

**PART 862—CLINICAL CHEMISTRY  
AND CLINICAL TOXICOLOGY  
DEVICES**

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

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

■ 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.

Dated: June 23, 2003.

**Linda S. Kahan,**

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

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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](mailto:visaregs@state.gov).

**FOR FURTHER INFORMATION CONTACT:** Elizabeth J. Harper, Legislation and Regulations Division, Visa Services, Department of State, Washington, DC 20520-0106, (202) 663-1221.

**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 thorough 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