SUPPORTING STATEMENT JUSTIFICATION FOR
ACCREDITATION OF LABORATORIES, TRANSACTIONS, AND EXEMPTIONS

1. Circumstances Making Collection Of Information Necessary:

This is a request to renew the information collection related to the accreditation of laboratories, transactions, and exemptions for meat, poultry, and egg products inspection.

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, poultry, and egg products are safe, wholesome, and properly labeled.

The Federal Meat Inspection Act (21 U.S.C. 642) and the Poultry Products Inspection Act (21 U.S.C. 460 (b)) require certain parties to keep records that fully and correctly disclose all transactions involved in their businesses related to relevant animal carcasses and parts and egg products.

FSIS requires FSIS accredited non-Federal analytical laboratories to maintain certain information collection records. The Agency uses this collected information to ensure that all meat and poultry establishments produce safe and wholesome product, and that non-federal laboratories operate in accordance with FSIS regulations.

In addition, FSIS also collects information to ensure that meat and poultry establishments exempted from Agency inspection do not commingle inspected and non-inspected meat and poultry products, and to ensure that retail operations determined to have violated the requirements associated with the retail exemptions keep sales purchase and sales records to ensure future compliance.

2. How, By Whom and Purpose Information Is To Be Used:

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

Schedule of Operations

Each establishment is required to furnish FSIS with its schedule of operations to permit assignment of inspectors. Each establishment must notify the inspectors about scheduling changes about once a year (9 CFR 307.4 and 381.37).

Transactions Recordkeeping

Establishments and other businesses are required to keep records of their transactions for meat, poultry, or egg products (9 CFR 320.1(b), 381.175(b), and 590.200). FSIS requires this information in case of need to track product.

Accreditation of Laboratories

FSIS requires accredited non-Federal analytical laboratories to maintain certain records (9 CFR 439.20 & 590.580). The Agency uses this collected information to ensure that non-Federal laboratories act in accordance with FSIS regulations. FSIS collects this information using several FSIS forms (10,000-7, 10,120-1a, 10,120-1b, 10,120-1c, and 10,120-1d).

According to the type of accreditation sought, check samples of meat and poultry products with either known quantities of fat, water, salt, or protein (food chemistry samples) or known quantities of drug or other residues (residue samples) are sent by FSIS to the labs. The labs report the results on FSIS Form 10,120-1, *Proficiency Testing Sample Results.* FSIS uses this information to determine whether the labs report the correct results and, therefore, should be accredited.

Recordkeeping for Certain Exemptions

Establishments engaging in custom exempt slaughter must keep records showing numbers and kinds of livestock slaughtered on a custom basis, the quantities and types of products prepared on a custom basis, and the names and addresses of the owners of the livestock and products (9 CFR 303.1(b)(3) and 381.10(a)(1)). FSIS reviews this information about once a year to ensure that custom operations are in compliance with the regulations.

If the Agency has reason to believe that a retail firm is in violation of retail store provisions, that operator must keep records during a probation period that reflect the monthly sales of product (§303.1(d)(3) and 381.10(d)(3)). FSIS will use this information to determine when establishments can be taken off probation.

There are a total of 113,458 burden hours for the information collection requests relating to the accreditation of laboratories, transactions, and exemptions for meat, poultry, and egg products inspection.

3. Use Of Improved Information Technology:

Under the E-Gov Act of 2002, FSIS is offering electronic versions of FSIS Forms: 10,000-7, and 10,120-1. Records may be maintained electronically provided that appropriate controls are implemented to ensure the integrity of the electronic data. The Agency estimates that 100% of the information collection and recordkeeping will be done electronically.

4. Efforts To Identify Duplication:

No USDA agency, or any other Government agency, requires information regarding application for inspections, registration, exemptions, or accreditation of laboratories relating to meat, poultry, and egg products. There is no available information that can be used or modified.

5. Methods To Minimize Burden On Small Business Entities:

Data collected from small businesses are the same as for large ones. There are 17,000 small businesses.

6. Consequences If Information Were Collected Less Frequently:

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

To maintain food safety, certain forms and recordkeeping requirements in this information collection will be done more than quarterly. All information collection and recordkeeping activities in this submission are consistent with the guidelines in 5 CFR 1320.6.

8. Consultation With Persons Outside The Agency:

In accordance with the Paperwork Reduction Act, FSIS published a 60-day notice in the **Federal Register** (91 FR 30273) on May 22, 2026, requesting public comments on this information collection request. FSIS received one comment recommending that the Agency assess the extent to which required recordkeeping remains paper-based versus electronic. FSIS has conducted, and continues to conduct, analyses of how required records are maintained and is actively enhancing PHIS to support electronic recordkeeping and reduce administrative burden.

FSIS also consulted several external industry experts to obtain feedback on the burden estimates for FSIS forms. These individuals included the Director of Lab Services at Pilgrim's (479-790-7207), the Manager at Eurofins US (brita.marzen@ft.eurofinsus.com), and the Senior Chemist at Foster Farms (209-394-6914). All three confirmed that the FSIS burden estimates were accurate; therefore, the Agency did not make any changes to the estimated burden.

9. Payment or Gifts to Respondents:

Respondents will not receive any gifts or payments.

10. Confidentiality Provided To Respondents:

No assurances other than routine protection provided under the Freedom of Information Act have been

provided to respondents.

11. Questions Of A Sensitive Nature:

The applicants are not asked to furnish any information of a sensitive nature.

12. Estimate of Burden

The total burden estimate for the reporting and recordkeeping requirements associated with this information collection is 113,458 hours. The burden estimates are broken down into four categories described in the pages that follow.

Schedule of Operations	507.9
Transactions Recordkeeping	111,633.3
Accreditation for Laboratories	34.5
Exemptions	1,282
Total	113,458 hours

Schedule of Operations

FSIS estimates that 6,095 establishments will submit their Schedule of Operations once a year for a total of 6,095 responses. And the average response time will be 5 minutes for a total of 507.9 hours per year.

SCHEDULE OF OPERATIONS
(9 CFR 307.4(d)(1)/381.37(d)(1)

Type of Establishment	No. of Respondents	No. of Re-ponses per Respondent	Total Annual Responses	Time for Response in Mins.	Total Annual Time in Hours
Meat	2,189	1	2,189	5	182.4
Poultry	507	1	507	5	42.25
Meat & Poultry	3,399	1	3,399	5	283.25
All Estabs.	6,095	1	6,095	5	507.9

Transactions Recordkeeping

FSIS estimates that 16,745 establishments and brokers will make an average of 200 responses for an annual total of 3,349,000 responses. The response time will average 2 minutes for an annual total of 111,633.3 hours.

TRANSACTIONS RECORDKEEPING
(9 CFR 320.1(b), 381.175(b), & 590.200)

Type of Establishment	No. of Respondents	No. of Re-ponses per Respondent	Total Annual Responses	Time for Response in Mins.	Total Annual Time in Hours
All	16,745	200	3,349,000	2	111,633.3

Accreditation of Labs

The Agency estimates that 51 laboratories will complete FSIS Form 10,120-1, Proficiency Testing Sample Results, six a year for an annual total of 306 responses. It will take an average of 5minutes per response for an annual total of 25.5 hours.

PROFICIENCY TESTING SAMPLE RESULTS
(9 CFR 439.20/FSIS Form 10,120-1)

Type of Establishment	No. of Respondents	No. of Re-ponses per Respondent	Total Annual Responses	Time for Response in Mins.	Total Annual Time in Hours
Labs.	51	6	306	5	25.5

LABORATORY QUALITY DIVISION AUDIT EVALUATION FORM
(9 CFR 439.20 & 590.580/FSIS Form 10,000-7)

Type of Establishment	No. of Respondents	No. of Re-ponses per Respondent	Total Annual Responses	Time for Response in Mins.	Total Annual Time in Hours
Labs	25	1	25	20	9

Exemptions

FSIS estimates that 3,130 establishments will respond twelve times a year in filing their custom exempt records for an annual total of 37,560 responses. Establishments will average two minutes in filing their forms for a total of 1,252 annual hours.

CUSTOM EXEMPT RECORDKEEPING
(9 CFR 303.1(b)(3) & 381.10(a)(1))

Type of Establishment	No. of Respondents	No. of Re-ponses per Respondent	Total Annual Responses	Time for Response in Mins.	Total Annual Time in Hours
All Ests.	3,130	12	37,560	2	1,252

FSIS estimates that 74 firms required to keep certain records because of previous retail exempt violations will take two minutes to file the records once a year for an annual total of 888 responses and 30 hours.

ORDERED RETAIL STORE RECORDKEEPING
(9 CFR 303.1(d)(3) & 381.10(d)(3))

Type of Establishment	No. of Respondents	No. of Re-ponses per Respondent	Total Annual Responses	Time for Response in Mins.	Total Annual Time in Hours
All ests.	74	12	888	2	30

The cost to the respondents is estimated at $5,812,453 annually. The Agency estimates that it will cost respondents $51.23 an hour, including fringe benefits, in fulfilling these information collection requirements. Respondents will spend an annual total of 113,458 hours and $5,812,453. The hourly rate for the respondents was attained from the Department of Labor Bureau of Labor and Statistics wage data, May, 2025.

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 $958,200 annually. The costs arise primarily from the inspection review duties necessary to verify that establishments comply with the information collection responsibilities. The Agency estimates a cost of $47.91 per hour, including fringe benefits for inspector time.

15. Reasons For Changes In Burden:

There is no change in the estimated burden. The collection has 26,120 respondents, 3,393,874 responses, and 113,458 total estimated annual burden hours.

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 recordkeeping activities.

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.