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16. ECRI, "Physiologic Patient Monitors," update, *Health Devices*, vol. 21, Nos. 3-4, pp. 123-128, March-April 1992.

17. ECRI, "Ambulatory Telemetry Arrhythmia Monitoring Systems (including Guidance Section: Implementation and Effective Use of Telemetry Arrhythmia Monitoring Systems)," *Health Devices*, vol. 23, No. 7, pp. 267-305, July 1994.

18. Badura, F., "Nurse Acceptance of a Computerized Arrhythmia Monitoring System," *Instrumentation for Critical Care*, vol. 9, pp. 1044-48, 1980 (included in Ref. 1).

19. Emergency Cardiac Care Committee of the American College of Cardiology, "Recommended Guidelines for In-Hospital Cardiac Monitoring of Adults for Detection of Arrhythmias," *Journal American of College Cardiology*, vol. 18, pp. 1431-1433, 1991 (included in Refs. 1 and 8).

List of Subjects in 21 CFR Part 870

Medical devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, it is proposed that 21 CFR part 870 be amended 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 870.1 is amended by adding paragraph (e) to read as follows:

§ 870.1 Scope.

* * * * *

(e) Guidance documents referenced in this part are available on the Internet at <http://www.fda.gov/cdrh/guidance.html>.

2. Section 870.1025 is revised to read as follows:

§ 870.1025 Arrhythmia detector and alarm.

(a) *Arrhythmia detector and alarm (including ST-segment measurement and alarm)*—(1) *Identification*. An arrhythmia detector and alarm is system that monitors the electrocardiogram and is designed to produce a visible or audible signal or alarm when an atrial

or ventricular arrhythmia, such as a premature contraction or ventricular fibrillation, exists.

(2) *Classification*. Class II (special controls). The special control for this device is the FDA guidance document entitled "Class II Special Controls Guidance Document: Arrhythmia Detector and Alarm; Guidance for Industry and FDA." See § 870.1 for the availability of this guidance document.

(b) *Automated external defibrillator*—(1) *Identification*. An automated external defibrillator is a low-energy device with a rhythm recognition detection system that delivers into a 50 ohm test load an electrical shock of a maximum of 360 joules of energy used for defibrillating (restoring normal heart rhythm) the atria or ventricles of the heart. The device analyzes the patient's electrocardiogram, interprets the cardiac rhythm and automatically delivers an electrical shock (fully automated AED), or advises the user to deliver the shock (semi-automated or shock advisory AED) to treat ventricular fibrillation or pulseless ventricular tachycardia.

(2) *Classification*. Class III (premarket approval).

(3) *Date PMA or notice of PDP is required*. No effective date has been established of the requirement for premarket approval.

Dated: October 23, 2002.

Linda S. Kahan,

Deputy Director, Center for Devices and Radiological Health.

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DEPARTMENT OF STATE

22 CFR Part 41

[Public Notice 4215]

Documentation of Nonimmigrants Under the Immigration and Nationality Act, As Amended—Elimination of Crew List Visas

AGENCY: Department of State.

ACTION: Proposed rule with request for comments.

SUMMARY: Under current regulations, crewmen working on vessels and aircraft bound for the United States are able to obtain crew list visas without submitting individual application forms or undergoing background checks that would apply to many if they applied for individual visas. In light of the security concerns resulting from the events of September 11, 2001, the Department can no longer justify issuance of a visa without the full application process.

This rule proposes to amend the regulations to eliminate the crew list visa.

DATES: Written comments must be received on or before February 11, 2003.

ADDRESSES: Written comments may be submitted to the Chief, Legislation and Regulations Division, Visa Services, Department of State, Washington, DC 20520-0106, by fax to 202-663-3898 or by e-mail to VisaRegs@state.gov.

FOR FURTHER INFORMATION CONTACT: Pam Chavez, Legislation and Regulations Division, Visa Services, Department of State, Washington, DC 20520-0106, 202-663-1206 or e-mail chavezpr@state.gov.

SUPPLEMENTARY INFORMATION:

What Is a Crew List Visa?

The Department's current regulation at 22 CFR 41.42(a) defines crew list visa as follows: "A crew list visa is a nonimmigrant visa issued on a manifest of crewmen of a vessel or aircraft and includes all aliens listed in the manifest unless otherwise stated. It constitutes a valid nonimmigrant visa within the meaning of INA 212(a)(7)(B)(i)(II)."

What Are the Statutory Authorities Pertaining to the Crew List Visa?

Authority for the issuance of a crew list visa is derived from sections 101(a)(15)(D) and 221(f) of the Immigration and Nationality Act, 8 U.S.C. 1101(a)(15)(D) and 1201(f), respectively. Section 101(a)(15)(D) exempts aliens serving in good faith as crewmen on board a vessel (other than a fishing vessel having its home port or an operating base in the United States, unless temporarily landing in Guam), or aircraft from being deemed immigrants. Section 221(f) permits an alien to enter the United States on the basis of a crew manifest that has been issued by a consular officer. However, the latter section does not require a consular officer to issue a crew manifest and in those cases where the consular officer does agree to do so, it authorizes the officer to deny admission to any alien from the crew list visa. Further, the use of the visaed crew list appears to have been intended principally as a temporary or emergency measure to be used only until such time as it becomes practicable to issue individual documents to each member of a vessel's or aircraft's crew.

What Are the Requirements for Obtaining a Crew List Visa?

To obtain a crew list visa, the representative or agent of a foreign vessel or aircraft must submit a master list of all crewmen employed on the

vessel or aircraft along with whatever other information the consular officer finds necessary to determine eligibility.

Applicants applying for crew list visas are not required to complete the Forms DS-156, Nonimmigrant Visa Application, or DS-157, Supplemental Nonimmigrant Visa Application or submit a passport, nor are they required to undergo an interview.

Are Such Crewmen Subject to Background Checks?

While consular officers are required to conduct background checks, including a check of the computerized name check system, for applicants for crew list visas, background checks are not as reliable for crew list applicants since it is not possible to verify with certainty that the names submitted on the crew list are spelled correctly. In addition, since crew list visa applicants ordinarily are not interviewed, consular officers have no opportunity to question them regarding such things as employment history or knowledge of their trade.

Why Does the Department Want To Amend Its Regulations?

The Enhanced Border Security and Visa Entry Reform Act of 2002 (Pub. L. 107-173) requires that all visas issued after October 26, 2004 have a biometric indicator. This means crew list visas would necessarily be eliminated by that date. Additionally, since September 11, the Department has been amending its regulations to ensure that every effort is made to screen out undesirable aliens. The Department is, therefore, amending its regulations to eliminate crew list visas and ensure that each crewmember entering the United States will complete the nonimmigrant visa application forms, submit a valid passport and undergo an interview and background checks.

What Will Be the Economic Impact and the Impact on Manning of Vessels and Aircraft if This Rule Goes Into Effect?

In terms of the actual cost of a visa, per crewman, in general the cost of an individual visa will be no more than it is, per crewman, on a crew list visa, and in most cases over a period of years will average out to be less. For crew list visas each crewman already pays an individual processing, *i.e.*, machine-readable visa (MRV) fee of \$100.00. Although reciprocity fees are waived for individuals on a crew list visa and are not for individual visas, that cost should be more than offset in most cases by the fact that the crewman will be receiving

(depending upon reciprocity for each individual's country of nationality) a multiple entry, long term visa instead of the one entry, 6 month crew list visa.

Nevertheless, in preliminary discussions with representatives of the shipping industry, most comments about the economic impact of this proposed rule have been associated with the difficulties and costs that will be presented to the industry should issuance of individual visas result in long and expensive delays waiting in port for visas to be issued. These representatives say that tight and sometimes erratic scheduling, and a constant shifting of crew members are features of the industry that need to be taken into consideration in implementing a requirement for individual visas. Therefore, the Department invites all interested parties to comment specifically on the economic and manning impacts of this rule, as proposed, and to suggest measures the Department might consider when implementing the rule that would minimize any negative impacts of this type.

How Does the Department Propose To Amend Its Regulations?

This rule proposes to remove the Department's regulations at 22 CFR 41.42 that establish the crew list visa. By doing so, all crewmembers entering the United States would be required to apply for individual crew visas.

Regulatory Analysis and Notices

Administrative Procedure Act

The Department is publishing this rule as a proposed rule with a 60-day provision for post-promulgation public comments.

Regulatory Flexibility Act

The Department of State, in accordance with the Regulatory Flexibility Act (5 U.S.C. 605(b)), has reviewed this regulation and, by approving it, certifies that this rule will not have a significant economic impact on a substantial number of small entities.

Unfunded Mandates Reform Act of 1995

This rule will not result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of \$100 million or more in any year and it will not significantly or uniquely affect small governments. Therefore, no actions were deemed necessary under the provisions of the

Unfunded Mandates Reform Act of 1995.

Small Business Regulatory Enforcement Fairness Act of 1996

This rule is not a major rule as defined by section 804 of the Small Business Regulatory Enforcement Act of 1996. 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 significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of United States-based companies to compete with foreign-based companies in domestic and export markets.

Executive Order 12866

The Department of State considers this rule to be a "significant regulatory action" under Executive Order 12866, section 3(f), Regulatory Planning and Review. Therefore, it has been submitted for review by the Office of Management and Budget.

Executive Order 13132

This regulation will not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. Therefore, in accordance with section 6 of Executive Order 13132, it is determined that this rule does not have sufficient federalism implications to warrant the preparation of a federalism summary impact statement.

List of Subjects in 22 CFR Part 41

Aliens, Nonimmigrants, Passports, Visas.

In view of the foregoing, 22 CFR Part 41 is amended as follows:

PART 41—[AMENDED]

1. The authority citation for Part 41 continues to read:

Authority: 8 U.S.C. 1104; Pub. L. 105-277, 112 Stat. 2681-795 through 2681-801.

§ 41.42 [Removed and Reserved]

Remove and reserve section 41.42.

Dated: December 2, 2002.

Maura Harty,

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

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