

SUPPORTING STATEMENT JUSTIFICATION FOR CERTIFICATES OF MEDICAL EXAMINATION INFORMATION COLLECTION

1. Circumstances Making Collection of Information Necessary:

This is a request to revise the information collection related to certificates of medical examination for FSIS regulatory programs. FSIS is adding two new forms to the existing information collection.

The Food Safety and Inspection Service (FSIS) has been delegated the authority to exercise the functions of the Secretary as provided in the Federal Meat Inspection Act (FMIA) (21 U.S.C. 601 et seq.), the Poultry Products Inspection Act (PPIA) (21 U.S.C. 451 et seq.), and the Egg Products Inspection Act (EPIA) (21 U.S.C. 1031 et seq.). These statutes mandate that FSIS protect the public by ensuring that meat and poultry products are safe, wholesome, unadulterated, and properly labeled and packaged.

FSIS uses the form titled *Certificate of Medical Evaluation (FSIS 4339-1)* to collect information to determine whether or not an applicant for an FSIS Food Inspector, Consumer Safety Inspector, or Veterinary Medical Officer in-plant position meets the Office of Personnel Management (OPM) approved medical qualification standards. FSIS employees will ask their health care providers to complete *FSIS Form 4306-5, "Medical Documentation for Employee's Reasonable Accommodation Request,"* if they apply for a reasonable accommodation, and *FSIS Form 4630-8, "Confidential Medical Information,"* if they apply for the FSIS Leave Bank Program.

2. How, By Whom and Purpose For Which Information is to be Used:

The following is a discussion of the required information collection activities.

FSIS collects certificates of medical examination to determine whether or not an applicant for a Food Inspector, Consumer Safety Inspector, or Veterinary Medical Officer in-plant position meets the Office of Personnel Management (OPM)-approved medical qualification standards for the position. This form, *Certificate of Medical Evaluation (FSIS 4339-1)*, ensures accurate collection of the required data. The OPM-approved medical qualification standards apply only to positions in FSIS, not positions in other Federal agencies.

When requesting that applicants for the positions listed above undergo the medical examination, a representative from FSIS

notifies the applicants in writing of the reasons for the examination, the process, and the consequences of the failure to report for an examination or provide medical documentation. Any physical condition which would hinder an individual's full, efficient, and safe performance of his or her duties is considered disqualifying for employment, except when convincing evidence is presented that the individuals can perform the essential functions of the job efficiently and without hazard to themselves or others.

FSIS will use the FSIS Form 4306–5, “Medical Documentation for Employee’s Reasonable Accommodation Request,” to help determine whether the Agency will provide reasonable accommodation to qualified individuals. In accordance with the Rehabilitation Act of 1973 and the Americans with Disabilities Act Amendments Act of 2008, FSIS will make reasonable accommodations for the known physical or mental limitations of qualified individuals with disabilities, unless the accommodation would impose an undue hardship on the operation of FSIS. FSIS will require medical information from a health care provider to determine whether the person’s condition rises to the level of disability under the law and to determine whether the limitations can be effectively accommodated. Second, FSIS will use FSIS Form 4630–8 “Confidential Medical Information,” to assist employees who qualify as leave recipients under the FSIS Leave Bank Program (LBP), which FSIS intends to establish in accordance with 5 CFR 630, subpart J.

3. Use of Improved Information Technology:

Under the E-Gov Act, individuals may submit the forms electronically. FSIS makes available electronic versions (PDF fillable) of the FSIS Forms 4339-1, 4306-5, and 4630-8. The forms can be filled out on the computer and then either emailed or printed off and submitted to the appropriate office.

4. Efforts to Identify Duplication:

FSIS has determined that this information collection will not duplicate any other information collections. The required records could be available through the use of OPM Optional Form 178 (OMB 3206-0250), but FSIS requires more extensive medical information in order to assess whether candidates meet the medical qualification standards for inspection positions. The forms in this collection are designed to improve data-gathering to align more closely with FSIS needs and save time by reducing the need for follow-up.

5. Methods to Minimize Burden on Small Business Entities:

There are no small businesses affected by this information collection.

6. Consequences If Information Were Collected Less Frequently:

To conduct the information collections less frequently will reduce the effectiveness of the meat and poultry products inspection program.

7. Circumstances that Would Cause the Information Collection to be Conducted in a Manner:

- **requiring respondents to report information to the agency more often than quarterly;**
- **requiring respondents to prepare a written response to a collection of information in fewer than 30 days after receipt of it;**
- **requiring respondents to submit more than an original and two copies of any document;**
- **requiring respondents to retain records, other than health, medical, government contract, grant-in-aid, or tax records for more than three years;**
- **in connection with a statistical survey, that is not designed to produce valid and reliable results that can be generalized to the universe of study;**
- **requiring the use of a statistical data classification that has not been reviewed and approved by OMB;**
- **that includes a pledge of confidentiality that is not supported by authority established in statute or regulation, that is not supported by disclosure and data security policies that are consistent with the pledge, or which unnecessarily impedes sharing of data with other agencies for compatible confidential use; or**
- **requiring respondents to submit proprietary trade secret, or other confidential information unless the agency can demonstrate that it has instituted procedures to protect the information's confidentiality to the extent permitted by law.**

There are no circumstances that would cause the guidelines above not to be met by this information collection.

8. Consultation with Persons Outside the Agency:

In accordance with the Paperwork Reduction Act, FSIS published a 60-day notice in the *Federal Register* on July 9, 2019, (84 FR 32704) requesting comments regarding this information collection. The Agency received no comments in response to the *Federal Register* notice. FSIS also contacted persons outside the Agency regarding the FSIS burden estimate. FSIS requested input

on the Agency's burden estimate from three knowledgeable people on the FSIS Form 4339-1. The commenters agreed that it will take 90 minutes or less to complete the form (Susan Budig, 952-926-9812; Leann Sargeant, 619-985-6529; and Dustin Sward, 757-898-8117). FSIS contacted Dr. Michael Montopoli, 301-492-4085; Dr. Neal Presant, 301-392-4518; and Dr. Lou Glad, 651-241-9700, to request input on the FSIS burden estimates for the FSIS Forms 4306-5 and 4630-8. The three individuals agreed that the FSIS burden estimate of 10 minutes to complete FSIS Form 4306-5 and 15 minutes to complete FSIS Form 4630-8 were accurate. Based on input from the commenters, the Agency is making no changes to the estimated burden for completion of the forms.

9. Payment or Gifts to Respondents:

Respondents will not receive any gifts or payments.

10. Confidentiality Provided to Respondents:

No additional assurance of confidentiality is provided with this information collection. Any and all information obtained in this collection shall not be disclosed except in accordance with 5 U.S.C.552a.

11. Questions of a Sensitive Nature:

The applicants are asked to furnish social security numbers and personal medical information. The information becomes part of the employee Medical Folder, which is maintained and protected in accordance with OPM regulations 5 CFR 293, Subpart E. These records are also protected by the Privacy Act of 1974, 5 U.S.C. 552a and are covered by OPM/GOVT-10, Employee Medical File System Records. The social security number is requested in order to more accurately identify and retrieve health care records of individuals.

12. Estimate of Burden

The total burden estimate for this information collection is 809 hours. The Agency has increased the burden estimate by 59 hours due to the addition of the two forms. FSIS Form 4306-5 was in use without approval and FSIS Form 4630-8 is a new form.

Certificate of Medical Examination

The Agency estimates that 500 individuals will once a year spend 90 minutes to complete a certificate of medical examination for a grand total of 500 responses and 750 burden hours.

**CERTIFICATE OF MEDICAL EXAMINATION (FSIS 4339-1)
(5 CFR 339 Medical Qualification Determinations)**

Type of Respondent	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Time for Response in Mins.	Total Annual Time in Hours
Individuals	500	1	500	90	750

The Agency estimates that 200 individuals will once a year spend 10 minutes to complete a certificate of medical examination for a grand total of 200 responses and 34 burden hours.

**CERTIFICATE OF MEDICAL EXAMINATION (FSIS 4306-5)
(5 CFR 339 Medical Qualification Determinations)**

Type of Respondent	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Time for Response in Mins.	Total Annual Time in Hours
Individuals	200	1	200	10	34

The Agency estimates that 100 individuals will once a year spend 15 minutes to complete a certificate of medical examination for a grand total of 100 responses and 25 burden hours.

CERTIFICATE OF MEDICAL EXAMINATION (FSIS 4630-8)

(5 CFR 339 Medical Qualification Determinations)

Type of Respondent	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Time for Response in Mins.	Total Annual Time in Hours
Individuals	100	1	100	15	25

The cost to the respondents is estimated at \$107,079 annually. The Agency estimates that it will cost medical health respondents \$132.36 an hour, including fringe benefits, in fulfilling these paperwork requirements. Respondents will spend an annual total of 809 hours and \$107,079. The hourly rate for the respondents was attained from the Department of Labor Bureau of Labor and Statistics wage data, May, 2018.

13. Capital and Start-up Cost and Subsequent Maintenance

There are no capital and start-up costs and subsequent maintenance burdens.

14. Annual Cost to Federal Government and Respondents:

The cost to the Federal Government for these information collection requirements is \$18,344 annually. The costs arise primarily from the time spent by FSIS staff reviewing protocols and data. The Agency estimates a cost of \$45.35 per hour, including fringe benefits, for the FSIS staff.

15. Reasons for Changes in Burden:

The Agency has increased the total burden estimate for the collection by 59 hours and 300 responses due to the addition of the two forms. FSIS Form 4306-5 was in use without approval and FSIS Form 4630-8 is a new form.

16. Tabulation, Analyses and Publication Plans:

There are no plans to publish the data for statistical use.

17. OMB Approval Number Display:

FSIS will display the OMB approval number on any instructions it publishes relating to the FSIS Forms. The OMB approval number will appear on required FSIS forms.

18. Exceptions to the Certification:

There are no exceptions to the certification. This information collection accords with the certification in item 19 of the OMB 83-I.