
POLICY AND PROCEDURES

OFFICE OF STRATEGIC PROGRAMS

CDER Division IT Coordinator Services

Table of Contents

PURPOSE1

BACKGROUND1

POLICY2

RESPONSIBILITIES2

REFERENCES.....4

DEFINITIONS4

EFFECTIVE DATE.....5

CHANGE CONTROL TABLE.....5

 ATTACHMENT 1: CDER Software Request Process.....6

 ATTACHMENT 2: Sample Data Call Request.....7

 ATTACHMENT 3: Sample Statistical & PC Tools
 Data Calls.....8

PURPOSE

OIMT Information Technology (IT) policies and procedures ensure CDER projects will have the highest levels of support and security. CDER’s Office of Strategic Programs (OSP)’s Office of Business Informatics (OBI) provides policy memoranda, operational manuals, and standard operating procedures for IT related projects of all sizes. This MAPP describes service requirements for CDER Division IT Coordinators.

BACKGROUND

In 2009, Division IT Coordinators were identified in CDER Offices to facilitate the distribution of information from CDER’s IT Liaison (CITL) to CDER’s employees and to provide feedback from CDER staff to the CDER CITL and OIMT. Division IT Coordinators are appointed from each CDER Office and Division to serve as the point of contact for the IT Liaisons to direct inquiries and information regarding to services from the Office of Management and Technology (OIMT). As of 2017, the number of coordinators has grown to nearly 110 CDER individuals from 14 parent CDER offices and over 150 divisions.

In 2016, the Centers were no longer able to transfer funds to OIMT. Due to this change, we have added a Budget component to the responsibilities of the IT Coordinator. The IT Coordinators will be asked to work within their Super Offices to obtain Budget Approval before executing any of their duties regarding new purchases, software, or any IT related purchases.

POLICY

1. Each CDER office maintains their own procedures for responding to IT requests and providing feedback from CDER staff.
2. IT Requests are:
 - Reviewed and approved for accuracy prior to initial deployment, installation, and use.
 - Revised as needed, based on priority, availability, and requirements.
 - Provided the appropriate level of support by OIMT.
 - Cleared by security, to prevent unintended use or unauthorized access.
 - Forwarded for guidance on next steps and next level support, if required.
 - Reviewed for Budget Approval before an IT purchase is approved.
3. OSP's Office of Business Informatics (OBI) ensures updated copies of all relevant forms, approval documentation, and contacts are posted on the CDER IT Liaison page of Inside.FDA.

RESPONSIBILITIES

Office of Business Informatics (OBI) Director, or designee

- Serves as designee to OSP Director.
- Elected as the Associate Deputy Chief Information Officer (ADCIO) for CDER.
- Provides advice and consent on all major IT investments, technical and operational activities at OIMT Council board meetings.
- Appoints and oversees the CDER IT Liaison.
- Receives reports from CDER IT Liaison.
- Gives direction to CDER IT Liaison.
- Works with CDER representatives on the Scientific Computing Board, High-Performance Computing (HPC) Advisory Board, and Modeling and Simulation Working Group.

Informatics Program Manager (OBI) or designee

- Communicates with OSP Director regarding resource utilization for major CDER IT initiatives.
- Acts as a program advisor to ADCIO regarding IT projects, tasks, and operations with higher scope issues.

- Assesses program performances and aim to maximize ROI for the center.
- Advises CDER's directors and other key agency officials about the performance of CDER planning, analysis, budgets and business informatics activities.

CDER Super Office or Office Executive Officer

- Appoints primary and alternate IT Coordinators for each division within their Office.
- Ensures IT Coordinators receive appropriate training for approving and tracking purchases of IT equipment and software from OIMT.
- Ensures Division IT Coordinators attend quarterly Division IT Coordinators Meetings.
- Receives comments and feedback from IT Coordinators to determine whether the IT business needs are being met.
- Works with the Office of Management (OM) on approving and transferring office funds for specific IT equipment, products and/ or services.

CDER IT Liaison (CITL)

- Serves as point of contact for all CDER IT related questions, comments, and concerns.
- Facilitates a close working relationship with OIMT and all CDER IT Coordinators.
- Conducts data calls with OM and provides specific deadlines for the verification of data calls.
- Provides template and due dates for data calls.
- Demonstrates IT expertise and offers IT policies and best practices for the CDER user community.
- Approves IT submittals for new technologies, projects and provision requests.
- Ensures approved software and technologies are added to the Master Approved Technologies (MAT) List.
- Hosts quarterly Division IT Coordinator Meetings to:
 - Provide recommended best practices regarding to IT.
 - Distribute IT-related information regarding FDA and CDER.
 - Share priorities, information on upcoming IT projects, news and tasks.
- Ensures all forms regarding approval documentation, and contacts are posted on the CDER IT Liaison page of Inside.FDA.
- Provides format for Division IT Coordinators to track all software licenses, license assignments, and software purchased for the Division.
- Reaches out to Division IT coordinators to identify areas that need improvement for both OIMT and the CITL's office
- Can be contacted via email at CDERITLiaison@fda.hhs.gov.

Division IT Coordinators

- Serves as the primary Point of Contact within his or her CDER Office or Division for IT questions, requests, and concerns that are not handled by ERIC.
 - Attends quarterly Division IT Coordinator Meetings. If unable to attend the meeting in person, reviews recorded session and slides, and forwards questions to the CITL.
 - Informs management in their Office or Division of IT processes, and upcoming IT projects and events.
 - Tracks all software licenses, license assignments, and software purchased by his or her division, using the format provided by the CITL.
 - Verifies whether software or technology is part of the Master Approved Technologies (MAT) List.
 - Manages and verifies division staff eligible for a computer refresh within the given fiscal year. Ensures refreshes for all Office or Division computers are in compliance with the FDA 3-year refresh cycle.
 - Responds to CITL requests to poll his or her division, to identify interested individuals to participate in testing and pilot initiatives within the Agency or Center.
 - Provides feedback on quality of IT services from OIMT recommended providers.
 - Works with the CDER IT Budget Approver on purchases.
 - Updates the Super Office Management and Budget Officers with new guidance on IT related purchases.
 - Creates and maintains a record of Super Office licenses and software.
-

REFERENCES

1. HHS, 2011, Employee Handbook: Policy for Information Systems Security and Privacy.
-

DEFINITIONS

Agency Refresh: The FDA initiative scheduling all computers on the FDA network to be replaced on a 3-year cycle.

Data Call: Request for data gathering or data verification (i.e., software in use, hardware assignments, pilot volunteer inquiries, etc.) that each IT Coordinator will need to provide for their division.

ERIC: Employee Resource Information Center. ERIC serves as the primary IT service provider for FDA employees. ERIC can be reached for IT issues at ITCallCenter@fda.hhs.gov. For non-IT related requests, ERIC can be reached at ERIC@fda.hhs.gov.

IT Request Form: The FDA required form to request approval for introducing a new piece of hardware or software technology, or new IT project to the FDA.

Master Approved Technology List (MAT List): A listing of potentially-approved technologies, for use throughout the FDA.

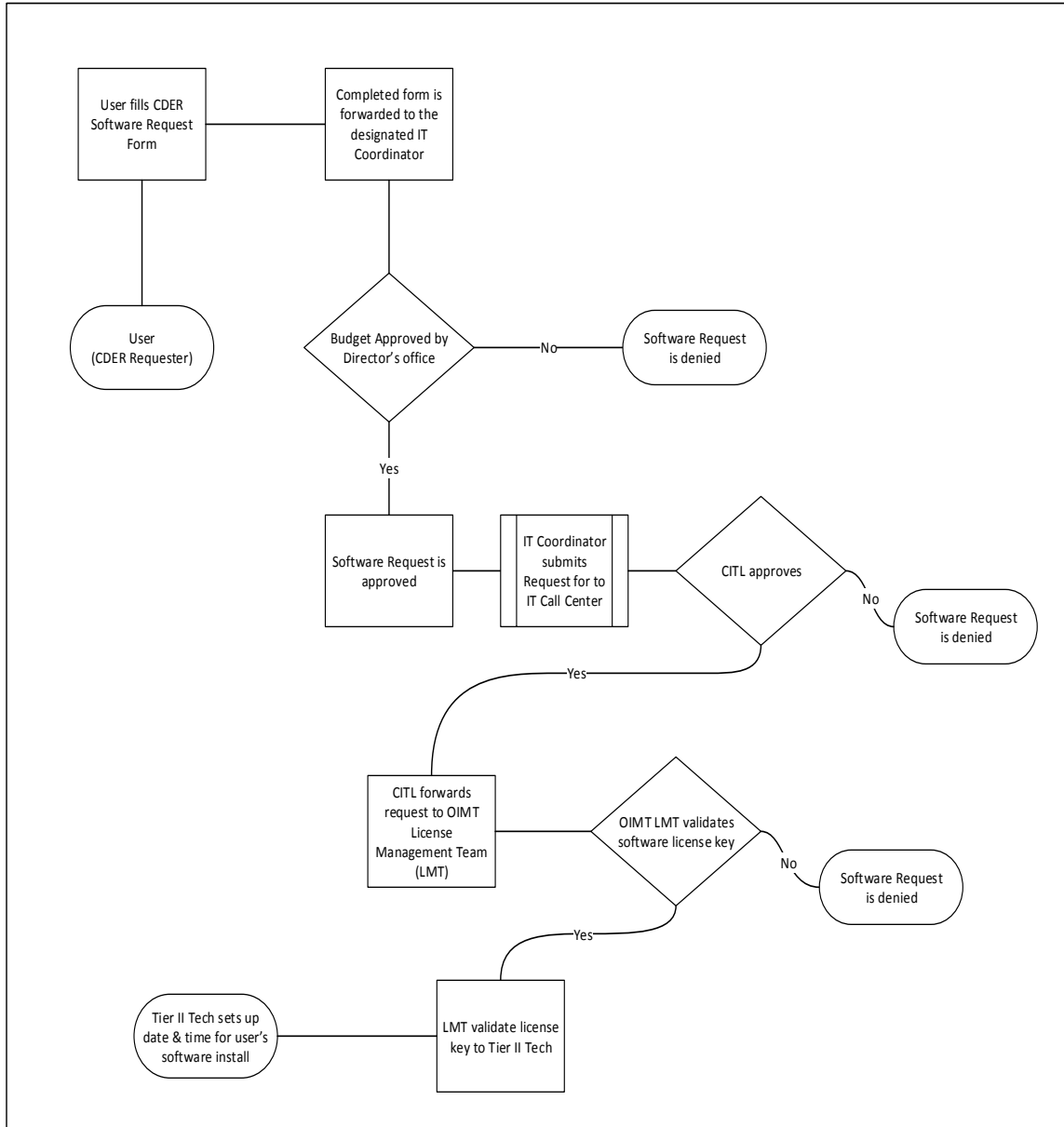
EFFECTIVE DATE

This MAPP is effective upon date of publication.

CHANGE CONTROL TABLE

Effective Date	Revision Number	Revisions
	Initial	n/a

ATTACHMENT 1: CDER Software Request Process



ATTACHMENT 2: Sample Data Call Request

Manufacturer Part Number	Description	Total Price (New Contract)	Budgetary Estimates	Option Period 4 Pricing
076-01776	Prjet ALNG LicSA MVL (<u>Project Standard</u>)	\$658.59	\$898.03	\$408.56
4ST-00001	PrjetProforO365G ShrdSvr ALNG SubsVL MVL PerUsr (<u>Project Professional with Cloud Option</u>)	\$237.12	\$1,496.69	\$681.16
P3U-00001	VisioProforO365G ShrdSvr ALNG SubsVL MVL PerUsr (<u>Visio Professional with Cloud Option</u>)	\$123.36	\$897.44	\$158.21
D86-01175	VisioStd ALNG LicSA MVL (<u>Visio Standard</u>)	\$291.48	\$768.16	\$349.42

ATTACHMENT 3: Sample Statistical & PC Tools Data Calls

Licenses	Previous Year Qty	GSA Price	ISDP Price	Qty	Total Cost
SPSS					
SPSS - ISDP Customized SPSS Bundle - New (basic)		\$ 14,114.00	\$ 9,053.88	0	\$ -
Customized)		\$ 2,138.00	\$ 228.30	0	\$ -
Customized)		\$ 6,414.00	\$ 684.89	0	\$ -
Total SPSS License Fees					\$ -
TIBCO Spotfire S-Plus					
S-Plus 2 year Term License plus 1st year Maintenance	122	\$ 2,049.55	\$ 2,049.55	0	\$ -
Total S-Plus License Fees					\$ -
Parallels					
Parallels - New		\$ 94.66	\$ 49.17	0	\$ -
Total Parallels License Fees					\$ -
Adobe					
Adobe Creative Suite: Design & Web Premium					
Adobe Creative Suite: Design & Web Premium - New		\$ 1,589.02	\$ 1,255.27	1	\$ 1,255.27
Adobe Creative Suite: Design & Web Premium - Upgrade		\$ 430.92	\$ 412.17	0	\$ -
Adobe Creative Suite: Master Collection					
Adobe Creative Suite: Master Collection - New		\$ 2,299.00	\$ 1,718.09	0	\$ -
Adobe Creative Suite: Master Collection - Upgrade		\$ 1,236.76	\$ 618.00	0	\$ -
Adobe Fireworks					
Adobe Fireworks - New		\$ 236.14	\$ 198.08	0	\$ -
Adobe Fireworks - Upgrade		\$ 114.39	\$ 103.26	0	\$ -
Adobe Flash Professional					
Adobe Flash Professional - New		\$ 618.38	\$ 462.74	0	\$ -
Adobe Flash Professional - Upgrade		\$ 176.22	\$ 137.23	0	\$ -
Adobe Illustrator					
Adobe Illustrator - New		\$ 529.03	\$ 396.26	0	\$ -
Adobe Illustrator - Upgrade		\$ 175.52	\$ 137.23	0	\$ -
Adobe InDesign					
Adobe InDesign - New		\$ 618.38	\$ 462.36	0	\$ -
Adobe InDesign - Upgrade		\$ 176.22	\$ 171.92	0	\$ -
Adobe Photoshop					
Adobe Photoshop - New		\$ 618.38	\$ 462.74	0	\$ -
Adobe Photoshop - Upgrade		\$ 176.22	\$ 137.23	0	\$ -
Total Adobe License Fees					\$ 1,255.27
Total PC Tools License Fees					\$ 1,255.27

Licenses	Previous Year Qty	GSA Price	ISDP Price	Qty	Total Cost
Adobe (Renewals Only)					
Acrobat Professional Conversion Term Licensing		n/a	\$ 11.57	0	\$ -
Acrobat Standard Conversion Term Licensing		n/a	\$ 8.01	0	\$ -
Total Adobe License Fees					\$ -
Parallels (New licenses and renewals/coterm of licenses purchased during FY 13 Q1 (yearly renewal), Q2, Q3 and Q4 (coterm) are included in this data call)					
Parallels - New		\$ 94.66	\$ 49.01	0	\$ -
Parallels - Renewal of Licenses		\$ 19.99	\$ 10.29	0	\$ -
Total Parallels License Fees					\$ -
SPSS (New Licenses Only - next renewal to occur in Q4 FY 14; any licenses purchased during Q2, Q3 of FY 13 will be renewed during those corresponding periods in FY 14)					
SPSS - ISDP Customized SPSS Bundle - New (basic)		\$ 14,114.00	\$ 9,053.88	1	\$ 9,053.88
SPSS - ISDP Professional SPSS Bundle - New (in addition to Customized)		\$ 2,138.00	\$ 228.30	0	\$ -
SPSS - ISDP Premium SPSS Bundle - New (in addition to Customized)		\$ 6,414.00	\$ 684.89	0	\$ -
Total SPSS License Fees					\$ 9,053.88
Total Stats & PC Tools License Fees					\$ 9,053.88