The authority citation for part 29 continues to read as follows:

**Authority:** 49 U.S.C. 106(g), 40113, 44701–44702, 44704.

- 2. Amend § 29.773 by revising paragraph (a)(2) to read as follows:

#### § 29.773 Pilot Compartment View

(a) \* \* \*

(2) Each pilot compartment must be free of glare and reflection that could interfere with the pilot's view. If certification for night operation is requested, this must be shown by ground or night flight tests.

\* \* \* \* \*

Issued under authority provided by 49 U.S.C. 106(f), 44701(a), and 44703 in Washington, DC, on October 6, 2016.

**Dorenda D. Baker,**

*Director, Aircraft Certification Service.*

[FR Doc. 2016–24957 Filed 10–14–16; 8:45 am]

**BILLING CODE 4910–13–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

#### 21 CFR Part 807

[Docket No. FDA–2016–N–2491]

**RIN 0910–AG79**

### Electronic Submission of Labeling for Certain Home-Use Medical Devices

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

**ACTION:** Proposed rule.

**SUMMARY:** The Food and Drug Administration (FDA) is proposing to implement provisions of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) to require electronic submission of the device label and package insert of certain home-use devices when these devices are listed with FDA. FDA plans to make this device labeling available to the public through the Internet and would also provide search tools to facilitate locating information concerning a particular home-use device or a particular type of home-use device.

**DATES:** Submit either electronic or written comments on the proposed rule by January 17, 2017. In accordance with 21 CFR 10.40(c), in finalizing this rulemaking FDA will review and consider all comments submitted before the time for comment on this proposed regulation has expired.

Submit comments on information collection issues under the Paperwork Reduction Act of 1995 by November 16, 2016; see section VI, the “Information Collection Requirements” section of this document. See section VIII of this document for the proposed effective

date of a final rule based on this proposed rule.

**ADDRESSES:** You may submit comments as follows:

#### Electronic Submissions

Submit electronic comments in the following way:

- **Federal eRulemaking Portal:** <http://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <http://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <http://www.regulations.gov>.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see “Written/Paper Submissions” and “Instructions”).

#### Written/Paper Submissions

Submit written/paper submissions as follows:

- **Mail/Hand delivery/Courier (for written/paper submissions):** Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

- For written/paper comments submitted to the Division of Dockets Management, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in “Instructions.”

**Instructions:** All submissions received must include the Docket No. FDA–2016–N–2491 for “Electronic Submission of Labeling for Certain Home-Use Medical Devices.” Received comments will be placed in the docket and, except for those submitted as “Confidential Submissions,” publicly viewable at <http://www.regulations.gov> or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

- **Confidential Submissions—**To submit a comment with confidential information that you do not wish to be made publicly available, submit your