This guidance specifically addresses software design and technology modifications, including firmware. This guidance does not apply to software for which the Agency has stated in guidance that it does not intend to enforce compliance with applicable regulatory controls (*e.g.,* ''Mobile Medical Applications: Guidance for Industry and FDA Staff,'' issued February 9, 2015, available on the internet at *https://www.fda.gov/downloads/medicaldevices/.../ucm263366.pdf*) and software that does not meet the definition of a medical device at section 201(h) of the FD&C Act (21 U.S.C. 321(h)).

In the **Federal Register** on August 8, 2016, FDA announced the availability of the draft guidance and interested parties were requested to comment by November 7, 2016. FDA considered comments received on the draft guidance and revised the guidance as appropriate.

This guidance is not intended to implement significant policy changes to FDA's current thinking on when submission of a new 510(k) is required for a software change to an existing device. Rather, the intent of this guidance is to enhance the predictability, consistency, and transparency of the ''when to submit'' decision-making process by providing a least burdensome approach, and describing in greater detail the regulatory framework, policies, and practices underlying such a decision, specifically as it relates to software changes. The recommendations discussed in this guidance for evaluating when a software change to an existing device would trigger the requirement that a manufacturer submit a new 510(k) to the Agency are consistent with the least burdensome principles (Refs. 1 and 2). This guidance applies the least burdensome principles, in part, by reliance on risk management and the quality system regulation (21 CFR part 820) to determine whether submission of a new 510(k) is required for a software change to an existing device.

Elsewhere in this issue of the **Federal Register**, FDA is announcing the availability of the guidance document entitled ''Deciding When to Submit a 510(k) for a Change to an Existing Device,'' to aid manufacturers of medical devices who intend to make non-software changes to an existing device during the process of deciding whether the modification exceeds the regulatory threshold of § 807.81(a)(3) for submission and clearance of a new 510(k).

II. Significance of Guidance

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on ''Deciding When to Submit a 510(k) for a Software Change to an Existing Device.'' It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. This guidance is not subject to Executive Order 12866.

III. Electronic Access

Persons interested in obtaining a copy of the guidance may do so by downloading an electronic copy from the internet. A search capability for all Center for Devices and Radiological Health guidance documents is available at *https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm.* Guidance documents are also available at *https://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/default.htm* or *https://www.regulations.gov.* Persons unable to download an electronic copy of ''Deciding When to Submit a 510(k) for a Software Change to an Existing Device'' may send an email request to *CDRH-Guidance@fda.hhs.gov* to receive an electronic copy of the document. Please use the document number 1500055 to identify the guidance you are requesting.

IV. Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in 21 CFR part 820 are approved under OMB control number 0910–0073; the collections of information in 21 CFR part 807, subpart E are approved under OMB control number 0910–0120; the collections of information in 21 CFR part 803 are approved under OMB control number 0910–0437; and the collections of information in 21 CFR parts 801 are approved under OMB control number 0910–0485.

V. References

The following references are on display in the Dockets Management Staff (see **ADDRESSES**) and are available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; they are also available electronically at *https://www.regulations.gov.* FDA has verified the Web site addresses, as of the date this document publishes in the **Federal Register**, but Web sites are subject to change over time.

1. ''The Least Burdensome Provisions of the FDA Modernization Act of 1997: Concept and Principles,'' dated October 4, 2002, available at: *https://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm085999.pdf.*
2. ''Suggested Format for Developing and Responding to Deficiencies in Accordance with the Least Burdensome Provisions of FDAMA,'' dated November 2, 2000, available at: *https://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm073680.pdf.*

Dated: October 20, 2017.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2017–23196 Filed 10–24–17; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

Notice of Interest Rate on Overdue Debts

Section 30.18 of the Department of Health and Human Services' claims collection regulations (45 CFR part 30) provides that the Secretary shall charge an annual rate of interest, which is determined and fixed by the Secretary of the Treasury after considering private consumer rates of interest on the date that the Department of Health and Human Services becomes entitled to recovery. The rate cannot be lower than the Department of Treasury's current value of funds rate or the applicable rate determined from the ''Schedule of Certified Interest Rates with Range of Maturities'' unless the Secretary waives interest in whole or part, or a different rate is prescribed by statute, contract, or repayment agreement. The Secretary of the Treasury may revise this rate quarterly. The Department of Health and Human Services publishes this rate in the **Federal Register**.

The current rate of 9¾%, as fixed by the Secretary of the Treasury, is certified for the quarter ended September 30, 2017. This rate is based on the Interest Rates for Specific Legislation, ''National Health Services Corps Scholarship Program (42 U.S.C. 254o(b)(1)(A))'' and ''National Research Service Award Program (42 U.S.C. 288(c)(4)(B)).'' This interest rate will be applied to overdue

debt until the Department of Health and Human Services publishes a revision.

Dated: October 17, 2017.

David C. Horn,

Director, Office of Financial Policy and Reporting.

[FR Doc. 2017–23092 Filed 10–24–17; 8:45 am]

BILLING CODE 4150–04–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

Office of the Assistant Secretary for Administration; Statement of Organization, Functions, and Delegations of Authority

Part A, Office of the Secretary, Statement of Organization, Functions, and Delegations of Authority for the Department of Health and Human Services (HHS) is being amended at Part A, Chapter AJ, Office of the Assistant Secretary for Administration (ASA), which was last amended at 77 FR 2729, dated January 19, 2012, and most recently at 77 FR 71004, dated November 28, 2012. Part A, Chapter AB, Section AB.20 a paragraph on Office of Security and Strategic Information (ABE), is being inserted. Part P, Program Support Center (PSC), Statement of Organization, Functions, and Delegations of Authority, which was last amended at 75 FR 369–370, dated January 5, 2010, is not being amended. This notice transfers the onboarding/suitability and physical security functions of the Office for Security and Strategic Information (OSSI) to PSC. This transfer of functions complements the existing PSC component's facilities management functions, parking garage entrance, safety-related programs, and other administrative functions. This notice also updates information regarding OSSI's direct report to the Deputy Secretary, organizational structure, as well as the new roles and responsibilities for the Assistant Deputy Secretary for National Security and Secretary's Senior Intelligence Official and for OSSI.

A. Part P, Program Support Center, the statement of organization, functions, and delegations of Authority therein need not be changed as the transferred functions are within the scope of the functions of PSC as described.

B. Under Chapter AJ, Section AJ.20, Functions, delete the last paragraph, which begins with ''Office of Security and Strategic Information (AJS),'' in its entirety.

C. Under Chapter AB, Section AB.20, Functions, insert the following new paragraph at the end of the section with the following:

Office of Security and Strategic Information (ABE)

The Office of Security and Strategic Information is headed by the Assistant Deputy Secretary for National Security, who reports directly to the Deputy Secretary and also serves as the Secretary's Senior Intelligence Official on intelligence and counterintelligence issues. The Assistant Deputy Secretary for National Security has been delegated original classification authority by the Secretary. The Assistant Deputy Secretary for National Security manages the Office of Security and Strategic Information (OSSI). OSSI's vision is for HHS personnel to successfully accomplish missions worldwide in a security-informed manner and with the actionable intelligence needed, at the right time, for operational and policy decisions. OSSI's responsibilities include: Integrating intelligence and security information into HHS policy and operational decisions; assessing, anticipating, and warning of potential security threats to the Department and our national security; and, providing policy guidance on and managing the OS implementation of the Department's security, intelligence and counterintelligence programs. OSSI's programs include national security adjudication, classified national security information management, secure compartmented information facilities management, communications security, safeguarding and sharing of classified information, cyber threat intelligence, and counterintelligence. In coordination with the Director of National Intelligence, OSSI has been designated as a Federal Intelligence Coordinating Office and the Assistant Deputy Secretary for National Security serves as the HHS Federal Senior Intelligence Coordinator. OSSI has responsibilities to establish implementing guidance, provide oversight, and manage the Department's policy for the sharing, safeguarding, and coordinated exchange of information related to national or homeland security with other federal departments and agencies, including law enforcement organizations and the Intelligence Community, in compliance with HHS policies and applicable laws, regulations, and Executive Orders.

E. Delegation of Authority. Pending further redelegation, directives or orders made by the Secretary or Deputy Secretary, all delegations and redelegations of authority made to officials and employees of affected organizational components will continue in them or their successors pending further redelegations, provided they are consistent with this reorganization.

Eric D. Hargan,

Acting Secretary, Department of Health and Human Services.

[FR Doc. 2017–23091 Filed 10–24–17; 8:45 am]

BILLING CODE 4151–17–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Aging; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute on Aging Special Emphasis Panel; Infrastructure Development for Interdisciplinary Aging Studies.

Date: November 21, 2017.

Time: 12:00 p.m. to 3:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institute on Aging, Gateway Building, Suite 2W200, 7201 Wisconsin Ave., Bethesda, MD 20892 (Telephone Conference Call).

Contact Person: Isis S. Mikhail, MD, MPH, DRPH, National Institute on Aging, Gateway Building, 7201 Wisconsin Avenue, Suite 2C212, Bethesda, MD 20892, 301–402–7704, *MIKHAILI@MAIL.NIH.GOV.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.866, Aging Research, National Institutes of Health, HHS)

Dated: October 19, 2017.

Melanie J. Pantoja,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2017–23127 Filed 10–24–17; 8:45 am]

BILLING CODE 4140–01–P