descriptions in AQS and detailed documentation and the schedule shall apply for those data which will or may influence the initial designation of areas for those NAAQS. EPA anticipates revising Table 1 as necessary to accommodate revised data submission schedules for new or revised NAAQS.

TABLE 1—SCHEDULE FOR EXCEPTIONAL EVENT FLAGGING AND DOCUMENTATION SUBMISSION FOR DATA TO BE USED IN DESIGNATIONS DECISIONS FOR NEW OR REVISED NAAQS

NAAQS pollutant/standard/(level)/promulgation date	Air quality data collected for calendar year	Event flagging and initial description deadline	Detailed documentation submission deadline
$PM_{2.5}$/24-Hr Standard (35 μg/m^3) Promulgated October 17, 2006.	2004–2006	October 1, 2007 [a]	April 15, 2008 [a].
Ozone/8-Hr Standard (0.075 ppb) Promulgated March 12, 2008.	2005–2007	December 31, 2008 [b]	March 12, 2009 [b].
	2008	March 12, 2009 [b]	March 12, 2009 [b].
	2009	January 8, 2010 [b]	January 8, 2010 [b].

[a] These dates are unchanged from those published in the original rulemaking, and are shown in this table for informational purposes.
[b] Indicates change from general schedule in 40 CFR 50.14.
Note: EPA notes that the table of revised deadlines only applies to data EPA will use to establish the final initial designations for new or revised NAAQS. The general schedule applies for all other purposes, most notably, for data used by EPA for redesignations to attainment.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

42 CFR Part 34

[Docket No. CDC–2008–0002]

RIN 0920–AA20

Medical Examination of Aliens—Revisions to Medical Screening Process

AGENCY: Centers for Disease Control and Prevention, U.S. Department of Health and Human Services.

ACTION: Interim final rule with comment period.

SUMMARY: The Centers for Disease Control and Prevention (CDC), within the U.S. Department of Health and Human Services (HHS), is amending its regulations that govern medical examinations that aliens must undergo before they may be admitted to the United States. HHS/CDC is amending the definition of *communicable disease of public health significance.* HHS/CDC is also amending the provisions that describe the scope of the medical examination for aliens by incorporating a more flexible, risk-based approach, based on medical and epidemiologic factors. This approach will assist HHS/CDC in determining which diseases the medical screening, testing, and treatment of aliens should include in areas of the world that are experiencing unforeseen outbreaks of those diseases. In addition, HHS/CDC is updating the screening requirements for tuberculosis to be consistent with current medical knowledge and practice.

These changes will reduce the health-security threat to the United States from emerging diseases without imposing an undue burden on either the aliens or the health-care system in U.S. resettlement communities.

DATES: The interim rule is effective on October 6, 2008. Interested parties must submit written comments on or before December 5, 2008. HHS/CDC will consider comments received after this period only to the extent practicable.

ADDRESSES: You may submit written comments, identified by Docket No. CDC–2008–0002, to the following address: Division of Global Migration and Quarantine, Centers for Disease Control and Prevention, U.S. Department of Health and Human Services, *ATTN:* Part 34 Comments, 1600 Clifton Road, NE., E03, Atlanta, GA 30333.

Comments will be available for public inspection from Monday through Friday, except for legal holidays, from 9 a.m. until 5 p.m., Eastern Time, at 1600 Clifton Road, NE., Atlanta, GA 30333.

Please call ahead to 1–866–694–4867, and ask for a representative in the Division of Global Migration and Quarantine to schedule your visit.

Comments are also available for viewing at the following Internet addresses: *http://www.cdc.gov/ncidod/dq* and *http://www.globalhealth.gov.* You may submit written comments electronically via the Internet at the following address: *http://www.regulations.gov,* or via e-mail to *Part34publiccomments@cdc.gov.*

To download an electronic version of the rule, please go to the following Internet address: *http://www.regulations.gov.*

FOR FURTHER INFORMATION, CONTACT: Stacy M. Howard, Division of Global Migration and Quarantine, Centers for Disease Control and Prevention, U.S. Department of Health and Human Services, 1600 Clifton Road, NE., E03, Atlanta, GA 30333; telephone 404–498–1600.

SUPPLEMENTARY INFORMATION: The Preamble to this interim rule is organized as follows:

I. Legal Authority

HHS/CDC is promulgating this rule under the authority of 42 U.S.C. 252 and 8 U.S.C. 1182 and 1222.

II. Background

Under section 212(a)(1) of the Immigration and Nationality Act (INA) (8 U.S.C. 1182(a)(1)), any alien determined to have a specified health-related condition is inadmissible to the United States. Those aliens outside the United States with a specified health-related condition (see below) are ineligible to receive a visa and ineligible to be admitted into the United States. The grounds of inadmissibility for specified health-related conditions also pertain to aliens in the United States who are applying for adjustment of immigration status to that of a lawful permanent resident.

Aliens are currently inadmissible into the United States if they have a communicable disease of public health significance, defined as follows: Active tuberculosis, infectious syphilis,

gonorrhea, infectious leprosy, chancroid, lymphogranuloma venereum, granuloma inguinale, and HIV infection.

Medical examinations, including a physical and mental evaluation, to determine whether an alien may have such a health-related condition, are authorized under section 232 of the INA (8 U.S.C. 1222). Under sections 212(a)(1) and 232 of the INA, and section 325 of the Public Health Service (PHS) Act (42 U.S.C. 252), the Secretary of Health and Human Services promulgates regulations to establish the requirements for the medical examination and to list the health-related conditions that make aliens ineligible for entry into the United States. The regulations, administered by HHS/CDC, are promulgated at 42 FR part 34.

As currently listed in § 34.1, the provisions in this part apply to the medical examination of (1) aliens outside the United States who are applying for an immigrant visa at an embassy or consulate of the United States; (2) aliens arriving in the United States; (3) aliens required by the U.S. Department of Homeland Security (DHS) [formerly required by the Immigration and Naturalization Service (INS)] to have a medical examination in connection with the determination of their admissibility into the United States; and (4) applicants in the United States who apply for adjustment of their immigration status to that of permanent resident.

Panel physicians, designated by consular officers of the U.S. Department of State, perform medical examinations abroad, and civil surgeons, designated by the U.S. Citizenship and Immigration Services, perform medical examinations for aliens who are already present in the United States. Aliens determined to have a communicable disease of public health significance may request a waiver to enter the United States under sections 212(d)(3)(a) and 212(g) of the INA (8 U.S.C. 1182(d)(3)(a) and 1182(g)).

Aliens are inadmissible if they are determined: (1) To have a communicable disease of public health significance; (2) to have a physical or mental disorder and behavior associated with the disorder that may pose, or has posed, a threat to the property, safety, or welfare of the alien or others; (3) to have had a physical or mental disorder and a history of behavior associated with the disorder, which has posed a threat to the property, safety, or welfare of the alien or others and which is likely to recur or lead to other harmful behavior; or (4) to be a drug abuser or addict. In addition, except for certain adopted children 10 years of age or younger, any alien who seeks admission as an immigrant, or seeks adjustment of immigration status to legal permanent resident, is inadmissible if the alien fails to present documentation of having received vaccination against mumps, measles, rubella, polio, tetanus and diphtheria toxoids, pertussis, *Haemophilus influenzae* type B, hepatitis B and any other vaccination recommended by the Advisory Committee for Immunization Practices.

Annually, the U.S. Government admits more than 1,000,000 immigrants and refugees to reside permanently in this country. The majority arrives from Asia, Africa and Central and South America, regions with recently reported outbreaks of emerging, infectious diseases, including yellow fever, dengue, Ebola and Marburg hemorrhagic fevers and the H5N1 strain of highly pathogenic avian influenza. These regular outbreaks, many of which affect both urban and rural areas, and the movement of large population resettlements from these regions, highlight the serious threat to public health in the United States to which the Centers for Disease Control and Prevention (CDC) within the U.S. Department of Health and Human Services (HHS) has to respond on very short notice.

In the recent past, the demographics of U.S.-bound refugees have shifted to populations that are at higher risk for communicable diseases. These newer groups of refugees have lower baseline rates of vaccination, higher rates of parasitic infections and more limited access to basic medical care and preventive health interventions before resettlement. Between 1996 and 2003, at least half of all arriving refugees were European. In 1998, 70 percent were European. Beginning in 2003, however, the numbers of refugees from Europe rapidly declined. In 2008, only three percent of all refugees arriving in the United States were European. At the same time, a larger proportion of refugees have come from countries with poorer economies, weaker health infrastructure, and limited access to basic medical care. As a result, these refugees have a higher incidence of major infectious diseases.

This demographic shift is one of the most important factors that have led to the substantial increase in the number and nature of outbreaks of communicable diseases that have affected refugee resettlements. These new populations bring new diseases but the diseases for which individuals are inadmissible into the United States have remained much the same as at the end of the nineteenth century.

The highest rates of tuberculosis among immigrants and refugees are for those born in sub-Saharan African and Southeast Asian countries, with rates of at least 250 cases per 100,000. By comparison, the rate in the United States is fewer than five cases per 100,000. Overall, approximately one-third of the world's population has the infection, and over 50 percent of TB cases in the United States are in foreign-born residents.

Panel physicians miss up to 67 per cent of tuberculosis (TB) cases based on the current scope of medical examination requirements. Implementation of these revisions to the regulations would ensure the methods for screening and testing TB used during the medical examination of aliens reflect the most current medical practice.

The resettlement of these populations, many of which are coming from high-risk countries, is a strong argument for an immediate implementation of the changes in the list of communicable diseases of public health significance to reduce the potential of emerging disease threats in this higher-risk caseload. Urgent changes to this list are needed to prevent importing communicable diseases into our country. The current regulations do not address emerging and re-emerging diseases in immigrant or refugee populations. HHS is adding diseases to the communicable diseases of public health significance that better reflect the true threats that our Nation faces, including cholera, diphtheria, plague, smallpox, yellow fever, viral hemorrhagic fevers, and severe acute respiratory syndrome (SARS). These diseases currently exist in the list of quarantinable, communicable diseases defined by Presidential Executive Order, but do not appear on the list of communicable diseases of public-health significance. These diseases cause severe illness and death in regions of the world that are home to large numbers of immigrants and refugees bound for the United States.

In addition, the revision to part 34 is consistent with relevant provisions of the revised International Health Regulations (2005), which came into force in July of 2007.

HHS/CDC also issues technical instructions and provides technical consultation and guidance to panel physicians and civil surgeons who conduct the medical examinations of aliens. The HHS/CDC *Technical Instructions for Medical Examination of Aliens,* including the most current updates, which panel physicians and civil surgeons must follow in accordance with these regulations, are

available to the public on the HHS/CDC Web site, located at the following Internet address: *http://www.cdc.gov/ncidod/dq/technica.htm.* HHS/CDC will also post and maintain a list of all medical conditions and locations for which additional screening requirements are in effect pursuant to this rule. This list will be available at the same Internet address: *http://www.cdc.gov/ncidod/dq/technica.htm,* and *http://www.globalhealth.gov.*

III. Summary of Changes to 42 CFR Part 34

HHS/CDC is amending the definition of a *communicable disease of public health significance.* Current communicable diseases of public health significance are: active tuberculosis, infectious syphilis, gonorrhea, infectious leprosy, chancroid, lymphogranuloma venereum, granuloma inguinale, and HIV infection.

The definition of a *communicable disease of public health significance* in this rule remains as those diseases currently listed in § 34.2(b), plus the addition of (1) quarantinable diseases designated by Presidential Executive Order, and (2) those diseases that meet the criteria of a public health emergency of international concern which require notification to the World Health Organization (WHO) under the revised International Health Regulations of 2005. A delay in implementing these updates to Part 34 poses a risk of further severe illness for refugees and immigrants as they move into receiving U.S. communities and presents American taxpayers with elevated medical costs. Updating the list of communicable diseases of public health significance will diminish complex and costly measures such as vaccination, chemoprophylaxis and isolation, and lessen illness and death among the affected migrating populations.

The following is a section-by-section analysis of proposed changes:

Section 34.2 Definitions

The revision updates the definition provided in § 34.2(b) for a *communicable disease of public health significance* to include two new categories of disease. The first category, added as § 34.2(b)(2), is the quarantinable, communicable diseases specified by the President in Executive Order, as provided under Section 361(b) of the Public Health Service Act. The second category, added as § 34.2(b)(3), is any communicable disease that requires notification to the World Health Organization as an event that may constitute a public health emergency of international concern, pursuant to the revised International Health Regulations of 2005.

Section 34.3 Scope of Examinations

HHS/CDC is publishing section 34.3 in its entirety for clarity, including republication of some provisions that are unchanged. HHS/CDC has revised section 34.3 to include screening and testing for the updated list of communicable diseases of public health significance, as defined in § 34.2(b). HHS/CDC has also revised section 34.3 to require additional medical screening and testing using a more flexible risk-based approach for those medical examinations performed outside of the United States. HHS/CDC has also revised the specific requirements concerning the required evaluation for tuberculosis.

The U.S. Department of Homeland Security (DHS) currently is the entity responsible for administering the immigration authority and functions previously administered by the Immigration and Naturalization Service (INS), which was within the U.S. Department of Justice. The revised rule text changes the reference to INS in existing § 34.3(b)(2)(i) to U.S. Department of Homeland Security in new § 34.3(e)(3)(i).

Specific Changes to the Scope of the Medical Examination, and the Risk-Based Approach

The title of § 34.3(b) has changed to *Scope of all medical examinations*, and provides that all medical examinations will include a general physical examination and medical history, evaluation for tuberculosis, serologic testing for syphilis and HIV, and also a physical examination and medical history for diseases specified in §§ 34.2(b)(1) and 34.2(b)(4) through 34.2(b)(10). The unindented paragraph currently at the end of § 34.3(a) has been moved to § 34.3(b)(2).

The title of § 34.3(c) has been changed to *Additional medical screening and testing for examinations performed outside of the United States* and provides that HHS/CDC may require additional screening and testing for medical examinations performed outside the United States for diseases specified in §§ 34.2(b)(2) and 34.2(b)(3) by applying the risk-based medical and epidemiologic factors listed in § 34.3(d)(2). It provides that such examinations shall be conducted in a defined population, in a geographic region or area outside the United States, for a period of time as determined by HHS/CDC. Additional medical screening and testing shall include a medical interview, physical examination, laboratory testing, radiologic exam, or other diagnostic testing as determined by HHS/CDC. Section 34.3(c)(4) and (5) indicate that additional medical screening and testing will continue until HHS/CDC determines such activity is not necessary, based on medical and epidemiologic factors, and that HHS/CDC will provide medical examiners with information pertaining to all additional screening and testing requirements, and will also post the information on the HHS/CDC Web site.

Section 34.3(d) is entitled *Risk-based approach*, and provides the medical and epidemiological factors that HHS/CDC will use to determine whether a disease as specified in § 34.2(b)(3)(ii) is a *communicable disease of public health significance*, which diseases in §§ 34.2(b)(2) and (b)(3) merit additional screening and testing, and the geographic area in which HHS/CDC will require this screening. These factors include the seriousness of the disease's public health impact; whether the emergence of the disease was unusual or unexpected; the risk of the spread of the disease to the United States; the transmissibility and virulence of the disease; the impact of the disease at the geographic location of medical screening; and other specific pathogenic factors that would bear on a disease's ability to threaten the health security of the United States.

Specific Changes to Tuberculosis Screening Requirements

HHS/CDC has revised § 34.3 to require testing for tuberculosis of children under the age of 15 years old when they have symptoms of tuberculosis, a history of tuberculosis, or possible exposure to a transmissible tuberculosis case in a household or other enclosed environment for a prolonged period. With regard to additional testing requirements for an applicant that has a radiograph that indicates an abnormality suggestive of tuberculosis disease, HHS/CDC has revised § 34.3 to require additional testing for tuberculosis. Specific changes regarding the required evaluation for tuberculosis appear below.

Section 34.3(b), entitled *Persons subject to requirement for chest x-ray examination and serologic testing* is now § 34.3(e). The revision adds § 34.3(e)(2)(ii) to include a chest x-ray examination for applicants under 15 years of age if they have symptoms of tuberculosis, a history of tuberculosis, or evidence of possible exposure to a transmissible tuberculosis case in a household or other enclosed

environment for a prolonged period. The paragraph describing requirements for tuberculin skin test (TST) examination is now § 34.3(e)(3), and has been renamed *Immune response to Mycobacterium tuberculosis antigens* to reflect updated, current equivalent tests that are increasingly used in clinical settings and may eventually be used as an alternative to the tuberculin skin test for refugee and immigrant screening. The Quantiferon-TB Gold (QFT–G) test is one recommended method for screening for tuberculosis in clinical practice in most circumstances instead of the TST. The incorporation of Immune Globulin Release Assays (IGRAs), which include QFT–G, is under consideration by CDC for screening for tuberculosis in aliens. This change will insure that current, updated medical technology will be used, as appropriate, by panel physicians and civil surgeons conducting the medical examinations. This section also includes the addition of § 34.3(e)(3)(iii) which requires a tuberculin skin test, or an equivalent test for showing an immune response to *Mycobacterium tuberculosis* antigens, for applicants outside of the United States who are required to have a medical examination and, if indicated, a chest x-ray examination, if the applicant is of sufficient age to be considered contagious.

Section 34.3(e)(3)(iv) requires both a tuberculin skin test, or an equivalent test for showing an immune response to *Mycobacterium tuberculosis* antigens, and a chest x-ray examination for any applicant outside of the United States, regardless of age, if the applicant has symptoms of tuberculosis, a history of tuberculosis, or possible exposure to a transmissible tuberculosis case in a household or other enclosed environment for a prolonged period.

Section 34.3(e)(4), entitled *Additional testing requirements*, indicates that all applicants subject to the chest x-ray examination and for whom the radiograph shows an abnormality suggestive of tuberculosis disease must undergo additional testing for tuberculosis. This change allows for the use of the most current testing procedures for tuberculosis disease.

References to the Attorney General in existing §§ 34.3(b)(4) and (e) are changed to the Secretary of Homeland Security in new §§ 34.3(e)(5) and (h) to reflect the creation of DHS in 2003 and its assumption of applicable authorities and responsibilities. Reference to *INS* in existing § 34.3(b)(2)(i) is changed to *U.S. Department of Homeland Security* in new § 34.3(e)(3)(i). These ministerial corrections are the only amendments to these sections which are otherwise republished unchanged.

IV. Revised Definition of *Communicable Disease of Public Health Significance*

As stated in Section 212(a)(1) of the INA, aliens are inadmissible into the United States if they are determined to have a specified health condition, which includes a *communicable disease of public health significance*. Currently, medical examinations require the screening of all aliens subject to these requirements for all listed communicable diseases of public health significance. Regulations have historically defined the term *communicable disease of public health significance* by listing specific diseases. The current definition in 42 CFR 34.2(b) includes chancroid, gonorrhea, *granuloma inguinale*, human immunodeficiency virus (HIV) infection, infectious leprosy, *lymphogranuloma venereum*, infectious-stage syphilis, and active tuberculosis.

Recent experience has demonstrated that a fixed list of diseases does not allow HHS/CDC the flexibility it needs to rapidly respond to unanticipated emerging or re-emerging outbreaks of disease. Rather, HHS/CDC requires an approach based on potential risks and consequences instead of a static list that does not reflect the potential for future outbreaks of novel diseases. National and international health agencies have recently developed guidelines for defining diseases of public health significance that threaten global health security and require an urgent response. This guidance provides the framework to update the list of communicable diseases of public health significance for the United States to screen and test aliens during disease outbreaks in real time.

HHS/CDC is adding the following two disease categories to the current list of communicable diseases of public health significance:

(1) Quarantinable, communicable diseases specified by Presidential Executive Order, as provided under Section 361(b) of the Public Health Service Act; and

(2) Any communicable disease that requires notification to the World Health Organization as an event that may constitute a public health emergency of international concern, pursuant to the revised International Health Regulations of 2005.

Quarantinable Communicable Diseases Specified by Presidential Executive Order, as Provided Under Section 361(b) of the Public Health Service Act

Section 361 of the Public Health Service Act authorizes the Secretary of HHS to enact rules and regulations for preventing the introduction, transmission, and spread of communicable diseases from foreign countries into the United States, and from one State or possession into another. Executive Order 13295 of April 4, 2003, as amended by Executive Order 13375 of April 1, 2005, contains the most recent list of quarantinable, communicable diseases, and includes the following: Cholera, yellow fever, plague, viral hemorrhagic fevers, diphtheria, infectious tuberculosis, smallpox, severe acute respiratory syndrome (SARS), and influenza caused by novel or re-emergent influenza viruses that are causing, or have the potential to cause, a pandemic (pandemic influenza). HHS/CDC is adding diseases listed by Presidential Executive Order to the definition of *communicable diseases of public health significance*, subject to screening and testing requirements outlined in the section on the scope of examinations.

Any Communicable Disease That Requires Notification to the World Health Organization as an Event That May Constitute a Public Health Emergency of International Concern, Pursuant to the Revised International Health Regulations of 2005

In May 2005, the World Health Assembly adopted the revised International Health Regulations (IHR (2005)). These regulations entered into force for most of the Member States of the WHO in June 2007 and for the U.S. in July 2007. The purpose and scope of the IHR (2005) are to prevent, protect against, control and provide a public health response to the international spread of disease, while minimizing interference with world travel and trade. Annex 2 of the IHR (2005) contains an algorithm for identifying a *public health emergency of international concern*, and can be located at the following Internet address: *http://www.who.int/gb/ghs/pdf/IHR_IGWG2_ID4-en.pdf*.

The IHR (2005) define a *public health emergency of international concern* as an extraordinary event which is determined: (i) To constitute a public health risk to other [Member] States through the international spread of disease and (ii) to potentially require a coordinated international response. Under the IHR (2005), Member States must notify the World Health

Organization of any disease event that fulfills the criteria presented in the three categories of the algorithm in Annex 2. The definition in the revised part 34 rule text is intended to capture those diseases that require notification by any country to the WHO under the IHR (2005) and determined to be an event that may constitute a public health emergency of international concern. The revised part 34 rule text references IHR (2005) category (1), below, in § 34.2(b)(3)(i), and categories (2) and (3), below, together in § 34.2(b)(3)(ii).

(1) Diseases Listed in the IHR (2005) for Which a Single Case Requires Notification Through the Use of the IHR (2005) Algorithm

Annex 2 of the IHR (2005) specifies that smallpox, poliomyelitis from wild-type poliovirus, pandemic influenza and severe acute respiratory syndrome (SARS) are diseases with serious public health impact, and that a single case, irrespective of context, requires immediate notification to the WHO. HHS/CDC is adding diseases listed in this category to the definition of a *communicable disease of public health significance*, subject to screening and testing requirements outlined in the section on the scope of examinations.

The impact of the SARS outbreak demonstrates the importance of using the IHR (2005) algorithm to quickly detect and identify emerging and re-emerging pathogens in this category. SARS coronavirus is a droplet-spread illness that rapidly emerged as a global threat in 2003, caused more than 8,000 cases and 800 deaths, and required isolation and quarantine control measures. Although now contained, the disease (or one similar to it) could re-emerge at any time. The use of the IHR (2005) process for disease notification to the WHO will ensure the earliest possible protection of citizens in the United States through medical screening of a pathogen like SARS when the next outbreak occurs. Smallpox, which causes high mortality and morbidity, is another disease in this category. Because smallpox is now successfully eradicated, it poses an ongoing threat as a bioterrorism agent.

(2) Other Diseases Listed in the IHR (2005) for Which Notification Is Required Through the Use of the IHR (2005) Algorithm

In addition to the single-case notification diseases, Annex 2 indicates that an event that involves the following diseases shall always lead to the use of the IHR (2005) algorithm to determine whether the disease occurrence amounts to a public health emergency of international concern, because these diseases have demonstrated the ability to cause serious public health impact and to spread rapidly internationally:

—Cholera;
—Pneumonic plague;
—Yellow fever;
—Viral hemorrhagic fevers (Ebola, Lassa, Marburg);
—West Nile fever; and
—Other diseases that are of special national or regional concern (e.g. dengue fever, Rift Valley fever, and meningococcal disease).

HHS/CDC is adding diseases listed in this category to the definition of a *communicable disease of public health significance*, subject to screening and testing requirements and risk-based factors outlined in the section on the scope of examinations.

Ongoing threats in this category include Ebola hemorrhagic fever, a severe, often fatal disease, easily spread through close personal contact. An outbreak of Ebola in the Democratic Republic of the Congo, confirmed in September 2007, resulted in 26 laboratory-confirmed cases of illness as of October 2007. There have been a total of 264 suspected cases, and Ebola is believed to have killed up to 187 people over eight months. A subsequent outbreak of Ebola in the Republic of Uganda produced 149 suspect cases and killed 37 people. Cholera, which can cause severe diarrhea and death, also continues to be active. From August 2007 through November 2007, an outbreak spread throughout Iraq and caused over 4500 cases of illness and 23 deaths.

(3) Other Unspecified Diseases That Require Notification Through the Use of the IHR (2005) Algorithm

Annex 2 also refers to any event of potential international health concern, including those of unknown causes or sources, and those that involve events or diseases, other than the IHR (2005) single-case notifiable and other specified notifiable diseases (listed in (1) and (2) above), that lead to use of the IHR (2005) algorithm. HHS/CDC is adding diseases listed in this category to the definition of a *communicable disease of public health significance*, subject to screening and testing requirements and risk-based factors outlined in the section on scope of examinations. Addition of this last category to the definition of diseases of public health significance allows HHS/CDC to respond rapidly to emerging disease threats in a way that adding specific diseases to a fixed list does not.

Once HHS/CDC acknowledges an event from the IHR (2005) algorithm as a disease of public health significance, HHS/CDC will immediately advise the physicians who conduct medical examinations of the additional medical screening or testing required for the identified disease(s) via electronic notification, coordination with embassies, consulates and the International Organization for Migration, by publication on the HHS/CDC Web site, and publication of a notice in the **Federal Register**. HHS/CDC will also provide any required disease notifications to appropriate DOS bureaus. HHS/CDC will also maintain a current list of diseases and locations subject to additional medical screening and will update addenda to the *Technical Instructions for Medical Examination of Aliens* regarding these diseases, available to the public on the HHS/CDC Division of Global Migration and Quarantine Web site, located at the following Internet address: *http://www.cdc.gov/ncidod/dq/technica.htm*, and also at *http://www.globalhealth.gov*.

The HHS/CDC Division of Global Migration and Quarantine is the current name of the former Division of Quarantine used in existing § 34.3(f), and section 34.3(i) of the revised rule text uses the correct name. The section is otherwise republished unchanged.

V. Revised Scope of Medical Examination

HHS/CDC is amending the scope of the medical examination in 42 CFR 34.3 to allow greater agility to respond to significant outbreaks of communicable diseases of public health significance for applicants examined in geographic locations where these diseases exist, and for which importation into the United States would pose a threat. HHS/CDC believes a risk-based approach that uses medical and epidemiologic factors to detect additional diseases of public health significance provides a flexible, fair and practical means to address infectious disease threats among at-risk aliens without placing an undue burden on other applicants.

Beginning on the effective date of this rule, HHS/CDC will also make a distinction between the medical examinations performed for aliens outside the United States, and those performed for aliens already in the United States who are applying for adjustment of status to that of permanent resident, in that the risk-based approach to detect additional diseases of public health significance will apply only to medical examinations outside the United States and only in those geographic areas where the risk is high. Applicants already within the United States who apply for adjustment

of immigration status will not be subject to additional screening or testing using the risk-based approach. Disease outbreaks in aliens who are within the United States primarily fall under the jurisdiction of state and local public health authorities. For both groups of aliens, those applying for status adjustment from within the United States and those applying for admission from outside the United States, the medical screening examination will continue to consist of a general physical examination and medical history, evaluation for tuberculosis, and serologic testing for syphilis and HIV. In addition, under the new risk-based approach, HHS/CDC may require aliens outside the United States applying for U.S. immigration to undergo additional screening and testing for specific communicable diseases of public health significance.

Quarantinable, Communicable Diseases Specified by Presidential Executive Order as Provided Under Section 361(b) of the Public Health Service Act

Medical screening for these diseases will be achieved through physical examination and medical history. Accomplish HHS/CDC may require additional screening or testing for these diseases for aliens receiving medical examinations at the specific location or area where outbreaks of the disease or diseases may be occurring. This additional screening and testing will involve applying the defined risk-based approach by using medical and epidemiologic factors (shown below in this section.)

This change addresses diseases in immigrant and refugee populations (and, in extreme cases, non-immigrant aliens) outside the United States, and ensures the lists of quarantinable diseases and inadmissible conditions remain consistent. Whenever this Executive Order is amended in the future to add additional diseases, HHS/CDC will be able to immediately begin testing and screening for these diseases.

Any Communicable Disease That Requires Notification to the World Health Organization as an Event That May Constitute a Public Health Emergency of International Concern, Pursuant to the Revised International Health Regulations of 2005

(1) Diseases Under the IHR (2005) for Which a Single Case Requires Notification to WHO as an Event That May Constitute a Public Health Emergency of International Concern

HHS/CDC will consider all the diseases in this category, including diseases included by WHO in the future, as communicable diseases of public health significance and subject to medical screening through physical examination and medical history. HHS/CDC will also consider imposing additional screening and testing, as determined by the specific circumstances of the event, for diseases in this category that meet requirements of the risk-based approach composed of medical and epidemiologic factors (shown below in this section) and for which HHS/CDC determines a threat exists for importation into the United States, and that may potentially affect the health of the American public.

(2) Other Diseases That Require Notification to WHO as an Event That May Constitute a Public Health Emergency of International Concern Through the Use of the IHR (2005) Algorithm (Includes Categories (2) and (3) of the IHR (2005) Algorithm Referenced Previously in Section IV—Revised Definition of a Communicable Disease of Public Health Significance)

HHS/CDC will consider the diseases in this category as communicable diseases of public health significance and subject to medical screening through physical examination and medical history if they meet one or more of the risk-based criteria of medical and epidemiologic factors (shown below in this section), and HHS/CDC determines (1) a threat exists for importation into the United States, and (2) such diseases may potentially affect the health of the American public. HHS/CDC will also consider imposing additional screening and testing for diseases in this category, as determined by the specific circumstances of the event.

Risk-Based Approach of Medical and Epidemiologic Factors

HHS/CDC will determine which diseases merit additional screening and testing, and the geographic area in which HHS/CDC will require this screening, by applying a risk-based approach that takes into account the following medical and epidemiologic factors: (a) The seriousness of the disease's public health impact; (b) whether the emergence of the disease was unusual or unexpected; (c) the risk of the spread of the disease to the United States; (d) the transmissibility and virulence of the disease; (e) the impact of the disease at the geographic location of medical screening; and (f) other, specific pathogenic factors that would bear on a disease's ability to threaten the health security of the United States. HHS/CDC will consider diseases identified through the International Health Regulations algorithm (other than diseases for which a single case requires notification) as communicable diseases of public health significance when they meet one or more of the criteria listed above, and for which HHS/CDC determines (A) a threat exists for importation into the United States, and (B) such diseases may potentially affect the health of the American public.

This risk-based approach will facilitate a meaningful public health response to existing and emerging threats, without overwhelming the entire health system with needless testing. The changes to the scope of the examination will allow HHS/CDC to tailor testing requirements to those areas where the severity of communicable diseases of public health concern are actually affecting populations at the time of the medical examination.

When HHS/CDC requires screening for additional communicable diseases of public health significance for applicants from specific geographic areas, HHS/CDC may require additional screening, including additional medical interviews, a physical examination, laboratory testing, radiologic exams, or other diagnostic procedures.

Screening and testing for newly identified diseases as a part of the list of communicable diseases of public health significance will continue until HHS/CDC determines the particular situation does not warrant this designation, based on factors such as the results of disease investigations; response efforts; the effectiveness of containment and control measures; and the current determination or termination of the public health emergency of international concern by the Director General of the WHO.

HHS/CDC will provide physicians the technical instructions regarding the required additional medical screening and testing to perform for a disease as part of the examination. In most instances, additional medical screening and testing may only consist of epidemiologic questions and further physical examination relating to the disease. HHS/CDC will also update the *Technical Instructions for Medical Examination of Aliens*, as needed, regarding the additional medical screening and testing protocol for a disease, and this information will also be immediately available to the public on the HHS/CDC Division of Global Migration and Quarantine Web site, located at the following Internet address: *http://www.cdc.gov/ncidod/dq/technica.htm*; and at *http://www.globalhealth.gov*. A listing of current documents regarding the

additional medical screening and testing protocol for specific diseases will also be available on the HHS/CDC Web site.

VI. Updating Tuberculosis Screening Requirements

HHS/CDC is amending the medical examination rule for aliens by updating the screening requirements for tuberculosis, to be consistent with current medical knowledge and practice. HHS/CDC is amending 42 CFR 34.3(b) by revising the requirement for a chest X-ray examination to include applicants under the age of fifteen years old, when there is reason to suspect tuberculosis infection. The practical effect of this change is to expand this testing protocol to alien applicant children under the age of 15, when medically appropriate. This change will allow HHS/CDC the flexibility to ensure the tuberculosis screening and testing methods used for medical examination of aliens are current and effective.

HHS/CDC is amending § 34.3(b)(1)(v) by adding the expanded tuberculin skin test requirement, or an equivalent test for showing an immune response to *Mycobacterium tuberculosis* antigens, to the exceptions that may be authorized for good cause upon application approved by the Director of CDC.

HHS/CDC is amending § 34.3(b)(2) to indicate that any alien applicant outside the United States shall have a tuberculin skin test or an equivalent test for showing an immune response to *Mycobacterium tuberculosis* antigens and, if indicated, a chest X-ray examination if the applicant is of sufficient age to be considered contagious. Additionally, any alien applicant outside the United States, regardless of age, shall have both a tuberculin skin test or an equivalent test for showing an immune response to *Mycobacterium tuberculosis* antigens, and a chest X-ray examination if the applicant has symptoms of tuberculosis disease, has a history of tuberculosis, or has exposure to a transmissible tuberculosis case in a household or other enclosed environment for a prolonged period. HHS/CDC is amending this section to make it consistent with current medical knowledge and practice.

HHS/CDC is amending § 34.3 by adding a new provision, entitled *Additional Testing Requirements*, with the following rule text: All applicants subject to the chest X-ray examination requirement and for whom the radiograph shows an abnormality suggestive of tuberculosis disease shall be required to undergo additional testing for tuberculosis disease.

The current, outdated rule requires sputum smears for anyone with signs, or x-ray findings, suggestive of tuberculosis. Current medical guidelines require mycobacterial culture, which is three times as sensitive as a sputum smear for detecting active tuberculosis.

HHS/CDC is also updating language in 34.3(e) and (f) to replace x-ray film with x-ray image. This change is needed to reflect updated radiology technology such as CD–R and laser-printed x-ray formats. Language concerning chest x-rays being attached to the alien's visa in such a manner to be readily detached at the U.S. port of entry has also been deleted since x-rays are not required to be presented at the port of entry.

VII. Urgent Need for Regulatory Change

The U.S. Department of State proposed 80,000 refugee admissions for Fiscal Year 2008 under the requirements of Section 207(e)(1)–(7) of the Immigration and Nationality Act. This is greater than a ten percent increase from FY 2007 projections. As of June 2008, approximately 35,000 refugees have been resettled, and around 27,000 still expected by the end of September 2008. Major diseases of concern in these incoming refugee populations include multi-drug-resistant tuberculosis (MDR TB), measles, highly pathogenic avian influenza, and cholera. The potential for transmitting viral hemorrhagic fevers, such as Ebola and Marburg, also exists among some of the African populations being resettled. In addition, several vector-borne (animal-transmitted) diseases including chikungunya, dengue and, possibly, Rift Valley fever, are circulating in refugee camps with populations bound for the United States. Vectors (i.e. mosquitoes) prevalent in the United States are capable of widely spreading these diseases.

Allowing serious diseases to enter into the United States can result in significant harm to both the American public and American business. The existing definition of *communicable diseases of public health significance* and the evaluation criteria for tuberculosis in the current regulation are outdated and no longer in keeping with current medical knowledge. Therefore, immediate changes are needed to improve the ability of the United States to prevent the introduction and spread of infectious diseases that are currently causing severe illness and death abroad. The scope of examination for medical screening is also outdated, and needs immediate changes to allow for medical screening by using a risk-based approach that considers medical and epidemiologic factors. The current regulations do not have a process for allowing HHS/CDC to adapt rapidly to new health threats, and they reference outdated public health practices that do not take advantage of the latest biomedical knowledge and epidemiologic data. Changes are needed now to reduce the potential for significant harm from emerging diseases and outbreaks of infectious diseases that currently threaten U.S. health security.

Newly emerging communicable disease threats are arising with increased frequency because of multiple factors, such as increases in global travel and mobility, migration patterns, human susceptibility to novel infections, and microbial adaptation and mutation, as cited in the latest report of the U.S. Institute of Medicine on emergence of infectious diseases, *Microbial Threats to Health: Emergence, Detection and Response*, National Academies Press, 2003. Infectious disease outbreaks (e.g., SARS in 2003) or potential threats like pandemic influenza are evidence that virulent diseases with short incubation periods can be carried over a border before signs of illness can be observed. Additionally, when disease outbreaks occur in refugees or immigrants coming to the United States, public health control actions such as vaccination, treatment, chemoprophylaxis and isolation must be implemented immediately to prevent the importation of disease into the United States.

Annually, approximately 1,000,000 immigrants and refugees enter the United States to reside here permanently. The majority arrive from Asia, Africa and Central and South America, regions with recently reported outbreaks of emerging infectious diseases, including yellow fever, dengue and the H5N1 strain of avian influenza. The 50,000–80,000 refugees who resettle in the United States each year are the most vulnerable populations, as they often come from difficult environmental conditions with limited water, sanitation and health care. Living conditions for many refugees include poor to nonexistent health and public health infrastructure; thus, it is difficult to have adequate knowledge of their current and potential medical problems. In refugee camps, disease surveillance and laboratory resources are often limited, which increases the difficulty of maintaining good health and preventing outbreaks of infectious diseases. Historically, outbreaks of communicable diseases have occurred frequently in refugee camps. These regular outbreaks, and the inherent nature of large population resettlements, highlight the health threats to which

HHS/CDC has to respond on very short notice.

The shift in the demographics of refugee and immigrant populations bound for the United States and consequent changes in their health risks mandate a change in the definition of a *communicable disease of public health significance*, because of the current uncertainty of global disease trends. This demographic shift is the single most important cause of the substantial increase in the number and nature of outbreaks of communicable diseases among immigrants who are resettling into the United States.

HHS/CDC is unable to forecast constantly changing migration patterns, and thus must have the flexibility to respond swiftly as unpredictable, problematic health and humanitarian crises arise. The current definition of a *communicable disease of public health significance* does not adequately accommodate the demographic shifts that have dramatically altered the pattern of diseases among new arrivals in the United States.

HHS/CDC has found that the origins of U.S.-bound populations are increasingly unpredictable, and these populations increasingly originate in areas with challenging and unpredictable communicable diseases of public health significance. Immigration statistics (*http://www.dhs.gov/ximgtn/statistics*) show more U.S.-bound refugees and immigrants now come from regions with a higher risk for communicable diseases. In recent years, the disease burden to the United States has increased as the proportion of refugees resettling from Africa and Asia has increased (*http://www.state.gov/g/prm/refadm/rls/85970.htm*). As an example, the proportion of refugees resettled to the United States from Africa have increased in the recent past. African refugee arrivals have averaged 16,000 per year since FY 2005. These newer groups of refugees have lower baseline rates of vaccination, higher rates of malaria and other parasitic infections (unfamiliar to most American clinicians), and very limited access to basic medical care and preventive health interventions before resettlement. Failure to address these conditions adequately because of the outdated definition of *communicable diseases of public health significance* has meant that HHS/CDC has had to respond to at least 25 outbreaks of disease among U.S.-bound refugees since 2004.

Major outbreaks of dangerous, communicable diseases around the world in 2007 included Ebola in the Democratic Republic of the Congo in September, and in Uganda in December; cholera in Iraq in August; yellow fever in Togo in February, and in Brazil and Paraguay in December; and 85 animal-to-human cases of the highly pathogenic H5N1 strain of avian influenza throughout the year. These outbreaks have been of diseases that do not naturally occur in the United States, or occur rarely, which could result in disability and death in U.S.-bound immigrants and refugees and secondary spread in the communities in the United States that receive immigrants.

The WHO classifies yellow fever as a disease that has demonstrated the ability to cause serious public health impact, and is a good example of a threat to the health security of the United States. The Ministry of Health in Togo reported an outbreak of yellow fever to the WHO that lasted from December 2006 through February 2007. Moreover, Sudan, Senegal, Mali, Côte d'Ivoire, Burkina Faso, Guinea, Brazil, Peru, Paraguay, Bolivia and Argentina have also reported ongoing outbreaks of yellow fever to the WHO. In total, the WHO considers 46 countries, including 33 African countries and 11 countries in Central and South America, to be currently at risk of yellow fever. Substantial numbers of U.S.-bound immigrants and refugees originate from areas in which yellow fever is endemic, and therefore pose a risk of the importation of this disease. Since mosquitoes that spread yellow fever exist in the United States, and areas of our country experienced outbreaks of the disease throughout the nineteenth century, importation could potentially result in sustained transmission in this country. Yellow fever is not currently included in the specific disease list in the regulation, but HHS/CDC would be classify it as a *communicable disease of public health significance* under the newly proposed definition, because it is a quarantinable disease by Presidential Executive Order and a disease that requires notification to WHO as an event that may constitute a public health emergency of international concern under the IHR (2005).

The examples below enumerate some of the most recent (and largely unpredictable) disease outbreaks encountered as refugees resettle into the United States:

—*March 2007 to the present:* Imported malaria outbreak in Burundian refugees from Tanzania. Over 40 cases of malaria *have occurred as of October* 2007 in more than 12 U.S. states, including 18 cases in children less than 10 years old, despite the administration of a pre-departure drug treatment regimen. Single cases or small domestic outbreaks through mosquitoes are another potential risk from this outbreak.

—*October 2007 to the present:* at least 12 cases of cholera have been reported in several thousand U.S.-bound refugees *from the Dadaab refugee camp* in Kenya, which led to a temporary suspension of resettlement. This was the second outbreak of cholera in this camp in 2007; an earlier outbreak affected more than 200 refugees in June 2007.

—*July 2007 to the present:* cholera in Mae La refugee camp in Thailand, with over 200 cases reported as of October 2007.

—*April to June 2007:* 288 cases of cholera were reported in Dadaab refugee camp in Kenya. These cases included four deaths and necessitated a five-day holding period for U.S.-bound refugees before travel.

—*January to May 2007:* A measles outbreak affected over 100 persons in Dadaab refugee camp in Kenya and showed unusual epidemiology: 43 percent of cases were in persons 15 years of age and older (measles usually affects only children, and thus most vaccination campaigns only cover those under 5 years of age).

—*November 2006 to May 2007:* Rift Valley Fever in Kenya (including in the Dadaab camp), Somalia, and the United Republic of Tanzania, with over 300 deaths.

—*October 2006:* A case of polio reported in the Dadaab refugee camp in Kenya, in the first reported local transmission of wild poliovirus for over 20 years in Kenya; only quick action by HHS/CDC avoided the importation of wild poliovirus (WPV) into the United States. (The last indigenous case of WPV in the United States was in 1979, and the last imported case of WPV was in 1993.)

Vector-borne diseases involve a pathogen transmitted from an infected individual or animal, usually by an insect or other arthropod such as a mosquito or tick. There are several vector-borne diseases that are circulating in areas with U.S.-bound immigrants and refugees, all of which could spread into the U.S. population. These include exotic illnesses like chikungunya, dengue, and possibly Rift Valley fever.

Pandemic Influenza

The changes in the medical screening rules will also provide HHS/CDC officials with the authority to screen applicants that are coming into the United States from areas affected by a possible pandemic influenza. The *World Health Report 2007—A safer future: global public health security in the 21st*

century, issued by the WHO, emphasizes the danger of an influenza pandemic. A pandemic strain of influenza would be far more contagious than SARS, since it spreads by coughing and sneezing, and is transmitted with a short incubation period that reduces the time for tracing the spread of disease and isolating patients. An influenza pandemic could extend the enormous health consequences seen with SARS in Asia and Canada to every corner of the world within a matter of months.

Although HHS/CDC cannot predict the timing and exact strain, science and history suggest the world will suffer at least one influenza pandemic this century, which has the potential to have a rapid and immense impact on all segments of the U.S. population and our economy. In the 20th century, the greatest influenza pandemic occurred in 1918–1919, which caused an estimated 40–50 million deaths worldwide. A severe pandemic, as happened in 1918, could now have a much greater impact. When pandemic strains emerge, they sweep through nations with frightening velocity. The three pandemics of the 20th century each encircled the world within months of their emergence into humans. Based on the current speed and volume of international movement of people and animals, there is no reason to think the next pandemic would spread any slower.

Although health care has improved in the past decades, the WHO is predicting that today an influenza pandemic could result in 2–7.4 million deaths globally. [1] The WHO estimates that if a pandemic virus emerged now, the spread of the disease would be rapid. Based on experiences with past pandemics, some experts have predicted an illness that could affect around 25 percent of the world's population—more than 1.5 billion people. Should these forecasts prove accurate, the impact an influenza pandemic would have on national and international public health, and on economic and political security, would be enormous. Even if the virus caused relatively mild symptoms, the economic and social disruption that would arise from sudden surges of illness in so many people—occurring almost simultaneously throughout the world—would be incalculable.[2]

Interpandemic (seasonal) influenza results in more than 200,000 hospitalizations every year and causes an average of 36,000 deaths annually in the United States. Modeling studies suggest that, in the absence of effective control measures, a medium-level pandemic (in which 15 to 35 percent of the population of the United States develops influenza) could result in 89,000 to 207,000 deaths, between 314,000 and 734,000 hospitalizations, 18 to 42 million outpatient visits, and 20 to 47 million sick people. The associated economic impact in the United States alone could range between $71.3 and $166.5 billion.

The H5N1 virus that is currently circulating in Asia, Africa and Europe provides an example of the immense potential impact of an emerging influenza virus. As of March 19, 2008, the H5N1 strain of influenza virus has killed over 63 percent of the 373 humans affected, and authorities fear the disease could mutate into a form that could pass quickly and efficiently from human to human, which could spark a global pandemic. The 14 countries that have reported laboratory-confirmed human cases of H5N1 infection as of March 19, 2008, are Azerbaijan, The People's Republic of China, Djibouti, Thailand, Egypt, Vietnam, Cambodia, Indonesia, Laos, Nigeria, Pakistan, Burma, Turkey, and Iraq. Before the next pandemic virus becomes well-adapted to humans, there is an urgent need for the United States to be prepared to detect human cases, and to prevent a novel influenza virus from being imported to the United States. One of the most effective ways to protect the American population is the preventive medical screening of aliens which would thereby help avert the entry and importation of a pandemic strain, or at least delay its arrival.

HHS/CDC is implementing these new provisions immediately because the United States needs to respond effectively to any potential emerging communicable disease. HHS/CDC is taking this immediate action because the existing definition of *communicable diseases of public health significance* and the scope of medical screening do not adequately reflect current threats or protect against the significant harm to the American public currently ongoing and future outbreaks represent. Changing our approach to identifying, screening and testing for communicable diseases of public health significance will greatly improve our ability to detect, treat, and mitigate the potential introduction into—and spread throughout our country—of newly emerging and re-emerging diseases.

Under the provisions of the Administrative Procedure Act at 5 U.S.C. 553(b)(3)(B) and (d)(3), HHS/CDC finds that good cause exists to waive prior notice and comment and a 30 day delay in effective date on this rule is impracticable and contrary to the public interest. It is critical, for the reasons stated above, that HHS/CDC act quickly to ensure appropriate response, now and in the immediate future, to urgent disease threats that could have significant consequences in the United States. As noted, CDC is eager to consider public comment and will revise the rule as appropriate after receiving and analyzing any comments submitted.

VIII. Analysis of Impacts

A. Review Under Executive Order 12866, the Regulatory Flexibility Act, and the Unfunded Mandates Act of 1995

HHS/CDC has examined the impact of the Interim Final Rule under Executive Order 12866, the Regulatory Flexibility Act, and the Unfunded Mandates Reform Act (UMRA) of 1995.

Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits.

HHS/CDC commissioned an analysis of the rule, which is included in the docket. The analysis examined the increased costs to immigrants, refugees and other entities, and the benefits of additional screening in preventing the spread of disease in the U.S. population.

Based on recent history of disease outbreaks worldwide, the analysis estimates an additional cost of $4 million per year to immigrants and refugees. Immigrants will bear the additional medical testing costs for themselves, and the U.S. government will bear the additional medical testing costs for refugees. The benefit to the U.S. population associated with reduced incidence of secondary infections is estimated to be $30 million.

These estimates only reflect the costs and benefits based on recent history. The study examined the benefits and costs associated with a new or re-emerging disease separately, but did not include them in the annualized values because of the inherent inability to estimate the frequency of an unknowable event.

Based on the analysis, HHS/CDC has determined that the rule is not economically significant, as defined under Executive Order 12866.

HHS/CDC considered the proposed regulation's effects on small entities, as required by the Regulatory Flexibility Act, and certifies that the final rule will

[1] Pandemic influenza preparedness and mitigation in refugee and displaced populations, WHO guidelines for humanitarian agencies, May 2006.

[2] The World Health Report 2007—A safer future: global public health security in the 21st century, WHO, August 2007.

not have a significant economic impact on small entities.

HHS/CDC evaluated the rule requirements for compliance with the UMRA of 1995. This rule does not contain Federal mandates under the regulatory provisions of Title II of the UMRA for State, local or tribal governments, nor for the private sector. Finally, the rule's provisions will not affect small governments.

B. Environmental Impact

HHS has determined that provisions that amend 42 CFR part 34 will not have a significant impact on the human environment.

C. Federalism

In accordance with Executive Order 13132, HHS/CDC determines that this rule does not have sufficient federalism implications to warrant the preparation of a federalism summary impact statement.

D. Civil Justice Reform

HHS/CDC has reviewed this rule under Executive Order 12988, on Civil Justice Reform. This rule (1) preempts all State and local laws and regulations that are inconsistent with this rule; (2) has no retroactive effect; and (3) does not require administrative proceedings before parties may file suit in court to challenge this rule.

IX. Paperwork Reduction Act of 1995

The Paperwork Reduction Act applies to the data collection requirements found in 42 CFR part 34. The U.S. Department of State (DoS) is responsible for providing forms to panel physicians to document the medical examination and screening information for aliens. The Office of Management and Budget (OMB) last approved this data collection under OMB Control No. 1405–0113, on September 30, 2007. DoS will update its information collection request to reflect the changes made to the forms by this Interim Final Rule.

X. References

The following references are available at the following Internet address: *http://www.who.int.*

1. Pandemic influenza preparedness and mitigation in refugee and displaced populations, WHO guidelines for humanitarian agencies, May 2006.

2. The World Health Report 2007—A safer future: global public health security in the 21st century, WHO, August 2007.

List of Subjects in 42 CFR Part 34

Aliens, Health Care, Scope of Examination, Passports and Visas, Public Health.

■ For the reasons stated in the preamble, the Centers for Disease Control and Prevention (CDC), within the U.S. Department of Health and Human Services (HHS), is amending 42 CFR part 34 as follows:

PART 34—[AMENDED]

■ 1. The authority citation for part 34 is amended to read as follows:

Authority: 42 U.S.C. 252; 8 U.S.C. 1182 and 1222.

■ 2. Amend § 34.2 by revising paragraph (b) to read as follows:

§ 34.2 Definitions.

* * * * *

(b) *Communicable disease of public health significance.* Any of the following diseases:

(1) Chancroid.

(2) Communicable diseases as listed in a Presidential Executive Order, as provided under Section 361(b) of the Public Health Service Act. The current revised list of quarantinable communicable diseases is available at *http://www.cdc.gov* and *http://www.archives.gov/federal-register.*

(3) Communicable diseases that may pose a public health emergency of international concern if it meets one or more of the factors listed in § 34.3(d) and for which the CDC Director has determined (A) a threat exists for importation into the United States, and (B) such disease may potentially affect the health of the American public. The determination will be made consistent with criteria established in Annex 2 of the revised International Health Regulations (*http://www.who.int/csr/ihr/en/*), as adopted by the Fifty-Eighth World Health Assembly in 2005, and as entered into effect in the United States in July, 2007, subject to the U.S. Government's reservation and understandings:

(i) Any of the communicable diseases for which a single case requires notification to the World Health Organization (WHO) as an event that may constitute a public health emergency of international concern, or

(ii) Any other communicable disease the occurrence of which requires notification to the WHO as an event that may constitute a public health emergency of international concern.

HHS/CDC's determinations will be announced by notice in the **Federal Register**.

(4) Gonorrhea.

(5) Granuloma inguinale.

(6) Human immunodeficiency virus (HIV) infection.

(7) Leprosy, infectious.

(8) Lymphogranuloma venereum.

(9) Syphilis, infectious stage.

(10) Tuberculosis, active.

* * * * *

■ 3. Section 34.3 is revised to read as follows:

§ 34.3 Scope of examinations.

(a) *General.* In performing examinations, medical examiners shall consider those matters that relate to the following:

(1) A communicable disease of public health significance;

(2)(i) A physical or mental disorder and behavior associated with the disorder that may pose, or has posed, a threat to the property, safety, or welfare of the alien or others;

(ii) A history of a physical or mental disorder and behavior associated with the disorder, which behavior has posed a threat to the property, safety, or welfare of the alien or others and which behavior is likely to recur or lead to other harmful behavior;

(3) Drug abuse or addiction; and

(4) Any other physical abnormality, disease, or disability serious in degree or permanent in nature amounting to a substantial departure from normal well-being.

(b) *Scope of all medical examinations.* (1) All medical examinations will include the following:

(i) A general physical examination and medical history, evaluation for tuberculosis, and serologic testing for syphilis and HIV.

(ii) A physical examination and medical history for diseases specified in §§ 34.2(b)(1), and 34.2(b)(4) through 34.2(b)(10).

(2) The scope of the examination shall include any laboratory or additional studies that are deemed necessary, either as a result of the physical examination or pertinent information elicited from the alien's medical history, for the examining physician to reach a conclusion about the presence or absence of a physical or mental abnormality, disease, or disability.

(c) *Additional medical screening and testing for examinations performed outside the United States.* (1) HHS/CDC may require additional medical screening and testing for medical examinations performed outside the United States for diseases specified in §§ 34.2(b)(2) and 34.2(b)(3) by applying the risk-based medical and epidemiologic factors in paragraph (d)(2) of this section.

(2) Such examinations shall be conducted in a defined population in a geographic region or area outside the United States as determined by HHS/CDC.

(3) Additional medical screening and testing shall include a medical interview, physical examination, laboratory testing, radiologic exam, or other diagnostic procedure, as determined by HHS/CDC.

(4) Additional medical screening and testing will continue until HHS/CDC determines such screening and testing is no longer warranted based on factors such as the following: Results of disease outbreak investigations and response efforts; effectiveness of containment and control measures; and the status of an applicable determination of public health emergency of international concern declared by the Director General of the WHO.

(5) HHS/CDC will directly provide medical examiners information pertaining to all applicable additional requirements for medical screening and testing, and will post these at the following Internet addresses: *http://www.cdc.gov/ncidod/dq/technica.htm* and *http://www.globalhealth.gov*.

(d) *Risk-based approach.* (1) HHS/CDC will use the medical and epidemiological factors listed in paragraph (d)(2) of this section to determine the following:

(i) Whether a disease as specified in § 34.2(b)(3)(ii) is a communicable disease of public health significance.

(ii) Which diseases in §§ 34.2(b)(2) and (b)(3) merit additional screening and testing, and the geographic area in which HHS/CDC will require this screening.

(2) Medical and epidemiological factors include the following:

(i) The seriousness of the disease's public health impact;

(ii) Whether the emergence of the disease was unusual or unexpected;

(iii) The risk of the spread of the disease in the United States;

(iv) The transmissibility and virulence of the disease;

(v) The impact of the disease at the geographic location of medical screening; and

(vi) Other specific pathogenic factors that would bear on a disease's ability to threaten the health security of the United States.

(e) *Persons subject to requirement for chest X-ray examination and serologic testing.* (1) As provided in paragraph (e)(2) of this section, a chest X-ray examination, and serologic testing for syphilis and serologic testing for HIV shall be required as part of the examination of the following:

(i) Applicants for immigrant visas;

(ii) Students, exchange visitors, and other applicants for non-immigrant visas required by a U.S. consular authority to have a medical examination;

(iii) Applicants outside the United States who apply for refugee status;

(iv) Applicants in the United States who apply for adjustment of their status under the immigration statute and regulations.

(2) *Chest X-ray examination and serologic testing.* Except as provided in paragraph (e)(2)(iv) of this section, applicants described in paragraph (e)(1) of this section shall be required to have the following:

(i) For applicants 15 years of age and older, a chest x-ray examination;

(ii) For applicants under 15 years of age, a chest x-ray examination if the applicant has symptoms of tuberculosis, a history of tuberculosis, or evidence of possible exposure to a transmissible tuberculosis case in a household or other enclosed environment for a prolonged period;

(iii) For applicants 15 years of age and older, serologic testing for syphilis and HIV.

(iv) *Exceptions.* Serologic testing for syphilis and HIV shall not be required if the alien is under the age of 15, unless there is a reason to suspect infection with syphilis or HIV. HHS/CDC may authorize exceptions to the requirement for a tuberculin skin test, an equivalent test for showing an immune response to *Mycobacterium tuberculosis* antigens, or chest X-ray examination for good cause, upon application approved by the Director.

(3) *Immune Response to Mycobacterium tuberculosis antigens.* (i) All aliens 2 years of age or older in the United States who apply for adjustment of status to permanent residents, under the immigration laws and regulations, or other aliens in the United States who are required by the U.S. Department of Homeland Security to have a medical examination in connection with a determination of their admissibility, shall be required to have a tuberculin skin test or an equivalent test for showing an immune response to *Mycobacterium tuberculosis* antigens. Exceptions to this requirement may be authorized for good cause upon application approved by the Director. In the event of a positive tuberculin reaction, a chest X-ray examination shall be required. If the chest radiograph is consistent with tuberculosis, the alien shall be referred to the local health authority for evaluation. Evidence of this evaluation shall be provided to the civil surgeon before a medical notification may be issued.

(ii) Aliens less than 2 years old shall be required to have a tuberculin skin test, or an equivalent, appropriate test to show an immune response to *Mycobacterium tuberculosis* antigens, if there is evidence of contact with a person known to have tuberculosis or other reason to suspect tuberculosis. In the event of a positive tuberculin reaction, a chest X-ray examination shall be required. If the chest radiograph is consistent with tuberculosis, the alien shall be referred to the local health authority for evaluation. Evidence of this evaluation shall be provided to the civil surgeon before a medical notification may be issued.

(iii) Aliens outside the United States required to have a medical examination shall be required to have a tuberculin skin test, or an equivalent, appropriate test to show an immune response to *Mycobacterium tuberculosis* antigens, and, if indicated, a chest radiograph.

(iv) Aliens outside the United States required to have a medical examination shall be required to have a tuberculin skin test, or an equivalent, appropriate test to show an immune response to *Mycobacterium tuberculosis* antigens, and a chest radiograph, regardless of age, if they have symptoms of tuberculosis, a history of tuberculosis, or evidence of possible exposure to a transmissible tuberculosis case in a household or other enclosed environment for a prolonged period.

(4) *Additional testing requirements.* All applicants subject to the chest radiograph requirement, and for whom the radiograph shows an abnormality suggestive of tuberculosis disease, shall be required to undergo additional testing for tuberculosis.

(5) *How and where performed.* All chest radiograph images used in medical examinations performed under the regulations in this Part shall be large enough to encompass the entire chest (approximately 14 by 17 inches; 35.6x43.2 cm.). Serologic testing for HIV shall be a sensitive and specific test, confirmed when positive by a test such as the Western blot test or an equally reliable test. For aliens examined abroad, the serologic testing for HIV must be completed abroad, except that the Secretary of Homeland Security after consultation with the Secretary of State and the Secretary of Health and Human Services may in emergency circumstances permit serologic testing of refugees for HIV to be completed in the United States.

(6) *Chest X-ray, laboratory, and treatment reports.* The chest radiograph reading and serologic test results for syphilis and HIV shall be included in the medical notification. When the medical examiner's conclusions are based on a study of more than one chest X-ray image, the medical notification

shall include at least a summary statement of findings of the earlier images, followed by a complete reading of the last image, and dates and details of any laboratory tests and treatment for tuberculosis.

(f) *Procedure for transmitting records.* For aliens issued immigrant visas, the medical notification and chest X-ray images, if any, shall be placed in a separate envelope which shall be sealed. When more than one chest X-ray image is used as a basis for the examiner's conclusions, all images shall be included.

(g) *Failure to present records.* When a determination of admissibility is to be made at the U.S. port of entry, a medical hold document shall be issued pending completion of any necessary examination procedures. A medical hold document may be issued for aliens who:

(1) Are not in possession of a valid medical notification, if required;

(2) Have a medical notification which is incomplete;

(3) Have a medical notification which is not written in English;

(4) Are suspected to have an excludable medical condition.

(h) The Secretary of Homeland Security, after consultation with the Secretary of State and the Secretary of Health and Human Services, may in emergency circumstances permit the medical examination of refugees to be completed in the United States.

(i) All medical examinations shall be carried out in accordance with such technical instructions for physicians conducting the medical examination of aliens as may be issued by the Director. Copies of such technical instructions are available upon request to the Director, Division of Global Migration and Quarantine, Mailstop E03, HHS/CDC, Atlanta GA 30333.

Dated: June 25, 2008.

Michael O. Leavitt,

Secretary, Department of Health and Human Services.

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DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 622

[Docket No. 040205043–4043–01]

RIN 0648–XK40

Fisheries of the Caribbean, Gulf of Mexico, and South Atlantic; Reef Fish Fishery of the Gulf of Mexico; Reopening of the 2008 Deepwater Grouper and Tilefish Commercial Fisheries

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Temporary rule; reopening.

SUMMARY: NMFS reopens the commercial fishery for deepwater grouper (misty grouper, snowy grouper, yellowedge grouper, warsaw grouper, and speckled hind) and tilefishes in the exclusive economic zone (EEZ) of the Gulf of Mexico. NMFS previously determined that the quotas for these commercial fisheries would be reached by May 10, 2008. The latest estimates for deepwater grouper and tilefish landings indicate the quotas were not reached by that date. Consequently, NMFS will reopen these fisheries for 10 days. The purpose of this action is to allow the fisheries to maximize harvest benefits and at the same time protect the deepwater grouper and tilefish resources.

DATES: The reopening is effective 12:01 a.m., local time, November 1, 2008, until 12:01 a.m., local time, on November 11, 2008. The fisheries will then be closed until 12:01 a.m., local time, January 1, 2009.

FOR FURTHER INFORMATION CONTACT: Susan Gerhart, telephone 727–824–5305, fax 727–824–5308, e-mail *Susan.Gerhart@noaa.gov*.

SUPPLEMENTARY INFORMATION: The reef fish fishery of the Gulf of Mexico is managed under the Fishery Management Plan for the Reef Fish Resources of the Gulf of Mexico (FMP). The FMP was prepared by the Gulf of Mexico Fishery Management Council and is implemented under the authority of the Magnuson-Stevens Fishery Conservation and Management Act (Magnuson-Stevens Act) by regulations at 50 CFR part 622. Those regulations set the commercial quota for deepwater grouper in the Gulf of Mexico at 1.02 million lb (463,636 kg) and for tilefish in the Gulf of Mexico at 440,000 lb (200,000 kg) for the current fishing year, January 1 through December 31, 2008.

Under 50 CFR 622.43(a), NMFS is required to close the commercial fishery for a species or species group when the quota for that species or species group is reached, or is projected to be reached, by filing a notification to that effect with the Office of the **Federal Register**. NMFS projected the fisheries for deepwater grouper and tilefishes would reach their respective quotas on May 10, 2008, and closed the fisheries on that date (73 FR 24883, May 6, 2008). Based on current statistics, NMFS has determined that only 89 percent of the available commercial quotas for deepwater grouper and tilefishes were landed. Based on 2008 daily landings rates and the pounds remaining on each quota (approximately 100,000 lb (45,359 kg) for deepwater grouper and 46,000 lb (20,865 kg) for tilefishes), NMFS has determined these fisheries can reopen for 10 days. Accordingly, NMFS is reopening the commercial deepwater grouper and tilefish fisheries in the Gulf of Mexico EEZ from 12:01 a.m., local time, on November 1, 2008, until 12:01 a.m., local time, on November 11, 2008. The fisheries will then be closed until 12:01 a.m., local time, on January 1, 2009. November 1 was chosen as the opening day based on feedback from the fishing industry and weather concerns. Many fishers indicated that this was the most productive time for the reopening. NMFS also chose to wait until after the peak of hurricane season to promote safety at sea, consistent with National Standard 10 of the Magnuson-Stevens Act.

The operator of a vessel with a valid commercial vessel permit for Gulf reef fish may not fish for or possess deepwater grouper or tilefishes prior to 12:01 a.m., local time, November 1, 2008, and must have landed and bartered, traded, or sold such deepwater grouper or tilefishes prior to 12:01 a.m., local time, November 11, 2008.

During the closure, the bag and possession limits specified in 50 CFR 622.39(b) apply to all harvest or possession of deepwater grouper and tilefishes in or from the Gulf of Mexico EEZ, and the sale or purchase of deepwater grouper and tilefishes taken from the EEZ is prohibited. The prohibition on sale or purchase does not apply to sale or purchase of deepwater grouper or tilefishes that were harvested, landed ashore, and sold prior to 12:01 a.m., local time, November 11, 2008, and were held in cold storage by a dealer or processor. Vessels with commercial quantities of Gulf reef fish on board are prohibited from retaining a recreational bag limit of Gulf reef fish.