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III. Paperwork Reduction Act of 1995
While this guidance contains no new collection of information, it does refer to previously approved FDA collections of information. The previously approved collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521). The collections of information in the following table have been approved by OMB:

21 CFR part; guidance; or FDA form	Topic	OMB control No.
807, subpart E	Premarket notification	0910–0120
814, subparts A through E	Premarket approval	0910–0231
814, subpart H	Humanitarian Use Devices; Humanitarian Device Exemption ..	0910–0332
812	Investigational Device Exemptions	0910–0078
860, subpart D	De Novo classification process	0910–0844
“Requests for Feedback and Meetings for Medical Device Submissions: The Q-Submission Program”.	Q-submissions and Early Payor Feedback Request Programs for Medical Devices.	0910–0756
810	Recalls	0910–0432
806	Medical Devices; Reports of Corrections and Removals	0910–0359
820	Current Good Manufacturing Practice (CGMP); Quality System (QS) Regulation.	0910–0073

Grace R. Graham,
Deputy Commissioner for Policy, Legislation, and International Affairs.
[FR Doc. 2025–19947 Filed 11–14–25; 8:45 am]
BILLING CODE 4164–01–P

DEPARTMENT OF HOMELAND SECURITY
Agreement Between the Government of the United States of America and the Government of the Republic of Ecuador Relating to the Transfer of Third-Country Nationals to Ecuador
AGENCY: Department of Homeland Security.
ACTION: Notice of Agreement.
SUMMARY: The Department of Homeland Security is publishing the Agreement

between the Government of the United States of America and the Government of the Republic of Ecuador relating to the transfer of third-country nationals to Ecuador, effected by exchange of diplomatic notes on July 16, 2025 and July 23, 2025. The text of the diplomatic notes is set out below.
(Authority: 8 U.S.C. 1158(a)(2)(A).)
Joseph N. Mazzara,
Acting General Counsel, U.S. Department of Homeland Security.
BILLING CODE 9110–9M–P

No. POL 520/2025

The Embassy of the United States of America presents its compliments to the Ministry of Foreign Affairs and Human Mobility of the Republic of Ecuador. The Embassy, on behalf of the Government of the United States of America, has the honor to propose the following Agreement between the Government of the United States of America and the Government of the Republic of Ecuador (hereinafter referred to individually as a "Party" and collectively as the "Parties").

Under this Agreement, the Parties seek to ensure the dignified, safe, and timely transfer from the United States to Ecuador of third-country nationals present in the United States who may seek international protection against return to their home country or country of former habitual residence. The Government of the United States of

DIPLOMATIC NOTE

America shall in its complete discretion propose to the Government of the Republic of Ecuador the transfer of such third-country nationals, and the Government of the Republic of Ecuador shall in its complete discretion consider accepting such a proposal in whole or in part. Both Parties' actions under this Agreement shall be in accordance with their obligations under the 1951 Convention Relating to the Status of Refugees, done at Geneva on July 28, 1951; the Protocol Relating to the Status of Refugees, done at New York on January 31, 1967; the Convention against Torture and Other Cruel, Inhuman or Degrading Treatment or Punishment, adopted in New York on December 10, 1984; and any other respective international obligations, national constitutions, laws, regulations, and immigration and visa policies of the Parties, including consideration by the Government of the Republic of Ecuador of requests by these third-country nationals for asylum, refugee protection, or equivalent temporary protection.

The Government of the Republic of Ecuador agrees not to return any person transferred to Ecuador by the Government of the United States of America to their home country or country of former habitual residence until a final decision has been made regarding any pending protection claims. The Government of the Republic of Ecuador shall determine a procedure, consistent with its relevant obligations, to resolve the status of those who may abandon pending international protection claims or fail to seek protection from the Government of Ecuador. The Government of the United States of America shall not transfer unaccompanied minors pursuant to this Agreement.

The Parties shall develop operating procedures to assist with the implementation of this Agreement through a subsequent instrument, including, among others, clear criteria to determine eligibility for transfer to the Republic of Ecuador, as well as any necessary bilateral assistance to implement this Agreement.

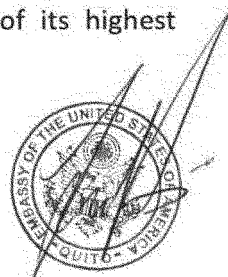
In the event of a conflict of interpretation or implementation, the Parties commit to resolve such matters through dialogue or diplomatic channels.

Either Party may terminate or suspend this Agreement at any time by notifying the other Party in writing. The Parties may agree in writing to any amendments to this Agreement, and such amendments shall constitute an integral part of this Agreement, consistent with any applicable legal requirements. Nothing set forth in this Agreement shall be interpreted in such a way that commits the disbursement or allocation of funds by the Parties. The implementation of this Agreement shall be subject to the availability of funds and technical capacity of each Party.

If this proposal is acceptable to the Government of the Republic of Ecuador, the Government of the United States of America has the honor to propose that this note, along with the affirmative reply from

the Government of the Republic of Ecuador, shall form an Agreement between the two governments, which shall enter into force upon the date of the Government of the Republic of Ecuador's reply note.

The Embassy of the United States of America avails itself of this opportunity to renew to the Ministry of Foreign Affairs and Human Mobility of the Republic of Ecuador the assurances of its highest consideration.



Embassy of the United States of America,

Quito, July 16, 2025.

U.S. Department of State
Office of Language Services
Translating Division



LS No. 2025-0128065
Spanish/English
BBM/AFV

Translation|

[Coat of Arms]

**Republic of Ecuador
Ministry of Foreign Affairs and Human Mobility**

Note No. MREMH/MREMH/2025/0077/NV

The Ministry of Foreign Affairs and Human Mobility presents its compliments to the Embassy of the United States of America and has the honor to refer to Embassy note No. POL 520/2025, of July 16, 2025, which reads as follows:

Quote:

No. POL 520/2025

The Embassy, on behalf of the Government of the United States of America, has the honor to propose the following Agreement between the Government of the United States of America and the Government of the Republic of Ecuador (hereinafter referred to individually as a "Party" and collectively as the "Parties").

Embassy of the United States of America,
Quito.

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Under this Agreement, the Parties seek to ensure the dignified, safe, and timely transfer from the United States to Ecuador to third-country nationals present in the United States who may seek international protection against return to their home country or country of former habitual residence. The Government of the United States of America shall in its complete discretion propose to the Government of the Republic of Ecuador the transfer of such third-country nationals, and the Government of the Republic of Ecuador shall in its complete discretion consider accepting such a proposal in whole or in part. Both Parties' actions under this Agreement shall be in accordance with their obligations under the 1951 Convention Relating to the Status of Refugees, done at Geneva on July 28, 1951; the Protocol Relating to the Status of Refugees, done at New York on January 31, 1967; the Convention against Torture and Other Cruel, Inhuman or Degrading Treatment or Punishment, adopted in New York on December 10, 1984; and any other respective international obligations, national constitutions, laws, regulations, and immigration and visa policies of the Parties, including consideration by the Government of the Republic of Ecuador of requests by these third-country nationals for asylum, refugee protection, or equivalent temporary protection.

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The Government of the Republic of Ecuador agrees not to return any person transferred to Ecuador by the Government of the United States of America to their home country or country of former habitual residence until a final decision has been made regarding any pending protection claims. The Government of the Republic of Ecuador shall determine a procedure, consistent with its relevant obligations, to resolve the status of those who may abandon pending international protection claims or fail to seek protection from the Government of Ecuador. The Government of the United States of America shall not transfer unaccompanied minors pursuant to this Agreement.

The Parties shall develop operating procedures to assist with the implementation of this Agreement through a subsequent instrument, including, among others, clear criteria to determine eligibility for transfer to the Republic of Ecuador, as well as any necessary bilateral assistance to implement this Agreement.

In the event of a conflict of interpretation or implementation, the Parties commit to resolve such matters through dialogue or diplomatic channels.

Either Party may terminate or suspend this Agreement at any time by notifying the other Party in writing. The Parties may agree in writing to any amendments to this Agreement, and such amendments shall constitute an



integral part of this Agreement, consistent with any applicable legal requirements. Nothing set forth in this Agreement shall be interpreted in such a way that commits the disbursement or allocation of funds by the Parties. The implementation of this Agreement shall be subject to the availability of funds and technical capacity of each Party.

If this proposal is acceptable to the Government of the Republic of Ecuador, the Government of the United States of America has the honor to propose that this note, along with the affirmative reply from the Government of the Republic of Ecuador, shall form an Agreement between the two governments, which shall enter into force upon the date of the Government of the Republic of Ecuador's reply note.

The Embassy of the United States of America avails itself of this opportunity to renew to the Ministry of Foreign Affairs and Human Mobility of the Republic of Ecuador the assurances of its highest consideration.

Embassy of the United States of America,
Quito, July 16, 2025

Unquote.

In this regard, the Ministry of Foreign Affairs and Human Mobility, on behalf of the Government of the Republic of Ecuador states its agreement with the above proposal, which, along with this note in reply shall constitute an

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agreement between both Governments which shall enter into force on the date of this note.

The Ministry of Foreign Affairs and Human Mobility avails itself of this opportunity to renew to the Embassy of the United States of America the assurances of its highest and most distinguished consideration.

Quito, July 23, 2025

[Initialed]

[Ministry stamp]

[FR Doc. 2025–19939 Filed 11–14–25; 8:45 am]

BILLING CODE 9110–9M–C

DEPARTMENT OF THE INTERIOR

National Park Service

[N6559; NPS–WASO–NAGPRA–NPS0041182; PPWOCRADN0–PCU00RP14.R50000]

Notice of Inventory Completion: Tennessee Department of Environment and Conservation, Division of Archaeology, Nashville, TN

AGENCY: National Park Service, Interior.

ACTION: Notice.

SUMMARY: In accordance with the Native American Graves Protection and Repatriation Act (NAGPRA), the Tennessee Department of Environment and Conservation, Division of Archaeology (TDEC–DOA) has completed an inventory of human remains and associated funerary objects from Davidson County, Tennessee and has determined that there is a cultural affiliation between the human remains and associated funerary objects and Indian Tribes or Native Hawaiian organizations in this notice.

DATES: Repatriation of the human remains and associated funerary objects in this notice may occur on or after December 17, 2025.

ADDRESSES: Send written requests for repatriation of the human remains and

associated funerary objects in this notice to Phillip R. Hodge, Tennessee Department of Environment and Conservation, Division of Archaeology (TDEC–DOA), 1216 Foster Avenue, Cole Building #3, Nashville, TN 37243, email Phil.Hodge@tn.gov.

SUPPLEMENTARY INFORMATION: This notice is published as part of the National Park Service's administrative responsibilities under NAGPRA. The determinations in this notice are the sole responsibility of the TDEC–DOA, and additional information on the determinations in this notice, including the results of consultation, can be found in its inventory or related records. The National Park Service is not responsible for the determinations in this notice.

Abstract of Information Available

Human remains representing, at least, 238 individuals have been identified. The 449 associated funerary objects include 193 artifacts and two hundred and 256 lots of artifacts described below.

Unknown Site, Davidson County, TN

Human Remains representing, at least, 35 individuals. Remains of at least 16 individuals contain no record of timing of acquisition. Remains of at least four individuals were transferred to TDEC–DOA by the Davidson County Medical Examiner. Remains of at least three individuals were donated to TDEC–DOA by the Tennessee State Museum in 1995. Remains of at least 12 individuals

were donated to TDEC–DOA by private citizens in 1989, 1991, 2008, 2020, and 2024. There is no known exposure to hazardous substances or treatments.

Site 40DV2, Davidson County, TN

Human remains representing, at least, one individual. These remains were encountered during construction and collected by the Davidson County Medical Examiner. They were transferred to TDEC–DOA in 2010. There is no known exposure to hazardous substances or treatments.

Site 40DV3, Davidson County, TN

Human remains representing, at least, 27 individuals and nine associated funerary objects consisting of one ceramic effigy vessel, six ceramic sherds, one lot of unsorted artifacts, and one lot of freshwater shell. Remains of at least 15 individuals and one lot of AFOs were excavated by TDEC–DOA staff in 1973 prior to construction of Interstate 440; Remains of at least three individuals were donated to TDEC–DOA by the Davidson County Medical Examiner in 1998, with no additional information available regarding the circumstances of collection; Remains of at least four individuals, one effigy vessel, six ceramic sherds, and one lot of AFOs were donated to TDEC–DOA by private citizens in 1971, 2005, 2007, and 2014 with no additional information available regarding the circumstances of collection. Remains of at least four individuals were donated to TDEC–