SUPPORTING STATEMENT FOR PAPERWORK REDUCTION ACT SUBMISSION

Medical Examination for Visa or Immigration Benefit
OMB Number 1405-0230
DS-2054,
DS-3025,
DS-3026,
DS-3030,
and DS-7794

A. JUSTIFICATION

1. Why is this collection necessary and what are the legal statutes that allow this?

Forms in this collection record the medical information necessary to determine whether an alien seeking entry to the United States has a medical or other condition affecting his or her eligibility for a visa or immigration benefit. Forms are completed by panel physicians to record the medical information of visa applicants, refugees, refugees and asylees (including "following-to-join"), some nonimmigrant visa applicants, and certain parolees. The information requested includes the result of any diagnostic tests required for the diagnosis of diseases identified as communicable and of public health significance, as well as other evaluations identified as necessary to confirm a medical or other ineligibility under the Immigration and Nationality Act (INA) at INA § 212, 8 U.S.C. § 1182.

Pursuant to INA § 221(d), 8 U.S.C. § 1201(d), prior to issuance of an immigrant visa to any alien, a consular officer shall require such alien to submit to a physical and mental examination in accordance with such regulations as may be prescribed. Prior to the issuance of a nonimmigrant visa to any alien, the consular officer may require such alien to submit to a physical and/or mental examination, if such examination is deemed necessary to ascertain whether such alien is eligible to receive a visa.

Additionally, INA § 207 and INA § 208, 8 U.S.C. §§ 1157 and 1158, require medical screening of follow-to-join refugee and asylum applicants. INA § 412(b)(4)(B), 8 U.S.C. § 1522(b)(4)(B), further requires the United States government to "provide for the identification of refugees who have been determined to have medical conditions affecting the public health and requiring treatment."

Under INA § 212(d)(5) [8 U.S.C. § 1182(d)(5)], the Secretary of Homeland Security may use discretion to temporarily parole aliens into the United States for urgent humanitarian reasons or significant public benefit. Consular officers aid the Department of Homeland Security (DHS) in carrying out this function on a case-by-case basis by issuing boarding foils to these aliens after they receive an authorization memo from USCIS and complete required processing steps, which may include medical examinations. Some aliens paroled or

seeking parole into the United States not issued a boarding foil are also required to undergo a medical examination under DHS and Secretary of Health and Human Services (HHS) authority to prevent the introduction, transmission, and spread of communicable diseases into the United States (42 U.S.C. § 264). The scope of the information required in the medical examination of an alien is defined at 42 CFR Part 34.

2. *What business purpose is the information gathered going to be used for?*

The DS-2054 (Report of Medical Examination by Panel Physician), DS-3025 (Vaccination Documentation Worksheet), DS-3026 (Medical History and Physical Examination Worksheet), DS-3030 (Tuberculosis Worksheet), and DS-7794 (eMedical) are designed to record the results of the medical examination required by INA § 221(d), 8 U.S.C. § 1201(d).

A panel physician designated by the consular post performs the medical examination of the applicant and completes the forms in accordance with the technical instructions issued by the Centers for Disease Control (CDC). The business purpose of the forms is to allow panel physicians to complete the requirements for medical examination and communicate results to the Department of State ("Department") in accordance with the panel physician agreement.

The results determine whether an alien has a medical condition that renders the individual ineligible to receive the immigration benefit sought or a medical condition that, although not constituting a specific excludable condition, represents a departure from the normal health or well-being that is significant enough to interfere with the applicant's ability to care for himself or to attend school or work, or that may require medical treatment or institutionalization in the future.

Nonimmigrant visa applicants are not subject to the vaccine requirements in INA § 212(a)(1)(A)(ii); however, applicants for the K nonimmigrant visas are strongly encouraged to complete all required vaccines before traveling to the United States. The vaccine worksheet is used to record the complete vaccine history for all aliens subject to medical examinations. This helps ensure that an alien has the proper vaccines, should the alien seek adjustment of status, and has a complete vaccine record for subsequent use after the individual is admitted to the United States.

The Department uses the data obtained from the forms to adjudicate applications for visas and other immigration benefits. CDC retains the information to match against U.S. arrival records and notify alien-receiving states when further health-related follow-up is necessary to protect Americans from disease. This process ensures newly arrived persons entering the United States do not pose a public health threat.

The information collected is retained in the Department's systems. It is also provided to the CDC and DHS. The medical finding by the panel physician or the CDC, if referred to that agency, is binding on the consular officer in adjudicating the alien's eligibility for a visa to enter the United States.

3. *Is this collection able to be completed electronically (e.g., through a website or application)?*

   Yes, the DS-7794 is the online equivalent of the combined DS-3025, DS-3026, DS-3030, and DS-2054.

4. *Does this collection duplicate any other collection of information?*

   This information collection does not duplicate any other collection of information.

   Panel physicians only need to complete either the four paper medical forms (DS-3025, DS-3026, DS-3030, and DS-2054), or the DS-7794 e-form. The CDC issues guidance to physicians on which information collection instruments are necessary for a given applicant-type, and the Department will process the medical information accordingly.

5. *Does this collection impact small business?*

   This collection does not impact U.S. small businesses.

6. *What are consequences if this collection is not done?*

   The Department is statutorily obligated to assess the medical condition of aliens seeking entry to the United States, including visa, refugee, asylum, and certain parole applicants. These obligations extend to nonimmigrant visa applicants when a consular officer requests a medical examination to ascertain eligibility to receive a visa as outlined in INA § 221(d), 8 U.S.C. § 1201(d). Failure to complete this information collection would leave the Department unable to comply with federal law.

   The CDC does not have a separate information collection that would allow for the screening of aliens seeking to enter the United States. There is an information sharing agreement between CDC and the Department governing access to medical information received through this information collection. Aliens entering the United States without first submitting to a medical exam would result in public harm, to include a higher risk of transmission of communicable disease and potentially fatal disease outbreaks in U.S. communities. Moreover, requiring panel physicians to provide more assessments concerning applicant health or potential long-term institutionalization assists consular officers in making a rigorous public charge analysis of the applicant.

   It is not possible to collect the information less frequently since up to date (i.e. confirmed less than 6 months prior) medical information is necessary to determine an alien's health status and eligibility for an immigrant visa or benefit.

7. *Are there any special collection circumstances?*

   No. There are no special collection circumstances associated with this collection.

8. *Did the Department solicit public comments on the collection?*

   The Department is publishing a notice in the Federal Register soliciting comments from the public for a period of 60 days.

9. *Are payments or gifts given to the respondents?*

   No. The federal government generally does not provide payments or gifts to respondents. Responding panel physicians are generally compensated by the aliens who must subject themselves to the required medical examination, with limited exceptions. Fees are agreed to in writing as part of a panel physician agreement.

10. *Is any assurance of privacy/confidentiality provided to respondents?*

    The form includes a confidentiality statement as assurance of privacy and confidentiality. The applicant is informed that, in accordance with INA section 222(f), 8 U.S.C. § 1202(f), information obtained from respondents in the application process is considered confidential and is to be used only for the formulation, amendment, administration, or enforcement of the immigration, nationality, and other laws of the United States. The statement further notes that, at the discretion of the Secretary of State, copies of visa records may be made available to a court which certifies that the information contained in such records is needed in a case pending before the court.

11. *Are any questions of a sensitive nature asked?*

    Yes, the medical forms contain questions and fields which collect sensitive health and medical information. The questions in this information collection are necessary to determine whether an applicant is eligible for a visa under § 212(a)(1) of the INA, 8 U.S.C. § 1182(a)(1), among other grounds of ineligibility.

    The sensitive questions are also necessary to determine whether refugees have medical conditions affecting the public and requiring treatment under INA § 412(b)(4)(B), 8 U.S.C. § 1522(b)(4)(B).

    Questions concerning tattoos, scars or other markings would constitute important information for consular officers to determine potential ineligibility pursuant to INA § 212(a).

Additionally, the questions are needed to determine whether an alien can legally be issued a boarding foil for the purpose of parole, consistent with DHS policy under INA § 212(d)(5), 8 U.S.C. 1182(d)(5).

Aliens will be advised that the sensitive information collected from the medical examination may be accessible to other U.S. government agencies with statutory or lawful authority to use such information, including for law enforcement and immigration enforcement purposes.

12. What is the hour time burden and the hour cost burden on the respondent needed to complete this collection?

Annual responses: **696,000**

The Department estimates that approximately 696,000 aliens will be required to undergo a medical examination to receive an immigrant visa or immigration benefit each year. An exam is valid for up to six months, after which, an individual may need to submit to a second exam. However, most aliens seeking to enter the United States will only be required to undergo a single examination. Of those 696,000 medical examinations, an estimated 146,000 will be completed using the paper visa medical forms (DS-2054, DS-3025, DS-3026, and DS-3030). This estimate is derived by aggregating the most recent annual data for the categories of individuals who have historically been required to submit paper medical forms: parolees (12,000), asylees and refugees (14,000), K-visa applicants (60,000), and diversity visa recipients (60,000). The Department also estimates that approximately 550,000 medical examinations will be completed through the DS-7794 eMedical portal.

Annual respondents**: 696,800**

Each response to this information collection requires two respondents— the panel physician and the alien applicant.

Globally, there are approximately 800 panel physicians who are authorized to conduct these exams and complete the forms to provide the Department with the results. If each medical examination includes a unique alien case, there should be approximately 696,000 individual applicants. This means there are total of 696,800 annual respondents.

Annual Response Time**: 1,740,000 hours**

If there are 696,000 responses, two respondents per response, and each respondent spends 1.25 hours (75 minutes) responding to the collection, the total hour time burden for this collection is equal to 1,740,000 hours (696,000 responses * 2 respondents per response * 1.25 hours).

Alien Applicant Hour Cost Burden: **$21,323,700**

Alien Applicant Burden Figures – Medical Examination Forms

Form Number	Annual Respondents / Responses	Responses per respondent	Per Response Time Burden	Total Annual Burden Hours	Total Annual Hour Cost Burden (@$24.51/hour)
DS-2054	146,000*	1	10 minutes	24,333	$596,401.83
DS-3025	146,000*	1	20 minutes	48,667	$1,192,828.17
DS-3026	146,000*	1	30 minutes	73,000	$1,789,230
DS-3030	146,000*	1	15 minutes	36,500	$894,615
DS-7794	550,000	1	75 minutes*	687,500	$16,850,625
Total	**696,000**	**1***	**75 minutes***	**870,000**	**$21,323,700**

NOTE: Paper forms are submitted as a single packet and all four forms must be submitted together to constitute a single response, so these form figures do not aggregate in the total.

*Figure does not aggregate.

Panel Physician Hour Cost Burden: **$113,387,100**

Panel Physician Burden Figures – Medical Examination Forms						
Form Number	Annual Respondents	Annual Responses	Average Responses per Respondent	Per Response Time Burden	Total Annual Burden Hours	Total Annual Hour Cost Burden (@$130.33/hour)
DS-2054	800	146,000	182.5	10 minutes	24,333	$3,171,319.89
DS-3025	800	146,000	182.5	20 minutes	48,667	$6,342,770.11
DS-3026	800	146,000	182.5	30 minutes	73,000	$9,514,090
DS-3030	800	146,000	182.5	15 minutes	36,500	$4,757,045
DS-7794	800	550,000	687.5	75 minutes*	687,500	$89,601,875
Totals	**800***	**696,000**	**870**	**75 minutes***	**870,000**	**$113,387,100**

NOTE: Paper forms are submitted as a single packet and all four forms must be submitted together to constitute a single response, so these form figures do not aggregate in the total.

*Figure does not aggregate.

Total Hour Cost Burden: **$134,710,800**

The total Hour Cost Burden is equal to the total alien applicant burden ($21,323,700) plus the total panel physician burden ($113,387,100), which is $134,710,800**.**

13. What is the monetary burden to respondents (out of pocket costs) needed to complete this collection?

Respondents are panel physicians and applicants who have a doctor-patient relationship. Real monetary costs associated with examinations are considered "customary and usual

business practices," and these costs are not included when calculating PRA burdens. In practice, panel physicians are paid all the costs associated with conducting and communicating the results of the medical exam by the applicant. Therefore, the cumulative out-of-pocket monetary burden for respondents is $0.

14. What are the costs incurred by the Federal Government to complete this collection?

There is no cost to the Federal Government associated with this collection. Costs associated with reviewing medical information as part of an application are accounted for in the corresponding application (e.g. DS-160, DS-260, etc.).

15. Are there any changes/adjustments to this collection since the previous submission?

The Department is merging the paper medical forms and eMedical form information collections under a single OMB Control Number: 1405-0230. This means the Department is discontinuing the former paper medical OMB Control Number: 1405-0113.

Additionally, the Department is proposing changes to this information collection. A list of changes is outlined in the table below, with all new language highlighted in yellow:

Revisions to "Medical Examination for Visa and Immigration Benefit" Paper Collection Instruments		
Form / Section	**Proposed changes**	**Justification**
DS-2054 / First Page Information Summary	**Add** fields: "Results of Controlled Substance/Alcohol Lab" "Results of Metabolic Lipid Laboratory" "Results of Other STD Laboratory"	To report results of additional medical tests.
DS-2054 / # 1, "Class A Conditions"	**Replace** the option, "Any physical or mental disorder *(excluding addiction or abuse of specific substance on the Controlled Substances Act but including other substance-related disorder)* harmful behavior or history of such behavior likely to recur (1A3)" **with** "Any physical or mental disorder, or addiction or abuse of a non-controlled substance, with harmful behavior (current or likely to recur) (1A3)".	To improve the accuracy of classification of individuals with mental health conditions, including for the classification of individuals in remission.
DS-2054 / # 1, "Class B Conditions"	**Replace** the option, "Any physical or mental disorder *(excluding addiction or abuse of specific substance on the Controlled Substances Act but including other substance-related disorder)* without harmful behavior or history of such behavior unlikely to recur" **with**	To improve the accuracy of classification of individuals with mental health conditions, including for the classification of individuals in remission.

	"Any physical or mental disorder, or addiction or abuse of a non-controlled substance, without harmful behavior or with past harmful behavior that is unlikely to recur (or in remission)"	
DS-2054 / # 1, "Class B Other"	**Add** the following language after "(Specify or give details from worksheets.": "In addition, for any Class B conditions, you must remark on the likely degree of disability or the need for extensive medical care or institutionalization.").	To clarify the need for the panel physician to make further remarks as outlined in the Technical Instructions.
DS-2054 / # 3, "Nature and Extent of Abnormalities"	**Add** a new section, with header that reads: "Nature and Extent of Abnormalities" Section includes the following: "I attest that after performing the applicant's medical examination, I conclude that:" ▫ "The nature and extent of abnormalities renders the applicant capable of normal physical activity, including but not limited to employment;" ▫ "The nature and extent of abnormalities is remediable; and" ▫ "The nature and extent of abnormalities will require extensive medical care or institutionalization." *Panel physician will indicate* "Yes", "No", or "N/A" *for each bullet.*	To more clearly affirm or deny the extent and long-term impact of the medical findings, in line with the Technical Instructions. This will provide additional information to consular officers when determining a visa applicant's eligibility under INA 212(a)(4).
DS-3026 / # 1, "Medical History—Psychiatry"	**Add** "gender dysphoria, delusional disorder, etc." to the parenthetic list under "Psychological/Psychiatric Disorder".	Clarifying instructions for panel physicians.
DS-3026 / # 1, "Medical History—Psychiatry"	**Replace** the option, "Substance use or substance induced disorders of substances on the Controlled Substances Act (CSA)" **with** "Substance use disorder involving a substance on the Controlled Substances Act (CSA)" **Replace** the option, "Substance use or substance induced disorders of substances not on the CSA (including alcohol)" **with** "Substance use disorder involving a substance not on the CSA (including alcohol)"	To allow panel physicians to accurately report findings according to the updated Technical Instructions, which no longer include substance "induced" disorders.
DS-3026 / # 1, "Medical History—Obstetrics"	**Add** "Last Menstrual Period," before "LMP" under "Pregnant on day of exam" section.	To clarify what "LMP" refers to in this context.

DS-3026 / # 1, "Medical History—Sexually Transmitted Diseases (STDs)"	**Add** the following fields to the list under "Previous treatment for STDs – Specify date (mm-yyyy) and treatment received:" • Chlamydia _____ (*No/Yes checkboxes*) • Trichomoniasis _____ (*No/Yes checkboxes*) • Herpes _____ (*No/Yes checkboxes*) • Other STDs (specify) ___ (*No/Yes checkboxes*)	To document additional details about the duration of expected treatment, which will assist consular officers in making visa eligibility determination
DS-3026 / # 1, "Medical History—Hematologic/Lymphatic"	**Add** "High Cholesterol" field to the list with *No/Yes* checkbox options.	To document additional details about the duration of expected treatment, which will assist consular officers in making visa eligibility determination
DS-3026 / # 1, "Medical History—Other"	**Replace** "Diagnosed" with "Date Tested" under the "An abnormal or reactive HIV blood test" option. **Replace** "Completed" with "Completion date" under the "Hansen's Disease History" option.	To document additional details about the duration of expected treatment, which will assist consular officers in making visa eligibility determination
DS-3026 / # 2, "Current Medications (List all current medications. Use additional sheets, if required.)"	**Replace** the lines with a two-column table, with "Name of Medication" in the first column and "Expected Time to Take Medications *Short Term = Less than 6 months Medium Term = 6-12 months Long Term = More than 12 months*" in the second column.	To document additional details about the duration of expected treatment, which will assist consular officers in making visa eligibility determination.
DS-3026 / # 3, "Previous Surgeries"	**Add** the following language after "(List all previous surgeries" ", including but not limited to those related to other health conditions, heart disease, pregnancy, or elective surgeries to attempt to change male traits to female and vice versa. Use additional sheets, if required.")	Clarifying instructions for panel physicians.
DS-3026 / # 4, "Vital Signs and Vision"	**Add** "BMI _____ kg/m^2" after "Weight___".	To add Body Mass Index (BMI), a screening tool used to identify potential weight-related health risks that may affect the applicant's ability to pursue work in the United States or require extensive health care or institutionalization.
DS-3026 / #5, "Physical Examination"	**Remove** the word "Exposed" from "Exposed Skin" option.	To reflect a comprehensive skin exam aligned with standard medical practice.
DS-3026 / #6, "Mental Health ~~Specialist~~"	**Delete** "Specialist" from the section header. **Replace** the phrase,	To align with the Technical Instructions while explicitly indicating the inclusion of substance use disorders

	"(excluding addiction or abuse of specific substance on the Controlled Substances Act but including other substance-related disorder)" **with** "or substance use disorder of non-controlled substance, such as alcohol" **Replace** the option, "Class A, with harmful behavior, list disorder(s)" **with** "Class A, with harmful behavior (current or likely to recur): list disorder(s) and/or non-controlled substances" **Replace** the option, "Class B, with harmful behavior, list disorder(s)" **with** "Class B, without harmful behavior, or with past harmful behavior that is unlikely to recur (or in remission): list disorder(s) and/or non-controlled substances" **Replace** the phrase, "Addiction or abuse of a specific substance" **with** "Substance use disorder of a specific substance"	involving non-controlled substances. Recent updates to the Technical Instructions modified use of 'addiction' and 'abuse' to "substance use disorder," which aligns with current medical terminology

DS-3026 /
#6, "Mental Health
	Add new subsection, "Testing for abuse of controlled substances and alcohol (Urine)" that contains the following.
	• A single row table with two columns that read,
	  ○ "Test Name"
	  ○ "Date result reported (mm-dd-yyyy)"
	• Two large checkbox options:
	  ○ "**No Substances Detected**"
	  ○ "Laboratory Testing Not Done"
	• Instructions that read, "Check box if the corresponding controlled substances was positively detected. Annotate if inconclusive result or test unavailable." Then after this instruction, this list of checkbox options:
	  ○ Amphetamines _____
	  ○ Barbiturates _____
	  ○ Benzodiazepines _____
	  ○ Cocaine Metabolites / Benzoylecgonine _____
	  ○ Cannabis / Marijuana Metabolites ____
	  ○ Other:_____
	  ○ Other:_____
		To document additional details about the duration of expected treatment, which will assist consular officers in making visa eligibility determinations.

	○ Methadone _____ ○ Buprenorphine _____ ○ Methaqualone _____ ○ Opiates _____ ○ Phencyclidine_____ ○ MDA Analogues_____ ○ Alcohol_____	
DS-3026 / #9, "Other Sexually Transmitted Diseases Laboratory Results"	**Add** new section with header, that reads "Other Sexually Transmitted Diseases Laboratory Results". **Add** check box for, "Laboratory Testing Not Done". **Add** a five-column table with the following table headers: • "STD Screening" • "Test Name" • "Date result reported (mm-dd-yyyy)" • "Positive" • "Negative" Include a row for each of the following • "Hepatitis B (Blood)" • "Hepatitis C (Blood)" • "Herpes (HSV-1/HSV-2) (Blood)" • "Chlamydia (Urine)" • "Trichomoniasis (Urine)" • "HIV/AIDs" • "Other STDs (specify): _____" • "_____"	To document additional details about the duration of expected treatment, which will assist consular officers in making visa eligibility determination
DS-3026 / # 11, "Tattoos, Scars, and Markings (Submit a photograph of all tattoos, scars and markings and include a description and where it is located on the body. Use additional sheets, if needed.)"	**Add** new section with header that reads, "Tattoos, Scars, and Markings (Submit a photograph of all tattoos, scars and markings and include a description and where it is located on the body. Use additional sheets, if needed.)" **Add** a two-column table, with "Description of Tattoo, Scar or Marking" in first column and "Location on Body" in the second column.	To provide indicators of public safety risk/s.
DS-3026 / #12, "Metabolic Lipid Panel"	**Add** new section with header that reads, "Metabolic Lipid Panel" which contains: • Check box for, "Laboratory Testing Not Done". • Two tables: Table 1 contains a single row, labelled "Screening", and three columns: ○ [Blank] ○ "Test Name" ○ "Date result reported (mm-dd-yyyy)"	To document additional details about overall applicant health and the duration of any expected treatment, which will assist consular officers in making visa eligibility determinations.

	Table 2 contains 5 rows and 3 columns: Column 1 ○ Row 1: "**Lipid Panel**" ○ Row 2: "Total Cholesterol" ○ Row 3: "Triglycerides" ○ Row 4: "HDL (High-Density Lipoprotein)" ○ Row 5: "LDL (Low-Density Lipoprotein)" Column 2 ○ Row 1: "**Result**" ○ Row 2: "_____MG/DL" ○ Row 3: "_____MG/DL" ○ Row 4: "_____MG/DL" ○ Row 5: "_____MG/DL" Column 3 ○ Row 1: "*Expected Range*" ○ Row 2: " < 200 MG/DL" ○ Row 3: " < 150 MG/DL" ○ Row 4: " > 39 MG/DL" ○ Row 5: " < 100 MG/DL"	
DS-3030 / Part #1, Test for Cell-Mediated Immunity to Tuberculosis	**Reformat** #1 into a table with two rows and four columns. • The first table cell will be labelled "IGRA performed, mark each test:" and each column in that row will contain the check box options. **Add new option**: • Column four in row one will contain a new option, "Other, please indicate test name below: _____". • Row 2 will contain a header, "Other IGRA (indicate optimal density value for each)" with text boxes for quantitative laboratory results underneath: ○ "Nil Control:" ○ "TB Antigen:" ○ "Mitogen:"	To properly report data based on updated Technical Instructions. Previously only two IGRA tests were approved for use. Additional test types are now approved, and this change also provides flexibility if other test types are approved before the next form revision.
DS-3030 / Part #2, Chest X-Ray Indication	**Add** option underneath "History of tuberculosis" that reads, "TB Contact age <5 years".	To reflect an additional indication for the chest X-ray requirement in the updated Technical Instructions.
DS-3030 / Part #4, Sputum Evaluation Decision	**Replace** header: "Sputum Smears and Culture Decisions" **with** "Sputum Evaluation Decision".	To shorten the section title to include all testing types, including molecular testing, which is now required in the Technical Instructions as a part of the sputum evaluation for infectious TB disease.

DS-3030 / Part #5 AFB Smears, Cultures and Molecular Testing Results	**Replace** header: "Sputum Smears and Culture Results" **with** "AFB Smears, Cultures and Molecular Testing Results"	To better capture the results of sputum testing and alternative specimen types specified in the Technical Instructions.
DS-3030 / Part #5 AFB Smears, Cultures and Molecular Testing Results	**Add section:** "Select only one specimen type:" This will have three checkbox options that read: ▫ "Sputum: Exam requirements: 3 specimens for smear and culture plus molecular testing of the first specimen End of treatment monitoring: 2 specimens for smear and culture ▫ Bronchial Lavage Fluid Exam requirements: 2 specimens for smear and culture plus molecular testing of both specimens ▫ Gastric Aspirate Exam requirements: 3 specimens for smear and culture plus molecular testing of the first specimen"	To clarify the different requirements based on specimen types allowed in the Technical Instructions. The addition of specimen type improves the ability to analyze and monitor the examination findings.
DS-3030 / Part #5 AFB Smears, Cultures and Molecular Testing Results	**Replace** table name "Sputum Smear Result" **with** "AFB Smear Results" **Replace** table name **"**Sputum Culture Results" **with** "Culture Results"	Because newer types of specimens besides sputum are permitted in Technical Instructions, this change allows the respondent to report different types of smear and culture results using a single table.
DS-3030 / Part #5 AFB Smears, Cultures and Molecular Testing Results	**Add section** with header, "Molecular Test Type (select one):" which contains the following checkbox options: ▫ "GeneXpert MTB/RIF Ultra" ▫ "Cobas MTB/RIF" ▫ "HAIN Line Probe Assay (LPA)" ▫ "Genotype MTBDRplus" ▫ "Other (specify): _____" **Add table** with 4 rows and 10 columns (*note certain cells will be merged*). Spaces not noted below are blank. Column 1 Row 1 & 2 *(merged)*: "Date Specimen Obtained (mm-dd-yyyy)" Column 2 Row 1 & 2 *(merged)*: "Date of Final Result (mm-dd-yyyy)"	The updated Technical Instructions require molecular testing on the first specimen collected. The new table is necessary to document the type of test administered and the test results.

	Columns 3 & 4 Row 1 (*columns merged*): "Mycobacterium Tuberculosis" Row 2: "Detected"/"Not Detected" Column 5, 6, & 7 Row 1 (*columns merged*): "Rifampin Resistance" Row 2: "Detected" / "Not Detected" / "Indeterminate" Columns 8 & 9 Row 1 (*columns merged*): "Isoniazid Resistance" Row 2: "Detected" / "Not Detected" / "Indeterminate"	
DS-3030 / Part #5 AFB Smears, Cultures and Molecular Testing Results	**Add check box option** "Stool" under the table. **Add text** under the check box option: "Exam requirements: 3 consecutively collected stool samples for molecular testing only. If positive, gastric aspirates must be completed and documented above." **Add text: "**Molecular Test Type (select one):" **Add checkboxes**: ▫ "GeneXpert MTB/RIF Ultra" ▫ "Other (specify): _____" **Add table** with 5 rows and 10 columns: Column 1 Row 1: "Date Specimen Obtained (mm-dd-yyyy)" Row 3: "1." Row 4: "2." Row 5: "3." Column 2 Row 1: "Date Result Reported (mm-dd-yyyy)" Columns 3 & 4 Row 1 (*columns merged*): "Mycobacterium Tuberculosis" Row 2: "Detected"/"Not Detected" Column 5 & 6 Row 1 (*columns merged*): "Rifampin Resistance" Row 2: "Detected" / "Not Detected" / "Indeterminate" Columns 7 & 8 Row 1 (*columns merged*): "Isoniazid Resistance"	To reflect updates to the Technical Instructions to allow alternative specimen types using molecular testing when applicants are unable to produce sputum specimens (e.g., young children). The new table is necessary to document the results of stool molecular testing.

	Row 2: "Detected" / "Not Detected" / "Indeterminate"	
DS-3030 / Part #6 Tuberculosis Classification	**Under "No TB Classification" option, delete text**: "CXR not suggestive of tuberculosis, no tuberculosis…. "	The previous descriptive text no longer accurately describes all scenarios that must be met or have a negative result.
DS-3030 / Part #6 Tuberculosis Classification	**Under "Class A" option, replace:** "has tuberculosis" **with** "has infectious tuberculosis"	To better reflect different types of tuberculosis and clarify that infectious tuberculosis disease is considered Class A.
DS-3030 / Part #6 Tuberculosis Classification	**Under "Class B1 TB, Pulmonary" option, replace:** "CXR suggests tuberculosis, or tuberculosis signs and symptoms…" **with** "Applicant required sputum collection but had negative cultures and was not diagnosed with infectious tuberculosis disease. This classification also includes applicants who were diagnosed with infectious tuberculosis disease by the panel physician, refused DGMH-defined DOT treatment, and are returning after treatment and completion of a minimum 1-year wait**."**	To accurately report the definition of Class B1 in alignment with the Technical Instructions.
DS-3030 / Part #7 History of Class A TB	Above "Smear result at diagnosis", **Add new section header**, "A. Specimen Type and Results (select one)" **and Check boxes:** ▫ Sputum ▫ Bronchial Lavage Fluid ▫ Gastric Aspirate **Replace** "Sputum" **with** "AFB" in the headers for the next two tables. **Add text header**, "Molecular Testing Result at Diagnosis" **Add section under this header,** "Molecular Test Type (select one):" which contains the following checkbox options: ▫ "GeneXpert MTB/RIF Ultra" ▫ "Cobas MTB/RIF" ▫ "HAIN Line Probe Assay (LPA)" ▫ "Genotype MTBDRplus" ▫ "Other (specify): _____"	With the addition of new laboratory testing methodologies, additional tables are needed to document the results, from the initial diagnosis of infectious TB disease, and after treatment.

	Add table with 4 rows and 10 columns. Spaces not noted below are blank. Column 1 Row 1 & 2 *(merged)*: "Date Specimen Obtained (mm-dd-yyyy)" Column 2 Row 1 & 2 *(merged)*: "Date of Final Result (mm-dd-yyyy)" Columns 3 & 4 Row 1 (*columns merged*): "Mycobacterium Tuberculosis" Row 2: "Detected"/"Not Detected" Column 5, 6, & 7 Row 1 (*columns merged*): "Rifampin Resistance" Row 2: "Detected" / "Not Detected" / "Indeterminate" Columns 8 & 9 Row 1 (*columns merged*): "Isoniazid Resistance" Row 2: "Detected" / "Not Detected" / "Indeterminate" **Add check box option** "Stool Molecular testing Results at Diagnosis" under the table. **Add text: "**Test Type:" **Add checkboxes**: ▫ "GeneXpert MTB/RIF Ultra" ▫ "Other (specify): _____" **Add table** with 5 rows and 10 columns: Column 1 Row 1: "Date Specimen Obtained (mm-dd-yyyy)" Row 3: "1." Row 4: "2." Row 5: "3." Column 2 Row 1: "Date Result Reported (mm-dd-yyyy)" Columns 3 & 4 Row 1 (*columns merged*): "Mycobacterium Tuberculosis" Row 2: "Detected" / "Not Detected" Column 5 & 6 Row 1 (*columns merged*): "Rifampin Resistance"	

	Row 2: "Detected" / "Not Detected" / "Indeterminate" Columns 7 & 8 Row 1 (*columns merged*): "Isoniazid Resistance" Row 2: "Detected" / "Not Detected" / "Indeterminate"	
DS-3030 / Part #7 History of Class A TB, Continued	**Add "B."** immediately before **"**Drug Susceptibility Test Results" as part of the header. In the table that immediately follows, **replace**: "Method of DST" **with** "Culture-based (phenotypic) DST " In the second table, **modify** the following cells: ➢ Column 1 ○ Row 1: "Required for:" ○ Rows 2-5 (*merged*): "First-line DST" ○ Row 6: "If Fluoroquinolone used" ○ Rows 7-13 (*merged)*: "Second-line DST for multidrug-resistant cases" ➢ Column 2 ○ Row 6: "Fluoroquinolone, specify:_____" ○ Row 10: **Replace** "Para-aminosalicyclic acid (PAS)" **with** "Other, specify" ○ Row 11: "Other, specify" ○ Row 12: "Other, specify" **Add a complex table** with 13 rows and 5 columns (*please see PDF mockup for layout*): Row 1: • "Molecular DST (Optional, does not replace culture-based DST)" (*in merged Columns 1-2)* • "Date specimen obtained: (mm-dd-yyyy) (*custom sized in columns 3-4)* • "Date DST reported (mm-dd-yyyy)" (*custom sized in columns 4-5)* Row 2 contains three check boxes in the first cell *(Columns 1-2 merged)*: ▫ "Xpert XDR" ▫ "GenoType MTBDRsl" ▫ "Other, specify:" ----------	Because the Fluoroquinolone drug class is no longer widely used to treat infectious TB disease, drug susceptibility testing for this drug class is only required when it is included in the treatment regimen. The Technical Instructions now include multiple approaches for drug susceptibility testing (DST), each with different strengths and weaknesses. A new table will allow for more accurate documentation of results, and appropriate interpretation based on type of testing performed.

	NOTE: Rows 3 to 13 are separated in terms of Left/Right visual columns ➢ *"LEFT COLUMN" = Table Columns 1-2* ➢ *"RIGHT COLUMN" = Table Columns 3-5* LEFT COLUMN – First box (*merged columns 1-2 and rows 3-4*): "Drug" Column 1 Rows 5-10 (*merged*): "Drugs tested" Row 11: "Other, (Please indicate)" Row 12: "Other, (Please indicate)" Row 13: "Other, (Please indicate)" Column 2 Row 5: "Isoniazid" Row 6: "Fluoroquinolone" Row 7: "Amikacin" Row 8: "Kanamycin" Row 9: "Capreomycin" Row 10: "Ethionamide" RIGHT COLUMN – First box (*merged columns 3-5 and row 1)*: "Resistance" Column 3 Row 5: "Detected or Inferred" Column 4 Row 5: "Not Detected or Not Inferred" Column 5 Row 5: "Indeterminate" Row 10: (*cell is blacked out and unfillable)*	

Equivalent changes to those listed in this table are also incorporated into the electronic DS-7794 collection instrument.

16. Will any data gathered by this collection be published?

No. The data gathered by this collection will not be published.

17. Will the OMB expiration date be displayed?

Yes. The Department will display the OMB expiration date on the collection.

18. Are any exceptions to the OMB certification statement being sought?

No. The Department is not seeking exceptions to the certification statement.

B. COLLECTION OF INFORMATION EMPLOYING STATISTICAL METHODS

This collection does not employ statistical methods.