

Section 7: Clarified the electronic submission format and the folder structure for study datasets.

Section 8: Renamed the section "Data Validation and Traceability" from "Data Fitness" and clarified several of the subsections, including Traceability Issues and Legacy Data Conversion.

II. Comments

Interested persons may submit either electronic comments regarding this document to <http://www.regulations.gov> or written comments to the Division of Dockets Management (see **ADDRESSES**). It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at <http://www.regulations.gov>.

III. Electronic Access

Persons with access to the Internet may obtain the Guide and the Catalog at either <http://www.fda.gov/forindustry/datastandards/studydatastandards/default.htm> or <http://www.regulations.gov>.

Dated: January 6, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015-00206 Filed 1-9-15; 8:45 am]

BILLING CODE 4164-01-P

DEPARTMENT OF HOMELAND SECURITY

Customs and Border Protection

[CBP Dec. No. 15-01]

Expansion of Global Entry Eligibility to Citizens of the Republic of Panama

AGENCY: U.S. Customs and Border Protection; Department of Homeland Security.

ACTION: General notice.

SUMMARY: U.S. Customs and Border Protection (CBP) has established the Global Entry international trusted traveler program at most major U.S. airports. Global Entry allows pre-approved, low-risk participants expedited entry into the United States using Global Entry kiosks located at designated airports. Currently, eligibility for participation in Global Entry is limited to U.S. citizens, U.S. nationals, U.S. lawful permanent residents, Mexican nationals, and certain eligible citizens of the Netherlands, the Republic of Korea, the

Federal Republic of Germany, the State of Qatar, and the United Kingdom. Additionally, participants in the NEXUS trusted traveler program and certain participants in the Secure Electronic Network for Travelers Rapid Inspection (SENTRI) trusted traveler program are permitted to use the Global Entry kiosks as part of their membership in those programs.¹ This document announces that CBP is expanding eligibility for Global Entry to include citizens of the Republic of Panama. All of these individuals must otherwise satisfy the requirements for participation in the Global Entry program. Additionally, this document announces that U.S. citizens who participate in Global Entry or U.S. citizens who can utilize Global Entry kiosks as NEXUS or SENTRI participants have the option to apply for membership in Panama Global Pass, the Republic of Panama's trusted traveler program.

DATES: The expansion of eligibility to citizens of the Republic of Panama will occur on January 12, 2015. Applications will be accepted from citizens of the Republic of Panama beginning January 12, 2015.

FOR FURTHER INFORMATION CONTACT:

Larry Panetta, Office of Field Operations, (202) 344-1253, Larry.A.Panetta@cbp.dhs.gov.

SUPPLEMENTARY INFORMATION:

Background

Global Entry Program

Global Entry is a voluntary program that allows for the expedited clearance of pre-approved, low-risk travelers arriving in the United States at Global Entry kiosks located at designated airports. CBP issued the final rule that promulgated the regulation to establish Global Entry as an ongoing voluntary regulatory program in the **Federal Register** (77 FR 5681) on February 6, 2012. The final rule contains a detailed description of the program, the eligibility criteria, the application and selection process, and the initial airport locations. See 8 CFR 235.12. Travelers who wish to participate in Global Entry must apply via the Global On-Line Enrollment System (GOES) Web site, <https://goes-app.cbp.dhs.gov>, and pay the applicable fee. Applications for Global Entry must be completed and submitted electronically.

Eligibility for participation in Global Entry is limited to U.S. citizens, U.S. nationals, U.S. lawful permanent

residents, and certain nonimmigrant aliens from countries that have entered into arrangements with CBP regarding international trusted traveler programs. Specifically, the regulation provides that certain nonimmigrant aliens from countries that have entered into arrangements with CBP concerning international trusted traveler programs may be eligible to apply for participation in Global Entry after CBP announces the arrangement by publication of a notice in the **Federal Register**. The notice will include the country, the scope of eligibility of nonimmigrant aliens from that country (e.g., whether only citizens of the foreign country or citizens and non-citizens are eligible) and other conditions that may apply based on the terms of the arrangement. See 8 CFR 235.12(b)(1)(ii). In the preamble of the Global Entry final rule, CBP recognized the existence of previous arrangements it had with Mexico and the Netherlands regarding the international trusted traveler programs and announced that Mexican nationals and certain citizens of the Netherlands were eligible to apply for the Global Entry program. It further specified that Mexican nationals and citizens of the Netherlands who were existing participants in the Global Entry pilot would be automatically enrolled in the ongoing Global Entry program. Additionally, in the preamble of the Global Entry final rule, CBP recognized that pursuant to a previous **Federal Register** notice,² participants in NEXUS and certain participants in SENTRI would still be allowed to use the Global Entry kiosks.

In a notice published in the **Federal Register** (78 FR 48706) on August 9, 2013, CBP expanded Global Entry eligibility to include citizens of the Republic of Korea who are participants in the Smart Entry System (SES), a trusted traveler program for pre-approved, low-risk travelers at designated airports in the Republic of Korea via the use of e-gates; a limited number of citizens of the Federal Republic of Germany who are participants in the Automated and Biometrics-Supported Border Controls (ABG) Plus, a trusted traveler program in the Federal Republic of Germany; a limited number of citizens of the State of Qatar; and a limited number of citizens of the United Kingdom who frequently travel to the United States.

This document announces the further expansion of the Global Entry trusted

¹ See the Utilization of Global Entry Kiosks by NEXUS and SENTRI Participants **Federal Register** notice, December 29, 2010 (75 FR 82202) for further information.

² See the Utilization of Global Entry Kiosks by NEXUS and SENTRI Participants **Federal Register** notice, December 29, 2010 (75 FR 82202) for further information.

traveler program to citizens of the Republic of Panama.

The Republic of Panama

On February 29, 2012, the U.S. Department of Homeland Security, CBP and the Ministry of Public Security of the Republic of Panama signed a Joint Statement regarding the development of an international trusted traveler initiative. As CBP and the Republic of Panama have negotiated the operational details and completed the necessary infrastructure updates, CBP is now ready to announce that, based on the Joint Statement, citizens of the Republic of Panama are eligible to apply for participation in Global Entry.

In order to participate, citizens of the Republic of Panama who apply for Global Entry will be required to complete the on-line application located on the GOES Web site, pay the non-refundable Global Entry fee, and satisfy all the requirements of Global Entry. These applicants will be permitted to participate in Global Entry only upon successful completion of a thorough risk assessment by both CBP and the Republic of Panama's Ministry of Public Security and completion of an interview with CBP. The vetting criteria were mutually developed and are consistent with each agency's applicable domestic laws and policies. Once the risk assessment has been completed, CBP will notify the applicants regarding whether or not they have been accepted into Global Entry.

Applicants may be denied enrollment in the Global Entry program for various reasons. An individual who is inadmissible to the United States under U.S. immigration law or has, at any time, been granted a waiver of inadmissibility or parole is ineligible to participate in Global Entry. Applications from such individuals will automatically be rejected. Applications for Global Entry may also be rejected if the applicant has ever been arrested for, or convicted of, a criminal offense, or if the individual has ever been found in violation of customs or immigration laws, or of any criminal law. Additionally, an applicant will not be accepted for participation in Global Entry if CBP determines that the applicant presents a potential risk of terrorism, or criminality (including smuggling), or if CBP cannot sufficiently determine that the applicant meets all the program eligibility criteria. The eligibility criteria are set forth in more detail in the Global Entry final rule and 8 CFR 235.12. See also <http://www.globalentry.gov>.

U.S. Citizens' Participation in Panama Global Pass

Pursuant to the Joint Statement, U.S. citizens who are Global Entry participants or U.S. citizens who can utilize Global Entry kiosks as NEXUS or SENTRI participants have the option to apply for Panama Global Pass membership. Panama Global Pass is a trusted traveler program in the Republic of Panama that uses self-service kiosks to offer expedited processing for air travelers through clearance formalities when entering the Republic of Panama. All U.S. applicants must apply for Panama Global Pass directly with the Government of Panama, be thoroughly vetted by both CBP and the Republic of Panama and be interviewed by the National Immigration Service of Panama in the Republic of Panama to complete the enrollment process. U.S. applicants are required to pay the Panama Global Pass non-refundable \$100 fee for a five-year membership. The Republic of Panama will notify the U.S. applicant directly about whether he or she was approved for Panama Global Pass. More information about how to apply for Panama Global Pass membership is available at <http://www.globalentry.gov>.

Dated: January 7, 2015.

John P. Wagner,

Acting Assistant Commissioner, Office of Field Operations.

[FR Doc. 2015-00258 Filed 1-9-15; 8:45 am]

BILLING CODE 9111-14-P

DEPARTMENT OF HOMELAND SECURITY

U.S. Customs and Border Protection

[CBP Dec. No. 15-02]

Expansion of Global Entry to Seven Additional Airports

AGENCY: U.S. Customs and Border Protection; Department of Homeland Security.

ACTION: General notice.

SUMMARY: The Global Entry international trusted traveler program allows pre-approved, low-risk participants expedited entry into the United States using Global Entry kiosks located at designated airports. U.S. Customs and Border Protection (CBP) previously announced in the **Federal Register** thirty-two designated Global Entry airports. This document announces the expansion of the program to include seven additional designated airports.

DATES: Global Entry will be available at all seven airport locations on or before

July 13, 2015. The exact starting date for each airport location will be announced on the CBP Global Entry Web site, <http://www.globalentry.gov>.

FOR FURTHER INFORMATION CONTACT:

Larry Panetta, Office of Field Operations, (202) 344-1253, Larry.A.Panetta@cbp.dhs.gov.

SUPPLEMENTARY INFORMATION:

Background

Global Entry Program

Global Entry is a voluntary program that allows for the expedited clearance of pre-approved, low-risk travelers arriving in the United States at Global Entry kiosks located at designated airports. The Global Entry final rule, published in the **Federal Register** on February 6, 2012 (77 FR 5681), promulgated the regulation to establish Global Entry as an ongoing regulatory program and contains a detailed description of the program, the eligibility criteria, the application and selection process, and the initial twenty designated airports. See 8 CFR 235.12. Global Entry was expanded to include four additional designated airports in a notice published in the **Federal Register** on March 26, 2012. (77 FR 17492) Additionally, Global Entry was expanded to include eight additional designated airports in a notice published in the **Federal Register** on June 25, 2013. (78 FR 38069) Travelers who wish to participate in Global Entry must apply via the CBP Global Entry Web site, <http://www.globalentry.gov> or through the Global On-Line Enrollment System (GOES) Web site, <https://goes-app.cbp.dhs.gov>. Applications must be completed and submitted electronically.

The thirty-two airports previously designated for Global Entry, listed alphabetically by state, and then city, include:

- Phoenix Sky Harbor International Airport, Phoenix, Arizona (PHX);
- Los Angeles International Airport, Los Angeles, California (LAX);
- San Diego International Airport, San Diego, California (SAN);
- San Francisco International Airport, San Francisco, California (SFO);
- John Wayne Airport, Santa Ana, California (SNA);
- Denver International Airport, Denver, Colorado (DEN);
- Ft. Lauderdale Hollywood International Airport, Fort Lauderdale, Florida (FLL), including the General Aviation Facility private aircraft terminal;
- Miami International Airport, Miami, Florida (MIA);
- Orlando International Airport, Orlando, Florida (MCO);