United States Department of Agriculture
Office of Inspector General

Adequacy of Controls to Prevent the Release of Sensitive Technology

Audit Report 02601-0001-21
March 2016

Adequacy of Controls to Prevent the Release of Sensitive Technology

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What Were OIG's Objectives

Our objective was to assess ARS' policies and procedures for identifying, approving, and monitoring sensitive or dual-use research. Additionally, we determined if ARS had designed and implemented the controls recommended in the prior audit to ensure sensitive technology is not susceptible to questionable transfer.

What OIG Reviewed

We visited ARS' national office, three research facilities, and three laboratories, and reviewed nine projects active as of April 4, 2014. We assessed how ARS implemented DURC policy, managed controlled, but unclassified, information, ensured suitability of non-Government scientists, and released information to foreign nationals.

What OIG Recommends

We recommended that ARS improve how it assesses research projects and manages the release of information, especially when projects involve select agents listed in DURC policy. ARS should also strengthen its review of non-Government scientists.

OIG audited ARS' controls over the release of information and technology related to research with dual-use applications.

What OIG Found

The Department of Agriculture's (USDA) Agricultural Research Service (ARS) conducts scientific research to solve technical agricultural issues, and collaborates with scientists from other organizations and countries to expedite research results to the private sector. Occasionally, research involves select agents and toxins (microorganisms or substances that can be manipulated to cause harm), so ARS must follow Dual-Use Research of Concern (DURC) policy to assess its research and manage the release of information. DURC can provide knowledge that, if misapplied, poses a significant threat to the public, agriculture, environment, or national security. ARS must also follow export requirements when releasing information and technology to foreign nationals.

OIG's 2005 audit reported that ARS did not have adequate controls to prevent the improper transfer of sensitive (dual-use) technology. ARS agreed to implement the 11 recommendations to strengthen the controls. However, OIG found that ARS only issued informal guidance and did not strengthen its controls as recommended.

OIG's current audit found that ARS did not assess all its research for DURC risk and limited regular monitoring to projects using select agents listed in DURC policy. Despite this weakness, OIG found that the nine reviewed projects did not release potential DURC information to the public. However, because of the dynamic nature of science, the possibility exists for a project to produce DURC results. ARS also did not track all non-Government scientists in its database, did not fully examine their background for criminal behavior, and did not obtain export licenses prior to sharing its information and technology with foreign nationals.

The agency agreed with our recommendations and we reached management decision for all 21 recommendations.

United States Department of Agriculture
Office of Inspector General
Washington, D.C. 20250

DATE: March 21, 2016

AUDIT NUMBER: 02601-0001-21

TO: Chavonda Jacobs-Young
Administrator
Agricultural Research Service

ATTN: Lisa Baldus
Associate Deputy Administrator
Administrative and Financial Management

FROM: Gil H. Harden
Assistant Inspector General for Audit

SUBJECT: Adequacy of Controls to Prevent the Release of Sensitive Technology

This report presents the results of the subject audit. Your written response to the official draft report, received on February 3, 2016, is included in its entirety at the end of this report. Your response and the Office of Inspector General's position are incorporated into the relevant sections of the report. Based on your written response, we are accepting management decision for all audit recommendations in the report, and no further response to this office is necessary.

In accordance with Departmental Regulation 1720-1 final action is to be taken within 1 year of each management decision to prevent being listed in the Department's annual Agency Financial Report. Please follow your internal agency procedures in forwarding final action correspondence to the Office of the Chief Financial Officer.

We appreciate the courtesies and cooperation extended to us by members of your staff during our audit fieldwork and subsequent discussions. This report contains publically available information and will be posted in its entirety to our website (http://www.usda.gov/oig) in the near future.

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Background & Objectives

Background

The Agricultural Research Service (ARS) is the Department of Agriculture's (USDA) chief in-house scientific agency. ARS conducts research to develop new knowledge and technology to solve technical agricultural problems of broad scope and high national priority.

The Office of National Programs (ONP) administers ARS' research through 17 national programs, 5 area offices, and over 90 research locations, including 262 laboratories. To achieve ARS' mission, ONP identifies critical problems affecting the nation's agriculture, and then plans and executes the strategies needed to address these problems. ARS' research areas include food safety, animal production and protection, crop production and protection, and natural resources. The type of research conducted includes, but is not limited to:

- reducing and controlling pathogens and toxins in agricultural products;
- understanding the mechanisms of disease resistance;
- developing tools to prevent, control, or eradicate diseases that threaten our food supply or public health;
- protecting plants from diseases and pests; and
- enhancing the nation's vast renewable natural resource base.

Use of Select Agents in ARS Research

ARS often uses select agents and toxins when conducting research in the area of animal production and protection. These are defined as "microorganisms (including, but not limited to, bacteria, viruses, fungi, or protozoa), or infectious substances, or any naturally occurring, bioengineered, or synthesized component of any such microorganism or infectious substance, capable of causing death, disease, or other biological malfunction in a human, an animal, a plant, or another living organism."[1]

Currently, Select Agent Regulations, administered by the Animal and Plant Health Inspection Services and the Center for Disease and Control Prevention, require appropriate oversight for biosafety and biosecurity purposes, of the possession and handling of pathogens and toxins that have the potential to pose a severe threat to human, animal, or plant health, or to animal and plant products.[2] Additional Federal policy complements existing regulations by requiring regular assessments of this type of research to mitigate risks where appropriate.[3]

[1] 9 C.F.R. 121.
[2] 7 C.F.R. 331 and 9 C.F.R. 121
[3] "The U.S. Government Policy for Institutional Oversight of Dual-Use Research of Concern," dated September 2014.

Dual-Use Research of Concern

"The United States Government Policy for Institutional Oversight of Life Sciences Dual Use Research of Concern" (hereafter referred to as "DURC policy") defines dual-use research of concern (DURC) as life sciences research[4] that can be reasonably anticipated to provide knowledge, information, products, or technologies that could be directly misapplied to pose a significant threat to public health, agricultural crops, or national security."[5] DURC policy states if a research project includes one of the select agents listed in the policy, and also falls under one of the categories of experiments identified as "most dangerous,"[6] then the agency must evaluate the project for DURC potential. According to DURC policy, agencies must regularly assess whether their research meets the select agents and experiment parameters discussed in the policy.

ARS must also assess the project for DURC risks and implement measures to reduce the risk of results being used for harmful purposes. A risk mitigation plan may include elements for applying specific or enhanced biosecurity or biosafety measures; evaluating existing evidence of medical countermeasures efficacy; or conducting experiments. Institutions must regularly review emerging research findings for additional DURC, and annual progress reports to determine if DURC results have been generated. If DURC results exist, institutions must apply mitigation measures, as necessary.

Research Collaborations with Non-Government Scientists

The exchange of research information is a common practice within the scientific community. This allows ARS to expedite the sharing of research results with the private sector, which can then stimulate new business and economic development, enhance U.S. trade, preserve the environment, and improve the quality of life for all Americans. As such, ARS scientists routinely collaborate with other domestic and foreign scientists. This collaboration is managed using different types of instruments, including cooperative agreements, grants, and other partnerships.

[4] "The U.S. Government Policy for Institutional Oversight of Dual-Use Research of Concern," dated September 2014, states that "life sciences pertains to living organisms (e.g., microbes, human beings, animals, and plants) and their products, including all disciplines and methodologies of biology such as agricultural science, plant science, animal science, bioinformatics, genomics, proteomics, synthetic biology, environmental science, public health, modeling, engineering of living systems, and all applications of the biological sciences."

[5] "The U.S. Government Policy for Institutional Oversight of Dual-Use Research of Concern," dated September 2014.

[6] DURC policy considers the following seven categories of experiments to be the most dangerous: experiments that (1) enhance the harmful consequences of the agent or toxin; (2) disrupt immunity or the effectiveness of an immunization against the agent or toxin without clinical and/or agricultural justification; (3) confer to the agent or toxin resistance to clinically and/or agriculturally useful prophylactic or therapeutic interventions against that agent or toxin or facilitates their ability to evade detection methodologies; (4) increase the stability, transmissibility, or the ability to disseminate the agent or toxin; (5) alter the host range or tropism of the agent or toxin; (6) enhance the susceptibility of a host population to the agent or toxin; or (7) generate or reconstitute an eradicated or extinct agent or toxin.

ARS must also manage the export of goods and technology to foreign countries and information shared with foreign nationals inside the United States, using the Department of Commerce requirements, as described in the Export Administration Regulations.[7] These regulations provide clear guidance on how to manage the export of equipment, materials, software, and technology.[8] Moreover, Export Administration Regulations allow the release of technology and software to foreign nationals if it is "basic and applied research in science and engineering, where the resulting information is ordinarily published and shared broadly within the scientific community."

Publication Process

According to ARS officials, ARS scientists are required to submit at least two manuscripts every year to scientific journals and publications regarding research performance and results.[9] According to regulation, ARS must release this information with a high degree of transparency to enable third parties to replicate the research, unless confidentiality protections preclude the release of such information.[10] Although the Scientific Integrity Memorandum issued by the President on March 9, 2009, encourages agencies to share the scientific information developed and used by the Federal Government, such sharing is subject to Executive Order 12968 which states that certain information must be maintained in confidence to protect the public.[11]

ARS uses the Agricultural Research Information System (ARIS) for recording, documenting, and publishing research project information. ARIS maintains detailed agency information related to research purposes and objectives, funding levels, publications and progress reports, and personnel involved with all ARS in-house and extramural research projects. Agency officials use ARIS to evaluate information that will be released to the public through abstracts, journals, book chapters, and presentations.

Prior Audit Work

In 2005, OIG evaluated ARS' controls over the transfer of sensitive (dual-use) technology to the public.[12] Our objective was to determine if ARS adequately identified, approved, and monitored sensitive research, and also to evaluate the agency's compliance with deemed export license

[7] ARS defines a foreign national as a person that is not a citizen or national of the United States.
[8] 15 C.F.R. 730 & 734.
[9] Per ARS policy, scientists use form ARS-115, "Request to Submit Manuscript for Publication," to track the review and approval of written or oral communication before results are released to ensure unauthorized technology is not disclosed.
[10] USDA Scientific Integrity Policy Handbook, Section 2a, "Information Quality and Peer Review" – "Objectivity of Influential Scientific Research Information."
[11] Executive Order No. 12968 (August 2, 1995).
[12] Audit 02601-0001-Ch, *The Adequacy of ARS Controls to Prevent the Improper Transfer of Sensitive Technology,* September 2005.

requirements. [13] In addition, we identified scientists working on the projects and determined that sensitive knowledge had not been transferred to questionable individuals. OIG reported, however, that ARS did not have adequate controls to prevent the improper transfer of sensitive technology. Specifically, we reported that ARS needed to identify, thoroughly review, and monitor dual-use research projects. In addition, we reported that ARS did not check all non-Government scientists for security suitability, and shared sensitive information with foreign nationals without applying for deemed export licenses. To strengthen ARS' controls, we recommended that ARS:

- formalize, in writing, agency research policies and procedures to manage the proposal, monitoring, and publication processes;
- designate and control sensitive security information (SSI);[14]
- develop procedures to evaluate the potential risk of dual-use research projects as a part of the approval process, including whether pre-publication review of research results is appropriate;
- oversee relationships with collaborators; and
- improve the management environment.

ARS agreed to develop and implement the actions OIG recommended; an assessment of ARS' actions is included in Exhibit A.

Objectives

Our objective was to assess ARS' policies and procedures for identifying, approving, and monitoring sensitive or dual-use research. Additionally, we determined if ARS had designed and implemented the controls recommended in the prior audit to ensure sensitive technology is not susceptible to questionable transfer.

[13] Export Administration Regulations, 15 C.F.R. 734.2, define an export as an "actual shipment or transmission of items out of the United States, or release of technology or software to a foreign national." A deemed export license must be obtained before releasing information to foreign nationals related to equipment or methods required for the replication, production, or isolation of materials covered by these regulations, and the information or methods are not in the public domain or being put in the public domain.

[14] Per Departmental Regulation (DR) 3440-002, "Control and Protection of Sensitive Security Information," SSI is "unclassified information of a sensitive nature that, if publicly disclosed, could be expected to have a harmful impact on the security of Federal operations or assets, the public health or safety of the citizens of the United States or its residents, or the nation's long-term economic prosperity."

Section 1: ARS Internal Controls

Finding 1: ARS Needs to Strengthen Its Overall Internal Control Structure

ARS had not developed adequate internal controls to minimize the risk that knowledge, information, or technology[15] generated by its research will be misused, despite its agreement to take such actions in response to a 2005 OIG audit.[16] Specifically, ARS did not consistently evaluate and monitor research with potential for DURC risk; approve and track non-Government scientists; manage the release of technology to foreign nationals; and validate adequate review of manuscripts before publication. This happened because ARS had not fully implemented any of the agreed-upon corrective actions. Additionally, ARS' emphasis on the scientific mission of the organization did not effectively consider the risk and impact of the release of research technology, especially risks related to select agents listed in the DURC policy. Although OIG did not identify any improper release of information in the nine sampled projects reviewed, the absence of these internal controls leaves the Department vulnerable to potential release of technology that could be used for harmful purposes and have an impact on national security.

Federal standards, issued in 1999 and 2014, state that appropriate internal controls help agencies achieve their goals and minimize operational problems. These controls "comprise the plans, methods and procedures used to meet the mission, goals and objectives."[17] Further, the Office of Management and Budget's Circular A-123 explains that "management has a fundamental responsibility to develop and maintain effective internal controls."[18]

We evaluated the controls, such as policies and procedures, the agency used to identify, classify, track, and monitor research projects and compared them to the recommendations made in our 2005 audit. We determined that ARS did not fully implement corrective actions recommended to strengthen controls used to manage the release of research technology, so we approached agency officials for explanations.

In general, officials cited a lack of time and staff, and that the institutional DURC policy was not finalized until September 2014, as a reason for the inaction. They also indicated that they viewed controls as a hindrance to the scientific process. Through discussions with program staff, we learned that ARS officials placed a priority on the scientific mission of the organization and the sharing of research information in order to make significant advancements in scientific research. ARS officials stated that they conducted research that was suitable for publication, and they said that the research performed by its scientists did not have any impact on national

[15] The American Heritage Dictionary of Student Science (2d ed. 2014) defines technology as the application of science, especially to industrial or commercial objectives. It includes the methods, theory, and practices governing such application and the total knowledge and skills available.
[16] Audit 02601-0001-Ch, *Adequacy of ARS Controls to Prevent the Improper Transfer of Sensitive Technology*, September 2005.
[17] United States Government Accountability Office, "Standards for Internal Control in the Federal Government," dated November 1999 and September 2014 (effective October 2015).
[18] Revisions to OMB Circular A-123, "Management's Responsibility for Internal Control," dated December 21, 2004, last amended in October 2014.

security. In contrast, when asked about ARS' use of internal controls, such as policy and procedures, to manage the release of research technology, officials frequently expressed concerns about how controls could diminish their ability to pursue their scientific mission and collaborate with the scientific community.

We commend ARS for its strong commitment to its scientific mission, and we do believe that establishing an adequate internal control structure would strengthen, rather than diminish, its ability to achieve this mission. According to Federal Standards, "an effective internal control system helps an entity adapt to shifting environments, evolving demands, changing risks, and new priorities."[19] Current Federal standards state that "management and employees should establish and maintain an environment throughout the organization that sets a positive and supportive attitude toward internal control."[20] New Federal standards also identify management's tone at the top and throughout the organization as fundamental to an effective internal control system.[21]

ARS Did Not Effectively Implement 11 Recommendations OIG Made in 2005

In 2005, we reported that ARS' management controls needed enhancement to prevent the transfer of sensitive knowledge to hostile individuals or countries.[22] OIG's concerns were that ARS had not identified which of its research projects were sensitive or dual-use; did not conduct thorough background checks on all non-Government scientists who worked on research projects involving sensitive knowledge; and had neither applied for deemed export licenses nor educated its staff about these policies. ARS agreed to take actions to fully address OIG recommendations, specifically establish formal policies and procedures to address issues noted and implement such requirements. When we evaluated ARS' documentation for the current audit, we found that, while management had taken some action to address OIG's concerns, none of the actions were designed to have lasting effects. For example, ARS issued interim guidance on January 12, 2006, to address five of OIG's recommendations. However, ARS did not have a process in place to ensure that interim guidance was formalized or incorporated into any new Government policy that could impact its activities. Our current audit documents the results of ARS not formalizing its corrective measures, as issues reported in 2005 continue to exist (see Exhibit A for further information).

[19] United States Government Accountability Office, "Standards for Internal Control in the Federal Government," dated September 2014 (effective October 1, 2015).
[20] United States Government Accountability Office, "Standards for Internal Control in the Federal Government," dated November 1999.
[21] United States Government Accountability Office, "Standards for Internal Control in the Federal Government," dated September 2014 (effective October 1, 2015).
[22] Audit 02601-0001-Ch, *Adequacy of ARS Controls to Prevent the Improper Transfer of Sensitive Technology,* September 2005.

ARS Did Not Formalize Its Policies and Procedures

We found that ARS officials used a series of informal memos to propose, evaluate, approve, and monitor research proposals. These documents had to be issued each time the process occurred, and ARS relied on past experience of individual staff members when interpreting criteria used to evaluate research proposals. Further, ARS did not have policies defining its monitoring activities.

We also found that ARS had not incorporated DURC requirements into its guidance when the policy was issued in 2012, although ARS had agreed to do so in response to OIG's 2005 audit.[23] As a result, some of the scientists interviewed were either not familiar with the DURC policy or with the term "dual-use." Some scientists asked ONP staff for help when addressing our DURC-related questions. Likewise, ARS relied on two officials to manage its DURC assessments, reviews, and reporting, which could be problematic if either or both individuals left the agency. We concluded that this lack of familiarity with DURC hindered the agency's ability to properly detect and mitigate DURC risk as required by the policy.

ARS management officials informed us that they had not established internal policies and procedures and incorporated DURC language into agency policy because they did not have the time or manpower to dedicate to this endeavor, and all of the DURC policies were not final.[24] While we appreciate the staffing challenges ARS faces, formalizing processes through written policies is an important internal control. According to Federal policy, agency managers bear a fundamental responsibility to develop and maintain control activities, including policies and procedures.[25] Formalizing policies and procedures in writing, as directives, manuals, or other authoritative documents, helps to create consistency and accountability.

[23] We recommended in 2005 that ARS establish policies and procedures to identify dual-use research (since the NIH Advisory Board had not developed DURC requirements), and to incorporate the Board's requirement when issued. The Board finalized the requirements in 2012.

[24] DURC policies, "United States Government Policy for Oversight of Life Sciences DURC" and "United States Government Policy for Institutional Oversight of Life Sciences DURC," were not finalized until March 2012 and September 2014, respectively. Both DURC policies impact ARS research as some of it is conducted by outside institutions. According to the "United States Government Policy for Institutional Oversight of Life Sciences Dual Use Research of Concern," dated September 2014, both policies are "complementary and emphasize a culture of responsibility by reminding all involved parties of the shared duty to uphold the integrity of science and prevent its misuse."

[25] Revisions to OMB Circular A-123, "Management's Responsibility for Internal Control," dated December 21, 2004, last amended in October 2014.

ARS Did Not Identify Sensitive Security Information[26]

OIG also determined that ARS had not designated any of its data as Sensitive Security Information (SSI) or established policies and procedures to address this requirement.[27] SSI is defined by the Department as "unclassified information of a sensitive nature that, if publicly disclosed, could be expected to have a harmful impact on the security of Federal operations or assets, the public health or safety of the citizens of the United States or its residents, or the nation's long-term economic prosperity."[28] When we raised this concern to ARS officials, they explained that they were awaiting Department guidance in this area, based on Executive Order 13556.[29] However, according to the Departmental Controlled Unclassified Information (CUI) working group, the Department is waiting for finalization of regulations being issued by the National Archives and Records Administration to revise Departmental guidance on control and protection of information.[30] ARS officials stated that their research was not sensitive, as it did not involve national security matters.[31]

OIG disagreed with ARS' position that its research was not sensitive because ARS was managing at least seven projects that incorporated the use of select agents. Based on the Department's definition of SSI, and the Select Agent regulation definition of select agents, projects using select agents could be designated as SSI because, if results were misapplied, they could have a harmful impact on human and animal health. However, further review of the Departmental regulations disclosed that the Department states that "the internet is not secure and should not be used to transmit SSI [information]."[32] As ARS officials stated, this would be a hindrance to ARS' mission as it would not be able to release results for projects classified as SSI on the internet.

OIG recognizes the limitations that the SSI designation would have on ARS' ability to release research information. However, OIG believes that ARS could take a step towards meeting SSI requirements and fulfill national security obligations by expanding its current publication policy to include select agent projects. This policy included special review procedures for the release of

[26] According to the "Memorandum for the Heads of Executive Departments and Agencies—Classified Information and Controlled Unclassified Information," dated May 27, 2009, Sensitive but Unclassified (which is also referred to as SSI) will be referred to as Controlled Unclassified Information (CUI). Executive Order 13556 defines CUI as unclassified information that requires safeguarding or dissemination controls, such as information that involves privacy, security, proprietary business interests, and law enforcement investigations (e.g., location of select agents).
[27] OIG reported a similar problem in 2005, when we found that ARS officials had not defined SSI and were publishing potentially sensitive information (such as the location of toxic materials) on the internet.
[28] DR No. 3440-002, "Control and Protection of Sensitive Security Information."
[29] Executive Order 13556 establishes an open and uniform program for managing information that requires safeguarding or dissemination controls pursuant to and consistent with law, regulations, and Government-wide policies, excluding information that is classified under Executive Order 13526, dated December 29, 2009, or the Atomic Energy Act, as amended.
[30] The CUI working group was established to implement CUI guidance. It anticipates the implementation to start in March 2016.
[31] We found ARS was conducting 49 projects with select agents listed in the DURC policy; however, it was not performing any of the 7 categories of experiments listed in the policy. Our review disclosed ARS research was focused on the prevention and control of these diseases. However, in the future this could change.
[32] DR No. 3440-002, "Control and Protection of Sensitive Security Information."

prominent issues,[33] which are defined as those that "(1) ha[ve] potential to attract media interest/attention, (2) [represent] a significant scientific advancement, (3) significantly [affect] existing or future policy, and (4) ha[ve] potential trade implications."[34] Expanding the current policy to include select agent projects would increase assurance that these projects are properly reviewed prior to public release.

While OIG understands ARS' role and that its current research does not broadly involve issues of national security, we stress that the dynamic nature of science itself could unexpectedly elevate ARS' work into a national security matter, if, for example, experimentation with these select agents unexpectedly increases the agent's virulence or resistance to immunization. Such a possibility requires that ARS proactively formulate protections against the release of sensitive information, especially when the research involves select agents listed in the DURC policy. Furthermore, by expanding its current publication policy, ARS would strengthen dissemination controls, which is something that may be required once Departmental policy is revised.

ARS Used Inadequate Templates to Establish Agreements with Collaborators

OIG also reviewed ARS' criteria for the release and exchange of information with collaborators.[35] It required collaborators to submit project results to the agency for advice and approval before they were released to any other interested parties.[36] OIG then reviewed ARS' collaboration agreement to ensure that it clearly instructed collaborators on how to manage the exchange and release of information. We found that the template only provided a link to a website, which collaborators were expected to review in order to satisfy ARS requirements. Thus, if collaborators did not review the linked information and understand how to manage the exchange and release of information, they unintentionally could release information without proper ARS review and approval.[37] When asked about this issue, ARS agreed that the template needed to be updated to include the actual requirements.

[33] An ARS official informed us that prominent issues are defined in general terms rather than as specific research areas, and may include other priorities as designated by the current administration.
[34] Agricultural Research Information System Online Handbook, dated February 2014.
[35] Collaborators engage with ARS on what is known as a sibling research project. Sibling research projects are spin-off projects related to the objectives of ARS projects funded by Congress. These sibling projects are initiated to obtain expertise not available within ARS to fulfill research goals, collaborate with extramural partners, or obtain other services and expertise. The projects are funded through agreements with collaborators, universities, or other entities.
[36] ARS can use seven types of agreements for sibling projects: (1) non-assistance cooperative agreements; (2) assistance type cooperative agreements; (3) grants; (4) research support agreements; (5) trust fund cooperative agreements; (6) reimbursable cooperative agreements (RCA); and (7) non-funded cooperative agreements.
[37] We did not find any instance of collaborators releasing information without ARS' knowledge.

Conclusion and Recommendations

OIG's discussions with program staff and agency officials confirmed substantial commitment to ARS' scientific mission, but also concerns that the scientific mission could be hindered by adding controls on how technology and information is shared. OIG's recommendations are not meant to restrict ARS' scientific mission, but rather to minimize the risk of information falling into the wrong hands and being misapplied for harmful purposes.

Recommendation 1

Communicate to research staff, via memorandum, the importance of establishing strong internal controls, and the impact research results are likely to have on public perception and national security.

Agency Response

In its February 3, 2016, response, ARS stated:

> ARS is preparing a new Dual-Use Research of Concern (DURC) policy and procedure (P&P), to be drafted within 90 days and finalized within 120 days of the issuance of the final report. Using the publication of the DURC P&P as a launch point, the Administrator of ARS will issue a memo to all scientific staff emphasizing the importance of establishing strong internal controls and the impact research results are likely to have on public perception and national security. ARS will develop the DURC P&P by April 30, 2016 and implement the P&P by October 31, 2016. The Administrator will issue the memo by May 31, 2016.

OIG Position

We accept management decision for this recommendation.

Recommendation 2

Incorporate into ARS policy the Federal policy on identifying, evaluating, approving, and monitoring Dual-Use Research of Concern (DURC) results in research projects.

Agency Response

In its February 3, 2016, response, ARS stated:

> The DURC P&P will incorporate Federal policy as recommended. The DURC P&P will be developed by April 30, 2016 and implemented by October 31, 2016.

OIG Position

We accept management decision for this recommendation.

Recommendation 3

Until final Departmental guidance is available regarding the control and protection of information, expand the current publication process to include select agent projects as a prominent issue.

Agency Response

In its February 3, 2016, response, ARS stated:

> ARS is preparing the new DURC P&P and it will document that research conducted with any of the 15 designated agents identified as potential DURC will require approval by the Office of National Programs (ONP). The DURC P&P will be developed by April 30, 2016 and implemented by October 31, 2016.

OIG Position

We accept management decision for this recommendation.

Recommendation 4

Coordinate with the Department the issuance of ARS policy, regarding the control and protection of information, that fulfills latest requirements in this area. This policy should state clearly whether research projects will require a specific designation. In addition, the policy should state whether any controls will be implemented to control or protect research information prior to release.

Agency Response

In its February 3, 2016, response, ARS stated:

> The DURC P&P will provide oversight on how all research conducted with the 15 agents identified in the US Government DURC guidelines will be reviewed as DURC within the agency.… In addition, the Office of the Chief Information Officer is working with the National Archives and Records Administration to solidify definitions and criteria surrounding "Controlled Unclassified Information" in accordance with E.O. 13556, Controlled Unclassified Information. ARS will apply the USDA guidelines/policy to research once the guidelines/policy are developed, as appropriate. If the guidance isn't available by publication of the new DURC P&P, we will revise the P&P once the guidance is revealed, as necessary. The DURC P&P will be developed by April 30,

> 2016 and implemented by October 31, 2016 and the P&P will state which projects require the potential DURC research designation...

OIG Position

We accept management decision for this recommendation.

Recommendation 5

Revise the templates of the agreements used with collaborators to include formal standards for the exchange and release of research results.

Agency Response

In its February 3, 2016, response, ARS stated:

> …Inclusion of requirements by reference is standard, accepted practice regarding agreement terms and conditions and includes references to laws, regulations, and other policies and requirements that appear in the US Code, the Code of Federal Regulations, and on agency web pages. All are legally binding and it is the collaborator's responsibility to read, understand, and comply with all such requirements – a responsibility they accept when they accept the agreement. ARS respectfully disagrees with this recommendation and prefers to follow the standard, government-wide practice.

OIG Position

We accept management decision for this recommendation.

Recommendation 6

Train more Office of National Programs (ONP) staff to handle DURC assessment, oversight, and reporting.

Agency Response

In its February 3, 2016, response, ARS stated:

> ARS will have at least two people on staff that review the experiments in DURC projects every six months as required. In addition, they oversee and discuss any potential DURC research that may occur between the biannual review processes. ARS will continue to have a National Program Leader (NPL) for Animal Health and a NPL for Food Safety that will be trained to evaluate experiments for DURC and as a backup person, the ARS

Biosafety Officer. ARS ONP will have at least two people on staff that will review potential DURC projects by February 29, 2016.

OIG Position

We accept management decision for this recommendation.

Recommendation 7

Establish a process to ensure interim corrective actions are integrated into official ARS policies, directives, or manuals.

Agency Response

In its February 3, 2016, response, ARS stated:

> ARS will update the DURC P&P when US Government guidelines are modified. Once the DURC P&P is complete, it will be reviewed on a periodic basis and revised as required by new policy and directives. The DURC P&P will be developed by April 30, 2016, and implemented by October 31, 2016.

OIG Position

We accept management decision for this recommendation.

Recommendation 8

Develop a process to promptly incorporate future changes in laws or regulations, especially those related to DURC policy that affect the release of information and technology into official ARS' policies, directives, or manuals.

Agency Response

In its February 3, 2016, response, ARS stated:

> Once the DURC P&P is complete, it will be reviewed on a periodic basis and revised as required by new policy and directives. The DURC P&P will be developed by April 30, 2016, and implemented by October 31, 2016.

OIG Position

We accept management decision for this recommendation.

Finding 2: ARS Needs to Strengthen its Evaluation and Monitoring of Research Projects

ARS did not conduct initial or ongoing assessments on all research projects for potential DURC elements.[38] This occurred due to deficiencies in ARS' research approval and monitoring processes. Specifically, when ARS evaluated and approved original research proposals, the agency did not check to determine if the proposed research was subject to DURC policy. In addition, as the research projects progressed, ARS had no procedures to evaluate deviations from initially approved project objectives and scope. If projects are not adequately evaluated, information that can be misapplied could be inadvertently released to the public. This could pose a significant threat to public health and safety, agricultural crops, plants, and animals.

DURC policy requires Federal agencies to "establish regular review of government funded or conducted research involving certain high-consequence pathogens and toxins for its potential to be DURC [designated research project], in order to mitigate risks where appropriate."[39] The policy requires ARS to monitor research projects for potential DURC risks, which is present when a research project involves 1 or more of 15 select agents that have the potential to pose a severe threat to humans, animals, plants, and animal products. The policy also requires oversight of research projects that fall under one of seven categories of experiments that have the potential to enhance the harmful consequences of the agent or disrupt the immunity against the agent. Federal agency oversight of DURC research projects is intended to preserve the benefits of life sciences research, while minimizing the risk of misuse of the knowledge, information, products, or technologies provided by such research. We reviewed the process ARS followed to assess and monitor how its research met DURC policy and concluded that the process was incomplete, as ARS limited its DURC assessments to projects performed in laboratories with select agents. Through the review of ARIS reports, memos, and other project data, we also found that ARS was not monitoring projects as they progressed, as required by DURC policy.

Although research was not assessed or monitored according to DURC policy, we concluded that information was not inappropriately released for the nine projects in our review. We reviewed 38 manuscripts for the 9 projects in our sample to assess the information released as a result of the research.[40] We found the information released was in compliance with the Select Agent Program. Also, nothing came to our attention that led us to believe that DURC information had been inappropriately released, as all projects involved experiments designed to diminish the virulence of the select agent and enhance immunization against it. While these manuscripts did not contain potentially harmful information, the potential exists for this to happen with future

[38] All research projects include projects performed by ARS with funds received from Congress and other organizations, as well as projects performed by other organizations with ARS funds.
[39] "The United States Government Policy for Institutional Oversight of Dual-Use Research of Concern," dated September 2014.
[40] ARS requires scientists to submit two manuscripts a year that contain the results of their experiments, materials used, and the methodology followed in performing the research. The methodology must include enough information to ensure a third party can reproduce the experiment with the same results unless other compelling interests (privacy, trade secrets, etc.) exist.

projects, due to weaknesses in ARS' current review process. ARS needs to monitor each of its research projects for the use of DURC select agents.

ARS Did Not Evaluate All Research Proposals for DURC

We assessed ARS' process for evaluating and approving research project proposals and determined that ARS' process was incomplete, as it did not include an assessment of the DURC requirements. Although ONP officials and the Office of Scientific Quality Review (OSQR) review each research proposal for scientific quality, neither assessed the proposals for DURC requirements.[41] When discussed with ARS officials, they stated that the National Program Leaders would be the most qualified to review projects for DURC and properly assess if there was any DURC potential involved in a proposed project. Without the DURC assessment, ARS would be unable to properly determine if proposed research would require specific risk mitigating measures to meet DURC policy.[42]

An ARS official stated that the agency met DURC requirements to evaluate experiments being performed because it evaluated certain projects on a semi-annual basis to determine whether the work being performed warranted DURC distinction. Although we agreed that the semi-annual review was appropriate, we concluded the review was incomplete because it was only performed on DURC-labeled projects.[43] The semi-annual review excluded research performed in 258 of 262 ARS laboratories. Although these laboratories were not performing DURC designated projects, we confirmed with the Select Agent Program staff that 2 of the 258 laboratories were authorized to use select agents. Additionally, other laboratories could be allowed to work with select agents if an authorization was requested and they were equipped for the work. Thus, including a DURC assessment in the initial evaluation of all research proposals, and tracking each decision in ARIS, would confirm that projects excluded from the semi-annual review did not involve select agents and were not in one of the categories of experiments described in the DURC policy.

ARS Did Not Evaluate Projects for DURC after Deviations in the Project's Plan

Based on the DURC policy, we determined DURC reviews should not be limited to an initial or semiannual review. The policy states that "research is by nature dynamic and can produce unanticipated results and, therefore, must be evaluated on an ongoing basis for dual-use potential."[44] Project deviations could include the introduction of a select agent or performance

[41] OSQR was established by the "Agricultural Research, Extension and Education Reform Act of 1998." The OSQR is a panel convened by ARS to evaluate research proposals. It consists of individuals who are scientific, technical, or industrial experts possessing relevant and extensive knowledge and experience. Participants are members of the academics, agency's customers, or stakeholders who must be free of conflicts of interest with regard to projects they review.

[42] "The United States Government Policy for Institutional Oversight of Dual-Use Research of Concern," dated September 2014, states research should be evaluated for possible risks to ensure that DURC "risks are appropriately managed and benefits realized."

[43] An ARS official stated that two laboratories authorized to use select agents were not included in this review because scientists used plant agents that were not included in the DURC policy.

[44] "The United States Government Policy for Institutional Oversight of Dual-Use Research of Concern," dated September 2014.

of an experiment not foreseen during the project's initial approval that may merit a DURC distinction and risk evaluation.

When we assessed how ARS managed deviations, we found ARS officials had not officially defined what would be considered a "deviation." The agency had issued a memorandum in January 2006 which required scientists to notify their area director and ONP staff when they proposed any changes to a research project.[45] During this audit, scientists informed us that if they had to deviate from the original project plan, they would notify ONP and their managers. Likewise, an ARS official informed us that research leaders and area officials were monitoring projects to ensure scientists were not going beyond their objectives and that contacts were made if any questions arose. An ARS official also stated that deviations meriting a closer review were elevated to the ONP level. However, we could not validate these claims, as deviations were not documented, and, thus ARS could not provide evidence of the requests or approvals. We concluded that properly documented notification, evaluation, and approval of key project deviations would allow ARS to determine if any DURC mitigating measures were needed.

ARS management should assess the likelihood of DURC and related risks at all stages of the research project, as it has a responsibility to minimize the risk of misuse of the knowledge provided by such research. This can only be done through continued assessments and oversight of ongoing research projects.

Recommendation 9

Include a DURC risk assessment when ARS evaluates each research proposal during the approval process.

Agency Response

AGENCY RESPONSE:

In its February 3, 2016, response, ARS stated:

> ARS is also drafting a P&P document providing guidance over Institutional Biological Safety Committees (IBC) throughout the Agency. In this new policy, ARS IBCs will review and approve the process and procedures used for nearly all forms of research utilizing biohazards including provisions for ARS IBC's to report any projects identified as potentially DURC (as defined in the 2014 U.S. Government Policy for Institutional Oversight of Life Sciences Dual Use Research of Concern) to the appropriate Area and National Program Staff for further DURC review. The IBC P&P will be developed by March 31, 2016, and implemented by October 31, 2016.

[45] Memorandum "Interim Guidelines for Special Review and Clearance of Research Results from Selected Projects before Public Release," signed by the Administrator on January 12, 2006.

OIG Position

We accept management decision for this recommendation.

Recommendation 10

Track results of risk assessments for all projects in the Agricultural Research Information System (ARIS). Any project that meets DURC requirements should be identified as such in ARIS.

Agency Response

In its February 3, 2016, response, ARS stated:

> … ARS has had no research consistent with the criteria for DURC, but is prepared to perform any necessary risk assessment in the event DURC is identified. This will be covered in the DURC P&P.
>
> The risk assessments for all potential DURC projects will be included in the project's record in the ARIS. Any project that conducts research on any of the 15 agents identified in the DURC guidelines will be identified as DURC potential research projects in ARIS. The DURC P&P will be developed by April 30, 2016 and implemented by October 31, 2016 and it will address the risk assessment process.

OIG Position

We accept management decision for this recommendation.

Recommendation 11

Develop a policy on research project deviations that defines deviations that merit close review and approval, and also specifies how the notification, evaluation, and approval of deviations from the project's objectives are to be addressed by research scientists and managers.

Agency Response

In its February 3, 2016, response, ARS stated:

> The DURC and IBC P&Ps will implement this recommendation. Specifically the DURC P&P will document the process for training of all ARS scientists and line management to recognize a potential DURC research and submit it for review prior to conducting the research. The DURC P&P will be developed by April 30, 2016, and implemented by October 31, 2016.

OIG Position

We accept management decision for this recommendation.

Recommendation 12

Assess whether approved project deviations will result in a change of the DURC risk.

Agency Response

In its February 3, 2016, response, ARS stated:

> The new DURC and IBC P&Ps will implement this recommendation. Any deviations in the protocols or results are to be reported to the appropriate review committee, which includes the ONP. The DURC and IBC P&P will be developed by April 30, 2016, and implemented by October 31, 2016.

OIG Position

We accept management decision for this recommendation.

Finding 3: ARS Needs to Strengthen Controls for Evaluating Non-Government Scientist

Foreign nationals who were disqualified from participating in United States Government programs due to commission or conviction of crimes against the Federal Government could be participating in active ARS research projects. This occurred because ARS officials had not checked the System for Award Management (SAM), as required by USDA guidance, when completing security clearances for these individuals.[46] In addition, ARS officials had not tracked non-Government scientists participating in ARS research projects to ensure that those requiring a security clearance were properly evaluated. As a result, there is a risk of misuse of research information by unauthorized parties to damage the nation's agriculture and public health.

Federal agencies are required to complete an evaluation of SAM data to determine the suitability of non-Government scientists before allowing persons to participate in covered transactions.[47] Federal regulations state that agencies may not enter into a covered transaction—such as a grant or cooperative agreement—with a person who is disqualified from that transaction, unless a waiver or exception is obtained.[48] Thus, the Department established procedures to assist USDA agencies with the identification of individuals who have been disqualified from other Federal programs.[49] The SAM database, the tool USDA uses for this verification, identifies parties who have been suspended or debarred from doing new business with the Federal Government because they have committed or have been convicted of crimes including, but not limited to, kickbacks, bribery, or international fraud and corruption.[50]

Frequently, non-Government scientists work in ARS facilities assisting ARS scientists as they conduct research.[51] Therefore, ARS has to conduct a security clearance review to determine the suitability of these individuals before allowing them access to government facilities and information.[52] We evaluated ARS' security clearance process for non-Government scientists and concluded it was inadequate because ARS officials did not check SAM when completing the security clearance process. Furthermore, we attempted to verify whether non-Government scientists, specifically foreign nationals working on the nine sampled projects, had received a security clearance. However, we were unable to complete the verification, because ARS did not track non-Government scientists for any of its projects.

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[46] The General Service Administration's SAM database identifies those individuals excluded by Federal government agencies from receiving certain types of Federal financial and nonfinancial assistance and benefits, Federal contracts, or Federally-approved subcontracts.
[47] DR 2280-001, *Suspension and Debarment*, January 16, 2013.
[48] 5 C.F.R. § 919.400 (a).
[49] DR 2280-001, *Suspension and Debarment*, January 16, 2013.
[50] 2 C.F.R. §180.800–"A federal agency may debar or suspend a person for a conviction of or civil judgment stemming from the: (1) commission of fraud or a criminal offense in connection with obtaining, attempting to obtain, or performing a public or private agreement or transaction; and (2) commission of embezzlement, theft, forgery, bribery, falsification of records, making false statements, tax evasion, receiving stolen property, making false claims, or obstruction of justice."
[51] Some of these collaborators are foreign nationals, while others are United States citizens.
[52] The level of clearance is determined using a position designation tool from the Office of Personnel Management. ARS employees and non-Government scientists must pass a limited background check.

ARS Did Not Evaluate the Database for Exclusions

In our 2005 audit, we reported that ARS did not check foreign nationals for security suitability.[53] Because of this, we had concerns that ARS shared knowledge about sensitive research, which could be used by questionable individuals for illicit purposes. To correct the issue, and to comply with USDA guidance, ARS implemented a process for obtaining personal information from all non-Government scientists involved in sensitive research projects.[54,55] After evaluating ARS' procedures, we found that the security clearance process for non-Government scientists was incomplete. Although ARS staff traced the names of foreign nationals to various lists maintained by the Department of Homeland Security to determine if any terrorist connections existed, they did not check the names in SAM to determine if the individuals had been suspended or debarred.[56] We found that ARS staff who oversaw the clearance process were unaware of the requirement to check SAM.

When we elevated our concern, an ARS official stated that this requirement did not apply to ARS, as research was considered a different class of business relationship. We noted that ARS management made the same point when OIG conducted its audit of USDA's Suspension and Debarment program in 2010.[57] During that audit, ARS shared with OIG a copy of a memorandum submitted to the Department conveying its decision to exclude from suspension and debarment authorities any of its "memoranda of understanding, research support agreements, trust fund cooperative agreements, reimbursable cooperative agreements, cooperative research and development agreements, and any transaction determined by the ARS Administrator to be exempt."[58] However, our review found that the new Departmental Regulation required managers to ensure that SAM be checked for suspended or debarred individuals, including those participating in grants, cooperative agreements, scholarships, fellowships, and contracts of assistance.[59] Therefore, we concluded ARS should have reviewed SAM when conducting its security clearance review for non-Government scientists.

[53] Audit 02601-0001-Ch, *Adequacy of ARS Controls to Prevent the Improper Transfer of Sensitive Technology,* September 2005.
[54] DR 4620-002, "Common Identification Standard for United States Department of Agriculture Employees and Contractors," January 14, 2009.
[55] Employment of Foreign Nationals Guide, Version 3, March 2012.
[56] 5 C.F.R. §919.120 states that "(a) the debarring Official may grant an exception permitting an excluded person to participate in a particular covered transaction; the exception must be in writing and state the reason(s) for deviating from the Government wide policy."
[57] Audit 50601-14-At, *Effectiveness and Enforcement of Suspension and Debarment Regulations in the USDA*, August 2010.
[58] Memorandum: Non-procurement Debarment and Suspension, March 30, 1990.
[59] DR 2280-001, *Suspension and Debarment*, January 16, 2013.

ARS Does Not Track All Non-Government Scientists

After evaluating the adequacy of ARS' security clearance process, we attempted to confirm that it had conducted a limited background check for all non-Government scientists in the nine sampled research projects. However, we could not complete the confirmation because ARS did not track non-Government scientists for each of its research projects.[60]

We requested a list of all non-Government scientists involved in the nine projects; however, ARS officials stated that they did not maintain a list. We then attempted to identify project participants by reviewing documents at the laboratories, but discovered that a complete list was not maintained at that level either. At the suggestion of one scientist, we checked the documents submitted to the Institutional Biosafety Committee.[61] However, we only found information for six of the nine sampled projects because submissions to the Committee were only required for projects using select agents or recombinant DNA.[62] Moreover, we could not rely on those documents because scientists stated that they occasionally forgot to include all participants and we could not verify if the names listed were correct and complete.

We asked ARS officials why this information was not available, since in our prior audit we had recommended that ARS maintain a list of all participating non-Government scientists and ARS agreed to do so.[63] Program officials stated that they did not need this type of information because scientists knew who collaborated on their projects, and officials could use the project's list of authors and co-authors if there was an inquiry. However, after reviewing a sample, we concluded the list of authors and co-authors was not a complete record of participants. Conversations with scientists revealed that not all work performed is included in publications, which meant that non-Government scientists' names may not make it to the list of authors.[64]

ARS officials also stated that tracking was not needed because access to their facilities and information was only allowed when the participants had a security clearance. Although we agree that a proper security clearance is necessary for access to research information, we do not believe this sole control sufficiently protects ARS' research, or minimizes the risk of its misuse. Adequate tracking and oversight of non-Government scientists helps minimize this risk. At this time, if unpublished and potentially threatening research information were released, ARS would be unable to quickly identify all parties with access to the information. When presented with this

[60] Based on the information we were able to gather, ARS had at least 170 non-Government scientists collaborating in the nine research projects sampled.

[61] Information submitted to the Institutional Biosafety Committee is intended to inform the committee of the training and background of the investigators and key personnel involved in a research project. The document indicates the key personnel involved, including name, highest degree, specific duties on project, training and experience, and whether the participant's duties involve infectious agents and/or recombinant DNA. However, the information does not necessarily indicate the participant's legal name or country of origin.

[62] We could not rely on the documentation provided for the six research projects because we could not confirm we had received copies of all documents submitted to the committee.

[63] On November 7, 2013, to complete final action on the audit recommendation, ARS presented a copy of a report issued and used to track the visits of non-Government scientists.

[64] An ARS scientist told us the results of experiments may be documented in lab notebooks; however, results may not be published if the experiments are a failure and/or the controls did not perform as expected.

concern, program officials stated that their data are open and published, and they were not worried about misuse because ARS research did not involve national security matters. Based on our review of research objectives for the nine sampled projects, we agree that release of current ARS research activities might not have an immediate impact on national security. However, as stated in DURC policy, the dynamic nature of science can yield unexpected results and security concerns may change with time. Because of this, and because ARS conducts research with select agents listed in the DURC policy, the agency should have controls in place that would allow it to properly manage and oversee the release of technology and allow the agency to identify and manage an inappropriate release, if it were to happen.

Recommendation 13

Incorporate into policy the required use of the System for Award Management (SAM) to ensure non-Government scientists required to have security clearances have not been suspended or debarred from any government program, and obtain written approval from ARS' Administrator for any deviations.

Agency Response

In its February 3, 2016, response, ARS stated:

> Per current Federal policy, all non-Government scientists who enter into an agreement with ARS are checked in SAM to verify whether an organization has been debarred from doing business from the Federal Government prior to entering into an agreement with them. Non-Government scientists that visit ARS laboratories generally do not enter into an agreement with ARS and they may not have an Employer Identification Number (EIN) or Taxpayer Identification Number (TIN). Without having an EIN or TIN for a non-Government scientist it is not possible to search the SAM database.

OIG Position

We accept management decision for this recommendation.

Recommendation 14

Maintain a list of all non-Government scientists that participate in ARS research projects with DURC potential.

Agency Response

In its February 3, 2016, response, ARS stated:

> ARS will maintain a list of all non-Government scientists that participate in ARS research projects that conduct research with any of the 15 agents identified in the DURC guidelines. This process will be included in the DURC P&P. The DURC P&P will be developed by April 30, 2016, and implemented by October 31, 2016.

OIG Position

We accept management decision for this recommendation.

Recommendation 15

Identify foreign nationals that are currently participating in projects involving select agents listed in the DURC policy. Verify names in SAM, confirm whether a security clearance was issued when the person started working with ARS, and document instances when a clearance was not granted.

Agency Response

In its February 3, 2016, response, ARS stated:

> As noted in the ARS response to recommendation 13, ARS checks SAM prior to entering into any grant, cooperative agreement, or contract. Foreign nationals that visit ARS laboratories generally do not enter into an agreement with ARS and they may not have an EIN or TIN. Without having an EIN or TIN for a foreign national it is not possible to search the SAM database.

OIG Position

We accept management decision for this recommendation.

Recommendation 16

Confirm that non-Government scientists, currently assisting in projects with select agents listed in the DURC policy, have not been listed in SAM as suspended or debarred. Any exceptions must be properly documented and approved in writing by the agency's Administrator.

Agency Response

In its February 3, 2016, response, ARS stated:

> Non-Government scientists that visit ARS laboratories may not have an EIN or TIN. Without having an EIN or TIN for a non-Government scientist it is not possible to search the SAM database.

OIG Position

We accept management decision for this recommendation.

Finding 4: ARS Needs to Strengthen Controls over the Deemed Export Licensing Process

ARS scientists regularly shared with foreign nationals copies of notes and electronic records regarding research, without tracking what information was released or verifying that the project was exempted from a deemed export license.[65] Although ARS had adequate policies and procedures to meet the deemed export licensing requirements, formal training had not been provided to its scientists. In addition, ARS did not conduct periodic reviews to ensure staff complied with the agency's procedures.[66] This increases the risk that foreign nationals could release information without ARS' knowledge and ultimately share this information with unauthorized parties who could then exploit the information.

The Department of Commerce issued Export Administration Regulations to control the release of technology to foreign nationals. Export Administration Regulations allow the release of technology and software to foreign nationals if it is "basic and applied research in science and engineering, where the resulting information is ordinarily published and shared broadly within the scientific community."

ARS Scientists Are Unfamiliar with the Agency's Procedures for Releasing Information to Foreign Nationals

We determined that ARS policies and procedures met export requirements. However, scientists were unfamiliar with the rules—even though they routinely released information to foreign nationals—because they had not been trained. We asked ARS how the procedures were shared with staff and were provided the training material used. This material related to other technology transfer agreements ARS used, none of which addressed deemed export license requirements. Therefore, information released to foreign nationals had not been properly reviewed because scientists were unfamiliar with the deemed export license requirements and ARS had not enforced the export requirements.

In 2005, we reported that ARS scientists routinely shared technology with foreign nationals, including some from countries of concern, and that ARS had not applied for deemed export licenses.[67] At that time, we recommended that ARS implement policy and procedures for submitting deemed export applications. In response to this recommendation, ARS developed a flowchart that allowed its scientists to determine if a deemed export license was required before releasing any technology to a foreign national. However, ARS' efforts were insufficient because the information was not properly shared with staff and procedures were not enforced. ARS had

[65] Export Administration Regulations, 15 C.F.R. 734.2.
[66] The DURC policy establishes regular review of government funded or conducted research with certain high-consequence pathogens and toxins for its potential to be DURC, in order to mitigate risks where appropriate. The mitigating measures would minimize, to the maximum extent possible, adverse impact on legitimate research; for example, they could address how to communicate the research responsibly by determining the venue and mode of communication—addressing content, timing, and possibly the extent of distribution of the information.
[67] Countries of concern are designated by the Department of State and are countries with which only certain information is to be shared.

not applied for a deemed export license because officials understood their research was exempted.

ARS Does Not Track the Release of Information to Foreign Nationals

We could not determine if ARS appropriately released technology for the nine sampled projects because scientists did not keep records of what was shared with the foreign nationals. Before releasing a scientist from a project, laboratory staff used an exit checklist to document the return of ARS-issued property, such as identification cards and travel credit cards. However, the exit checklist did not require laboratory staff to review and assess the information taken by foreign nationals. An ARS official stated ARS did not track what was shared with foreign nationals because foreign nationals were not allowed to remove information except during the manuscript drafting process.[68] We believe there should be records of any information released to foreign nationals to reduce the risk of information being taken without ARS' authorization. ARS officials shared concerns that tracking would not cover those individuals who may still attempt to take unauthorized items, but acknowledged that a process may be needed. We concluded that regular tracking of information released to foreign nationals could minimize the likelihood of these individuals taking unauthorized items.

ARS Did Not Regularly Review Research to Assess the Need for Deemed Export Licenses

In addition, we checked whether ARS had procedures requiring the periodic review of research projects since project deviations or research results may require agencies to adopt mitigating measures that could prevent the release of information and require a deemed export license. An ARS official stated the agency did not conduct such reviews, because ARS was not conducting research covered by DURC policy and if a mitigating plan was needed, it would have been established at the time of project approval. Our review of documentation for the nine sampled projects confirmed ARS was not conducting research covered by DURC policy and had not enacted any measures that could restrict the release of information. However, we concluded that periodic reviews of ARS' active projects were needed to ensure the projects had not changed, thus requiring a deemed export license.[69]

When we raised this concern, an ARS official stated that ARS did not need to determine whether a deemed export license was required because their projects are designed for publication, which exempts the agency from needing the licenses. We disagree with ARS' assertion. Although our review of active projects did not disclose any publication restrictions, DURC policy states that "life sciences research is by nature dynamic and can produce unanticipated results," thus ARS would be expected to periodically review its research. Changing conditions could result in

[68] An ARS official also stated that ARS had not established procedures to track information because these foreign nationals would have received a security clearance prior to being allowed access to ARS facilities and were considered trustworthy.

[69] Since ARS used funds from other Federal agencies to accomplish its research, we also verified whether there were any limitations imposed from those organizations that could affect ARS' ability to publish. Our review of nine ARS research projects disclosed that five received funds from other Federal agencies such as the Department of State, the Department of Defense, and the Department of Homeland Security; however, we did not identify any restrictions.

officials establishing measures impacting how results are released. Since the exemption from the requirement for a deemed export license is connected to the agency's ability to publish results, we concluded that ARS should have procedures in place to ensure that a project's exemption is still valid.

We recognize, as ARS officials stated, that ARS conducts research with the intention of sharing information among the scientific community, including foreign nationals. However, such exchanges need to be performed in ways that minimize the unauthorized release of information. ARS officials need to establish and strengthen controls to ensure information is not inadvertently or inappropriately released to foreign nationals.

Recommendation 17

Provide deemed export license training to all staff responsible for overseeing the exit checklist used when foreign nationals complete their work.

Agency Response

In its February 3, 2016, response, ARS stated:

> ARS has an in-house expert on deemed export licenses and will provide training to all staff responsible for overseeing the exit checklist used when foreign nationals conduct research on any of the 15 agents identified in the DURC guidelines. ARS will provide deemed export training by June 30, 2016.

OIG Position

We accept management decision for this recommendation.

Recommendation 18

Develop and implement a process to periodically review projects, designated as potential DURC research projects, to determine whether recent developments in the research project or environment would preclude scientists from publishing results and require deemed export licenses when information is released to foreign nationals.

Agency Response

In its February 3, 2016, response, ARS stated:

> The DURC P&P will incorporate this recommendation. The DURC P&P will be developed by April 30, 2016, and implemented by October 31, 2016.

OIG Position

We accept management decision for this recommendation.

Recommendation 19

Implement procedures and enhance the exit checklist to require foreign nationals to provide a detailed description of information they will take back to their countries, as well as an explanation for taking the information. In addition, ARS needs to determine if its exemptions are still valid, or if a deemed export license is required, prior to releasing any information.

Agency Response

In its February 3, 2016, response, ARS stated:

> ARS is just starting a significant Process Improvement Project on processing foreign national visitors into our labs, and will include this recommendation in the new business process. Target completion date is October 31, 2016.

OIG Position

We accept management decision for this recommendation.

Finding 5: ARS Needs to Strengthen Controls Over Its Publication Process

ARS management could not demonstrate that the 38 manuscripts in our sample had been properly reviewed and approved using ARS-115, "Request to Submit Manuscript for Publication."[70] The form did not include a complete record of the review and approval progression because ARS management did not see the need to have this information on the ARS-115 for review purposes. As such, ARS research results may be released without management's knowledge and approval.

ARS requires its scientists to publish at least two research manuscripts annually. Per agency guidance, scientists are required to submit ARS-115 through ARIS when publishing or presenting any research outside the agency. ARS-115 is used to track the review and approval of publications or presentations prior to release. In addition, according to the ARIS handbook, when a publication or presentation is identified as a prominent issue, or is associated with a research project that uses DURC policy select agents, that publication must be reviewed and approved by the area office and ONP.[71] In contrast, if the manuscript does not have any such designation, its review and approval is limited to the research leader and/or center director.[72]

As a part of our analysis of nine research projects, we tried to verify whether the 38 manuscripts were reviewed and approved in accordance with agency policy prior to publication. We evaluated the ARS-115 forms to determine who had reviewed and approved the forms, and when those actions occurred. We found that the approval date on all 38 forms preceded the date of review. For example, one ARS-115 form showed that the manuscript was approved on October 28, 2011, even though the date of review was August 07, 2012, 284 days after approval. In addition, we found 21 forms that included prominent issues, such as significant scientific advancements, or were associated with projects using select agents listed in the DURC policy, that were only reviewed by the research leader. The forms should have also shown that the manuscripts had been reviewed and approved by the area office and ONP.

When we asked ARS to explain these discrepancies, ARS informed us that the manuscripts had been properly reviewed before release, even though the related ARS-115s showed an approval date prior to the date of review.[73] An ARS official explained that each time the form was

[70] OIG selected 38 manuscripts out of 111 published during the period of our audit. The manuscripts were prepared for the nine research projects in our sample.
[71] ARIS Handbook Chapter 5 defines "Prominent Issues" as "research findings and interpretations related to hot topics and/or other special interest topics that are prominently visible to the general public, agriculture, and/or scientific communities." These issues are identified on the form as research that: potentially will attract media interest/attention; represents a significant scientific advancement; significantly affects existing or future policy; will have potential trade implications; or other.
[72] ARIS Handbook, Chapter 5—ARS-115 Publication Approval—"Approval of ARS-115s," dated February 2014.
[73] ARS did not retain any documentation outside of ARIS; therefore, we could not verify if review and approvals were conducted properly.

updated in ARIS, the reviewer and the original date of review were overridden.[74] Therefore, the form reflected the most recent reviewer data, while the approval date remained the same. The official stated that the ARS-115 was updated frequently after the manuscript was initially approved. For example, the form could be modified to reflect the date the manuscript was published or to add the publication citation.[75]

An ARS official stated that, even though the ARS-115 forms did not depict the progression and history of review and approval for each manuscript, the ARIS database retained that data.[76] Since the review and approval progression would allow ARS to validate that manuscripts were reviewed in accordance to policy, we asked an ARS official why this information was overridden and the history not recorded on the ARS-115. The official informed us that the agency did not have a need to add this information to the ARS-115 and review it regularly.[77] We concluded that ARS' position[78] is not consistent with Federal standards that require managers to establish control activities that ensure management directives are carried out, because ARS managers did not conduct periodic checks to ensure that publications were reviewed and approved as established in ARS policy.[79]

Although we did not find any manuscripts that had been released without ARS' knowledge, we determined ARS' management should have periodically validated that the ARS-115 forms were reviewed and approved in accordance with agency policy. This review would ensure that research results could be released, and that the information included could not be misused for harmful purposes.[80] This is important for all manuscripts released by ARS scientists, and especially for those research projects involving prominent issues, using select agents, or covered

[74] Our review of the ARIS Handbook disclosed that modification of the form ARS-115 may be needed at different times during the publication process. It allows for certain modifications to be made without approval from above the research leader level. These included: (1) date submitted to journal; (2) acceptance date; (3) publication date; (4) citation; (5) remarks; (6) repository uniform resource locator; and (7) volume and page. If modifications are made to any other field besides the seven identified in the ARIS handbook, the form ARS-115 would automatically be required to be reviewed and approved by all levels within ARS.

[75] ARIS Handbook, Chapter 5—ARS-115 Publication Approval—"Modifying ARS-115s," states that many fields on form ARS 115, such as date submitted to journal and acceptance date, were completed at different times, and that ARIS required them to be completed in a sequential order.

[76] We asked ARS to provide the history for 2 of the 38 ARS-115 forms reviewed to ensure the information was being retained in the system as required. Officials queried the system and confirmed that the review and approvals were performed as required by ARS policy. However, since the information was presented within the text of an email, we could not confirm that it was extracted from ARIS.

[77] Nonetheless, ARS acknowledged and we confirmed that this information was included on other forms generated by ARIS.

[78] Our review of the ARIS Handbook disclosed that it does not state that reviews need to be conducted. It only describes how to complete forms within the data system.

[79] According to the United States Government Accountability Office's "Standards for Internal Control in the Federal Government," dated November 1999, control activities are the policies, procedures, techniques, and mechanisms that enforce management's directives to achieve the entity's objectives and address related risks.

[80] The DURC policy states that despite its value and benefits, some research may provide knowledge, information, products, or technologies that could be misused for harmful purposes. As such, measures that mitigate the risks of DURC should be applied, where appropriate, in a manner that minimizes, to the extent possible, adverse impact on legitimate research. The policy requires regularly reviewing, at the institutional level, emerging research findings for additional DURC.

by DURC policy. Those manuscripts may contain information that could be used for harmful purposes if inadvertently released.[81] The lack of an actual review and approval progression on the ARS-115 hinders ARS' capacity to implement this control.

Recommendation 20

Create an additional query in ARIS to ensure that the ARS-115 includes all historical approval data.

Agency Response

In its February 3, 2016, response, ARS stated:

> The new DURC P&P will document the approval process for publications of research conducted with any of the 15 designated agents and the process will require signatures by the Research Leader and Area Office before approval by the NPL. The NPL will be provided the former approval information by line management. The ARS-115 approval data exists in ARIS and can be retrieved as needed. The DURC P&P will be developed by April 30, 2016 and implemented by October 31, 2016.

OIG Position

We accept management decision for this recommendation.

Recommendation 21

Conduct periodic reviews of the ARS-115s to ensure manuscripts are properly reviewed and approved prior to releasing research information to the public.

Agency Response

In its February 3, 2016, response, ARS stated:

> The new DURC P&P will document the approval process for the ARS-115 and will also document that the manuscript will be submitted to the ONP with the ARS-115. The P&P will also document that if any modifications are made to the manuscript, other than minor typographical changes, during the Journal submission and acceptance process then the revised manuscript will need to be re-reviewed by the ONP. The DURC P&P will be developed by April 30, 2016, and implemented by October 31, 2016.

[81] The DURC policy states the fundamental aim of agency oversight is to preserve the benefits of life sciences research while minimizing the risk of misuse of the knowledge, information, products, or technologies provided by such research.

OIG Position

We accept management decision for this recommendation.

Scope and Methodology

We conducted our audit at ARS' national office located in Beltsville, Maryland, and at three area office research facilities located in Wyndmoor, Pennsylvania; Athens, Georgia; and Beltsville, Maryland. We also conducted work at 3 of ARS' 262 laboratories that we selected non-statistically. We selected two of the laboratories because they were conducting six of the nine active "in-house" research projects that involved select agents. We selected the third laboratory because it was conducting the largest number of active "in-house" research projects that did not involve select agents. The laboratories were located in Orient Point, New York; Athens, Georgia; and Beltsville, Maryland. We assessed a non-statistical sample of ARS' 735 "in-house" research projects that were active as of April 4, 2014, and reviewed manuscripts issued for those projects in fiscal years (FY) 2012 and 2013.[82] We conducted field work from March 2014 through July 2015.

We reviewed the laws, regulations, and guidance that explained how ARS should approve and manage its research projects to gain an understanding of ARS' process. Specifically, we evaluated those related to the: implementation of DURC policy; management of select agents; safeguarding and dissemination of controlled unclassified information; administration of security clearances for non-Government scientists; and the release and exchange of information to scientific collaborators[83] using agreements or grants.

In addition, we reviewed prior OIG Audit Report 02601-0001-Ch, *Adequacy of Controls to Prevent the Improper Transfer of Sensitive Technology*, dated September 2005, to identify corrective actions ARS agreed to implement as a result of recommendations issued, and to determine if it had implemented the appropriate and agreed upon corrective actions.

We performed the following steps to accomplish our objectives:

- Determined whether ARS had adequate and sufficient controls in place to manage the release of research information considered Controlled Unclassified Information (CUI) or that involved select agents, especially when these were identified in the DURC policy.
- Selected a non-statistical sample of 9 active "in-house" research projects out of 735 to determine how ARS had evaluated, approved, and managed the projects. Six of the nine projects represented all of the projects being managed at two of four laboratories conducting research with select agents.[84] Three projects were selected non-statistically from the laboratory not using select agents in its research. We made our selection by dividing the total number of projects the laboratory managed by the total number of projects we were reviewing at each office.[85]

[82] ARS had 735 active Congressionally funded (or "in-house") research projects and 3,866 active subordinate (or "sibling") projects as of April 4, 2014.
[83] Collaborators are external scientific parties that work with ARS to conduct research. The collaborators can be foreign or domestic scientists.
[84] Each was conducting three research projects using select agents.
[85] The laboratory had 112 current active projects; we divided this number by the 3 projects we were going to review and selected every 37th project on the list.

- Reviewed and analyzed documentation for the nine projects selected to determine whether ARS complied with its policy and procedures. The documentation included research proposals, executive summaries, and any annual reports prepared after the research was approved.[86]
- Assessed documentation related to the 91 sibling projects connected to the 9 projects selected for review. Specifically, we reviewed documentation for these projects to determine if scientists used select agents, or if the work could be considered DURC, to ensure ARS had properly applied DURC policy. In addition, we determined the relevance of the research and its relation to the main research project. Likewise, we verified the type of information sibling projects were allowed to release as a result of research conducted, and determined if any exchange or release limitations were being imposed through the agreements.
- Assessed the information released in 38 of 111 manuscripts published in fiscal years (FYs) 2012 and 2013 for the 9 projects sampled. Our goal was to evaluate five manuscripts per project. For three of the projects, we reviewed all manuscripts issued during the period as there were less than five issued in total.[87] For six of the projects, we selected five manuscripts non-statistically. We selected the manuscripts by dividing the total number of approved manuscripts listed in the annual reports for the two fiscal years by the total number of manuscripts available for review (five).[88]
- Interviewed ARS national and area officials, as well as scientists and other staff in the laboratory offices, to assess how ARS implemented controls over the program.

During the course of our audit, we identified and assessed all applicable information technology (IT) systems employed by ARS to determine if any had policies, procedures, or controls related to our objective of assessing ARS' policies and procedures for identifying, approving, and monitoring sensitive or dual-use research. We also interviewed ARS officials to obtain additional clarification regarding the implementation and use of IT systems.[89] We used the ARIS data to perform our analysis of nine non-statistically selected research projects. Our efforts focused on providing reasonable assurance that ARIS data did not contain significant errors, which would undermine the credibility of our analyses and conclusions. However, we did not review, analyze, or verify the system's general and application controls.

We conducted our audit in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient and appropriate evidence to provide a reasonable basis for our findings and conclusions based on our objectives.

[86] ARS prepared annual reports for FYs 2012 and 2013. The reports discuss the milestones met, objectives reached, approaches used, and manuscripts published during the period of our audit.
[87] We reviewed the two manuscripts issued in one project and reviewed the three manuscripts issued in two other projects.
[88] The annual reports listed a log number for each Form ARS-115, "Request to Submit Manuscript for Publication," approved during the period. These forms are used to review and approve the release of manuscripts to scientific journals or other publications.
[89] We evaluated ARS' ARIS, which is the agency's key program management system used to administer research projects.

We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

Abbreviations

ARIS..... Agricultural Research Information System
ARS..... Agricultural Research Service
ARS-115..... ARS-115 "Request to Submit Manuscript for Publication"
CUI..... Controlled Unclassified Information
DR..... Departmental Regulation
DURC..... Dual-Use Research of Concern
FY..... fiscal year
IT..... information technology
NIH..... National Institutes of Health
NRC..... National Research Council of the National Academies
OGC..... Office of the General Counsel
ONP..... Office of National Programs
OSQR..... Office of Scientific Quality Review
OCIO..... Office of the Chief Information Officer
SSI..... Sensitive Security Information
SAM..... System for Award Management
USDA..... Department of Agriculture

Exhibit A: Analysis of Implementation of Recommendations in Audit Report 02601-0001-Ch

2005 Recommendation 1 Formalize in agency policies and procedures the criteria for identifying dual-use projects when it is issued by the Board; or seek guidance from other authoritative sources, such as the Office of Science and Technology Policy.	
ARS Response	**OIG Conclusion**
ARS agreed to develop policies and procedures adopting the Board's recommendations when issued. In the interim, ARS agreed to issue a memorandum to provide guidance on procedures for the review and monitoring of sensitive research projects which qualify as "experiments of concern," as defined by the National Research Council of the National Academies (NRC).	ARS issued a memo on January 12, 2006, which defined dual-use research, but did not adopt the Board's recommendations into its official policy when the Board issued the Government-wide policy in May 2012. (See Finding 1.)

2005 Recommendation 2 Until the Board develops criteria, establish policies and procedures to identify dual-use research using the NRC criteria; or, alternatively, consider all research projects involving select agents as candidates for the dual-use designation.	
ARS Response	**OIG Conclusion**
ARS agreed to use interim criteria to define and identify sensitive research projects. The interim criteria would be based upon the seven classes of experiments involving infectious agents and their products, defined as "experiments of concern" by the NRC.	ARS issued a memo on January 12, 2006, implementing interim guidelines. However, ARS did not issue an official policy when the Board issued the Government-wide policy in May 2012. (See Finding 1.)

2005 Recommendation 3 Develop procedures to evaluate the potential risks of dual-use research projects as part of the approval process, including whether pre-publication review of research results is appropriate.	
ARS Response	**OIG Conclusion**
ARS agreed to issue a memorandum to provide guidance on procedures to review and monitor sensitive research projects which qualify as "experiments of concern" under the interim criteria described in Recommendation 2; and agreed to develop procedures based on the Board's recommendations.	ARS issued a memo on January 12, 2006, implementing interim guidelines. However, ARS did not formally incorporate the procedures into the agency's policies and did not perform DURC risk assessments when evaluating all research proposals as of July 2015. (See Findings 1 and 2.)

2005 Recommendation 4 Require ARS scientists working on dual-use projects to immediately report any significant events or deviations from the approved objectives to headquarters, which should verify the reports and reevaluate the projects as necessary.	
ARS Response	**OIG Conclusion**
ARS agreed that research leaders and scientists must notify their area director and the National Program staff when they propose any change in an approved project plan.	ARS issued a memo on January 12, 2006, implementing interim guidelines requiring its research leaders and scientists to notify their area director and the National Program staff when they proposed any changes to an approved project plan. However, ARS did not formally incorporate deviation requirement procedures into the agency's policies. Moreover, the agency could not provide evidence that deviations were properly approved. (See Finding 2.)

2005 Recommendation 5 Develop monitoring procedures for dual-use projects, and ensure that they reflect the Board's guidance, when issued.	
ARS Response	**OIG Conclusion**
ARS agreed to have line management and the National Program Staff develop procedures which reflect the Board's guidance upon issuance.	ARS issued a memo on January 12, 2006, which stated that all new research projects would be routinely and systematically reviewed by National Program staff. However, we found the process was not formally incorporated into its policies and that ARS did not conduct DURC risk assessments when evaluating research proposals. (See Findings 1 and 2.)

2005 Recommendation 6 Develop policy and procedures for obtaining personal information from all non-Government scientists involved in sensitive research projects in order to perform security suitability determinations.	
ARS Response	**OIG Conclusion**
ARS agreed to work with the Office of the General Counsel (OGC) to develop the most effective and appropriate approach for obtaining personal information for all non-government scientists working on sensitive research projects as defined by ARS interim guidance.	We found that ARS was performing security suitability reviews of non-government scientists. However, we determined the review was incomplete as ARS staff did not verify whether participants had committed or had been convicted of crimes against the Federal Government. (See Finding 3.)

2005 Recommendation 7 Maintain a list of all participating non-Government scientists for each sensitive research project.	
ARS Response	**OIG Conclusion**
ARS agreed to develop a centralized system, with management oversight, to maintain and periodically review a roster of all non-government scientists working on sensitive research projects defined by ARS interim guidance.	Although ARS presented a list of non-government scientists to OCFO for Final Action, the list was not maintained for any period until after February 2011. Furthermore, ARS was unable to provide a list of all non-Government scientists for the nine sampled projects. (See Finding 3.)

2005 Recommendation 8 Develop and implement policy and procedures for establishing, based on risk factors, appropriate security suitability determinations for all non-Government scientists involved in sensitive research projects.	
ARS Response	**OIG Conclusion**
ARS agreed to develop policies and procedures to address both the risk factors and the appropriate security suitability requirements for non-government scientists involved in sensitive research projects defined by ARS interim guidance. These procedures would be reviewed by OGC.	ARS followed USDA Departmental Manual 4620-002 when determining security suitability of all non-Government scientists involved in research projects. However, we determined the review was incomplete as ARS staff did not verify whether participants had committed or had been convicted of crimes against the Federal Government. (See Finding 3.)

2005 Recommendation 9 Remove from the Internet all information regarding select agents, the names of individuals authorized to use them, and the location where they could be found.	
ARS Response	**OIG Conclusion**
ARS agreed to remove information on select agent research from the Internet if required by OGC guidance and the Board's guidance.	We found information was not removed from the Internet because OGC guidance and government-wide DURC policy, issued by the Board, did not require it. However, the DURC policy requires agencies to conduct risk assessments to determine if mitigating measures, such as those used to communicate research, were required. We found ARS was not conducting these assessments when evaluating all research proposals. (See Finding 2.)

2005 Recommendation 10 Develop criteria for identifying SSI and implement procedures to ensure this information is not included on the Internet.	
ARS Response	**OIG Conclusion**
ARS agreed to develop criteria for identifying SSI and implement procedures to ensure that SSI is not included on the Internet, if required by OGC guidance and the Board's guidance.	We found that the DURC policy did not discuss SSI, but required risk assessments to determine if mitigating measures were required. We concluded ARS was not conducting these assessments. (See Finding 2.) In addition, we found Executive Order 13556 required agencies to define CUI to ensure proper safeguarding and dissemination of such information. However, ARS had not defined CUI in its policy. (See Finding 1.)

2005 Recommendation 11 Implement policy and procedures for submitting deemed export applications to DOC prior to initiating dual-use research projects, and projects with controlled information, involving foreign nationals[90] working either in an ARS facility or from another location.	
ARS Response	**OIG Conclusion**
ARS agreed to develop policy and procedures on deemed export licenses. The agency agreed to update guidance when final deemed export requirements were issued.	We found ARS established policies and procedures on how to handle deemed export licenses. However, ARS staff was unfamiliar with the licensing process due to lack of training. Moreover, ARS lacked procedures to monitor and track the information taken by foreign nationals when they returned to their countries. (See Finding 4.)

[90] Audit 02601-0001-Ch, *The Adequacy of ARS Controls to Prevent the Improper Transfer of Sensitive Technology,* September 2005, used the term "foreign scientist" to describe foreign nationals.

AGRICULTURAL RESEARCH SERVICE'S RESPONSE TO AUDIT REPORT

SUBJECT: Adequacy of Controls to Prevent the Release of Sensitive Technology

TO: Gil H. Harden
Assistant Inspector General for Audit
Office of the Inspector General

Jon M. Holladay
Chief Financial Officer
Office of the Chief Financial Officer

FROM: Lisa A. Baldus /s/
Associate Deputy Administrator

The Agricultural Research Service (ARS) appreciates the thoughtful recommendations in Audit Report 02601-0001-21- Adequacy of Controls to Prevent the Release of Sensitive Technology related to research with dual-use applications. As was done in response to the Office of Inspector General's (OIG) 2005 audit, including ARS' establishment of processes for the oversight of Dual Use Research (DUR), ARS looks forward to quickly implementing many of the recommendations in the report. The following are ARS' specific responses to audit Recommendations 1-21.

Finding 1: ARS Needs to Strengthen Its Overall Internal Control Structure

Recommendation 1
Communicate to research staff, via memorandum, the importance of establishing strong internal controls, and the impact research results are likely to have on public perception and national security.

ARS Response:
ARS is preparing a new Dual-Use Research of Concern (DURC) policy and procedure (P&P), to be drafted within 90 days and finalized within 120 days of the issuance of the final report. Using the publication of the DURC P&P as a launch point, the Administrator of ARS will issue a memo to all scientific staff emphasizing the importance of establishing strong internal controls and the impact research results are likely to have on public perception and national security. ARS will develop the DURC P&P by April 30, 2016 and implement the P&P by October 31, 2016. The Administrator will issue the memo by May 31, 2016.

Recommendation 2
Incorporate into ARS policy the Federal policy on identifying, evaluating, approving, and monitoring DURC results in research projects.

ARS Response:
The DURC P&P will incorporate Federal policy as recommended. The DURC P&P will be developed by April 30, 2016 and implemented by October 31, 2016.

Recommendation 3
Until final Departmental guidance is available regarding the control and protection of information, expand the current publication process to include select agent projects as a prominent issue.

ARS Response:
ARS is preparing the new DURC P&P and it will document that research conducted with any of the 15 designated agents identified as potential DURC will require approval by the Office of National Programs (ONP). The DURC P&P will be developed by April 30, 2016 and implemented by October 31, 2016.

Recommendation 4
Coordinate with the Department the issuance of ARS policy, regarding the control and protection of information that fulfills latest requirements in this area. This policy should state clearly whether research projects will require a specific designation. In addition, the policy should state whether any controls will be implemented to control or protect research information prior to release.

ARS Response:
The DURC P&P will provide oversight on how all research conducted with the 15 agents identified in the US Government DURC guidelines will be reviewed as DURC within the agency. ARS complies with DURC reviews at the Department level as organized by the Department of Agriculture (USDA) Biosafety/Biosecurity Policy Committee (BBPC). The BBPC is co-chaired by the Directors of the Office of the Chief Scientist and the Office of Homeland Security and Emergency Coordination. In addition, the Office of the Chief Information Officer is working with the National Archives and Records Administration to solidify definitions and criteria surrounding "Controlled Unclassified Information" in accordance with E.O. 13556, Controlled Unclassified Information. ARS will apply the USDA guidelines/policy to research once the guidelines/policy are developed, as appropriate. If the guidance isn't available by publication of the new DURC P&P, we will revise the P&P once the guidance is revealed, as necessary. The DURC P&P will be developed by April 30, 2016 and implemented by October 31, 2016 and the P&P will state which research projects require the potential DURC research designation. ARS will apply, as appropriate, the USDA controlled unclassified information guidelines after they have been finalized.

Recommendation 5
Revise the templates of the agreements used with collaborators to include formal standards for the exchange and release of research results.

ARS Response:
In its report, OIG recognized that ARS provided the required information regarding the exchange and release of research results but are objecting to its inclusion in agreement terms and conditions through reference to an ARS web page instead of direct inclusion of the full language into the agreement. OIG is concerned that collaborators may not click on the link to review the language. However, inclusion of requirements by reference is standard, accepted practice regarding agreement terms and conditions and includes references to laws, regulations, and other policies and requirements that appear in the US Code, the Code of Federal Regulations, and on agency web pages. All are legally binding and it is the collaborator's responsibility to read, understand, and comply with all such requirements – a responsibility they accept when they accept the agreement. ARS respectfully disagrees with this recommendation and prefers to follow the standard, government-wide practice.

Recommendation 6
Train more ONP staff to handle DURC assessment, oversight, and reporting.

ARS Response:
ARS will have at least two people on staff that review the experiments in DURC projects every six months as required. In addition, they oversee and discuss any potential DURC research that may occur between the biannual review processes. ARS will continue to have a National Program Leader (NPL) for Animal Health and a NPL for Food Safety that will be trained to evaluate experiments for DURC and as a backup person, the ARS Biosafety Officer. ARS ONP will have at least two people on staff that will review potential DURC projects by February 29, 2016.

Recommendation 7
Establish a process to ensure interim corrective actions are integrated into official ARS policies, directives, or manuals.

ARS Response:
ARS will update the DURC P&P when US Government guidelines are modified. Once the DURC P&P is complete, it will be reviewed on a periodic basis and revised as required by new policy and directives. The DURC P&P will be developed by April 30, 2016 and implemented by October 31, 2016.

Recommendation 8
Develop a process to promptly incorporate future changes in laws or regulations, especially those related to DURC policy that affect the release of information and technology into official ARS' policies, directives, or manuals.

ARS Response:
Once the DURC P&P is complete, it will be reviewed on a periodic basis and revised as required by new policy and directives. The DURC P&P will be developed by April 30, 2016 and implemented by October 31, 2016.

Finding 2: ARS Needs to Strengthen its Evaluation and Monitoring of Research Projects

Recommendation 9
Include a DURC risk assessment when ARS evaluates each research proposal during the approval process.

ARS Response:
ARS is also drafting a P&P document providing guidance over Institutional Biological Safety Committees (IBC) throughout the Agency. In this new policy, ARS IBCs will review and approve the process and procedures used for nearly all forms of research utilizing biohazards including provisions for ARS IBC's to report any projects identified as potentially DURC (as defined in the 2014 U.S. Government Policy for Institutional Oversight of Life Sciences Dual Use Research of Concern) to the appropriate Area and National Program Staff for further DURC review. The IBC P&P will be developed by March 31, 2016 and implemented by October 31, 2016.

Recommendation 10
Track results of risk assessments for all projects in the Agricultural Research Information System (ARIS). Any project that meets DURC requirements should be identified as such in ARIS.

ARS Response:
The current Governmental policies on DURC require risk assessments to be performed if the research is deemed DURC. DURC research is defined as research with any of the 15 designated agents meeting the outlined criteria (seven effects) as designated in the official policy documents. ARS has had no research consistent with the criteria for DURC, but is prepared to perform any necessary risk assessment in the event DURC is identified. This will be covered in the DURC P&P.

The risk assessments for all potential DURC projects will be included in the project's record in the ARIS. Any project that conducts research on any of the 15 agents identified in the DURC guidelines will be identified as DURC potential research projects in ARIS. The DURC P&P will be developed by April 30, 2016 and implemented by October 31, 2016 and it will address the risk assessment process.

Recommendation 11
Develop a policy on research project deviations that defines deviations that merit close review and approval, and also specifies how the notification, evaluation, and approval of deviations from the project's objectives are to be addressed by research scientists and managers.

ARS Response:
The DURC and IBC P&Ps will implement this recommendation. Specifically the DURC P&P will document the process for training of all ARS scientists and line management to recognize a potential DURC research and submit it for review prior to conducting the research. The DURC P&P will be developed by April 30, 2016 and implemented by October 31, 2016.

Recommendation 12
Assess whether approved project deviations will result in a change of the DURC risk.

ARS Response:
The new DURC and IBC P&Ps will implement this recommendation. Any deviations in the protocols or results are to be reported to the appropriate review committee, which includes the ONP. The DURC and IBC P&P will be developed by April 30, 2016 and implemented by October 31, 2016.

Finding 3: ARS Needs to Strengthen Controls for Evaluating Non-Government Scientists

Recommendation 13
Incorporate into policy the required use of the System for Award Management (SAM) to ensure non-Government scientists required to have security clearances have not been suspended or debarred from any government program, and obtain written approval from ARS' Administrator for any deviations.

ARS Response:
Per current Federal policy, all non-Government scientists who enter into an agreement with ARS are checked in SAM to verify whether an organization has been debarred from doing business from the Federal Government prior to entering into an agreement with them. Non-Government scientists that visit ARS laboratories generally do not enter into an agreement with ARS and they may not have an Employer Identification Number (EIN) or Taxpayer Identification Number (TIN). Without having an EIN or TIN for a non-Government scientist it is not possible to search the SAM database.

Recommendation 14
Maintain a list of all non-Government scientists that participate in ARS research projects with DURC potential.

ARS Response:
ARS will maintain a list of all non-Government scientists that participate in ARS research projects that conduct research with any of the 15 agents identified in the DURC guidelines. This process will be included in the DURC P&P. The DURC P&P will be developed by April 30, 2016 and implemented by October 31, 2016.

Recommendation 15
Identify foreign nationals that are currently participating in projects involving select agents listed in the DURC policy. Verify names in SAM, confirm whether a security clearance was issued when the person started working with ARS, and document instances when a clearance was not granted.

ARS Response:
As noted in the ARS response to recommendation 13, ARS checks SAM prior to entering into any grant, cooperative agreement, or contract. Foreign nationals that visit ARS laboratories generally do not enter into an agreement with ARS and they may not have an EIN or TIN. Without having an EIN or TIN for a foreign national it is not possible to search the SAM database.

Recommendation 16
Confirm that non-Government scientists, currently assisting in projects with select agents listed in the DURC policy, have not been listed in SAM as suspended or debarred. Any exceptions must be properly documented and approved in writing by the Agency's Administrator.

ARS Response:
Non-Government scientists that visit ARS laboratories may not have an EIN or TIN. Without having an EIN or TIN for a non-Government scientist it is not possible to search the SAM database.

Finding 4: ARS Needs to Strengthen Controls over the Deemed Export Licensing Process

Recommendation 17
Provide deemed export license training to all staff responsible for overseeing the exit checklist used when foreign nationals complete their work.

ARS Response:
ARS has an in-house expert on deemed export licenses and will provide training to all staff responsible for overseeing the exit checklist used when foreign nationals conduct research on any of the 15 agents identified in the DURC guidelines. ARS will provide deemed export training by June 30, 2016.

Recommendation 18
Develop and implement a process to periodically review projects, designated as potential DURC research projects, to determine whether recent developments in the research project or environment would preclude scientists from publishing results and require deemed export licenses when information is released to foreign nationals.

ARS Response:
The DURC P&P will incorporate this recommendation. The DURC P&P will be developed by April 30, 2016 and implemented by October 31, 2016.

Recommendation 19
Implement procedures and enhance the exit checklist to require foreign nationals to provide a detailed description of information they will take back to their countries, as well as an explanation for taking the information. In addition, ARS needs to determine if its exemptions are still valid, or if a deemed export license is required, prior to releasing any information.

ARS Response:
ARS is just starting a significant Process Improvement Project on processing foreign national visitors into our labs, and will include this recommendation in the new business process. Target completion date is October 31, 2016.

Finding 5: ARS Needs to Strengthen Controls Over Its Publication Process

Recommendation 20
Create an additional query in ARIS to ensure that the ARS-115 includes all historical approval data.

ARS Response:
The new DURC P&P will document the approval process for publications of research conducted with any of the 15 designated agents and the process will require signatures by the Research Leader and Area Office before approval by the NPL. The NPL will be provided the former approval information by line management. The ARS-115 approval data exists in ARIS and can be retrieved as needed. The DURC P&P will be developed by April 30, 2016 and implemented by October 31, 2016.

Recommendation 21
Conduct periodic reviews of the ARS-115s to ensure manuscripts are properly reviewed and approved prior to releasing research information to the public.

ARS Response:
The new DURC P&P will document the approval process for the ARS-115 and will also document that the manuscript will be submitted to the ONP with the ARS-115. The P&P will also document that if any modifications are made to the manuscript, other than minor typographical changes, during the Journal submission and acceptance process then the revised manuscript will need to be re-reviewed by the ONP. The DURC P&P will be developed by April 30, 2016 and implemented by October 31, 2016.

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