DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Parts 61, 63, and 65

[Docket No.: FAA–2009–0923; Special Aviation Regulation No. 100–2]

RIN 2120–AJ54


AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Direct final rule; request for comments.

SUMMARY: The FAA is replacing Special Aviation Regulation 100–1 (SFAR 100–1), with SFAR 100–2 that continues to allow Flight Standards District Offices (FSDOs) to accept expired flight instructor certificates and inspection authorizations for renewals from U.S. military and civilian personnel (U.S. personnel) who are assigned outside the United States in support of U.S. Armed Forces operations. SFAR 100–2 also continues to allow FSDOs to accept expired airman written test reports for certain practical tests from U.S. personnel who are assigned outside the United States in support of U.S. Armed Forces operations. This action is necessary to avoid penalizing U.S. personnel who are unable to meet the regulatory time limits of their flight instructor certificate, inspection authorization, or airman written test report because they are serving outside the United States in support of U.S. Armed Forces operations. The effect of this action is to give U.S. personnel who are assigned outside the United States in support of U.S. Armed Forces operations extra time to meet certain eligibility requirements in the current rules.

DATES: This final rule is effective June 20, 2010.

Submit comments on or before April 5, 2010.

ADDRESSES: You may send comments identified by Docket Number FAA–2009–0923 using any of the following methods:

• Federal eRulemaking Portal: Go to http://www.regulations.gov and follow the instructions for sending your comments electronically.

• Mail: Send comments to Docket Operations, U.S. Department of Transportation, 1200 New Jersey Avenue, SE., West Building Ground Floor, Room W12–140, Washington, DC 20590.

Fax: Fax comments to Docket Operations at 202–493–2251.

Hand Delivery: 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.

For more information on the rulemaking process, see the SUPPLEMENTARY INFORMATION section of this document.

Privacy: We will post all comments we receive, without change, to http://www.regulations.gov, including any personal information you provide. Using the search function of our docket Web site, anyone can find and read the comments received into any of our dockets, including the name of the individual sending the comment (or signing the comment for an association, business, labor union, etc.). You may review DOTE’s complete Privacy Act Statement in the Federal Register published on April 11, 2000 (65 FR 19477–78) or you may visit http://DocketsInfo.dot.gov.

Docket: To read background documents or comments received, go to http://www.regulations.gov at any time or 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.


For legal questions about this SFAR, contact: Michael Chase, AGC–240, Office of Chief Counsel, Regulations Division, Federal Aviation Administration, 800 Independence Avenue, SW., Washington, DC 20591; telephone (202) 267–3110; e-mail to michael.chase@faa.gov.
SUPPLEMENTARY INFORMATION:

The Direct Final Rule Procedure

Under 14 CFR 11.13 the FAA may issue a direct final rule with request for comments which is a rule issued in final (with an effective date) that invites public comment on the rule. The FAA is using the direct final rule procedure because this rule is not controversial, not expected to result in the receipt of an adverse comment, and a notice of proposed rulemaking (NPRM) is not necessary. SFAR 100–2 will continue to provide a limited amount of regulatory relief to certain U.S. personnel who are assigned outside the United States in support of U.S. Armed Forces operations. The FAA finds good cause for issuing this direct final rule as an exception to notice and comment rulemaking procedures. Unless a written adverse comment, or a written notice of intent to submit an adverse comment, is received within the comment period the regulation will become effective on June 20, 2010. In previous issuances of this SFAR, we have received no comments.

After the comment period closes, the FAA will publish a document in the Federal Register indicating that no adverse comments were received and confirming the date on which the SFAR will become effective. In the event that the FAA receives a timely adverse comment, or a written notice of intent to submit such a comment, the FAA will withdraw the direct final rule. An NPRM may be published with a new comment period.

Comments Invited

The FAA invites interested persons to participate in this rulemaking by submitting written comments, data, or views. We also invite 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, please send only one copy of written comments, or if you are filing comments electronically, please submit your comments only one time.

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

Background

Currently, the U.S. Armed Forces are engaged in activities that have resulted in overseas assignments for both military and civilian personnel. Because of the unexpected duration of these assignments, the FAA has determined that the flight instructor certificates, inspection authorizations, and airman written test reports held by some U.S. military and civilian personnel may expire before they return to the United States. If so, these individuals would have to reestablish their qualifications. We believe it is unfair to penalize these military and civilian personnel in this manner. Therefore, the FAA has determined that we should provide relief to these U.S. personnel who are unable to comply with some of the regulatory time constraints as a result of their assignment outside the United States in support of U.S. Armed Forces operations.

Previous Regulatory Action

After the terrorist attacks of September 11, 2001, many U.S. military and civilian personnel were assigned outside the United States in support of Operation Enduring Freedom. For this reason, we adopted SFAR 96 to provide relief to a narrow range of individuals in a narrow set of circumstances. (67 FR 30524, May 6, 2002). As a result of the continuing conflicts, the FAA superseded SFAR 96 with SFAR 100 (68 FR 36902, June 20, 2003) that applied to all military and civilian personnel assigned overseas in support of any and all U.S. Armed Forces operations. Additionally, the FAA further extended SFAR 100 with the issuance of SFAR 100–1 (70 FR 37946–37949, June 30, 2005) with an expiration date of June 20, 2010. Most of these U.S. military and civilian personnel are or will be located at military bases that are away from their normal training or work environment. There are no FAA aviation safety inspectors, designated examiners, or FAA facilities readily available in the areas where these U.S. military and civilian personnel are assigned.

SFAR 100–2 replaces SFAR 100–1. SFAR 100–2 is being issued without an expiration date and will remain in effect until further notice. This ensures these U.S. personnel assigned outside of the United States, who continue to preserve, protect and defend the American public, can obtain additional time for renewal of their flight instructor certificates, inspection authorizations, and airman written test reports.

Who is affected by this SFAR?

To be eligible for the relief provided by this SFAR, a person must meet two criteria—one related to the person’s assignment and the second related to the expiration of the person’s certificate, authorization, or test report.

Assignment. The person must have served in a civilian or military capacity outside the United States in support of U.S. Armed Forces operations some time on or after September 11, 2001. The term “United States” is defined under 14 CFR 1.1 and means “the States, the District of Columbia, Puerto Rico, and the possessions, including the territorial waters and the airspace of those areas.” “In support of U.S. Armed Forces operations” means an assignment that supports operations being conducted by our U.S. Army, Navy, Air Force, Marine Corps, and Coast Guard, including their regular and reserve components. Members serving without component status are also covered. A person seeking relief under this SFAR must be able to show that he or she had an assignment as described above by providing appropriate documentation that is described below.

Expiration. The person’s flight instructor certificate, inspection authorization, or airman written test report must have expired some time on or after September 11, 2001.

Renewing a Flight Instructor Certificate

The FAA regulations governing flight instructor certificates provide that they expire 24 calendar months after the month of issuance. The regulations also provide that a flight instructor may renew his or her certificate before it expires, but if it expires, the flight instructor must get a new certificate. If you are interested in the details of how to get or renew a flight instructor certificate, please see 14 CFR 61.197 and 61.199.

This SFAR changes the existing regulations for a certain class of individuals by allowing FAA Flight Standards District Offices to accept for a limited amount of time an expired flight instructor certificate for the purpose of renewing the certificate. Therefore, a person who can show the kind of evidence required by this SFAR (described below) can apply for renewal of a flight instructor certificate under 14 CFR 61.197. A person cannot exercise the privileges of a flight instructor certificate if it has expired, but the person can renew the flight instructor certificate under the limited circumstances described in this SFAR.
Airman Written Test Reports of Parts 61, 63, and 65

Generally, FAA regulations give airmen a limited amount of time to take a practical test after passing a knowledge test. For example, 14 CFR 61.39(a)(1) gives a person 24 calendar months. This SFAR permits an extension of the expiration date of the airman written test reports of parts 61, 63, and 65. The extension can be for up to six calendar months after returning to the United States or termination of SFAR 100–2, whichever date is earlier.

Renewing an Inspection Authorization

Under 14 CFR 65.92, an inspection authorization expires on March 31 of each year. Under 14 CFR 65.93, a person can renew an inspection authorization for an additional 12 calendar months by presenting certain evidence to the FAA during the month of March. This SFAR changes the existing regulations for individuals eligible under this SFAR by allowing FAA Flight Standards District Offices to accept for a limited amount of time an expired inspection authorization for the purpose of renewing the authorization. Therefore, a person who can show the kind of evidence required by this SFAR (described below) can apply for renewal of an inspection authorization under 14 CFR 65.93. If an inspection authorization expires, the person may not exercise the privileges of the authorization until that person renews the authorization. In this case, to meet the renewal requirements the person must attend a refresher course (see § 65.93(a)(4)) or submit to an oral test (see § 65.93(a)(5)) within 6 calendar months after returning to the United States from an assignment outside the United States in support of U.S. Armed Forces operations.

Evidence of an Assignment Outside the United States in Support of U.S. Armed Forces Operations

A person must show one of the following kinds of evidence to establish that the person is eligible for the relief provided by this SFAR:

1. An official U.S. Government notification of personnel action, or equivalent document, showing the person was a U.S. civilian on official duty for the U.S. Government and was assigned outside the United States in support of U.S. Armed Forces operations at some time between September 11, 2001 to termination of SFAR 100–2;

2. An official military order that shows the person was assigned to military duty outside the United States in support of U.S. Armed Forces operations at some time after September 11, 2001 to termination of SFAR 100–2; or

3. A letter from the person’s military commander or civilian supervisor providing the dates during which the person served outside the United States in support of U.S. Armed Forces operations at some time between September 11, 2001 to termination of SFAR 100–2.

International Compatibility

In keeping with U.S obligations under the Convention on International Civil Aviation, it is FAA policy to comply with 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 regulations.

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. We have determined that there is no new information collection requirement associated with this final rule.

Regulatory Evaluation, Regulatory Flexibility Determination, International Trade Impact Assessment, and Unfunded Mandates Assessment

Changes to Federal regulations must undergo several economic analyses. First, Executive Order 12866 directs each Federal agency to propose or adopt a regulation only after a reasoned determination that the benefits of the intended regulation justify its costs. Second, the Regulatory Flexibility Act of 1980 requires agencies to analyze the economic impact of regulatory changes on small entities. Third, the Trade Agreements Act (19 U.S.C. 2531–2533) prohibits agencies from setting standards that create unnecessary obstacles to the foreign commerce of the United States. In developing U.S. standards, this Trade Act also requires agencies to consider international standards and, where appropriate, use them as the basis of U.S. standards. And fourth, the Unfunded Mandates Reform Act of 1995 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).

The Department of Transportation Order DOT 2100.5 prescribes policies and procedures for simplification, analysis, and review of regulations. If the expected cost impact is so minimal that a proposal does not warrant a full evaluation, this order permits a statement to that effect and the basis for it to be included in the preamble and a full regulatory evaluation need not be prepared. Such a determination has been made for this rule. The reasoning for that determination follows.

The FAA has determined that the expected economic impact of this final rule is so minimal that it does not need a full regulatory evaluation. This action imposes no costs on operators subject to this rule; however, it does provide some unquantifiable benefits to some who would avoid the costs of having to reestablish expired credentials. The expected outcome will have a minimal impact with positive net benefits, and a regulatory evaluation was not prepared.

Regulatory Flexibility Act

The Regulatory Flexibility Act (RFA) of 1980, 5 U.S.C. 601–612, directs the FAA to fit regulatory requirements to the scale of the business, organizations, and governmental jurisdictions subject to the regulation. We are required to determine whether a proposed or final action will have a “significant economic impact on a substantial number of small entities” as defined in the Act. If we find that the action will have such impacts, we must do a “regulatory flexibility analysis.”

This SFAR replaces Special Federal Aviation Regulation 100–1 (SFAR 100–1), with SFAR 100–2 that continues to allow Flight Standards District Offices (FSDOs) to accept expired flight instructor certificates and inspection authorizations for renewals from U.S. military and civilian personnel (U.S. personnel) who are assigned outside the United States in support of U.S. Armed Forces operations. SFAR 100–2 also continues to allow FSDOs to accept expired airman written test reports for certain practical tests from U.S. personnel who are assigned outside the United States in support of U.S. Armed Forces operations. Its economic impact is minimal. Therefore, we certify that this action will not have a significant economic impact on a substantial number of small entities.

International Trade 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 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 notes that this rule uses international standards as its basis and does not create unnecessary obstacles to the foreign commerce of the United States.

Unfunded Mandates

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 $136.1 million in lieu of $100 million. This final rule does not contain such a mandate. Therefore, the requirements of Title II of the Act do not apply.

Executive Order 13132, Federalism

The FAA has analyzed this SFAR under the principles and criteria of Executive Order 13132, Federalism. We determined that this action will 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. Therefore, it does not have federalism implications.

Environmental Analysis

FAA Order 1050.1E 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 312f and involves no extraordinary circumstances.

Regulations That Significantly Affect Energy Supply, Distribution, or Use

The FAA has analyzed this SFAR under Executive Order 13211, Actions Concerning Regulations that Significantly Affect Energy Supply, Distribution, or Use (May 18, 2001). We have determined that it is not a “significant energy action” under the executive order because it is not a “significant regulatory action” under Executive Order 12866, and it is not likely to have a significant adverse effect on the supply, distribution, or use of energy.

Availability of Rulemaking Documents

You can get an electronic copy of rulemaking documents using the Internet by—
1. Searching the Federal eRulemaking portal (http://www.regulations.gov);

You can also get a copy 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. Make sure to identify the amendment or docket number of this rulemaking.

Anyone is able to search the electronic form of all comments received into any of our dockets by the name of the individual submitting the comment (or signing the comment, if submitted on behalf of an association, business, labor union, etc.). You may review DOT’s complete Privacy Act Statement in the Federal Register published on April 11, 2000 (Volume 65, Number 70; Pages 19477–78) or you may visit http://DocketsInfo.dot.gov.

Small Business Regulatory Enforcement Fairness Act

The Small Business Regulatory Enforcement Fairness Act (SBREFA) of 1996 requires FAA to comply with small entity requests for information or advice about compliance with statutes and regulations within its jurisdiction. Therefore, any small entity that has a question regarding this document may contact their local FAA official, or the person listed under FOR FURTHER INFORMATION CONTACT. You can find out more about SBREFA on the Internet at our site—http://www.faa.gov/regulations_policies/rulemaking/sbre_act.

List of Subjects

14 CFR Part 61
Aircraft, Aircraft pilots, Airmen, Airplanes, Air safety, Air transportation, Aviation safety, Balloons, Helicopters, Rotorcraft, Students.

14 CFR Part 63
Air safety, Air transportation, Airman, Aviation safety, Safety, Transportation.

14 CFR Part 65
Airman, Aviation safety, Air transportation, Aircraft.

The Amendment

In consideration of the foregoing, the Federal Aviation Administration amends parts 61, 63, and 65 of Title 14 Code of Federal Regulations as follows:

PART 61—CERTIFICATION: PILOTS, FLIGHT INSTRUCTORS, AND GROUND INSTRUCTORS

1. The authority citation for part 61 continues to read as follows:

SFAR 100–1 [Removed]

2. Remove SFAR 100–1 from parts 61, 63 and 65.

3. Add Special Federal Aviation Regulation (SFAR) No. 100–2 to parts 61, 63 and 65 to read as follows: [The full text of the SFAR will appear in part 61]


1. Applicability. Flight Standards District Offices are authorized to accept from an eligible person, as described in paragraph 2 of this SFAR, the following:
   (a) An expired flight instructor certificate to show eligibility for renewal of a flight instructor certificate under §61.197, or an expired written test report to show eligibility under part 61 to take a practical test;
   (b) An expired written test report to show eligibility under §§63.33 and 63.57 to take a practical test; and
   (c) An expired written test report to show eligibility to take a practical test required under part 65 or an expired inspection authorization to show eligibility for renewal under §65.93.

2. Eligibility. A person is eligible for the relief described in paragraph 1 of this SFAR if:
   (a) The person served in a U.S. military or civilian capacity outside the
PART 65—CERTIFICATION: AIRMEN OTHER THAN FLIGHT CREWMEMBERS

§ 65.5 Authority citation for part 65 continues to read as follows:

Issued in Washington, DC, on February 22, 2010.
J. Randolph Babbitt,
Administrator.

[FR Doc. 2010–4580 Filed 3–3–10; 8:45 am]
BILLING CODE 4910–13–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 333

RIN 0910—AG00


Classification of Benzoyl Peroxide as Safe and Effective and Revision of Labeling to Drug Facts Format; Topical Acne Drug Products for Over-The-Counter Human Use; Final Rule

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: We, the Food and Drug Administration (FDA), are issuing this final rule to include benzoyl peroxide as a generally recognized as safe and effective (GRASE) active ingredient in over-the-counter (OTC) topical acne drug products. In addition, this final rule includes new warnings and directions required for OTC acne drug products containing benzoyl peroxide. We are also revising labeling for OTC acne drug products containing benzoyl peroxide. We are also revising labeling for OTC acne drug products containing benzoyl peroxide.

DATES: Effective Date: This rule is effective on March 4, 2011.

Compliance Date: The compliance date for products containing resorcinol, resorcinol monoacetate, salicylic acid, and/or sulfur subject to 21 CFR part 333 is March 4, 2015. The compliance date for products containing benzoyl peroxide subject to 21 CFR part 333 with annual sales less than $25,000 is March 2, 2012. The compliance date for products containing benzoyl peroxide subject to part 21 CFR part 333 with annual sales of $25,000 or more is March 4, 2011.

FOR FURTHER INFORMATION CONTACT:
Matthew R. Holman, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, MS 5411, Silver Spring, MD 20993, 301–796–2090.

SUPPLEMENTARY INFORMATION:

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I. Glossary

• ANPR: Advance Notice of Proposed Rulemaking
• CFR: Code of Federal Regulations
• CHPA: Consumer Healthcare Products Association (formerly Nonprescription Drug Manufacturers Association)
• Committee: Dermatologic Drugs Advisory Committee
• FDA: Food and Drug Administration
• FR: Federal Register
• GRASE: Generally Recognized as Safe and Effective
• NDA: New Drug Application—an application submitted to FDA to market a new drug under section

PART 63—CERTIFICATION: FLIGHT CREWMEMBERS OTHER THAN PILOTS

§ 63.4 Authority citation for part 63 continues to read as follows:

4. The authority citation for part 63 continues to read as follows: