



Health and Human Services (HHS) Fundamental Classification Guidance Review

June 27, 2012

In accordance with Section 1.9 of Executive Order (EO) 13526, Classified National Security Information, this report transmits the results of the initial fundamental classification review by the Department of Health and Human Services (HHS) to the Director of the Information Security Oversight Office (ISOO). The guidance in the Information Security Oversight Office Memorandum "Reporting Results of the Fundamental Classification Guidance Reviews to ISOO," dated January 23, 2012, recommends the report should at a minimum provide information concerning the following:

- The number of classification guides that were reviewed (1);
- The number of classification guides that were consolidated or cancelled (0);
- The number of projects, programs, or categories that were eliminated, revised, consolidated, or condensed, if any (0);
- The number of documents, topics, or categories that were downgraded in classification level, if any (18);
- The number of cases in which the duration of classification was modified or the number of cases in which exemptions from declassification were removed (0).

Background: On December 10, 2001, the President designated the HHS Secretary as an Original Classification Authority (OCA) for information up to the Secret level; a similar designation was made on December 29, 2009, under EO 13526. In January 2002 the HHS Secretary delegated OCA to two senior officials. In October 2011, HHS Secretary Sebelius determined that to more effectively manage the Department's classification and declassification program one additional senior position should be delegated OCA bringing the current total OCAs to four, including the Secretary and Deputy Secretary.

To ensure that HHS has strong oversight of our classification management program, the HHS Classified National Security Information Policy, which was revised in January 2012, requires each of the Department's component divisions to designate a Classification Security Officer (CSO). The federal employee who serves as the CSO is responsible for providing guidance, assistance, and oversight to their component division on the handling, sharing, safeguarding, marking, classifying, and declassifying of national security information. The CSOs also perform initial classification and declassification reviews for their divisions and forward their recommendations to the Office of Security and Strategic Information (OSSI), which serves as the functional OCA for the original classification or declassification of departmental information. Since December 2001, HHS has originally classified about 30 documents, some of which were drafts that were later destroyed when the original classified documents were completed.

Original Classification Review 2011-2012, Process and Results: The HHS classification review showed that about 75% of the originally classified documents were related to information in two HHS component divisions and focused on two subject areas.

Office of the Inspector General (OIG) Assessments: Six original classifications were OIG reports which were declassified as part of the 2011-2012 review after the OCA determined that the information contained the reports would no longer cause identifiable or describable damage to the national security.

Food and Drug Administration (FDA) Assessments: The majority of the remaining original classification decisions reviewed during 2011 and 2012 related to reports produced by the FDA, which began these assessments in 2002 and uses the outcome of the analysis to advise the food industry of improvements needed in food production and delivery to mitigate possible bioterrorism attacks using food products. These reports were originally classified at the secret level because portions of the final reports described information that could cause serious damage to the national security if it was disclosed to unauthorized individuals.

In 2007 the FDA worked with the HHS OCA to develop a classification guide. The FDA classification guide is currently the only HHS classification guide and it has a very limited focus. Only one subject matter expert uses the guide to make derivative classification decisions. To date, a total of 20 documents have been derivatively classified using this guide. The most recent report classified using the FDA guide was dated June 12, 2011.

During the 2011-12 Original Classification Review, the FDA classification guide was reviewed by a team consisting of an HHS OCA, the FDA CSO, and an FDA derivative classifier who is food safety subject matter expert. The team determined that the guide is still needed and its limited categories for classification meet EO 13526 standards. Some administrative amendments were made to the guide but it will maintain a stand-alone classification guide unless HHS determines that a department-wide classification guide is needed.

All of the FDA classified documents were reviewed and the HHS team conducting the review determined these documents need to remain classified.

Summary Conclusion: Of the few remaining HHS originally classified reports that meet EO 13526 standards for continued classification, none were downgraded in classification level during this review. The HHS classification review did not result in the modification of the duration of the classification of any of the remaining documents or the removal of any declassification exemptions.

HHS continues to tightly control the authority to originally classify information. Our comprehensive classification guidance review showed that we need to maintain our strong oversight program which relies on our trained CSOs to monitor classification decisions at the operational level. As a premier science-based department which conducts and fosters biological and life science research, HHS OCAs must continue to provide clear guidance in accordance with EO 13526 to ensure national security information is protected but basic scientific research information, not clearly related to the national security, is not classified.