

comments. We may change these special conditions based on the comments we receive.

### Background

On September 13, 2013, Embraer S.A. applied for an amendment to Type Certificate (TC) No. A57NM to include the new Model ERJ 190–300 series airplanes. The ERJ 190–300, which is a derivative of the ERJ 190–100 STD currently approved under TC No. A57NM, is a 97–114 passenger transport category airplane with two Pratt & Whitney Model PW1900G engines, a new wing design with a high aspect ratio and raked wingtip, digital fly-by-wire electronic flight control system, and an automatic braking system.

### Type Certification Basis

Under the provisions of Title 14, Code of Federal Regulations (14 CFR) 21.101, Embraer S.A. must show that the ERJ 190–300 meets the applicable provisions of the regulations listed in Type Certificate No. A57NM or the applicable regulations in effect on the date of application for the change, except for earlier amendments as agreed upon by the FAA. Embraer S.A. must show that the ERJ 190–300 meets the applicable provisions of 14 CFR part 25, as amended by Amendments 25–1 through 25–137.

If the Administrator finds that the applicable airworthiness regulations (*i.e.*, 14 CFR part 25) do not contain adequate or appropriate safety standards for the ERJ 190–300 because of a novel or unusual design feature, special conditions are prescribed under the provisions of § 21.16.

Special conditions are initially applicable to the Model for which they are issued. Should the type certificate for that model be amended later to include any other model that incorporates the same novel or unusual design features, or should any other model already included on the same type certificate be modified to incorporate the same novel or unusual design feature, these special conditions would also apply to the other model under § 21.101.

In addition to the applicable airworthiness regulations and special conditions, the ERJ 190–300 must comply with the fuel vent and exhaust emission requirements of 14 CFR part 34 and the noise-certification requirements of 14 CFR part 36.

The FAA issues special conditions, as defined in 14 CFR 11.19, in accordance with § 11.38, and they become part of the type certification basis under § 21.101.

### Novel or Unusual Design Features

The ERJ 190–300 will incorporate the following novel or unusual design features:

An automatic braking system with a pilot-selectable function that allows earlier braking at landing without pilot pedal input. When the autobrake system is armed before landing, it automatically commands a pre-defined braking action after the main wheels touch down. This might cause a high nose gear sink rate, and potentially higher gear and airframe loads than would occur with a traditional braking system.

### Discussion

These special conditions define a landing pitchover condition that accounts for the effects of the automatic braking system. The special conditions define the airplane configuration, speeds, and other parameters necessary to develop airframe and nose gear loads for this condition. The special conditions require that the airplane be designed to support the resulting limit and ultimate loads as defined in § 25.305.

These special conditions contain the additional safety standards that the Administrator considers necessary to establish a level of safety equivalent to that established by the existing airworthiness standards.

### Applicability

As discussed above, these special conditions are applicable to the ERJ 190–300 series airplanes. Should Embraer S.A. apply at a later date for a change to the type certificate to include another model incorporating the same novel or unusual design feature, these special conditions would apply to that model as well.

### Conclusion

This action affects only certain novel or unusual design features on one model of airplanes. It is not a rule of general applicability.

The substance of these special conditions has been subjected to the notice and comment period in several prior instances and has been derived without substantive change from those previously issued. It is unlikely that prior public comment would result in a significant change from the substance contained herein. Therefore, because a delay would affect the certification of the airplane, the FAA has determined that prior public notice and comment are unnecessary and impracticable, and good cause exists for adopting these special conditions upon publication in the **Federal Register**. The FAA is requesting comments to allow interested persons to submit views that may not

have been submitted in response to the prior opportunities for comment described above.

### List of Subjects in 14 CFR Part 25

Aircraft, Aviation safety, Reporting and recordkeeping requirements.

The authority citation for these special conditions is as follows:

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

### The Special Conditions

Accordingly, pursuant to the authority delegated to me by the Administrator, the following special conditions are issued as part of the type certification basis for the Embraer S.A. Model ERJ 190–300 series airplanes.

A landing pitchover condition must be addressed that takes into account the effect of the autobrake system. The airplane is assumed to be at the design maximum landing weight, or at the maximum weight allowed with the autobrake system on. The airplane is assumed to land in a tail-down attitude and at the speeds defined in § 25.481. Following main gear contact, the airplane is assumed to rotate about the main gear wheels at the highest pitch rate allowed by the autobrake system.

This is considered a limit load condition from which ultimate loads must also be determined. Loads must be determined for critical fuel and payload distributions and centers of gravity. The effect of the autobrake system on fatigue loading spectra must also be investigated. Nose gear loads, as well as airframe loads, must be determined. The airplane must meet § 25.305 for these loads.

Issued in Renton, Washington, on November 15, 2016.

**Paul Bernado,**

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

[FR Doc. 2016–29358 Filed 12–6–16; 8:45 am]

**BILLING CODE 4910–13–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

#### 21 CFR Part 1

[Docket No. FDA–2011–N–0146]

#### Third-Party Certification Body Accreditation for Food Safety Audits: Model Accreditation Standards; Guidance for Industry and Food and Drug Administration Staff; Availability

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

**ACTION:** Notification of availability.

**SUMMARY:** The Food and Drug Administration (FDA or we) is announcing the availability of a guidance for industry and FDA staff entitled “Third-Party Certification Body Accreditation for Food Safety Audits: Model Accreditation Standards.” The guidance contains FDA recommendations on third-party certification body qualifications for accreditation to conduct food safety audits and to issue food and/or facility certifications under an FDA program required by the FDA Food Safety Modernization Act (FSMA). The guidance is intended to describe the standards for accreditation of third-party certification bodies as required under the final rule entitled “Accreditation of Third-Party Certification Bodies to Conduct Food Safety Audits and to Issue Certifications.” In addition, this guidance discusses specific clauses of ISO/IEC 17021: 2015 and industry practice that are currently being used by third-party certification bodies and that FDA recommends accreditation bodies consider as a model when making accreditation decisions.

**DATES:** Submit either electronic or written comments on FDA guidances at any time.

**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-2011-N-0146 for “Third-Party Certification Body Accreditation for Food Safety Audits: Model Accreditation Standards; Guidance for Industry and Food and Drug Administration Staff.” 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 comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states “THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.” The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <http://www.regulations.gov>. Submit both copies to the Division of Dockets Management. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as “confidential.” Any information marked as “confidential” will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA’s posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: <http://www.fda.gov/regulatoryinformation/dockets/default.htm>.

*Docket:* For access to the docket to read background documents or the electronic and written/paper comments received, go to <http://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the “Search” box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Submit written requests for single copies of the guidance to the Center for Food Safety and Applied Nutrition (HFS-300), Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740. Send two self-addressed adhesive labels to assist that office in processing your request. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance.

**FOR FURTHER INFORMATION CONTACT:** Charlotte A. Christin, Center for Food Safety and Applied Nutrition, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993, 301-796-7526.

**SUPPLEMENTARY INFORMATION:**

**I. Background**

We are announcing the availability of a guidance for industry and FDA staff entitled “Third-Party Certification Body Accreditation for Food Safety Audits: Model Accreditation Standards.” We are issuing this guidance consistent with our good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

In the **Federal Register** of July 24, 2015 (80 FR 44137), we made available a draft guidance entitled “Draft Guidance for Industry and Food and Drug Administration Staff: Third-Party Auditor/Certification Body Accreditation for Food Safety Audits: Model Accreditation Standards” and gave interested parties an opportunity to submit comments by October 7, 2015, for us to consider before beginning work on the final version of the guidance. Section 808 of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 384d) was added by FSMA and directs FDA to establish a program for the recognition of accreditation bodies that accredit third-party certification bodies to conduct food safety audits and to issue food and/or facility certifications that FDA may use in certain circumstances to facilitate the entry of foods presented for import.

Section 808(b)(2) of the FD&C Act requires FDA to develop model accreditation standards that recognized accreditation bodies shall use to qualify third-party certification bodies for accreditation, and in so doing, to look to existing standards for certification bodies (as of the date of enactment of FSMA) to avoid unnecessary duplication of efforts and costs. This guidance constitutes the model accreditation standards referred to in section 808(b)(2) of the FD&C Act. The guidance contains FDA recommendations on third-party certification body qualifications for accreditation to conduct food safety audits and to issue food and/or facility certifications under an FDA program required by FSMA.

FDA was guided in developing this guidance, in part, by the National Technology Transfer and Advancement Act of 1995, which directs Federal Agencies to use voluntary consensus standards in lieu of government-unique standards, except where inconsistent with law or otherwise impractical.

In developing the guidance, FDA considered several voluntary consensus standards for their relevance to the qualifications of third-party certification bodies that would certify foreign food facilities and/or their foods for conformance with the requirements of the FD&C Act. FDA also sought to identify the standards most commonly used by stakeholders (*e.g.*, other governments, public and private accreditation bodies, the food industry, and the international standards community) in qualifying third-party certification bodies for conducting food safety audits. As a result, FDA was guided in developing the model accreditation standards guidance document by International Organization for Standardization (ISO)/International Electrotechnical Commission (IEC) ISO/IEC 17021: *Conformity Assessment—Requirements for bodies providing audit and certification management systems* (2015) (ISO/IEC 17021:2015) and ISO/IEC 17065: *Conformity Assessment—Requirements for bodies certifying products, processes and services* (2012) (ISO/IEC 17065:2012).

We received several comments on the draft guidance and have modified the final guidance where appropriate. We revised the guidance for clarity and conformance with the final rule. We also updated references to the ISO/IEC standards. The guidance announced in this notice finalizes the draft guidance dated July 2015.

## II. Paperwork Reduction Act of 1995

This guidance refers to previously approved collection of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information regarding “Accreditation of Third Party Certification Bodies to Conduct Food Safety Audits and Issue Certifications,” have been approved under OMB control number 0910–0750.

## III. Electronic Access

Persons with access to the Internet may obtain the guidance at either <http://www.fda.gov/FoodGuidances> or <http://www.regulations.gov>. Use the FDA Web site listed in the previous sentence to find the most current version of the guidance.

Dated: December 1, 2016.

**Leslie Kux,**

*Associate Commissioner for Policy.*

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## DEPARTMENT OF STATE

### 22 CFR Part 41

**RIN 1400–AD96**

**[Public Notice: 9638]**

### **Visas: Classification of Immediate Family Members as A, C–3, G, and NATO Nonimmigrants**

**AGENCY:** State Department.

**ACTION:** Final rule.

**SUMMARY:** This rule amends the definition of immediate family for purposes of A, C–3, G, and NATO visa classifications in two ways: It revises the eligibility requirements for unmarried adult sons and daughters age 21 or older for these visa classifications, and clarifies for purposes of G–4 visa classification that the international organization employing the principal alien must recognize an individual as immediate family to be eligible for derivative U.S. visa status. Furthermore, this rule permits qualified immediate family members of A–1, A–2, G–1, G–2, G–3, and G–4 nonimmigrants to be independently classified as NATO–1, NATO–2, NATO–3, NATO–4, NATO–5, and NATO–6.

**DATES:** This final rule is effective on December 7, 2016.

**FOR FURTHER INFORMATION CONTACT:** Paul-Anthony L. Magadia, U.S. Department of State, Office of

Legislation and Regulations, CA/VO/L/R, 600 19th Street NW., SA–17, Room 12–526B, Washington, DC 20522, 202–485–7641 or [magadiapl@state.gov](mailto:magadiapl@state.gov).

**SUPPLEMENTARY INFORMATION:** Prior to this amendment, an unmarried adult son or daughter who is not part of any other household and resides regularly in the household of the principal alien must be classified in A or G visa classifications, even if otherwise eligible for another nonimmigrant classification and regardless of age or the intention of the sending government or international organization. Yet for purposes of privileges and immunities, the Department of State accepts only unmarried children under the age of 21, or unmarried sons and daughters under the age of 23 and in full-time attendance as students at post-secondary educational institutions, as dependents. Similarly, under 8 CFR 214.2(a)(2) and (g)(2) for employment authorization purposes, Department of Homeland Security (DHS) regulations generally only consider unmarried children under the age of 21, or unmarried sons and daughters under the age of 23 and in full-time attendance as students at post-secondary educational institutions, to be dependents. (Under certain circumstances, DHS, under its regulations, may also recognize as dependents sons and daughters up to the age of 25 or of any age if physically or mentally challenged.) In practice, requiring A or G classification for sons and daughters above these age limits precludes them from obtaining a nonimmigrant classification that would enable them to accept employment in the United States.

This rule narrows the definition of immediate family in the A, C–3 (aliens in transit under section 212(d)(8) of the Immigration and Nationality Act, 8 U.S.C. 1182(d)(8)), G, and relevant NATO nonimmigrant visa classifications so that only unmarried sons and daughters residing with the principal who are under the age of 21, or under the age of 23 and in full-time attendance as students at post-secondary educational institutions, will continue to be considered immediate family. Any other unmarried son or daughter residing with the principal will only qualify if he or she meets the same criteria the rule imposes on other family members. In particular, he or she must be recognized as an “immediate family member” by the sending government or international organization for purposes of eligibility for rights and benefits and also is individually authorized by the Department. An adult son or daughter