

Supporting Statement for Paperwork Reduction Act Submission
Extension, without change, of a currently approved collection
Federal Bureau of Investigation Bioterrorism Preparedness Act: Entity/Individual Information

OMB Control# 1110-0039

Part A. Justification.

1. Necessity of Information Collection:

On June 13, 2002, the President of the United States signed the Public Health and Bioterrorism Preparedness and Response Act of 2002, (Bioterrorism Act), Public Law (Pub. L.) 107-188 into effect. Under this Act, the Secretaries of the United States Department of Agriculture (USDA) and Health and Human Services (HHS), in consultation with the United States Attorney General (AG), are responsible for establishing the appropriate safeguards and security requirements for persons possessing, using, or transferring select biological agents and toxins. Responsibility for implementing these requirements has been designated to the Animal and Plant Health Inspection Service and by the Secretary, USDA, and to the Centers for Disease Control and Prevention by the Secretary, HHS. Under the Bioterrorism Act, the Department of Justice/Federal Bureau of Investigation (FBI) is responsible for conducting a Security Risk Assessment (SRA) of individuals who have been identified by the USDA and HHS as requiring access to select biological agents and toxins.

On January 30, 2003, the AG directed the FBI to conduct the Bioterrorism SRAs under sections 201, 212 and 221 of the Public Health Security and Bioterrorism Act, Pub. L. 107-188, 166 Stat. 594 (2002). On March 25, 2003, FBI Director Mueller directed the Criminal Justice Information Services (CJIS) Division to conduct the Bioterrorism SRAs. Under this delegation, the FBI receives names and other identifying information submitted by individuals requesting access to specified agents and toxins; utilizes electronic databases and other sources of information to conduct SRAs of such individuals; and consult with appropriate officials of the HHS and the USDA to determine whether certain individuals should be denied access to or granted limited access to specified agents.

The HHS and USDA provide the CJIS Division with completed FD-961 Information Forms which contain identifying information on the individual seeking access to the listed agents and toxins. The CJIS Division uses identification information submitted by each individual to complete SRAs on the following databases:

Interstate Identification Index (III), the National Crime Information Center (NCIC) "hot files," the FBI Indices, the Bureau of Immigration and Customs Enforcement (ICE) Databases, and the FBI's Department of Veterans Affairs (DVA) Database. A "routine use" is being established to allow the CJIS Division access to the Department of Defense's (DoD) dishonorable discharge data for Bioterrorism SRAs.

A three-year extension of the currently approved collection is requested.

2. Needs and Uses:

The Bioterrorism Preparedness Act: Entity/Individual Information FD-961 forms are mandatory to conduct a Bioterrorism SRA by the CJIS Division. The CJIS Division is provided with completed FD-961 Information Forms which contain identifying information on the individual seeking access to the listed agents and toxins. The CJIS Division uses identifying information submitted by individuals to complete SRAs on the following databases: III, the NCIC “hot files,” the FBI Indices, the ICE Databases, and the FBI’s DVA Database. A “routine use” is being established to allow the CJIS Division access to the DoD’s dishonorable discharge data for Bioterrorism SRAs. The routine use is established per Title 42, Code of Federal Regulations (CFR) Section 73.10(e), Title 7 CFR §331.10(e), and Title 9 CFR §121.10(e).

Ultimately at length the SRAs are completed and weekly reports are emailed to HHS and USDA as to whether certain individuals should be denied access to or granted limited access to specific agents.

3. Use of Technology:

Currently, the FD-961 form is submitted both electronically and in hard copy to the CJIS Division. The FD-961 form is available online in a PDF format. The FD-961 form can be completed electronically online and can be emailed or mailed to the CJIS Division for processing. Applicants who are renewing their access can submit their FD-961 by email or by mail. New applicants must mail their FD-961 along with their fingerprint cards to CJIS. In fiscal year 2020, approximately 65 percent of all applicants were renewals.

Although fingerprint cards cannot be submitted electronically at this time, the possibility of submitting fingerprints electronically to the CJIS Division’s Bioterrorism Risk Analysis Group (BRAG) is still under consideration and review by the three agencies (CJIS Division, HHS and USDA) involved in the SRA process. However, any such enhancement will likely take time as there are many enhancements that need to be completed to allow for electronically delivery.

In view of the fact the current process for submission of electronic fingerprints does not allow for the response to be returned to BRAG, any attempted electronic fingerprint submission will be returned to the submitting agency. Additionally, civil fingerprints cards are often submitted with a retention code of “do not retain.” Any submission of fingerprints related to an SRA must be retained to be flagged for notification to BRAG of any changes to the criminal history, such as a new arrest or conviction. Accordingly, if the submitting agency were to transmit the fingerprints with a retention restriction or other information which does not meet the standard and the fingerprints were not retained properly for BRAG review, the applicant would be required to return to the submitting agency and be fingerprinted again to initiate the SRA.

The applicant is required to submit both the FD-961 and the fingerprint cards to initiate the SRA. The FD-961 cannot be submitted electronically with the fingerprint cards because the Next Generation Identification (NGI) system will not accept this type of submission. Also, the signature is required on the FD-961 because the individual is certifying that the information is correct and that false statements are a violation of federal law and may lead to criminal

prosecution or other legal action. If there were ever any legal action, the signature would be needed to verify the individual was the person who submitted the form. If the FD-961 and fingerprints were submitted separately, this would require BRAG to match the fingerprints with the correct FD-961 which would require some sort of tracking number to ensure that the fingerprints were not matched up with the wrong FD-961 (especially for individuals with common names). Currently, BRAG does not have the required staffing levels to support this effort.

4. Efforts to Identify Duplication:

This information collection was authorized in direct response to enactment of the Bioterrorism Act. The CJIS Division is the only agency collecting extensive data for SRAs. The information being collected is used for the sole purpose of conducting SRAs.

5. Methods to Minimize Burden on Small Businesses:

This information will have minimal effect on small entities or businesses.

6. Consequences of Less Frequent Collection:

If the FD-961 is not submitted, the agencies and/or individuals will not be in compliance with the requirements of the Bioterrorism Act.

7. Special Circumstances Influencing Collection:

Currently, all Bioterrorism SRA information is collected on dates not less than every three years. The change from a five-year renewal to a three-year renewal was implemented on June 1, 2011.

On January 9, 2009, President George W. Bush signed Executive Order (EO) 13486 entitled “Strengthening Laboratory Biosecurity in the United States.” The EO established a Working Group (WG) co-chaired by the Secretary of Defense and the Secretary of Health and Human Services. The scope of the WG activities pertained to the policy of the United States that facilities that possess biological select agents and toxins have appropriate security and personnel assurance practices to protect against theft, misuse, or diversion to unlawful activity of such agents and toxins. The WG provided final recommendations through careful consideration of proposals from subgroups, and comments received from select agent entities and the public. The report is available at: <http://orise.orau.gov/emi/scapa/files/biosecurity-report.pdf>.

One of the recommendations to enhance security was to perform an SRA required by the Select Agent Regulations (7 CFR § 331.10, 9 CFR § 121.10, 42 CFR § 73.10) every three years for all individuals with access to select agents and toxins instead of the current policy of performing the SRA every five years. The Federal Select Agent Program concurs with this recommendation.

8. Public Comments and Consultations:

This information collection has been overseen by a multi-agency forms steering committee. The final rule regarding possessing use transfer of specific toxins and agents was completed in March 2005. The 30- and 60-day notices were published, and the FBI received no comments.

9. Payments of Gifts to Claimants:

The Bioterrorism SRA program does not provide any payments or gifts to respondents.

10. Assurance of Confidentiality:

All information will be held confidential in accordance with Title 34, United States Code (U.S.C.) Section 10231. Information will be utilized by BRAG for the sole purpose of conducting Bioterrorism SRAs in accordance with the Bioterrorism Act and the regulations promulgated thereunder.

11. Justification for Sensitive Questions:

The FD-961 Form does ask sensitive questions which are covered under the Bioterrorism Act.

The Social Security Number (SSN) is requested on the form to conduct a thorough search of the databases. The SSN eliminates candidates who match the individual by name and descriptors which could delay the approval or possibly deny them access to select agents and toxins.

12. Estimate of Hour Burden:

We estimate the respondent's burden for this data collection as follows:

Number of respondents—3,007 (Fiscal Year (FY)2023)

Frequency of respondents varies depending upon individual applicants but not less than every five years

Total annual responses—3,007 (FY2023)

Estimated minutes per response for completing the FD-961 and reading the instructions—45 minutes

Estimated time to for travel to an agency to be fingerprinted—approximately 10 minutes (five minutes each way)

Estimated time for being fingerprinted—15 minutes

Estimated time for travel to obtain a photo—10 minutes (five minutes each way)

Estimated time spent obtaining the photograph—10 minutes
Total estimated time burden for individuals per response—1 hour and 30 minutes

*Annual hour burden – (90*3007)/60=4,510.5 hours*

13. Estimate of Cost Burden:

Respondents will incur the cost of \$3.07 for postage fees to submit the FD-961 form and two completed fingerprint cards. It is estimated that the cost to the applicant to submit a photograph that meets criteria specified in the instruction pages based on national averages would be \$15 at the post office. It is estimated that each applicant would travel approximately three miles one way and six miles round trip to a business to obtain their photo. This distance is estimated to take an amount of five minutes each way for a total of 10 minutes round trip. Also, to determine the travel cost to the respondent, the Department is factoring in the General Services Administration (GSA) reimbursement rate of \$0.67 mile for privately owned automobiles (POA) use as of January 1, 2024. Therefore, it is estimated the individual travel cost per respondent is \$4.02.

3,007 (number of respondents) x 6 (miles) x \$0.67 (amount per mile) = \$12,088.14

3,007 (number of respondents x \$3.07 (postage) = \$9,231.49

3,007 (number of respondents x \$15.00 (picture at United States Postal Office) = \$45,105

The total annual cost incurred by the FY2023 respondents is \$66,424.63 or \$22.09 per person. The fingerprint cards are furnished by the FBI at no cost to the individual. This is broken down as \$9,231.49 for postage, \$45,105 for the photo and \$12,088.14 for travel and mileage.

14. Estimated Annualized Cost to Federal Government:

The estimated average cost per SRA using 2024 figures is approximately \$266.00. The annual cost to the FBI (based solely on FY2023 respondents) is \$266 x 3,007 = \$799,862.

15. Reason for Change in Burden:

Decrease in the hour burden is due to a decrease in the number of SRAs received by BRAG. The increase in cost burden is due to the rise in postage rate, mileage rates, and photo rates.

16. Plans for Publication:

This data collection does not publish any results.

17. Expiration Date Approval:

All information collected under this clearance will display the OMB Clearance Number. Any forms disseminated from the FBI's Bioterrorism Risk Assessment Program will include the OMB clearance number.

18. Exceptions to the Certification Statement:

The FBI's CJIS Division does not request an exception to the certification of this information collection.