PART 862—CLINICAL CHEMISTRY AND CLINICAL TOXICOLOGY DEVICES

1. The authority citation for 21 CFR part 862 continues to read as follows:


2. Section 862.3080 is added to subpart D to read as follows:

§ 862.3080 Breath nitric oxide test system.

(a) Identification. A breath nitric oxide test system is a device intended to measure fractional nitric oxide in human breath. Measurement of changes in fractional nitric oxide concentration in expired breath aids in evaluating an asthma patient’s response to anti-inflammatory therapy, as an adjunct to established clinical and laboratory assessments of asthma. A breath nitric oxide test system combines chemiluminescence detection of nitric oxide with a pneumotachograph, display, and dedicated software.

(b) Classification. Class II (special controls). The special control is FDA’s guidance entitled “Class II Special Controls Guidance Document: Breath Nitric Oxide Test System.” See § 862.1(d) for the availability of this guidance document.


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DEPARTMENT OF STATE

22 CFR Part 41

[Public Notice 4393]

VISAS: Documentation of Nonimmigrants Under the Immigration and Nationality Act, as Amended; Personal Appearance

AGENCY: Department of State.

ACTION: Interim rule with request for comments.

SUMMARY: This interim rule brings Department regulations into line with, and allows further expansion of, post-9/11 policy guidance issued by the Department that has increasingly restricted the number of instances in which the interview of a nonimmigrant visa applicant may be waived. The regulation significantly reduces the number and kind of situations in which the usual requirement that a nonimmigrant visa applicant appear before an officer for a personal interview may be waived by the consular officer, while making express the Department’s authority to set interview policies centrally. The Department is taking this regulatory action in order to further develop the new legal framework necessary to support a series of steps undertaken in order to more adequately ensure the security and integrity of nonimmigrant visa application and issuance procedures. Upon publication of this rule, certain visa applicants who previously may have had their personal appearance before a consular officer for the purpose of applying for a nonimmigrant visa waived will be required by regulation to make such an appearance to be interviewed. In practice, however, many of these applicants are already being interviewed, based on internal Department guidance or decisions made at consular posts.

DATES: Effective date: This rule is effective August 1, 2003.

Comment date: Written comments may be submitted within 60 days of the date of publication of this document in the Federal Register.

ADDRESSES: Written comments may be submitted, in duplicate, to the Legislation and Regulations Division, Visa Services, Department of State, Washington, DC 20520–0106, or by e-mail to visaregs@state.gov.


SUPPLEMENTARY INFORMATION:

What Is the Origin of the Waiver of Appearance Rule?

The Immigration and Nationality Act, section 222(e), requires that all applicants for immigrant visas appear personally before a consular officer, but leaves the question of personal appearance of nonimmigrant visa applicants to be defined by regulation. The Department’s regulations state a usual requirement of personal appearance by nonimmigrant visa applicants, but for at least forty years have defined a range of applicants whose appearance may be waived by the consular officer—i.e., granted a “personal appearance waiver” or “PAW.”

What Change Is Being Made?

Because of heightened security concerns in the period immediately following September 11, the Department undertook a review of its visa application and issuance procedures. As a result of that review, consular officers have begun to interview a much larger percentage of nonimmigrant visa applicants than they did prior to September 11, both in response to Department internal guidance and as a result of decisions made at consular posts. Because of the continuing need to ensure that the visa process is focused on security concerns, the Department believes it is desirable to codify the changed practice into regulation and to provide a regulatory basis for further adjusting the interview exemptions through centralized direction, as appropriate. This rule is intended to reflect the current scope and use of consular and Departmental personal appearance waiver authority. This amended version of the regulation generally permits waivers of the interview by consular officers in significantly fewer kinds of cases than the regulation being amended. The one exception is that the regulation raises the age of children who may qualify for consular officer interview waivers from age 14 to age 16. Consular officers will no longer have broad discretion under regulation to grant PAWs with respect to applicants for B, C–1, H–1, I, J and crew visas. In certain circumstances, however, officers will have discretion to grant PAWs for applicants for any category of nonimmigrant visa who have previously been issued a visa in the same category for which they are applying. The amended regulation continues consular authority for granting PAWs to diplomats and officials of international organizations. Further, it will allow the Deputy Assistant Secretary for Visa Services to waive the personal appearance requirement in specific situations, i.e., when the Department determines, centrally, that the waiver would not be inconsistent with homeland security interests. Thus, the regulation effectively shifts to the Department authority to make a number of interview waiver decisions previously made at consular posts.

Which Applicants May Still Benefit From a Consul’s Authority To Waive Personal Appearance?

Under the revised regulation, a consular officer may waive the personal appearance of a visa applicant in six specific categories. These are: (1) Children age 16 and under; (2) persons age 60 years or older; (3) most of the applicants within a class of nonimmigrants classifiable under the visa symbols A, C–2, C–3, G, or NATO (with the exception of attendants, servants and personal employees); (4) aliens applying for diplomatic or official visas, as defined in 22 CFR 41.26 and

Federal Register / Vol. 68, No. 129 / Monday, July 7, 2003 / Rules and Regulations 40127
41.27, respectively; (5) applicants who within twelve months of the expiration of their previous visa are seeking re-issuance of a nonimmigrant visa in the same classification at the consular post of the alien’s usual residence, and for whom the consular officer has no indication of any noncompliance with U.S. immigration laws and regulations, and (6) aliens for whom a waiver of personal appearance is warranted in the national interest or because of unusual circumstances, as determined by the consular officer.

Experience shows that applicants in the first and second categories pose very little if any threat to our security. Persons in the third and fourth categories, diplomats and officers or employees of international organizations and their immediate families are ordinarily very well known to embassy staff members, or there is extensive background information available concerning them. In addition, international law, comity and reciprocity with regard to official personnel may appropriately be taken into account. In the fifth category, the previous personal appearance by and interview of the applicant would make it unlikely that further appearance and interview would reveal any basis for refusal. Applicants in the sixth category, except for those cases based on medical issues, will generally be important contacts of embassy officers and therefore well known to the embassy. It is important to understand, however, that, although the consular officer has discretion to waive personal appearance for an individual falling in one of the six categories, waiver is never required.

What Other Waiver Authority May Be Exercised?

In addition to the waiver authority granted to consular officers in the six specific categories listed above, as mentioned, the Deputy Assistant Secretary for Visa Services will have the authority to waive the requirement for personal appearance for a class of individuals when the Deputy Assistant Secretary is satisfied that the waiver is in the national interest or involves unusual circumstances.

Regulatory Flexibility Act

Pursuant to section 605 of the Regulatory Flexibility Act, the Department has assessed the potential impact of this rule, and the Department of State hereby certifies that it is not expected to 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 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 does not consider this rule a “significant regulatory action” under Executive Order 12866, section 3(f) Regulatory Planning and Review. Nevertheless, the Department has submitted the rule to the Office of Management and Budget for its review.

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 require consultations or warrant the preparation of a federalism summary impact statement.

Paperwork Reduction Act

This rule does not impose any new reporting or record-keeping requirements subject to the Paperwork Reduction Act, 44 U.S.C. Chapter 35.

List of Subjects in 22 CFR Part 41

Aliens, Passports and Visas.

Accordingly, for the reasons discussed in the preamble, Part 41 is amended as follows:

PART 41—[AMENDED]

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


2. Revise section 41.102 to read as follows:

§ 41.102 Personal appearance of applicant.

(a) Personal appearance before a consular officer is required except as otherwise provided in this section. Except when the requirement of personal appearance has been waived pursuant to paragraph (b) or (c) of this section, each applicant for a nonimmigrant visa must personally appear before and be interviewed by a consular officer, who shall determine on the basis of the applicant’s representations, the visa application and other relevant documentation:

(1) The proper nonimmigrant classification, if any, of the alien; and

(2) The alien’s eligibility to receive a visa.

(b) Waivers of personal appearance by consular officers. Unless otherwise instructed by the Deputy Assistant Secretary of State for Visa Services, a consular officer may waive the requirement of personal appearance in the case of any alien who the consular officer concludes presents no national security concerns requiring an interview and who:

(1) Is a child 16 years of age or under;

(2) Is a person 60 years of age or older;

(3) Is within a class of nonimmigrants classifiable under the visa symbols A–1, A–2, C–2, C–3, G–1, G–2, G–3, G–4, NATO–1, NATO–2, NATO–3, NATO–4, NATO–5, or NATO–6 and who is seeking a visa in such classification;

(4) Is an applicant for a diplomatic or official visa as described in §§ 41.26 and 41.27 of this chapter, respectively;

(5) Is an applicant who within 12 months of the expiration of the applicant’s previously issued visa is seeking re-issuance of a nonimmigrant visa in the same classification at the consular post of the applicant’s usual
Explanation of Provisions  
Section 280F(a) limits annual depreciation deductions for passenger automobiles in order to discourage overspending on passenger automobiles purchased for use in business. For the 2003 taxable year, these limitations delay a portion of the otherwise allowable depreciation deductions for passenger automobiles with a purchase price above $15,300 (for passenger automobiles qualifying for additional first-year depreciation under section 168(k)(1), added by the Job Creation and Worker Assistance Act of 2002 (JCWAA), or under section 168(k)(4), added by Jobs and Growth Tax Relief Reconciliation Act of 2003 (JGTRRA)), the delay affects depreciation deductions for vehicles that cost more than $17,500 or $17,850, respectively. Passenger automobiles are defined in section 280F(d)(5)(A) as any 4-wheeled vehicle which is manufactured primarily for use on public streets, roads, and highways, and which is rated at 6,000 pounds unloaded gross vehicle weight (or, in the case of a truck or van, 6,000 pounds gross vehicle weight) or less. Section 280F(d)(5)(B) provides exceptions from this definition, and allows the Secretary to promulgate regulations to exclude trucks and vans from the definition of passenger automobiles.

While a basic automobile may be fully depreciated over five years under these rules, small business advocates have suggested that taxpayers with a valid business need for a van or light truck cannot fully depreciate a basic van or light truck within the standard five-year recovery period. Treasury and the IRS recognize that these vehicles generally cost more than other passenger automobiles and that even the most basic van or light truck may be subject to the section 280F(a) depreciation limits.

Some commenters on this issue suggested that the dollar limits on trucks and vans should be raised to reflect the higher cost of these vehicles. Although there is no general authority in section 280F to raise the dollar limits for specific types of vehicle, section 280F(d)(7) provides for adjustments to the dollar limits to reflect automobile price inflation since 1988. Moreover, much of the disparity between the cost of vans and light trucks and the cost of other passenger automobiles is attributable to the higher rate of price inflation for vans and light trucks since 1988. Accordingly, the revenue procedure setting forth the inflation-adjusted dollar limits for vehicles placed in service in 2003 will respond to the suggestion by providing higher dollar limits for vans and light trucks to reflect this higher rate of price inflation.

In addition, as noted above, JCWAA and JGTRRA have provided temporary relief by substantially increasing the first-year depreciation limits for all new passenger automobiles, including vans and light trucks. Thus, a taxpayer electing the 50-percent additional first-year depreciation permitted by JGTRRA can recover the full cost of a new automobile costing nearly $23,000 over the five-year recovery period. The revenue procedure described above would provide an even higher limit for new vans and light trucks.

Comments also suggested that Treasury and the IRS should exercise the regulatory authority in section 280F(d)(6) to provide an exclusion from the section 280F(a) depreciation limitations for all trucks and vans or for vehicles that are used in a specified manner. Treasury and the IRS have concluded that a limited exclusion is appropriate so long as it is based on objective factors and does not provide an incentive to purchase a truck or van when a less-expensive automobile would be sufficient to fulfill the taxpayer’s business needs. Accordingly, the temporary regulations exclude from the definition of passenger automobile any truck or van that is a qualified nonpersonal use vehicle as defined in §1.274-5T(k) of the Income Tax Regulations. Qualified nonpersonal use vehicles include not only the trucks and vans listed in §1.274-5T(k)(2), but also trucks and vans described in §1.274-5T(k)(7) (relating to trucks and vans that have been specially modified, such as by installation of permanent shelving and painting the vehicle to display advertising or the company’s name, so that they are not likely to be used more than a de minimis amount for personal purposes). These specially manufactured or modified vehicles do not provide significant elements of personal benefit, and a taxpayer is unlikely to purchase these vehicles unless motivated by a valid business purpose that could not be met with a less-expensive vehicle. We welcome comments on other options that provide administrable objective standards and are consistent with the statutory purpose.

The temporary regulations also strike from §1.280F-6T language relating to expired provisions of the Code.

Effective Date
The temporary regulations apply to property placed in service on or after July 7, 2003.