

authority delegated to the Commissioner of Food and Drugs, 21 CFR part 870 is amended as follows:

PART 870—CARDIOVASCULAR DEVICES

■ 1. The authority citation for 21 CFR part 870 continues to read as follows:

Authority: 21 U.S.C. 351, 360, 360c, 360e, 360j, 371.

■ 2 Section 870.3460 is added to subpart D to read as follows:

§ 870.3460 Endovascular Suturing System.

(a) *Identification.* An endovascular suturing system is a medical device intended to provide fixation and sealing between an endovascular graft and the native artery. The system is comprised of the implant device and an endovascular delivery device used to implant the endovascular suture.

(b) *Classification.* Class II (special controls). The special controls for this device are:

(1) The device should be demonstrated to be biocompatible;

(2) Sterility and shelf life testing should demonstrate the sterility of patient-contacting components and the shelf-life of these components;

(3) Non-clinical and clinical performance testing should demonstrate substantial equivalence in safety and effectiveness, including durability, compatibility, migration resistance, corrosion resistance, and delivery and deployment;

(4) Non-clinical testing should evaluate the compatibility of the device in an magnetic resonance (MR) environment;

(5) Appropriate analysis and non-clinical testing should validate electromagnetic compatibility (EMC) and electrical safety;

(6) The sale, distribution, and use of the device are restricted to prescription use in accordance with 21 CFR 801.109 of this chapter; and

(7) Labeling must bear all information required for the safe and effective use of the device as outlined in § 801.109(c) of this chapter, including a detailed summary of the non-clinical and clinical evaluations pertinent to use of the device.

Dated: February 9, 2012.

Nancy K. Stade,

Deputy Director for Policy, Center for Devices and Radiological Health.

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DEPARTMENT OF STATE

22 CFR Part 41

[Public Notice 7796]

Visas: Issuance of Full Validity L Visas to Qualified Applicants

AGENCY: State Department.

ACTION: Final rule.

SUMMARY: This rule permits the issuance of L visas with validity periods based on the visa reciprocity schedule; whereas the current rule limits L visas to the petition validity period, which is determined by the Department of Homeland Security.

DATES: This rule is effective February 14, 2012.

FOR FURTHER INFORMATION CONTACT: Lauren A. Prosnik, Legislation and Regulations Division, Visa Services, Department of State, 2401 E Street NW., Room L-603D, Washington, DC 20520-0106, (202) 663-1260.

SUPPLEMENTARY INFORMATION:

Why is the department promulgating this rule?

Current Department regulations require that L visa duration be limited to the validity period of the petition, which, under Department of Homeland Security (DHS) regulations, cannot exceed three years. Petitioners may apply to U.S. Citizenship and Immigration Services (USCIS) for extension of petition validity in increments of up to two years, but the total period of stay may not exceed five years for aliens employed in a specialized knowledge capacity, or seven years for aliens employed in a managerial or executive capacity. The Department is changing this regulation to delink visa and petition validity periods, as currently required by 22 CFR 41.54(c), "Validity of visa". As a result, L visa validity will be governed by 22 CFR 41.112, which provides that, except as provided in paragraphs (c) and (d) of that section, a nonimmigrant visa shall have the validity prescribed in schedules provided to consular officers by the Department, which reflect the reciprocal treatment the applicant's country accords U.S. nationals, U.S. permanent residents, or aliens granted refugee status in the United States. The change would assist beneficiaries of petitions for L status who are nationals of countries for which the reciprocity schedule prescribes visa validity for a longer period of time than the initial validity indicated in the petition approved by DHS and who have extended their L stay while in the

United States. Subject to 22 CFR 41.112(c), such individuals generally would not need to apply again for an L visa at a U.S. Embassy or Consulate overseas if they were to travel outside the United States during the period indicated in the applicable reciprocity schedule, as is currently required when petition validity has been extended. Under 8 CFR 214.2(l)(11), an alien may apply for admission in L status only while the individual or blanket petition is valid.

Regulatory Findings

Administrative Procedure Act

This regulation involves a foreign affairs function of the United States and, therefore, in accordance with 5 U.S.C. 553(a)(1), is not subject to the rule making procedures set forth at 5 U.S.C. 553.

Regulatory Flexibility Act/Executive Order 13272: Small Business

Because this final rule is exempt from notice and comment rulemaking under 5 U.S.C. 553, it is exempt from the regulatory flexibility analysis requirements set forth at sections 603 and 604 of the Regulatory Flexibility Act (5 U.S.C. 603 and 604). Nonetheless, consistent with section 605(b) of the Regulatory Flexibility Act (5 U.S.C. 605(b)), the Department certifies that this rule will not have a significant economic impact on a substantial number of small entities. This regulates individual aliens applying for visas under INA § 101(A)(15)(L) and does not affect any small entities, as defined in 5 U.S.C. 601(6).

Unfunded Mandates Reform Act of 1995

Section 202 of the Unfunded Mandates Reform Act of 1995, Public Law 104-4, 109 Stat. 48, 2 U.S.C. 1532, generally requires agencies to prepare a statement before proposing any rule that may result in an annual expenditure of \$100 million or more by State, local, or tribal governments, or by the private sector. This rule will not result in any such expenditure, nor will it significantly or uniquely affect small governments.

Small Business Regulatory Enforcement Fairness Act of 1996

This rule is not a major rule as defined by 5 U.S.C. 804, for purposes of congressional review of agency rulemaking under the Small Business Regulatory Enforcement Fairness Act of 1996, Public Law 104-121. This rule will not result in an annual effect on the economy of \$100 million or more; a major increase in costs or prices; or adverse effects on competition,

employment, investment, productivity, innovation, or the ability of United States-based companies to compete with foreign-based companies in domestic and import markets.

Executive Order 12866

The Department of State has reviewed this proposed rule to ensure its consistency with the regulatory philosophy and principles set forth in Executive Order 12866 and has determined that the benefits of this final regulation justify its costs. The Department does not consider this final rule to be an economically significant action within the scope of section 3(f)(1) of the Executive Order since it is not likely to have an annual effect on the economy of \$100 million or more or to adversely affect in a material way the economy, a sector of the economy, competition, jobs, the environment, public health or safety, or State, local or tribal governments or communities.

Executive Orders 12372 and 13132: Federalism

This regulation will not have substantial direct effects on the States, on the relationship between the national government and the States, or the distribution of power and responsibilities among the various levels of government. Nor will the rule have federalism implications warranting the application of Executive Orders No. 12372 and No. 13132.

Executive Order 12988: Civil Justice Reform

The Department has reviewed the regulations in light of sections 3(a) and 3(b)(2) of Executive Order No. 12988 to eliminate ambiguity, minimize litigation, establish clear legal standards, and reduce burden.

Executive Order 13563: Improving Regulation and Regulatory Review

The Department has considered this rule in light of Executive Order 13563, dated January 18, 2011, and affirms that this regulation is consistent with the guidance therein.

Paperwork Reduction Act

This rule does not impose information collection requirements under the provisions of the Paperwork Reduction Act, 44 U.S.C. Chapter 35.

List of Subjects in 22 CFR Part 41

Documentation of nonimmigrants.

For the reasons stated in the preamble, the Department of State amends 22 CFR part 41 to read as follows:

PART 41—[AMENDED]

■ 1. The authority citation for part 41 continues to read as follows:

Authority: 8 U.S.C. 1104; Pub. L. 105–277, 112 Stat. 2681–795 through 2681–801; 8 U.S.C. 1185 note (section 7209 of Pub. L. 108–458, as amended by section 546 of Pub. L. 109–295).

■ 2. Section 41.54 is revised to read as follows:

§ 41.54 Intracompany transferees (executives, managers, and specialized knowledge employees)

(a) *Requirements for L classification.* An alien shall be classifiable under the provisions of INA section 101(a)(15)(L) if:

(1) The consular officer is satisfied that the alien qualifies under that section; and either

(2) In the case of an individual petition, the consular officer has received official evidence of the approval by DHS of a petition to accord such classification or of the extension by DHS of the period of authorized stay in such classification; or

(3) In the case of a blanket petition,

(i) The alien has presented to the consular officer official evidence of the approval by DHS of a blanket petition listing only those intracompany relationships and positions found to qualify under INA section 101(a)(15)(L);

(ii) The alien is otherwise eligible for L–1 classification pursuant to the blanket petition; and,

(iii) The alien requests that he or she be accorded such classification for the purpose of being transferred to, or remaining in, qualifying positions identified in such blanket petition; or

(4) The consular officer is satisfied the alien is the spouse or child of an alien so classified and is accompanying or following to join the principal alien.

(b) *Petition approval.* The approval of a petition by DHS does not establish that the alien is eligible to receive a nonimmigrant visa.

(c) *Alien not entitled to L–1 classification under individual petition.*

The consular officer must suspend action on the alien's application and submit a report to the approving DHS office if the consular officer knows or has reason to believe that an alien applying for a visa as the beneficiary of an approved individual petition under INA section 101(a)(15)(L) is not entitled to such classification as approved.

(d) *Labor disputes.* Citizens of Canada or Mexico shall not be entitled to classification under this section if the Secretary of Homeland Security and the Secretary of Labor have certified that:

(1) There is in progress a strike or lockout in the course of a labor dispute

in the occupational classification at the place or intended place of employment; and,

(2) The alien has failed to establish that the alien's entry will not affect adversely the settlement of the strike or lockout or the employment of any person who is involved in the strike or lockout.

(e) *Alien not entitled to L–1 classification under blanket petition.*

The consular officer shall deny L classification based on a blanket petition if the documentation presented by the alien claiming to be a beneficiary thereof does not establish to the satisfaction of the consular officer that

(1) The alien has been continuously employed by the same employer, an affiliate or a subsidiary thereof, for one year within the three years immediately preceding the application for the L visa;

(2) The alien was rendering services in a capacity that is managerial, executive, or involves specialized knowledge throughout that year; or

(3) The alien is destined to render services in such a capacity, as identified in the petition and in an organization listed in the petition.

(f) *Former exchange visitor.* Former exchange visitors who are subject to the two-year foreign residence requirement of INA section 212(e) are ineligible to apply for visas under INA section 101(a)(15)(L) until they have fulfilled the residence requirement or obtained a waiver of the requirement.

Dated: January 31, 2012.

Janice L. Jacobs,

*Assistant Secretary for Consular Affairs,
Department of State.*

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DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 1

[TD 9576]

RIN 1545–BF73

Definition of a Taxpayer

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Final regulations.

SUMMARY: This document contains final Income Tax Regulations which provide guidance relating to the determination of who is considered to pay a foreign income tax for purposes of the foreign tax credit. These regulations provide rules for identifying the person with legal liability to pay the foreign income