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DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Parts 91, 120, and 135

[Docket No.: FAA-2010-0982; Amdt. Nos. 91-330, 120-2; 135-129]

RIN 2120-AK47

Extension of Effective Date for the Helicopter Air Ambulance, Commercial Helicopter, and Part 91 Helicopter Operations Final Rule

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule; delay of effective date and request for comments.

SUMMARY: The FAA is delaying the effective date of the Helicopter Air Ambulance, Commercial Helicopter, and Part 91 Helicopter Operations final rule published on February 21, 2014. In that rule, the FAA amended its regulations to revise the helicopter air ambulance, commercial helicopter, and general aviation helicopter operating requirements. The April 22, 2014 effective date does not provide an adequate amount of time for the affected certificate holders to implement the new requirements. By extending the effective date to April 22, 2015, the affected certificate holders will have sufficient time to implement the new requirements. This action will only affect the effective date of the provisions of the rule scheduled to take effect April 22, 2014. Other provisions in the rule with specified compliance dates will not be affected.

DATES: The effective date of the rule amending 14 CFR Parts 91, 120, and 135 published February 21, 2014 (79 FR 9932), is delayed until April 22, 2015. The amendment to § 135.293 in this document is effective April 22, 2015.

Submit comments on or before May 21, 2014.

ADDRESSES: Send comments identified by docket number FAA-2010-0982 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, as described in the system of records notice (DOT/ALL-14 FDMS), which can be reviewed at 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 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 Andy Pierce, Air Transportation Division, AFS-200, Federal Aviation Administration, 800 Independence Avenue SW., Washington, DC 20591; telephone (202) 267-8238; email andy.pierce@faa.gov.

For legal questions concerning this action, contact Dean E. Griffith, Office of Chief Counsel, AGC-220, Federal Aviation Administration, 800 Independence Avenue SW., Washington, DC 20591; telephone (202) 267-3073; email dean.griffith@faa.gov.

SUPPLEMENTARY INFORMATION:

Good Cause for Dispensing With Notice and Comment and for Immediate Adoption

Section 553(b)(3)(B) of Title 5, United States Code, (the Administrative Procedure Act) authorizes agencies to dispense with notice and comment procedures for rules when the agency for “good cause” finds that those procedures are “impracticable, unnecessary, or contrary to the public interest.” Under this section, an agency, upon finding good cause, may issue a final rule without seeking comment prior to the rulemaking.

The FAA finds that prior notice and public comment to this final rule are contrary to the public interest. This final rule extends the effective date for the Helicopter Air Ambulance, Commercial Helicopter, and Part 91 Helicopter Operations final rule from April 22, 2014 to April 22, 2015. By extending the effective date, affected entities will have sufficient time to implement the new requirements. Without the extension of the effective date, regulated entities would not have sufficient time to prepare to meet the new requirements that were scheduled to take effect April 22, 2014. If these entities are not prepared to meet the new requirements then, beginning April 23, 2014, they would not be able to continue conducting part 135 operations and would not be able to meet the new part 91 requirements. Therefore, the FAA has determined that prior notice and public comment are contrary to the public interest.

The Administrative Procedure Act also allows agencies to dispense with the 30-day delayed effective date requirement for “good cause found and published with the rule.” 5 U.S.C. 553(d)(3). The FAA has determined that good cause exists to make this rule immediately effective upon publication. As discussed above the Helicopter Air Ambulance, Commercial Helicopter, and Part 91 Helicopter Operations final rule takes effect April 22, 2014. If the delay of the effective date is not made immediately effective there would be a period of time under which certificate holders would be in jeopardy of not being able to continue part 135 operations because of inability to satisfy the new requirements and part 91 operators would not be able to meet new requirements applicable to them. The delayed effective date must take effect

before April 22, 2014 to ensure certificate holders can continue to operate.

Comments Invited

The FAA is adopting this final rule without prior notice and public comment because delaying the amendment could result in a negative impact to certificate holders conducting part 135 rotorcraft operations, part 91 rotorcraft operators, and the public that relies on those certificate holders. The Regulatory Policies and Procedures of the Department of Transportation (DOT) (44 FR 11034; Feb. 26, 1979), provide that to the maximum extent possible, operating administrations for the DOT should provide an opportunity for public comment on regulations issued without prior notice. All comments will be considered by the Administrator and this amendment may be changed in light of the comments received. We note that, although the FAA will consider comments, this rule will be effective upon publication of this document in the **Federal Register**.

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(f) 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 promulgated under the authority described in Subtitle VII, Part A, Subpart III, Section 44701. Under that section, the FAA is charged with prescribing regulations and minimum standards 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 safety of rotorcraft operations.

I. Overview of Final Rule With Request for Comments

This final rule with request for comments extends the effective date for the Helicopter Air Ambulance, Commercial Helicopter, and Part 91 Helicopter Operations final rule published on February 21, 2014 (79 FR 9932). In that rule, the FAA established several operational rules for part 91 rotorcraft operators and part 135 rotorcraft operators which are scheduled to take effect April 22, 2014. This final rule extends the effective date to April 22, 2015 to provide a sufficient amount of time for the affected operators and certificate holders to implement the new requirements. This action does not

affect the provisions of the rule with a specific compliance date that are discussed later in this document.

II. Background

A. Statement of the Problem

There are approximately 5,465 rotorcraft pilots and 496 certificate holders conducting part 135 rotorcraft operations that are affected by the new requirements established in the February 21 rule. Moreover, all part 91 operations in class G airspace under visual flight rules will be affected by this rule. Multiple steps are required by the FAA and the regulated community for operators to implement the new requirements. However, it is not feasible for the FAA or rotorcraft operators to complete all the necessary steps by April 22, 2014. Consequently, operators will not be able to meet the operational requirements and thus will not be able to conduct part 135 operations or follow the new part 91 requirements beginning April 23, 2014. Therefore, the FAA is extending the rule's effective date to April 22, 2015 to provide a sufficient amount of time for the affected entities to complete all the necessary steps to implement the new requirements.

III. Discussion of Final Rule With Request for Comments

As stated above, the current effective date of the Helicopter Air Ambulance, Commercial Helicopter, and Part 91 Helicopter Operations final rule is April 22, 2014. Since the publication of the rule, it has become evident that this effective date does not allow certificate holders sufficient time to complete all the necessary steps to implement the new rule.

As one example, pilots are currently required to complete written or oral knowledge testing and a flight competency check every 12 calendar months. New § 135.293(a)(9) requires rotorcraft pilots to complete knowledge testing on "procedures for aircraft handling in flat-light, whiteout, and brownout conditions, including methods for recognizing and avoiding those conditions" during their next written or oral test after April 22, 2014. New § 135.293(c) requires rotorcraft pilots to complete "a demonstration of the pilot's ability to maneuver the rotorcraft solely by reference to instruments" during their next competency check after April 22, 2014.

In order to implement these new requirements, certificate holders must complete several steps, such as developing the procedures for testing aircraft handling in flat-light, whiteout, and brownout conditions, revising the

approved training program to address the new requirements, and training instructors and check pilots prior to beginning the training, testing, and checking of rotorcraft pilots. The April 22, 2014 compliance date does not provide adequate time for certificate holders to complete these necessary steps and therefore the compliance date will be delayed to April 22, 2015. We note that this is the only provision requiring a specific change of rule text. In addition, we are revising the rule text to clarify the compliance date for this section.

In addition, the FAA has determined that the April 22, 2014 effective date does not provide sufficient time for the FAA or the regulated community to implement the other operational rules which are currently scheduled to take effect on that date. However, the FAA has determined that provisions with delayed compliance dates in the Helicopter Air Ambulance, Commercial Helicopter, and Part 91 Helicopter Operations final rule do not need to be extended under this action. This is because the FAA will have sufficient time to prepare guidance for regulated entities in advance of the compliance dates for these provisions. The FAA is not extending the compliance dates of the following provisions:

- 135.160, Radio altimeters for rotorcraft operations—compliance date April 24, 2017.
- 135.168, Emergency equipment: Overwater rotorcraft operations (406 MHz emergency locator transmitter)—compliance date April 24, 2017.
- 135.603, Pilot-in-command instrument qualifications—compliance date April 24, 2017.
- 135.605, Helicopter terrain awareness and warning system (HTAWS)—compliance date April 24, 2017.
- 135.607, Flight Data Monitoring System—compliance date April 23, 2018.
- 135.619, Operations control centers—compliance date April 22, 2016.

IV. 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 final rule.

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 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 final rule. The reasoning for this determination follows.

The FAA is extending the effective date for the rules published in the Helicopter Air Ambulance, Commercial Helicopter, and Part 91 Helicopter Operations final rule on February 21, 2014 that are scheduled to take effect on April 22, 2014. The effective date of April 22, 2014 does not provide an adequate amount of time for the affected certificate holders to implement the new requirements. By extending the effective date to April 22, 2015, the affected certificate holders will have sufficient time to implement the new requirements.

The expected outcome will be cost relieving for certificate holders operating rotorcraft under part 135 and part 91 operators, and therefore a regulatory evaluation was not prepared. The FAA requests comments with supporting justification about the FAA determination of minimal impact.

The FAA has, therefore, determined that this final 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.

This final rule does not impose any additional costs on affected entities. Therefore, as provided in section 605(b), 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 final rule and determined that it will have only a domestic impact and therefore no effect on international trade.

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 \$151 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.

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 is no new requirement for information collection associated with this immediately adopted final rule.

F. International Compatibility and Cooperation

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 reviewed the corresponding ICAO Standards and Recommended Practices and has identified no differences with these proposed regulations.

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.

G. 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.

H. Regulations Affecting Intrastate Aviation in Alaska

Section 1205 of the FAA Reauthorization Act of 1996 (110 Stat. 3213) requires the FAA, when modifying its regulations in a manner affecting intrastate aviation in Alaska, to consider the extent to which Alaska is not served by transportation modes other than aviation, and to establish appropriate regulatory distinctions. As discussed in the Helicopter Air Ambulance, Commercial Helicopter, and Part 91 Helicopter Operations final rule which instituted the requirements being delayed by this action, the FAA finds that there is no need to make any regulatory distinctions in the provisions of this rule. See 79 FR 9932, 9971–72.

V. Executive Order Determinations

A. Executive Order 13132, Federalism

The FAA has analyzed this immediately adopted final rule under the principles and criteria of Executive Order 13132, Federalism. The agency 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, and, therefore, does not have Federalism implications.

B. Executive Order 13211, Regulations That Significantly Affect Energy Supply, Distribution, or Use

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

VI. How To Obtain Additional Information

A. Rulemaking Documents

An electronic copy of a rulemaking document may be obtained by using the Internet—

1. Search the Federal eRulemaking Portal (<http://www.regulations.gov>);

2. Visit the FAA’s Regulations and Policies Web page at http://www.faa.gov/regulations_policies/ or

3. Access the Government Printing Office’s Web page at: <http://www.gpo.gov/fdsys/>.

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

B. Comments Submitted to the Docket

Comments received may be viewed by going to <http://www.regulations.gov> and following the online instructions to search the docket number for this action. Anyone is able to search the electronic form of all comments received into any of the FAA’s 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.).

C. 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. A small entity with questions regarding this document, may contact its local FAA official, or the person listed under the **FOR FURTHER INFORMATION CONTACT** heading at the beginning of the preamble. To find out more about SBREFA on the Internet, visit http://www.faa.gov/regulations_policies/rulemaking/sbre_act/.

List of Subjects in 14 CFR Parts 91, 120, and 135

Air taxis, Aircraft, Airmen, Aviation safety, Reporting and recordkeeping requirements.

The Amendment

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

PART 135—OPERATING REQUIREMENTS: COMMUTER AND ON DEMAND OPERATIONS AND RULES GOVERNING PERSONS ON BOARD SUCH AIRCRAFT

■ 1. The authority citation for part 135 continues to read as follows:

Authority: 49 U.S.C. 106(f), 106(g), 41706, 40113, 44701–44702, 44705, 44709, 44711–44713, 44715–44717, 44722, 44730, 45101–

45105, Pub. L. 112–95, 126 Stat. 58 (49 U.S.C. 44730).

■ 2. Amend § 135.293 by removing the phrase “After the next scheduled competency check after April 22, 2014” from the beginning of paragraph (a)(9) and adding paragraph (h) to read as follows:

§ 135.293 Initial and recurrent pilot testing requirements.

* * * * *

(h) Rotorcraft pilots must be tested on the subjects in paragraph (a)(9) of this section when taking a written or oral knowledge test after April 22, 2015. Rotorcraft pilots must be checked on the maneuvers and procedures in paragraph (c) of this section when taking a competency check after April 22, 2015.

Issued under authority provided by 49 U.S.C. 106(f), 44701(a), and 44703 in Washington, DC, on April 15, 2014.

Michael G. Whitaker,

Deputy Administrator, Federal Aviation Administration.

[FR Doc. 2014–09034 Filed 4–17–14; 11:15 am]

BILLING CODE 4910–13–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 886

[Docket No. FDA–2013–N–0069]

Medical Devices; Ophthalmic Devices; Classification of the Eyelid Weight

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA or Agency) is classifying the eyelid weight into class II (special controls). The Agency is exempting the external eyelid weight from premarket notification, but continuing to require premarket notification for implantable eyelid weights in order to provide a reasonable assurance of safety and effectiveness of the device. Both external and implantable eyelid weight devices are subject to special controls. The eyelid weight may be adhered to the outer skin of the upper eyelid (external eyelid weight) or implanted into the upper eyelid (implantable eyelid weight), and is intended for the gravity assisted treatment of lagophthalmos (incomplete eyelid closure).

DATES: *Effective Date:* July 21, 2014.

Compliance Dates: Premarket notification submissions (510(k)s for