U.S. Department of Justice
Office of the Inspector General
Evaluation and Inspections Division

Inspection of the FBI's Security Risk Assessment Program for Individuals Requesting Access to Biological Agents and Toxins

I-2005-003

March 2005

EXECUTIVE SUMMARY

The Department of Justice Office of the Inspector General conducted an inspection of the Federal Bureau of Investigation's (FBI) Security Risk Assessment (SRA) Program, which was established under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (Bioterrorism Act), Pub. Law No. 107-188. The SRA Program is part of an interagency effort to regulate the possession and use of dangerous biological agents and toxins, such as anthrax and the Ebola virus.

Under the Bioterrorism Act, a laboratory may not provide an individual with access to dangerous agents or toxins unless that individual has been approved by the Secretary of either the Departments of Health and Human Services (HHS) or Agriculture (USDA), based on an SRA. The SRA is conducted by the FBI, which searches electronic databases and other sources of information to determine whether the individual meets one or more of the criteria found in the USA Patriot Act (Pub. Law No. 107-56) and the Bioterrorism Act that would render the individual a "restricted person" ineligible for access to the biological agents and toxins controlled under the Bioterrorism Act.

We initiated the inspection in response to concerns about a backlog at the FBI of pending SRA applications submitted by researchers seeking access to controlled agents and toxins. To conduct this review, we examined SRA-related legislation and regulations, interviewed officials involved in the FBI's SRA program, analyzed FBI monthly productivity reports showing the number and status of SRA applications in their Bioterrorism Database, and reviewed the case files of appeals of SRA decisions.

RESULTS IN BRIEF

Our inspection showed that the FBI had 3,855 SRA applications pending in November 2003, but by June 2004, had reduced that number to 401. The FBI maintained a stable average monthly caseload of approximately 339 pending SRA applications through December 2004 and was routinely processing the applications in 45 days or less.

We also found that the FBI has instituted effective management controls that enabled it to identify and correct program vulnerabilities in a timely manner. The FBI set productivity goals for processing SRA applications and was closely monitoring its progress toward meeting those goals. It also established an appeals process for individuals who want to challenge "restricted persons" designations. In addition, to resolve interagency issues

affecting the SRA Program, the FBI participates in an interagency working group that includes HHS, USDA, and other federal agencies concerned with regulating the possession and use of biological agents and toxins. We conclude that the FBI is effectively managing its SRA responsibilities under the Bioterrorism Act.

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INTRODUCTION

This report presents the results of an Office of the Inspector General (OIG) inspection of the Security Risk Assessment (SRA) program that the Federal Bureau of Investigation (FBI) established under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (Bioterrorism Act), Pub. Law No. 107-188. The OIG initiated the inspection in response to concerns about a backlog at the FBI of pending SRA applications submitted by researchers seeking access to dangerous biological agents and toxins controlled under the Bioterrorism Act. The objectives of our inspection were to:

- Determine whether the FBI had a backlog of pending SRA applications and, if so, why; and

- Identify any program vulnerabilities that needed to be corrected.

We initiated our review on September 20, 2004, and analyzed productivity data through January 10, 2005.

BACKGROUND

Congress drafted the Bioterrorism Act shortly after anthrax was released through the U.S. mail in the fall of 2001, killing 5 people, making 17 others ill, and widely disrupting business and government activities at an estimated cost of more than $5 billion.[1] The President signed the Bioterroism Act in June 2002. Among other provisions, the Act controls access to select biological agents and toxins that can pose severe threats to the health of humans, animals, and plants – substances that include anthrax and the Ebola virus.[2]

In passing the Bioterrorism Act, Congress set three goals for the provisions pertaining to select agents and toxins:

1) Ensuring prompt reporting to the federal government of possession of select agents and toxins by individuals and research facilities;

2) Increasing security over select agents and toxins (including controlling access and screening personnel); and

[1] Regulatory Impact Analysis, 42 C.F.R. Part 73: Select Biological Agents and Toxins Interim Final Rule; CDC, HHS, December 9, 2002, pp. 2 and 8-9.

[2] See Appendix I for a complete list of select agents and toxins.

3) Establishing a comprehensive and detailed national database of the location and characterization of select agents and toxins and the identities of those in possession of them.

Title II of the Act provides that these select biological agents and toxins may be accessed only by people who have demonstrated a legitimate need to handle these substances and who have been cleared based on an SRA. The SRAs are intended to keep individuals who have engaged in criminal or terrorist activities from gaining access to dangerous materials. Civil and criminal penalties also can be imposed on individuals and laboratory facilities for allowing anyone to possess, use, or transfer a select agent or toxin if that person has not registered and had their access approved by the government.[3]

Violations of the Bioterrorism Act can result in substantial fines or imprisonment for up to five years, or both. In addition, violations can result in a civil money penalty of up to $250,000 for individuals and $500,000 for a laboratory. As discussed below, the Bioterrorism Act and the USA Patriot Act (Pub. Law No. 107-56) provide specific criteria for determining who may possess and use select agents and toxins.

The SRA program is part of an interagency effort by the Departments of Health and Human Services (HHS), Agriculture (USDA), and Justice (Department) to regulate the possession and use of biological agents and toxins in the United States. Title II of the Bioterrorism Act provides for SRAs and states that a laboratory may not provide an individual with access to a select agent or toxin unless the individual has been approved by the Secretary of either HHS or USDA, based on an SRA conducted by the Attorney General, who has delegated that responsibility to the FBI.

Most of the responsibility for carrying out the Bioterrorism Act's provisions rests with the HHS's Centers for Disease Control and Prevention (CDC), the USDA's Animal and Plant Health Inspection Service (APHIS), and the FBI's Criminal Justice Information Services (CJIS) Division. CDC and APHIS are responsible for regulating the possession of biological agents and toxins that pose a severe threat to public health and safety and for enforcing safety standards and procedures for the possession, use, and transfer of these agents. They also have authority to grant or deny access to select agents and toxins based on the results of an SRA conducted by the FBI's CJIS Division.

[3] Select Biological Agents and Toxins, 42 C.F.R. Part 73, effective February 7, 2003; Possession, Use, and Transfer of Biological Toxins, 7 C.F.R. Part 331; and Agricultural Bioterrorism Protection Act of 2002; Possession, Use, and Transfer of Biological Agents, and Toxins, 9 C.F.R. Part 121. "Access" is defined as the ability of an individual to gain entry into a space where a select agent or toxin is used or stored.

In December 2002, CDC and APHIS issued interim regulations that established requirements for possessing and using select agents and toxins, including requirements for obtaining an SRA. In general, the regulations apply "to academic institutions and biomedical centers; commercial manufacturing facilities (the pharmaceutical industry); federal, state, and local laboratories, including clinical and diagnostic laboratories; and research facilities."[4] These laboratories use select agents and toxins in research critical for biodefense, public health, and the battle against infectious diseases. Laboratories affected by the regulations are required to identify a responsible official to ensure compliance with the Bioterrorism Act. For each laboratory, SRAs must be obtained by the laboratory owner, responsible official, alternate responsible official, and researchers who need access to select agents and toxins.[5]

Laboratories must ensure that they meet all work safety requirements for select agents and toxins, keep records of select agents and toxins transferred to and from their facilities, and ensure that only authorized personnel have access to select agents and toxins. According to federal regulations, CDC and APHIS certify laboratories before allowing them to use, possess, or transfer select agents and toxins. Certification is valid for three years.

On March 25, 2003, the FBI Director assigned responsibility for conducting SRAs to the CJIS Division. The CJIS Division receives applications submitted by individuals requesting access to specific agents or toxins, and uses electronic databases and other sources of information to conduct SRAs of those individuals. The CJIS Division carries out its responsibilities for conducting SRAs through its Bioterrorism Risk Assessment Group (BRAG), which was established in April 2003 at the CJIS Division facility in Clarksburg, West Virginia.

BRAG employees conduct SRAs on all persons applying for access to select agents and toxins. In conducting SRAs, BRAG employees search electronic databases and conduct fingerprint checks to determine whether an individual is eligible for access based on specific criteria described below. BRAG is responsible for reporting the results of its SRAs to CDC and APHIS. BRAG also maintains a database that includes the names and locations of persons granted access to select agents and toxins. BRAG employees refer to this database as the Bioterrorism Database.

[4] In this report, the term "laboratory" is used when referring collectively to all entities subject to select agent and toxin regulations.

[5] Diagnostic laboratories or laboratories licensed under the Clinical Laboratory Improvement Act that conduct diagnostic testing, verification, or proficiency testing are exempt from the regulation.

To begin the SRA process, BRAG employees review application packages, which must include FBI Form FD-961 and two sets of legible fingerprint cards.[6] An FBI Form FD-961 includes basic identifying information such as name, date and place of birth, Social Security number, address, and place of employment. It also includes applicants' answers to questions concerning criminal indictments and convictions, fugitive status, controlled substance abuse, alien status, mental health history, and whether they have been dishonorably discharged from the U.S. Armed Services.

BRAG employees enter the applicants' information into the Bioterrorism Database and check a series of other national databases that contain criminal, mental health, immigration, military, intelligence, counterterrorism, and fingerprint records. BRAG's objectives are to determine whether applicants meet one or more criteria that would render them ineligible for access to select agents and toxins.

BRAG has limited discretion in determining eligibility because the criteria for possessing, using, or transferring select agents, which are outlined in the USA Patriot Act and the Bioterrorism Act, are specific. Along with the eight criteria found in the USA Patriot Act (listed in the box on this page), under the Bioterrorism Act BRAG must designate applicants as "restricted persons" if they are reasonably suspected by a federal law enforcement or intelligence agency of:

1) Committing a crime set forth in section 2332(g)(5) of title 18 of the U.S. Code;[7]

USA Patriot Act Criteria for "Restricted Persons"

BRAG must restrict access if an individual is or has been:

- Under indictment for a crime punishable for a term exceeding one year;
- Convicted of a crime punishable by imprisonment for a term exceeding one year;
- A fugitive from justice;
- An unlawful user of any controlled substance;
- An alien illegally or unlawfully in the United States;
- Adjudicated as a mental defective or has been committed to any mental institution;
- An alien (other than an alien lawfully admitted for permanent residence) who is a national of a country. . . that has repeatedly provided support for acts of international terrorism; or
- Discharged from the Armed Services of the United States under dishonorable conditions.

[6] Originally, the instructions for filing Form FD-961 directed applicants to mail their application packages to CDC or APHIS officials, who then forwarded them to the CJIS Division. Since August 25, 2004, the instructions tell applicants to send their applications directly to the CJIS Division.

[7] Title 18 U.S.C. § 2332(g)(5) deals with the "federal crime of terrorism."

2) Knowing involvement with an organization that engages in domestic or international terrorism (as defined in 18 U.S.C. 2331) or with any other organization that engages in intentional crimes of violence;[8] or

3) Being an agent of a foreign power (as defined in 50 U.S.C. 1801).[9]

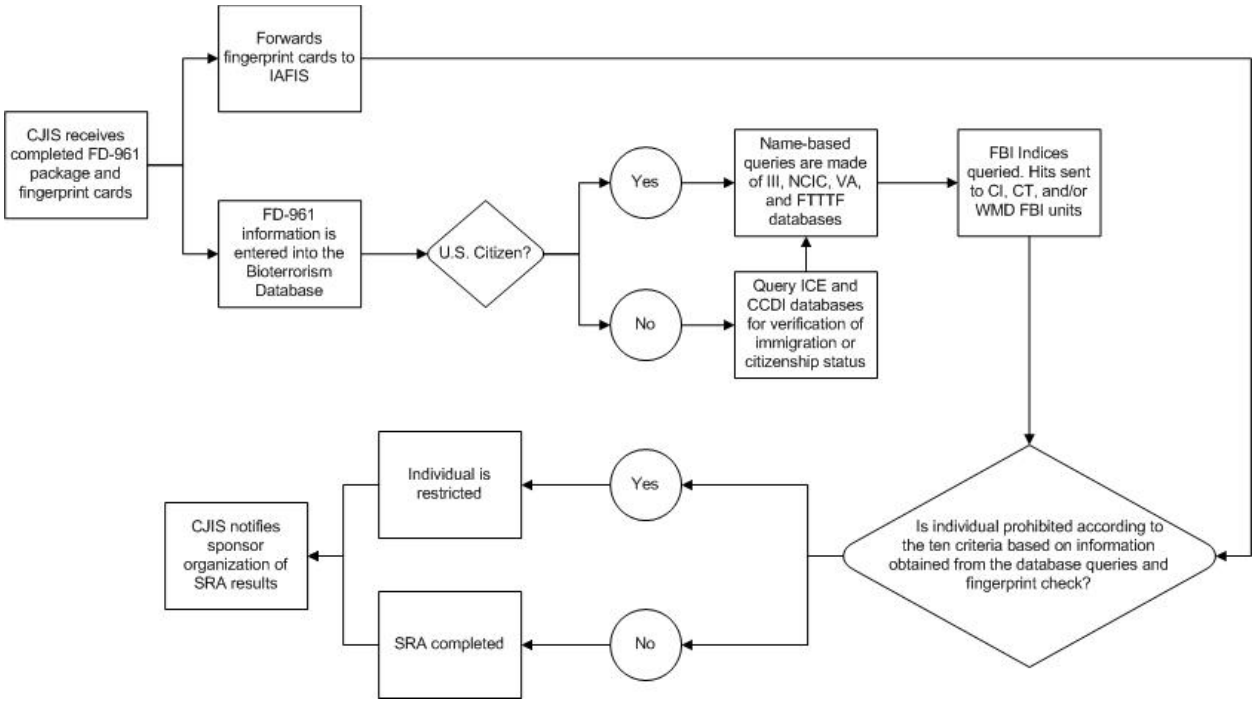
Although there are 11 specific criteria defined by law, BRAG combined the 2 criteria that deal with involvement with organizations engaging in or supporting domestic or international crimes of violence or terrorism in their procedural guidance. Consequently, BRAG's concept of operations refers to only ten criteria.

Once BRAG determines an individual's eligibility for access, it forwards a recommendation on access to CDC or APHIS, which makes the final decision on whether the individual will be allowed access to select agents and toxins. CDC or APHIS reports their access decision to the individual applicant. Unless CDC or APHIS terminates approval sooner, an SRA is valid for five years. However, BRAG re-runs fingerprint checks every three years. Chart 1 provides a diagram of BRAG's SRA process.

[8] Title 18 U.S.C. § 2331 defines several terms dealing with international terrorism.

[9] Title 50 U.S.C. § 1801 defines a number of terms such as "foreign power," "agent of foreign power," "International terrorism," and "sabotage."

Chart 1:
BRAG's SRA Process



Source: BRAG approved OIG modification of BRAG flow chart.

Legend

CCDI	Consular Consolidated Database Indices
CI	Counterintelligence
CJIS	Criminal Justice Information Services Division
CT	Counterterrorism
FTTTF	Foreign Terrorist Tracking Task Force
IAFIS	Integrated Automated Fingerprint Identification System
ICE	Immigration and Customs Enforcement
III	Interstate Identification Index
NCIC	National Crime Information Center
SRA	Security Risk Assessment
VA	Department of Veterans Affairs
WMD	Weapons of Mass Destruction

SCOPE AND METHODOLOGY

We initiated this inspection on September 20, 2004, in response to concerns expressed by the HHS OIG about a large number of pending SRAs in BRAG's Bioterrorism Database. We concluded our data collection and analysis on January 10, 2005. During our review, we analyzed SRA-related legislation and regulations to determine program responsibilities and requirements, and we interviewed BRAG's program managers and personnel security specialists to assess the SRA process and to identify any processing issues that might result in a large number of pending SRA applications. We also compared background checks done for SRA purposes with other types of background checks conducted by federal agencies. In addition, we talked with OIG officials at HHS and USDA and officials of the CDC and APHIS about BRAG's SRA program.

We also assessed the consistency of data in the Bioterrorism Database by comparing monthly productivity reports from April 2003 to January 2005, and we analyzed BRAG's work to reconcile discrepancies BRAG found in the CDC and APHIS applicant databases. By March 2004 BRAG had determined that the CDC and APHIS databases contained over 1,300 duplicate records when compared to the Bioterrorism database. CDC and APHIS created a new database record each time individuals who had already applied for access submitted additional SRA applications because of job or name changes. BRAG identified the duplications and significantly reconciled the CDC and APHIS databases with its Bioterrorism Database. We also reviewed all case files of appeals of SRA decisions.

Determining whether restricted persons appropriately were being denied access to select agents and toxins is the responsibility of HHS and USDA, and therefore we did not conduct that type of review. Rather, we reviewed BRAG's role in conducting SRAs, which are intended to detect individuals who should not have access to select agents and toxins.

INSPECTION RESULTS

BRAG ELIMINATED EARLY BACKLOG OF SRAS

BRAG had a large number of pending SRA applications in late 2003, but reduced the number significantly during the first six months of 2004.[10] In November 2003, BRAG had 3,855 pending SRA applications, which included a backlog of 628 SRA applications that had been pending for more than 45 days.[11] BRAG's large caseload of pending SRA applications was caused by processing issues that were resolved between November 2003 and June 2004. By June 2004, BRAG had reduced its number of pending SRA applications from 3,855 to 401 and eliminated its SRA application backlog. Since June 2004, BRAG has maintained a stable monthly caseload of approximately 339 pending SRA applications, which it is processing routinely in 45 days or less.[12]

BRAG Encountered Processing Problems During Phase-In Period

The interim federal regulations CDC and APHIS issued in December 2002 to implement the Bioterrorism Act established a six-month phase-in period to allow laboratories and individuals time to achieve full compliance with the new regulations for possessing, using, and transferring select agents and toxins, including obtaining SRAs. The phase-in period was designed to minimize the disruption that the regulations might cause for research and educational projects involving select agents and toxins that were under way.

The phase-in period for processing SRA applications ran from April 11, 2003, to November 12, 2003. All SRA applications were due to BRAG on April 11, 2003, and BRAG started processing SRA applications on April 14, 2003. The regulations gave laboratories and individuals until November 12,

[10] According to BRAG, its pending workload includes all SRA applications that have been entered into the Bioterrorism Database, but have not been finalized through a determination of eligibility.

[11] According to BRAG, a *backlog* occurs when it takes BRAG more than 45 days to determine an applicant's eligibility for access once BRAG has received a complete SRA application, which includes all requested data on the FBI FD-961 and two legible fingerprint cards.

[12] Forty-five days is the average processing time for BRAG to complete an SRA application. BRAG determined the average processing time by calculating the mean number of days BRAG took to complete pending SRAs during a three-month period.

2003, to achieve full compliance with the law, including obtaining SRAs for all of their employees who needed access. After November 12, 2003, individuals not in full compliance with the SRA requirements would not be eligible for access to special agents and toxins until they met the requirements.

BRAG officials said that during the six-month phase-in period, they:

- Received only 11 percent of all SRA applications by the April 11, 2003, SRA submission deadline;
- Received a total of 3,948 SRA applications from CDC and APHIS with missing or unusable data;
- Experienced a staffing change from 18 to 9 personnel that reduced BRAG's capacity for conducting SRAs from 1,200 to 500 each month just prior to the regulatory deadline for completing all SRAs; and
- Experienced problems obtaining some of the information needed to determine the eligibility of individuals with criminal histories and mental health issues.

Because of these problems BRAG accrued a large number of SRA cases for which it could not make final determinations of eligibility. As discussed below, these problems were addressed either by BRAG or through the joint actions of BRAG, CDC, APHIS, and the officials and individuals applying for access to select agents and toxins.

BRAG Received Only 11 Percent of All Applications by the April 11, 2003, Deadline. Although the regulations required that all applications were due to BRAG by April 11, 2003, BRAG received 89 percent of the applications after that date. As shown in Table 1, on April 11 BRAG had received only 1,108 (11 percent) of the 9,720 applications that it would eventually receive by the November 12, 2003, regulatory deadline for completing all SRAs.

Table 1: Number of SRA Applications Received by Month During the 2003 Phase-In Period	
April 11	1,108
May 31	1,601
June 30	2,285
July 31	1,790
August 31	703
September 30	645
October 31	727
November 12	861
Total	**9,720**

Source: Bioterrorism Workload Statistics - Internal, BRAG.

BRAG Received Several Thousand Incomplete SRA Applications. During the six-month phase-in period, BRAG received a large number of SRA applications for which it could not make a final eligibility determination because of missing data or illegible fingerprint cards. A complete SRA application package includes: 1) a completed FBI Form FD-961 that contains basic information, such as name and address; and 2) two legible fingerprint cards. As stated previously, BRAG received 9,720 SRA applications during the phase-in period, between April 11 and November 12, 2003. A total of 3,948 (41 percent) of those applications were missing data such as an FBI Form FD-961 or the required two fingerprint cards. Sometimes an application included an FBI Form FD-961 that was missing information or the prints on the fingerprint cards were not legible. In these cases, BRAG officials said that they could not complete the SRAs until they received the missing data, which sometimes took months.

The volume of incomplete applications received during the phase-in period also made it appear that BRAG had a large backlog of SRA cases and that it was not processing SRA applications in a timely manner. In fact, BRAG employees could not begin to conduct an SRA until the applicant submitted complete information. BRAG officials said that they sent thousands of letters to laboratory officials requesting the missing information prior to the November 12, 2003, deadline, but did not receive all of the data in time to complete the SRAs by the deadline.

BRAG Processing Capacity Was Significantly Reduced by a Change in Staffing. In April 2003, the FBI temporarily assigned employees to start SRAs while it began selecting a permanent staff for BRAG. However, BRAG's ability to meet the regulatory deadline of November 12, 2003, was significantly hampered by a staffing change that occurred at the end of October 2003.

Before October 31, 2003, the FBI had staffed BRAG with 18 temporary personnel security specialists from the CJIS Division's National Instant Criminal Background Check System. On October 31, 2003, the FBI replaced BRAG's temporary staff with a permanent staff of nine employees that included one unit manager, one supervisor, and seven personnel security specialists. As a result of the staffing change, BRAG's capability for conducting SRAs dropped from approximately 1,200 to 500 per month just prior to BRAG's November 12, 2003, deadline for completing all SRAs. The drop in capacity resulted from the reduction in the number of staff as well as the transition from an experienced to an inexperienced staff that required training.

BRAG's Need to Obtain Pertinent Information from External Sources Increased Processing Times. BRAG officials said that they had trouble obtaining some of the information they needed to determine the access eligibility of individuals with criminal histories and mental health issues. According to BRAG, it can take from two weeks to six months to obtain all the information it needs to make a determination of eligibility for access on one SRA application. BRAG's processing times can be significantly affected by: 1) the availability of automated state and local criminal history records, 2) difficulty obtaining mental health histories, and 3) BRAG's reliance on other agencies to conduct certain database searches.

For example, BRAG often needs to acquire copies of court records of dispositions in criminal cases to make its eligibility determinations. BRAG also must verify references to state and local court records, many of which are not automated and, therefore, only accessible through manual research.[13] Consequently, BRAG has to obtain copies of court documents and this process can extend the time it takes to conduct an SRA by several months.

In addition, processing times can increase when BRAG has to obtain mental health histories. SRA applicants indicate on Form FD-961 whether they have ever been adjudicated as a mental defective or committed to a mental

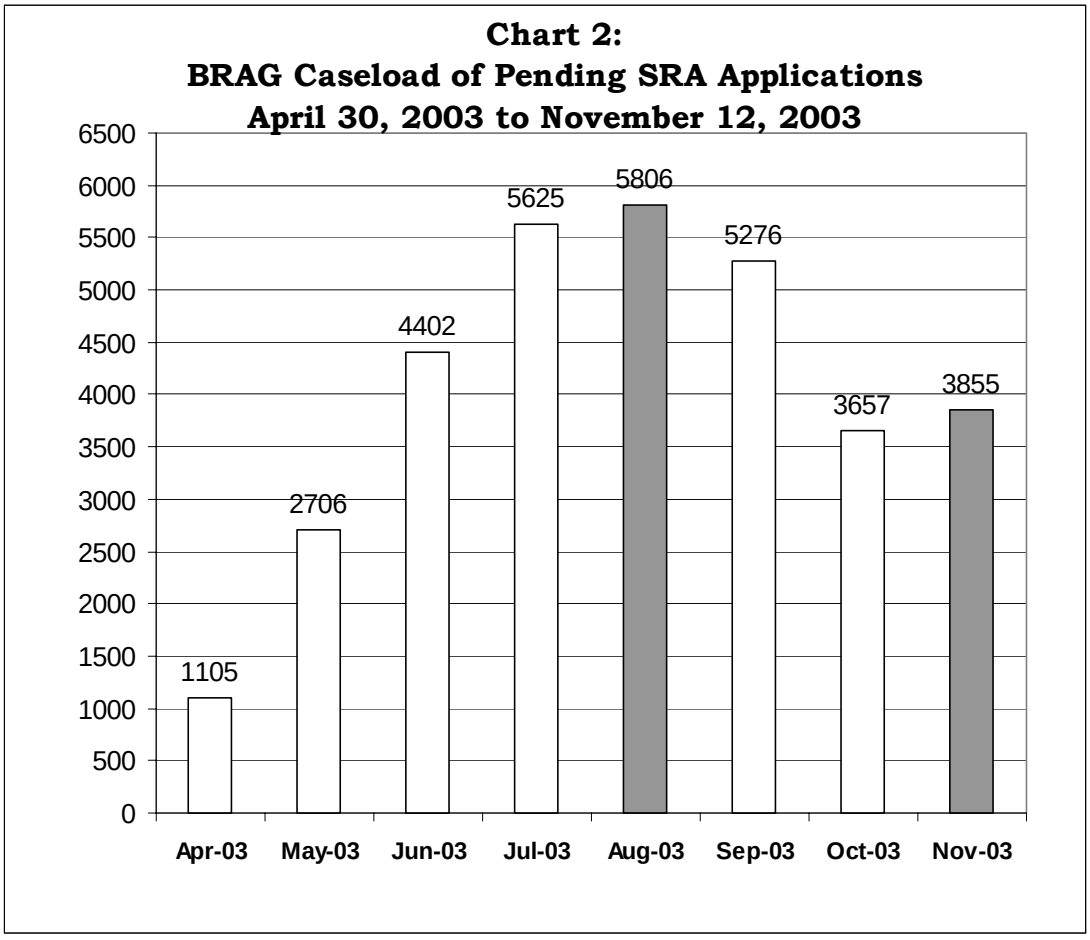
[13] As reported previously by the OIG, the lack of automated court records has an impact on other Department programs as well. The OIG report, *Review of the Bureau of Alcohol, Tobacco, Firearms and Explosives' Enforcement of Brady Act Violations Identified Through the National Instant Criminal Background Check System,* Report Number I-2004-006, July 2004, describes the same requirement to obtain court records, but at the expense of utilizing Alcohol, Tobacco, Firearms and Explosives' agent resources for this task.

institution. If an applicant answers "yes," BRAG employees must conduct research to determine whether the individual was voluntarily or involuntarily committed to a mental institution. According to BRAG officials, this research is time consuming, and some institutions are reluctant to share this information.

BRAG also depends on other agencies to complete portions of the SRA database searches. To obtain visa information on alien resident and work status, BRAG downloads applicant information from its Bioterrorism Database and supplies it to the Department of Homeland Security's Immigration and Customs Enforcement agency. BRAG also provides applicant information to the FBI's Foreign Terrorist Tracking Task Force to determine whether the applicant is a known terrorist. At times, these agencies are not able to search their databases based on the information BRAG provides. When that happens, BRAG must contact the applicant directly to request additional information, such as birth certificates or alien registration numbers. BRAG employees said complexities such as these can add weeks or months to the SRA application processing time.

BRAG Reduced Large Caseload of Pending SRA Applications

Chart 2 shows that BRAG accrued a large caseload of SRA applications during the phase-in period, with pending applications peaking in August 2003 at 5,809. BRAG had reduced its caseload to 3,855 by November 12, 2003.



Source: Bioterrorism Workload Statistics - Internal, BRAG.

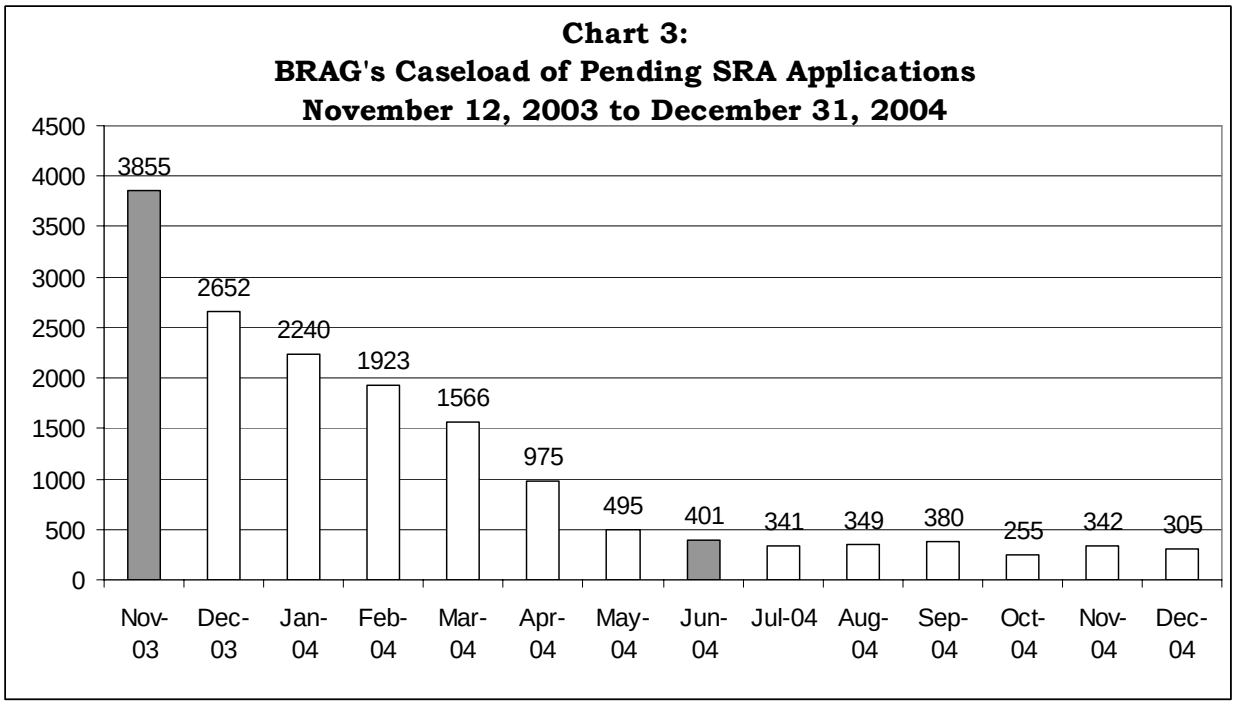
BRAG employees said that they kept CDC and APHIS officials fully informed of their processing issues and the need for CDC and APHIS to encourage laboratory owners and responsible officials to submit the data missing from SRA applications before the deadline. BRAG officials said they also informed CDC and APHIS that – because of BRAG's heavy caseload and processing times that averaged 45 days – even if all missing SRA application data were submitted immediately, the outstanding applications could not be processed by the November 12, 2003, deadline. On November 3, 2003, CDC and APHIS amended federal regulations, in part, to provide more time for BRAG to complete the pending SRA applications that it accrued during the phase-in period.

CDC and APHIS Amended Interim Final Rules to Allow Grants of Provisional Access. On November 3, 2003, CDC and APHIS officials amended the interim final rules on select agents and toxins. The amendments allowed CDC and APHIS to provide provisional grants of access to individuals who had submitted complete application packages to BRAG and met all other federal

requirements by November 12, 2003, but who had not yet obtained an SRA. The amendments did not extend the deadline for complying with SRA requirements, but they did allow for the continued operation of laboratory facilities vital to the public interest. At the same time, the amendments emphasized the need for applicants to provide missing application data. The amendments also gave BRAG more time to finalize individual SRAs for individuals who had submitted all of the required information by the deadline.

As of the November 12, 2003, deadline, BRAG had received 9,720 individual applications. Of those, 61 percent (5,865) had been finalized by the issuance of an eligibility determination (5,265) or by the cancellation of an SRA request by an applicant or responsible official (600). This left 3,855 pending applications. Of that number, BRAG had received 2,947 applications that included all necessary data and 908 applications that were missing data or legible fingerprint cards. Because the 908 individuals with incomplete applications had missed the deadline for submitting all required information, they were not eligible for access and, by regulation, could not work with select agents and toxins.

On November 13, 2003, BRAG reported that it expected to be able to complete 500 SRAs each month and therefore would process the remaining 3,855 pending applications in seven months, or by June 2004. Chart 3 shows the progress that BRAG made in reducing the number of pending applications. BRAG reduced the number of pending SRA applications to 401 as of June 2004 and has since maintained a relatively stable average monthly caseload of 339 pending SRA applications.



Source: Bioterrorism Workload Statistics - Internal, BRAG.

BRAG Significantly Reduced Its Pending Caseload. Table 2 shows that BRAG had received a total of 13,287 SRA applications and conducted 12,982 SRAs as of December 2004. From November 12, 2003, to December 31, 2004, BRAG reduced its pending SRA application caseload from 3,855 to 305 SRA applications and its incomplete SRA applications from 908 to 40.

Table 2:
BRAG Productivity Achievements
Before and After the Regulatory Deadline

Bioterrorism Database	**November 12, 2003** Regulatory Deadline	**December 31, 2003**	**September 19, 2004** OIG Inspection	**December 31, 2004** Current Status
Completed [a]	**5,865**	**7,392**	**12,045**	**12,982**
Pending [b]	**3,855**	**2,652**	**357**	**305**
With complete information [b]	2,947	2,190	316	265
With incomplete information [b]	908	462	41	40
Total SRA Applications	**9,720**	**10,044**	**12,402**	**13,287**

Source: Bioterrorism Workload Statistics - Internal, BRAG.
[a] Includes all records entered that show a decision in the database (cancelled, restricted, or unrestricted).
[b] Includes all records with no decision in the database (those with complete and incomplete applications).

MANAGEMENT CONTROLS AND MINIMUM STANDARDS FOR ACCESS ELIGIBILITY

Our review found that BRAG has effective management controls that have resulted in the timely identification and correction of several program vulnerabilities. BRAG monitors its processing capabilities and productivity using its Bioterrorism Database. In addition, BRAG has established an appeals process that, so far, has resulted in BRAG overturning 6 of its 20 "restricted persons" designations. The CJIS Division participates in an interagency working group, which includes HHS, USDA, the Department of Defense (DOD), Customs and Border Protection, and other organizations, to resolve interagency issues affecting the SRA Program. Since the Bioterrorism Act was implemented, the SRA process has provided a reasonably quick minimum standard (usually 45 days or less) for security checks on all persons seeking access to select agents.

BRAG Has Effective Management Controls

Since its creation in April 2003, BRAG has:

1) Established procedures for conducting background investigations and completing SRAs,
2) Set up a Bioterrorism Database for tracking SRAs, and
3) Hired a permanent staff to fulfill BRAG's SRA responsibilities.

As discussed below, BRAG's accomplishments are, in part, a product of strong management controls that have led to the early identification and timely correction of program vulnerabilities.

BRAG Closely Monitors the SRA Process and Caseload. BRAG monitors its processing capabilities in an effort to maintain a high level of employee productivity. Among other control measures, BRAG has instituted several productivity measures and goals, and routinely monitors its progress toward meeting those goals. For example, BRAG established a 45-day goal for finalizing SRA applications, and supervisors closely monitor the time that individual requests remain in the database before a final eligibility determination is made.

While BRAG still occasionally receives SRA applications that are missing required information or contain illegible fingerprint cards, those applications are now clearly identified in the Bioterrorism Database. Consequently, those

applications no longer appear as part of the backlog of cases pending more than 45 days as they did during the phase-in period.

BRAG has also improved the SRA process by revising the instructions on the FBI's Form FD-961. Since August 25, 2004, the instructions on Form FD-961 instruct applicants to send their applications directly to the CJIS Division instead of to CDC or APHIS as previously instructed. BRAG reported that this revision has helped to reduce processing times.

Of the total 12,982 SRAs it completed by December 2004, BRAG:

- Granted eligibility for unrestricted access to 11,830 applicants,
- Canceled 1,080 individual requests that were withdrawn, and
- Designated 72 applicants as "restricted persons."

As shown in Table 3, most ineligible applicants had been designated "restricted persons" because of felony convictions (54) or an illegal or unlawful alien status (7). Some of the 72 designations were based on more than one criterion. Twenty of the 72 appealed BRAG's eligibility restrictions.

Table 3:
Restrictions Applied by Criteria

Restriction Category	Restrictions Applied [a]
Felony conviction	53
Fugitive from justice	4
Illegal/unlawful alien	7
Adjudicated mental defective	3
Controlled substance abuser	3
Under indictment	2
Agent of foreign power	1
Dishonorable discharge	1
Terrorist related	0

Source: Bioterrorism Workload Statistics Division, BRAG, January 11, 2005.

[a] The table shows total restrictions by criteria (74); some of the 72 individuals found to be ineligible for access were restricted based on more than one criterion.

BRAG Established an Appeals Process. BRAG established an appeals process that, as of January 2005, had addressed 20 appeals of individual "restricted person" designations. BRAG sustained 14 of the 20 appeals and overturned 6 to grant the appellant eligibility for "unrestricted" access. BRAG

does not limit the number of times that an individual can appeal a restriction. In at least one case, BRAG overturned a restriction that it had previously sustained on appeal.

SRA applicants with past felony convictions can successfully appeal a "restricted" designation by getting the appropriate state or local government to expunge their criminal record from local, state, and national databases and other data repositories. Generally, the burden of proof in an appeal rests with the appellant.

If CDC or APHIS officials disagree with a BRAG employee's eligibility determination, they also can initiate an appeal. This provision of the appeals process, which has never been used, would work for an agency as it does for an individual applicant – the burden of proof would rest with the agency appealing BRAG's determination.

The CJIS Division Resolves Interagency Issues Through the Select Biological Agents and Toxins Working Group. The CJIS Division routinely participates in a working group that includes representatives from CDC, APHIS, DOD, Customs and Border Protection, and other organizations to resolve interagency issues. This group, called the Select Biological Agents and Toxins Working Group (Working Group), was established by the Bioterrorism Act to consider policy issues and render policy decisions related to security, regulations, and preparing for and preventing bioterrorism and other public health emergencies.

For example, the Working Group considered a request made by the Deputy Under Secretary of Defense for Counterintelligence and Security to the CJIS Division seeking to exempt DOD military and civilian personnel and contractors from SRA requirements. In October 2003, the Deputy Under Secretary wrote to the CJIS Division of her concern that 400 DOD employees would not be able to obtain an SRA by the regulatory deadline. She stated that the SRA process was similar enough to background investigations DOD conducted before granting access to classified information that the SRAs were redundant for individuals already possessing security clearances. Therefore, she wrote, "we take the position that those 400 individuals should be exempt from the risk assessment requirement by virtue of their having been granted security clearances based on favorably adjudicated background investigations."

The CJIS Division, as part of the Working Group, denied DOD's request for exemptions, citing a legal determination that the Bioterrorism Act does not allow such exemptions even for individuals with security clearances.

SRA Program Provides a Clear Standard for Access

Because of the issues DOD raised at the Working Group and other concerns expressed during our inspection regarding the possible redundancy of SRA background investigations for individuals with security clearances, we compared the scope of the SRA background investigation with that of other types of background investigations. We found that the SRA background investigation includes searches of databases that are not searched routinely during other types of background investigations, including those conducted for national security clearances. We also found that the SRA process provides a clear standard for conducting background investigations to determine eligibility for access to select agents and toxins.

The Bioterrorism Act allows for several exemptions from the SRA requirements. For example, if a laboratory is owned by a local, state, or federal agency, the head of the agency that "owns" the facility is exempt from the requirement of obtaining an SRA (42 C.F.R. 73.8(a)). Also, an owner of an accredited academic institution is not required to obtain an SRA. However, all responsible officials, alternate responsible officials, and individuals with access to select agents and toxins are required to obtain an SRA, regardless of whether they work for a government agency or an accredited academic institution. In addition, the Bioterrorism Act does not exempt federal employees who have a national security clearance from obtaining an SRA.

While the types of background investigations conducted to determine eligibility for access to Top Secret national security information and for a public trust position in the federal government include reviews of some of the same information sources as an SRA, there are differences. All three types of investigations include, for instance, a national agency check, which consists of a review of the:

- Investigative and criminal history files of the FBI, including the National Crime Information Center and fingerprint search;
- Office of Personnel Management's Security/Suitability Investigations Index; and
- DOD's Defense Clearance and Investigations Index.

The Minimum Background Investigation (MBI) required for a public trust position includes a national agency check, plus written inquiries and credit record searches, a face-to-face personal interview between the investigator and the subject, and telephone inquiries to selected employers. The Single Scope Background Investigation (SSBI) required for access to Top Secret information is a governmentwide investigation that covers the past seven years of an

individual's activities. It includes verification of citizenship and date and place of birth, as well as national records checks on the individual's spouse or cohabitant, and interviews with selected references and former spouses.

In contrast, BRAG employees conducting an SRA search databases that contain information to determine whether the applicant meets any 1 of the 11 criteria that would result in a restriction from access to select agents and toxins. Not all of these databases are searched routinely as part of an MBI or SSBI. For example, BRAG routinely searches the Foreign Terrorist Tracking Task Force database for information to determine whether an applicant is a known terrorist or has associated with known terrorists. This database is not searched as part of an MBI or SSBI. BRAG also searches the Immigration and Customs Enforcement database for information on whether an applicant has been determined to be an illegal or unlawful alien.

Table 4 on the next page lists other databases routinely searched for SRA investigations – but not for MBI or SSBI investigations – such as the FBI Indices via the Automated Case Support system, which contains FBI Headquarters' classified databases; the Department of Veterans Affairs' database for mental health information; and the Department of State's Terrorist Watch List and Consular Consolidated Database Indices. According to BRAG officials, BRAG is continuing to refine the SRA process and expand its electronic searches as new databases emerge, especially those that containing counterterrorism information.

Before passage of the Bioterrorism Act, less than half the nation's laboratories conducted background checks on employees with access to select agents and toxins, and the practice of conducting background checks varied greatly among the different types of laboratories. For instance, while approximately 80 percent of the laboratories owned by research institutes and commercial facilities conducted background checks on their employees with access to select agents and toxins, less than 20 percent of state and university laboratories conducted such checks.

When background investigations were conducted by laboratories, they usually included a basic criminal background check, but not all of the other elements of an SRA background investigation. Since the Bioterrorism Act was implemented, the SRA process has provided a reasonably quick minimum standard (usually 45 days or less) for security checks on all persons seeking access to select agents. The SRA process also contributes to the creation of a database that contains the names of all persons who are using or have used select agents, which agents they have used, and where they are working.

Table 4:
Comparative Analysis of Two Levels of Background Investigations and the SRA Process

	Types of Background Investigations		
Information Sources	**SRA**	**SSBI for a special-sensitive position [a]**	**MBI for a moderate-risk public trust position [b]**
National Crime Information Center	X	X	X
Interstate Identification Index	X	X	X
FBI Indices	X		
Fingerprint Identification	X	X	X
Foreign Terrorist Tracking Task Force	X		
Immigration and Customs Enforcement – check for citizenship only		X	
Immigration and Customs Enforcement – check for citizenship, naturalization status, immigration status, and Student and Exchange Visitor Information System status	X		
Defense Clearance Investigation Index		X	
Department of Defense Dishonorable Discharge Records		X	X
Department of Veterans Affairs mental defective records	X		
Office of Personnel Management's Security/Suitability Investigations Index (previous background investigation history)		X	
State Department Terrorist Watch List and the Consular Consolidated Database Indices for visa information	X		
Court records verification (if necessary) [c]	X	X	
Local law enforcement checks based on previous residences		X	X
Credit report		X	X
Education verification		X	X
Subject interview		X	X
Employment verification		X	X
Residence verification		X	X
Spouse interview		X	
Personal and professional references		X	X

[a] Information sources such as credit reports are reviewed for a 3- to 10-year period.
[b] Information sources such as credit reports are reviewed for a 5- to 7-year period.
[c] Court records are obtained, if an adjudication decision resulted in "restricted."

CONCLUSION

We found that BRAG had reduced its caseload of pending SRA applications from a high of 3,855 in November 2003 to 401 as of June 2004. Since June 2004, BRAG has maintained a stable monthly caseload of approximately 339 pending SRA applications, which it is processing routinely in 45 days or less. BRAG has also instituted management controls that enable it to identify and correct program vulnerabilities in a timely manner. As a result, we believe that BRAG is effectively managing its SRA responsibilities under the Bioterrorism Act.

APPENDIX I:
LIST OF SELECT AGENTS AND TOXINS

I. HHS non-overlap select agents and toxins

- Crimean-Congo haemorrhagic fever virus
- Coccidioides posadasii
- Ebola viruses
- Cercopithecine herpesvirus 1 (Herpes B virus)
- Lassa fever virus
- Marburg virus
- Monkeypox virus
- Rickettsia prowazekii
- Rickettsia rickettsii
  South American haemorrhagic fever viruses
  - Junin
  - Machupo
  - Sabia
  - Flexal
  - Guanarito

  Tick-borne encephalitis complex (flavi) viruses
  - Central European tick-borne encephalitis
  - Far Eastern tick-borne encephalitis
  - Russian spring and summer encephalitis
  - Kyasanur forest disease
  - Omsk hemorrhagic fever
- Variola major virus (Smallpox virus)
- Variola minor virus (Alastrim)
- Yersinia pestis
- Abrin
- Conotoxins
- Diacetoxyscirpenol
- Ricin
- Saxitoxin
- Shiga-like ribosome inactivating proteins
- Tetrodotoxin

II. USDA high consequence livestock pathogens and toxins (non-overlap agents and toxins)

- Akabane virus
- African swine fever virus
- African horse sickness virus
- Avian influenza virus (highly pathogenic)
- Blue tongue virus (Exotic)
- Bovine spongiform encephalopathy agent
- Camel pox virus
- Classical swine fever virus
- Cowdria ruminantium (Heartwater)
- Foot and mouth disease virus
- Goat pox virus
- Lumpy skin disease virus
- Japanese encephalitis virus
- Malignant catarrhal fever virus (Exotic)
- Menangle virus
- Mycoplasma capricoluml
- M.F38/M. mycoides capri
- Mycoplasma mycoides mycoides
- Newcastle disease virus (VVND)
- Peste Des Petits Ruminants virus
- Rinderpest virus
- Sheep pox virus
- Swine vesicular disease virus
- Vesicular stomatitis virus (Exotic)

III. High consequence livestock pathogens and toxins/select agents (overlap agents)

- Bacillus anthracis
- Brucella abortus
- Brucella melitensis
- Brucella suis
- Burkholderia mallei (formerly Pseudomonas mallei)
- Burkholderia pseudomallei (formerly Pseudomonas pseudomallel)
- Botulinum neurotoxin producing species of Clostridium
- Coccidioides immitis
- Coxiella burnetii
- Eastern equine encephalitis virus
- Hendra virus
- Francisella tularensis
- Nipah Virus
- Rift Valley fever virus
- Venezuelan equine encephalitis virus
- Botulinum neurotoxin
- Clostridium perfringens epsilon toxin
- Shigatoxin
- Staphylococcal enterotoxin
- T -2 toxin

IV. Listed plant pathogens

- Liberobacter africanus
- Liberobacter asiaticus
- Peronosclerospora philippinensis
- Phakopsora pachyrhizi
- Plum Pox Potyvirus
- Ralstonia solanacearum race 3, biovar 2
- Schlerophthora rayssiae var zeae
- Synchytrium endobioticum
- Xanthomonas oryzae
- Xylella fastidiosa (citrus variegated chlorosis strain)