PPS NO.
81
82
83
84
85
86

CENTER FOR DEVICES AND R
RESOURCE SU
FY 201

PROJECT TITLE
TOTAL
POSTMARKET ASSURANCE: DEVICES
COMPLIANCE: DEVICES
PRODUCT EVALUATION: DEVICES
SCIENCE: DEVICES
MAMMOGRAPHY QUALITY STANDARDS ACT (MQSA) AUTHORITY
RADIATION CONTROL AND HEALTH SAFETY ACT (RCHSA) AUTHORITY

ADIOLOGICAL HEALTH
JMMARY
7

INSPECTIONAL FTES			ANALYTICAL FTES			TOTAL OPERATIONAL FTEs
DOMESTIC	FOREIGN	IMPORT	DOMESTIC	FOREIGN	IMPORT	
155.8	50.7	46.2	15.7	0.8	11.1	280.3
1.5			0.1			1.6
96.2	45.0	37.9	2.2		10.2	191.5
29.2	3.8					33.0
			9.9			9.9
14.5	0.1					14.6
14.4	1.8	8.3	3.5	0.8	0.9	29.7

PROJECT SUMMARY SHEET

FY 2017

1. PROGRAM CATEGORY	2. PPS PROJECT NAME/NUMBER
Medical Devices and Radiological Health	Postmarket Assurance: Devices- 81

3. NO.	4. FDA COMPLIANCE PROGRAMS AND ASSIGNMENTS	5. PROGRAM ASSIGNMENT CODE	6. OPERATIONAL FTE			7. TOTAL OPERATIONAL FTEs	8. PAGE
			DOMESTIC	IMPORT	FOREIGN		
	TOTAL		**1.6**			**1.6**	
1	Medical Device Problem Reporting- MDR Follow- up	81010	0.6			0.6	81-2
2	Enforcement Of The Medical Device Reporting (MDR) Regulation	81011	1.0			1.0	81-3

CENTER PROJECT MANAGER/TELEPHONE	ORA PLANNER/TELEPHONE
Brandi Stuart 301-796-6573	Archana Mathur 301-796-4393

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
Medical Device Problem Reporting - MDR Follow-Up	Postmarket Assurance: Devices - 81

3. PROGRAM/ASSIGNMENT CODE(S)	4. WORK ALLOCATION PLANNED BY	5. OPERATIONAL FTE POSITIONS
81010	[X] ORA [ ] CENTER	0.6

REGION	6. ORGANIZATION	DOMESTIC INSPEC-TIONS (1)	DOMESTIC INVESTI-GATIONS (Hours) (2)	DOMESTIC SAMPLE COLL STER	DOMESTIC SAMPLE COLL ENG	DOMESTIC SAMPLE ANALYSIS STER (3)	DOMESTIC SAMPLE ANALYSIS ENG (4)			
	TOTAL ORA	**79**	**29**	**1**	**1**	**1**	**1**			
HQ	*HEADQUARTERS*	(b) (5), (b) (7)(E) [redacted]								
NE	**TOTAL FIELD**									
	REGIONAL STAFF									
	NEW ENGLAND									
	NEW YORK									
CE	*REGIONAL STAFF*									
	BALTIMORE									
	CHICAGO									
	CINCINNATI									
	DETROIT									
	MINNEAPOLIS									
	NEW JERSEY									
	PHILADELPHIA									
SE	*REGIONAL STAFF*									
	ATLANTA									
	FLORIDA									
	NEW ORLEANS									
	SAN JUAN									
SW	*REGIONAL STAFF*									
	DALLAS									
	DENVER									
	KANSAS CITY									
	SOUTHWEST IMPORT DISTRICT									
PA	*REGIONAL STAFF*									
	LOS ANGELES									
	SAN FRANCISCO									
	SEATTLE									
LABS	**TOTAL LABORATORY**									
	ARKANSAS REGIONAL LAB									
	DENVER LAB									
	DETROIT LAB									
	FORENSIC CHEM. CTR									
	KANSAS LAB									
	NORTHEAST REGIONAL LAB									
	PACIFIC REGIONAL LAB-NW									
	PACIFIC REGIONAL LAB-SW									
	PHILADELPHIA LAB									
	SAN FRANCISCO LAB									
	SOUTHEAST REGIONAL LAB									
	SAN JUAN LAB									
	WEAC									
ESTIMATED HOURS PER OPERATION		5.00		8.20	8.20	20.00	37.00			
TOTAL HOURS		395	29	8	8	20	37			
CONVERSION FACTOR		950	950	950	950	1180	1180			
TOTAL OPERATIONAL FTEs		0.4	0.03	0.01	0.01	0.02	0.03			

7. REMARKS

(1) Inspections may be based on direct Center assignment, as a result of receiving problem reports which are significant, or when a defect, injury, or death that has been reported directly to a district requires follow-up.
(2) Investigational hours for MDR followup at medical facilities.
(3) Sterility testing to confirm reports of defective packaging and gross bacterial contamination of filth.
(4) MDR samples to confirm reported defects.

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
Enforcement Of The Medical Device Reporting (MDR) Regulation	Postmarket Assurance: Devices - 81

3. PROGRAM/ASSIGNMENT CODE(S)	4. WORK ALLOCATION PLANNED BY	5. OPERATIONAL FTE POSITIONS
81011	[X] ORA [ ] CENTER	1.0

REGION	6. ORGANIZATION	DOMESTIC INSPEC-TIONS								
	TOTAL ORA	**310**								
HQ	*HEADQUARTERS*	(b) (5), (b) (7)(E)								
NE	**TOTAL FIELD**									
	REGIONAL STAFF									
	NEW ENGLAND									
	NEW YORK									
CE	*REGIONAL STAFF*									
	BALTIMORE									
	CHICAGO									
	CINCINNATI									
	DETROIT									
	MINNEAPOLIS									
	NEW JERSEY									
	PHILADELPHIA									
SE	*REGIONAL STAFF*									
	ATLANTA									
	FLORIDA									
	NEW ORLEANS									
	SAN JUAN									
SW	*REGIONAL STAFF*									
	DALLAS									
	DENVER									
	KANSAS CITY									
	SOUTHWEST IMPORT DISTRICT									
PA	*REGIONAL STAFF*									
	LOS ANGELES									
	SAN FRANCISCO									
	SEATTLE									
LABS	**TOTAL LABORATORY**									
	ARKANSAS REGIONAL LAB									
	DENVER LAB									
	DETROIT LAB									
	FORENSIC CHEM. CTR									
	KANSAS LAB									
	NORTHEAST REGIONAL LAB									
	PACIFIC REGIONAL LAB-NW									
	PACIFIC REGIONAL LAB-SW									
	PHILADELPHIA LAB									
	SAN FRANCISCO LAB									
	SOUTHEAST REGIONAL LAB									
	SAN JUAN LAB									
	WEAC									
ESTIMATED HOURS PER OPERATION		3.00								
TOTAL HOURS		930								
CONVERSION FACTOR		950								
TOTAL OPERATIONAL FTEs		0.98								

7. REMARKS

PROJECT SUMMARY SHEET

FY 2017

1. PROGRAM CATEGORY	2. PPS PROJECT NAME/NUMBER
Medical Devices and Radiological Health	Compliance: Devices- 82

3. NO.	4. FDA COMPLIANCE PROGRAMS AND ASSIGNMENTS	5. PROGRAM ASSIGNMENT CODE	6. OPERATIONAL FTE			7. TOTAL OPERATIONAL FTEs	8. PAGE
			DOMESTIC	IMPORT	FOREIGN		
	TOTAL		**98.4**	**48.0**	**45.0**	**191.5**	
1	Monitoring Devices of Foreign Origin - Import	82008 *		48.0		48.0	82-5
2	Inspection of Medical Device Manufacturers	82845, A- S	92.1		45.0	137.1	82-6-7
3	Center Initiated Assignments	82Z800	6.0			6.0	82-8
5	Forensic Evaluation and Sample Analysis	82R838	0.3			0.3	82-9
	* In addition to PAC 82008, includes reporting						
	PACs 82R824, 82R833, and 99R833, 82R320						

CENTER PROJECT MANAGER/TELEPHONE	ORA PLANNER/TELEPHONE
Brandi Stuart 301-796-6573	Archana Mathur 301-796-4393

FY 2017 ORA WORK PLAN October 1, 2016

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
Monitoring Devices of Foreign Origin - Import	Compliance: Devices - 82

3. PROGRAM/ASSIGNMENT CODE(S)	4. WORK ALLOCATION PLANNED BY	5. OPERATIONAL FTE POSITIONS
82008, 82R824, 82R833, 99R833, 82R320	[X] ORA [ ] CENTER	48.0

REGION	6. ORGANIZATION	ENTRY REVIEW HOURS (Hours)	IMPORT INVESTI-GATION (Hours) (1)	IMPORT SAMPLE COLL (Physical) ENG	IMPORT SAMPLE COLL (Physical) MICRO	IMPORT FIELD EXAMS (2)	IMPORT LABEL EXAMS (Hours) (3)	IMPORT PRIVATE LAB REVIEW (Hours)	IMPORT SAMPLE ANALYSIS MICRO	IMPORT SAMPLE ANALYSIS ENG
	TOTAL ORA	**26000**	**4900**	**400**	**172**	**13700**	**5220**	**590**	**172**	**400**
HQ	*HEADQUARTERS*	(b) (5), (b) (7)(E) [redacted]								
NE	**TOTAL FIELD**									
	REGIONAL STAFF									
	NEW ENGLAND									
	NEW YORK									
CE	*REGIONAL STAFF*									
	BALTIMORE									
	CHICAGO									
	CINCINNATI									
	DETROIT									
	MINNEAPOLIS									
	NEW JERSEY									
	PHILADELPHIA									
SE	*REGIONAL STAFF*									
	ATLANTA									
	FLORIDA									
	NEW ORLEANS									
	SAN JUAN									
SW	*REGIONAL STAFF*									
	DALLAS									
	DENVER									
	KANSAS CITY									
	SOUTHWEST IMPORT DISTRICT									
PA	*REGIONAL STAFF*									
	LOS ANGELES									
	SAN FRANCISCO									
	SEATTLE									
LABS	**TOTAL LABORATORY**									
	ARKANSAS REGIONAL LAB									
	DENVER LAB									
	DETROIT LAB									
	FORENSIC CHEM. CTR									
	KANSAS LAB									
	NORTHEAST REGIONAL LAB									
	PACIFIC REGIONAL LAB-NW									
	PACIFIC REGIONAL LAB-SW									
	PHILADELPHIA LAB									
	SAN FRANCISCO LAB									
	SOUTHEAST REGIONAL LAB									
	SAN JUAN LAB									
	WEAC									
ESTIMATED HOURS PER OPERATION				2.00	2.00	0.30			21.90	19.07
TOTAL HOURS		26000	4900	800	344	4110	5220	590	3767	7628
CONVERSION FACTOR		1200	950	950	950	950	950	1180	1180	1180
TOTAL OPERATIONAL FTEs		21.67	5.16	0.84	0.36	4.33	5.49	0.50	3.19	6.49

7. REMARKS

(1) Import investigation hours are for filer evaluations, follow-up to refusals and other operations.
(2) Import field exams (FEX) should be reported using Operation Code 21.
(3) Import label exams (LEX) should be reported using Operation Code 52.

- Int'l Mail Facility Review hours now consolidated with Entry Review hours, per DIO
- Filer Evaluations (operation code 95, PAC 99R833)

- Follow-up to Refusals (PAC 82R824)

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
Inspection of Medical Device Manufacturers	Compliance: Devices - 82

3. PROGRAM/ASSIGNMENT CODE(S)	4. WORK ALLOCATION PLANNED BY	5. OPERATIONAL FTE POSITIONS
82845, A,B,C,G,H,L,M,S	X ORA X CENTER	137.0 [134.3]

REGION	6. ORGANIZATION	DOMESTIC INSPECTIONS LEVEL I CLASS 1 82845A	DOMESTIC INSPECTIONS Class 2, 3 82845A, 82845B (82845)	DOMESTIC INSPECTIONS Class 2, 3 82845A, 82845B (1)	FOREIGN INSPECTIONS LEVEL II 82845B	DOMESTIC COMPLIANCE INSPECTIONS LEVEL III 82845C	DOMESTIC FOR CAUSE INSPECTIONS 82845G	FOREIGN FOR CAUSE INSPECTIONS 82845G	DOMESTIC FOR CAUSE HIGH RISK INSPECTIONS 82845H	FOREIGN FOR CAUSE HIGH RISK INSPECTIONS 82845H
	TOTAL ORA	**250**	**1191**	**893**	**594**	**163**	**152**	**15**	**95**	**74**
HQ	*HEADQUARTERS*	(b) (5), (b) (7)(E) [redacted]								
NE	**TOTAL FIELD**									
	REGIONAL STAFF									
	NEW ENGLAND									
	NEW YORK									
CE	*REGIONAL STAFF*									
	BALTIMORE									
	CHICAGO									
	CINCINNATI									
	DETROIT									
	MINNEAPOLIS									
	NEW JERSEY									
	PHILADELPHIA									
SE	*REGIONAL STAFF*									
	ATLANTA									
	FLORIDA									
	NEW ORLEANS									
	SAN JUAN									
SW	*REGIONAL STAFF*									
	DALLAS									
	DENVER									
	KANSAS CITY									
	SOUTHWEST IMPORT DISTRICT									
PA	*REGIONAL STAFF*									
	LOS ANGELES									
	SAN FRANCISCO									
	SEATTLE									
LABS	**TOTAL LABORATORY**									
	ARKANSAS REGIONAL LAB									
	DENVER LAB									
	DETROIT LAB									
	FORENSIC CHEM. CTR									
	KANSAS LAB									
	NORTHEAST REGIONAL LAB									
	PACIFIC REGIONAL LAB-NW									
	PACIFIC REGIONAL LAB-SW									
	PHILADELPHIA LAB									
	SAN FRANCISCO LAB									
	SOUTHEAST REGIONAL LAB									
	SAN JUAN LAB									
	WEAC									
ESTIMATED HOURS PER OPERATION		32.00	37.70		61.65	93.49	71.24	60.00	62.04	70.00
TOTAL HOURS		8000	44901		36620	15239	10828	900	5894	5180
CONVERSION FACTOR		950	950		950	950	950	950	950	950
TOTAL OPERATIONAL FTEs		8.42	47.26		38.55	16.04	11.40	0.95	6.20	5.45

7. REMARKS

(1) Please use the Risk Based Prioritized list provided by CDRH to inspect these firms, which is approximately 75% of the total goal. The risk based prioritized list is posted with the work plan on the WPB website. These operations have been planned using planning PAC 82845. Please report all accomplishments using either PAC 82845A or 82845B as appropriate.

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
Inspection of Medical Device Manufacturers	Compliance: Devices - 82

3. PROGRAM/ASSIGNMENT CODE(S)	4. WORK ALLOCATION PLANNED BY	5. OPERATIONAL FTE POSITIONS
82845, A,B,C,G,H,L,M,S	[X] ORA [X] CENTER	137.0 [2.7]

REGION	6. ORGANIZATION	DOMESTIC STERIL-IZATION INSPEC-TIONS 82845S	DOMESTIC INVESTI-GATIONS (Hours) 82845B	AUDITS/ INVESTI-GATIONS MDSAP (Hours) 82845L	AUDITS/ INVESTI-GATIONS MDSAP (Hours) 82845M	DOMESTIC SAMPLE COLL 82845 (2)	DOMESTIC SAMPLE ANALYSIS MICRO 82845 (3)	DOMESTIC SAMPLE ANALYSIS ENG 82845 (3)			
	TOTAL ORA	**20**	**840**	**479**	**479**	**18**	**9**	**9**			
HQ	*HEADQUARTERS*	(b) (5), (b) (7)(E) [redacted]									
NE	**TOTAL FIELD**										
	REGIONAL STAFF										
	NEW ENGLAND										
	NEW YORK										
CE	*REGIONAL STAFF*										
	BALTIMORE										
	CHICAGO										
	CINCINNATI										
	DETROIT										
	MINNEAPOLIS										
	NEW JERSEY										
	PHILADELPHIA										
SE	*REGIONAL STAFF*										
	ATLANTA										
	FLORIDA										
	NEW ORLEANS										
	SAN JUAN										
SW	*REGIONAL STAFF*										
	DALLAS										
	DENVER										
	KANSAS CITY										
	SOUTHWEST IMPORT DISTRICT										
PA	*REGIONAL STAFF*										
	LOS ANGELES										
	SAN FRANCISCO										
	SEATTLE										
LABS	**TOTAL LABORATORY**										
	ARKANSAS REGIONAL LAB										
	DENVER LAB										
	DETROIT LAB										
	FORENSIC CHEM. CTR										
	KANSAS LAB										
	NORTHEAST REGIONAL LAB										
	PACIFIC REGIONAL LAB-NW										
	PACIFIC REGIONAL LAB-SW										
	PHILADELPHIA LAB										
	SAN FRANCISCO LAB										
	SOUTHEAST REGIONAL LAB										
	SAN JUAN LAB										
	WEAC										
ESTIMATED HOURS PER OPERATION		10.0				7.58	17.94	45.05			
TOTAL HOURS		200	840	479	479	136	161	405			
CONVERSION FACTOR		950	950	950	950	950	1180	1180			
TOTAL OPERATIONAL FTEs		0.21	0.88	0.50	0.50	0.14	0.14	0.34			

7. REMARKS

(2) Domestic Sample Collections are planned using the new planning PAC (82845). Accomplishments for this operation should still be reported under the appropriate sub PAC.
(3) Domestic Sample Analysis are planned using the new planning PAC (82845). Accomplishments for this operation should still be reported under the appropriate sub PAC.

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
Center Initiated Assignments	Compliance: Devices - 82

3. PROGRAM/ASSIGNMENT CODE(S)	4. WORK ALLOCATION PLANNED BY	5. OPERATIONAL FTE POSITIONS
82Z800	[X] ORA [ ] CENTER	6.0

REGION	6. DISTRICT/ SPECIALIZED LABORATORY	INSPEC-TIONS CENTER-INITIATED	DOMESTIC SAMPLE COLL	METHOD DEVELOP-MENT ENG (Hours) (1)	DOMESTIC SAMPLE ANALYSIS MICRO	ALTERNATE PATH ACTIVITIES (Hours) (2)				
	TOTAL ORA	**24**	**8**	**1225**	**8**	**2860**				
HQ	*HEADQUARTERS*									
NE	**TOTAL FIELD**	(b) (5), (b) (7)(E) [redacted]								
	REGIONAL STAFF									
	NEW ENGLAND									
	NEW YORK									
CE	*REGIONAL STAFF*									
	BALTIMORE									
	CHICAGO									
	CINCINNATI									
	DETROIT									
	MINNEAPOLIS									
	NEW JERSEY									
	PHILADELPHIA									
SE	*REGIONAL STAFF*									
	ATLANTA									
	FLORIDA									
	NEW ORLEANS									
	SAN JUAN									
SW	*REGIONAL STAFF*									
	DALLAS									
	DENVER									
	KANSAS CITY									
	SOUTHWEST IMPORT DISTRICT									
PA	*REGIONAL STAFF*									
	LOS ANGELES									
	SAN FRANCISCO									
	SEATTLE									
LABS	**TOTAL LABORATORY**									
	ARKANSAS REGIONAL LAB									
	DENVER LAB									
	DETROIT LAB									
	FORENSIC CHEM. CTR									
	KANSAS LAB									
	NORTHEAST REGIONAL LAB									
	PACIFIC REGIONAL LAB-NW									
	PACIFIC REGIONAL LAB-SW									
	PHILADELPHIA LAB									
	SAN FRANCISCO LAB									
	SOUTHEAST REGIONAL LAB									
	SAN JUAN LAB									
	WEAC									
ESTIMATED HOURS PER OPERATION		60.00	8.00		53.80					
TOTAL HOURS		1440	64	1225	430	2860				
CONVERSION FACTOR		950	950	1180	1180	950				
TOTAL OPERATIONAL FTEs		1.52	0.07	1.04	0.36	3.01				

7. REMARKS

(1) This operation is to be primarily used for in-lab methods and accompanying research that is performed in response to an emerging Center need or request.
(e.g. gowns testing research. Silimed methods and sample analysis).

(2) Please use OP code 92 (Technical Assistance) to report accomplishments for Alternate Path Activities.

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
Forensic Evaluation and Sample Analysis	Compliance: Devices - 82

3. PROGRAM/ASSIGNMENT CODE(S)	4. WORK ALLOCATION PLANNED BY	5. OPERATIONAL FTE POSITIONS
82R838	[X] ORA [ ] CENTER	0.3

REGION	6. DISTRICT/ SPECIALIZED LABORATORY	FORENSIC ANALYSIS CHEM (Hours)
	TOTAL ORA	**362**
HQ	*HEADQUARTERS*	(b) (5), (b) (7)(E)
NE	**TOTAL FIELD**	
	REGIONAL STAFF	
	NEW ENGLAND	
	NEW YORK	
CE	*REGIONAL STAFF*	
	BALTIMORE	
	CHICAGO	
	CINCINNATI	
	DETROIT	
	MINNEAPOLIS	
	NEW JERSEY	
	PHILADELPHIA	
SE	*REGIONAL STAFF*	
	ATLANTA	
	FLORIDA	
	NEW ORLEANS	
	SAN JUAN	
SW	*REGIONAL STAFF*	
	DALLAS	
	DENVER	
	KANSAS CITY	
	SOUTHWEST IMPORT DISTRICT	
PA	*REGIONAL STAFF*	
	LOS ANGELES	
	SAN FRANCISCO	
	SEATTLE	
LABS	**TOTAL LABORATORY**	
	ARKANSAS REGIONAL LAB	
	DENVER LAB	
	DETROIT LAB	
	FORENSIC CHEM. CTR	
	KANSAS LAB	
	NORTHEAST REGIONAL LAB	
	PACIFIC REGIONAL LAB-NW	
	PACIFIC REGIONAL LAB-SW	
	PHILADELPHIA LAB	
	SAN FRANCISCO LAB	
	SOUTHEAST REGIONAL LAB	
	SAN JUAN LAB	
	WEAC	
ESTIMATED HOURS PER OPERATION		
TOTAL HOURS		362
CONVERSION FACTOR		1205
TOTAL OPERATIONAL FTEs		0.30

7. REMARKS

PROJECT SUMMARY SHEET

FY 2017

1. PROGRAM CATEGORY	2. PPS PROJECT NAME/NUMBER
Medical Devices and Radiological Health	Product Evaluation: Devices- 83

3. NO.	4. FDA COMPLIANCE PROGRAMS AND ASSIGNMENTS	5. PROGRAM ASSIGNMENT CODE	6. OPERATIONAL FTE			7. TOTAL OPERATIONAL FTEs	8. PAGE
			DOMESTIC	IMPORT	FOREIGN		
	TOTAL		**29.2**		**3.8**	**33.0**	
1	Medical Device Premarket Approval and Postmarket Inspections:						
	Premarket Approval Inspections	83001	4.2		1.6	5.8	83-11
	Postmarket Approval Inspections	83001A	1.5		1.0	2.5	83-11
	Bioresearch Monitoring						
2	Good Lab Practice Prgm(Nonclinical Labs)	83808	0.3			0.3	83-12
3	Institutional Review Board(IRB/ IRC) Prgm	83809	3.4			3.4	83-12
4	Sponsor,Monitor, Contract Research Org.Prgm	83810	4.2		0.2	4.5	83-12
5	Clinical Investigators	83811	15.6		1.0	16.6	83-12

CENTER PROJECT MANAGER/TELEPHONE	ORA PLANNER/TELEPHONE
Zack Showman 301-796-5818	Archana Mathur 301-796-4393

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
Medical Device Premarket Approval and Postmarket Inspections	Product Evaluation: Devices - 83

3. PROGRAM/ASSIGNMENT CODE(S)	4. WORK ALLOCATION PLANNED BY	5. OPERATIONAL FTE POSITIONS
83001, A	[X] ORA [ ] CENTER	8.3

REGION	6. DISTRICT/ SPECIALIZED LABORATORY	DOMESTIC INSPEC-TIONS PRE-APPROVAL 83001	FOREIGN INSPEC-TIONS PRE-APPROVAL 83001	DOMESITC INSPEC-TIONS POST APPROVAL 83001A	FOREIGN INSPEC-TIONS POST-APPROVAL 83001A					
	TOTAL ORA	**90**	**31**	**30**	**21**					
HQ	*HEADQUARTERS*	[redacted]								
NE	**TOTAL FIELD**									
	REGIONAL STAFF									
	NEW ENGLAND									
	NEW YORK									
CE	*REGIONAL STAFF*									
	BALTIMORE									
	CHICAGO									
	CINCINNATI									
	DETROIT									
	MINNEAPOLIS									
	NEW JERSEY									
	PHILADELPHIA									
SE	*REGIONAL STAFF*									
	ATLANTA									
	FLORIDA									
	NEW ORLEANS									
	SAN JUAN									
SW	*REGIONAL STAFF*									
	DALLAS									
	DENVER									
	KANSAS CITY									
	SOUTHWEST IMPORT DISTRICT									
PA	*REGIONAL STAFF*									
	LOS ANGELES									
	SAN FRANCISCO									
	SEATTLE									
LABS	**TOTAL LABORATORY**									
	ARKANSAS REGIONAL LAB									
	DENVER LAB									
	DETROIT LAB									
	FORENSIC CHEM. CTR									
	KANSAS LAB									
	NORTHEAST REGIONAL LAB									
	PACIFIC REGIONAL LAB-NW									
	PACIFIC REGIONAL LAB-SW									
	PHILADELPHIA LAB									
	SAN FRANCISCO LAB									
	SOUTHEAST REGIONAL LAB									
	SAN JUAN LAB									
	WEAC									
ESTIMATED HOURS PER OPERATION		44.19	50.00	47.66	44.00					
TOTAL HOURS		3977	1550	1430	924					
CONVERSION FACTOR		950	950	950	950					
TOTAL OPERATIONAL FTEs		4.19	1.63	1.51	0.97					

(b) (5), (b) (7)(E)

7. REMARKS

If additional resources are needed by any particular district, please contact Archana Mathur at DPEM for possible re-allocation of inspectional resources.

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
Bioresearch Monitoring	Product Evaluation: Devices - 83

3. PROGRAM/ASSIGNMENT CODE(S)	4. WORK ALLOCATION PLANNED BY	5. OPERATIONAL FTE POSITIONS
83808, 83809, 83810, 83811	[X] ORA [ ] CENTER	24.7

REGION	6. ORGANIZATION	DOMESTIC INSPECTIONS 83808	DOMESTIC INSPECTIONS 83809	DOMESTIC INSPECTIONS 83810	DOMESTIC INSPECTIONS 83811	FOREIGN INSPECTIONS 83810	FOREIGN INSPECTIONS 83811			
	TOTAL ORA	**5**	**58**	**51**	**200**	**3**	**11**			
HQ	*HEADQUARTERS*	(b) (5), (b) (7)(E) [redacted]								
NE	**TOTAL FIELD**									
	REGIONAL STAFF									
	NEW ENGLAND									
	NEW YORK									
CE	*REGIONAL STAFF*									
	BALTIMORE									
	CHICAGO									
	CINCINNATI									
	DETROIT									
	MINNEAPOLIS									
	NEW JERSEY									
	PHILADELPHIA									
SE	*REGIONAL STAFF*									
	ATLANTA									
	FLORIDA									
	NEW ORLEANS									
	SAN JUAN									
SW	*REGIONAL STAFF*									
	DALLAS									
	DENVER									
	KANSAS CITY									
	SOUTHWEST IMPORT DISTRICT									
PA	*REGIONAL STAFF*									
	LOS ANGELES									
	SAN FRANCISCO									
	SEATTLE									
LABS	**TOTAL LABORATORY**									
	ARKANSAS REGIONAL LAB									
	DENVER LAB									
	DETROIT LAB									
	FORENSIC CHEM. CTR									
	KANSAS LAB									
	NORTHEAST REGIONAL LAB									
	PACIFIC REGIONAL LAB-NW									
	PACIFIC REGIONAL LAB-SW									
	PHILADELPHIA LAB									
	SAN FRANCISCO LAB									
	SOUTHEAST REGIONAL LAB									
	SAN JUAN LAB									
	WEAC									
ESTIMATED HOURS PER OPERATION		60.00	55.00	78.54	74.24	72.00	84.00			
TOTAL HOURS		300	3190	4006	14848	216	924			
CONVERSION FACTOR		950	950	950	950	950	950			
TOTAL OPERATIONAL FTEs		0.32	3.36	4.22	15.63	0.23	0.97			

7. REMARKS

PROJECT SUMMARY SHEET

FY 2017

1. PROGRAM CATEGORY	2. PPS PROJECT NAME/NUMBER
Medical Devices and Radiological Health	Science: Devices - 84

3. NO.	4. FDA COMPLIANCE PROGRAMS AND ASSIGNMENTS	5. PROGRAM ASSIGNMENT CODE	6. OPERATIONAL FTE			7. TOTAL OPERATIONAL FTEs	8. PAGE
			DOMESTIC	IMPORT	FOREIGN		
	TOTAL		**9.9**			**9.9**	
1	Test Method Development and Evaluation	84Z002	5.9			5.9	84-14
2	Methods Validation/Development Program	84R816	4.0			4.0	84-15

CENTER PROJECT MANAGER/TELEPHONE	ORA PLANNER/TELEPHONE
Brandi Stuart 301-796-6573	Archana Mathur 301-796-4393

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
Test Method Development and Evaluation	Science: Devices - 84

3. PROGRAM/ASSIGNMENT CODE(S)	4. WORK ALLOCATION PLANNED BY	5. OPERATIONAL FTE POSITIONS
84Z002	[ ] ORA [X] CENTER	5.9

REGION	6. DISTRICT/ SPECIALIZED LABORATORY	METHOD DEVELOP-MENT ENG (Hours) (1)								
	TOTAL ORA	**6962**								
HQ	*HEADQUARTERS*	(b) (5), (b) (7)(E)								
	TOTAL FIELD									
	REGIONAL STAFF									
NE	NEW ENGLAND									
	NEW YORK									
	REGIONAL STAFF									
	BALTIMORE									
	CHICAGO									
CE	CINCINNATI									
	DETROIT									
	MINNEAPOLIS									
	NEW JERSEY									
	PHILADELPHIA									
	REGIONAL STAFF									
	ATLANTA									
SE	FLORIDA									
	NEW ORLEANS									
	SAN JUAN									
	REGIONAL STAFF									
	DALLAS									
SW	DENVER									
	KANSAS CITY									
	SOUTHWEST IMPORT DISTRICT									
	REGIONAL STAFF									
PA	LOS ANGELES									
	SAN FRANCISCO									
	SEATTLE									
	TOTAL LABORATORY									
	ARKANSAS REGIONAL LAB									
	DENVER LAB									
	DETROIT LAB									
	FORENSIC CHEM. CTR									
	KANSAS LAB									
LABS	NORTHEAST REGIONAL LAB									
	PACIFIC REGIONAL LAB-NW									
	PACIFIC REGIONAL LAB-SW									
	PHILADELPHIA LAB									
	SAN FRANCISCO LAB									
	SOUTHEAST REGIONAL LAB									
	SAN JUAN LAB									
	WEAC									
ESTIMATED HOURS PER OPERATION										
TOTAL HOURS		6962								
CONVERSION FACTOR		1180								
TOTAL OPERATIONAL FTEs		5.90								

7. REMARKS

(1) Above resources are for participation in the development of test methods and testing protocol. Projects will be coordinated by the CDRH Laboratory Staff.

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
Methods Validation/Development Program	Science: Devices - 84

3. PROGRAM/ASSIGNMENT CODE(S)	4. WORK ALLOCATION PLANNED BY	5. OPERATIONAL FTE POSITIONS
84R816	[X] ORA [ ] CENTER	4.0

REGION	6. DISTRICT/ SPECIALIZED LABORATORY	APPLIED TECHNOLOGY CENTER METHOD DEVELOPMENT MIC (Hours)	METHOD DEVELOP-MENT/ VALID-ATION MIC (Hours)							
	TOTAL ORA	**2360**	**2410**							
HQ	*HEADQUARTERS*	(b) (5), (b) (7)(E) [redacted]								
NE	**TOTAL FIELD**									
	REGIONAL STAFF									
	NEW ENGLAND									
	NEW YORK									
CE	*REGIONAL STAFF*									
	BALTIMORE									
	CHICAGO									
	CINCINNATI									
	DETROIT									
	MINNEAPOLIS									
	NEW JERSEY									
	PHILADELPHIA									
SE	*REGIONAL STAFF*									
	ATLANTA									
	FLORIDA									
	NEW ORLEANS									
	SAN JUAN									
SW	*REGIONAL STAFF*									
	DALLAS									
	DENVER									
	KANSAS CITY									
	SOUTHWEST IMPORT DISTRICT									
PA	*REGIONAL STAFF*									
	LOS ANGELES									
	SAN FRANCISCO									
	SEATTLE									
LABS	**TOTAL LABORATORY**									
	ARKANSAS REGIONAL LAB									
	DENVER LAB									
	DETROIT LAB									
	FORENSIC CHEM. CTR									
	KANSAS LAB									
	NORTHEAST REGIONAL LAB									
	PACIFIC REGIONAL LAB-NW									
	PACIFIC REGIONAL LAB-SW									
	PHILADELPHIA LAB									
	SAN FRANCISCO LAB									
	SOUTHEAST REGIONAL LAB									
	SAN JUAN LAB									
	WEAC									
ESTIMATED HOURS PER OPERATION										
TOTAL HOURS		2360	2410							
CONVERSION FACTOR		1180	1205							
TOTAL OPERATIONAL FTEs		2.00	2.00							

7. REMARKS

PROJECT SUMMARY SHEET

FY 2017

1. PROGRAM CATEGORY	2. PPS PROJECT NAME/NUMBER
Medical Devices and Radiological Health	Mammography Quality Standards Acts (MQSA) Authority - 85

3. NO.	4. FDA COMPLIANCE PROGRAMS AND ASSIGNMENTS	5. PROGRAM ASSIGNMENT CODE	6. OPERATIONAL FTE			7. TOTAL OPERATIONAL FTEs	8. PAGE
			DOMESTIC	IMPORT	FOREIGN		
	TOTAL		**14.5**		**0.1**	**14.6**	
1	Mammography Facilities Inspection Program	85014 A,C,F	14.5		0.1	14.6	85-17

CENTER PROJECT MANAGER/TELEPHONE	ORA PLANNER/TELEPHONE
Kate Sheridan. 301-796-5714	Archana Mathur 301-796-4393

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
Mammography Facilities Inspection Program	Mammography Quality Standards Act (MQSA) Authority - 85

3. PROGRAM/ASSIGNMENT CODE(S)	4. WORK ALLOCATION PLANNED BY	5. OPERATIONAL FTE POSITIONS
85014 A,C,F	X ORA X CENTER	14.6

REGION	6. DISTRICT/ SPECIALIZED LABORATORY	DOMESTIC INSPEC-TIONS 85014 (1)	FOREIGN INSPEC-TIONS 85014	DOMESTIC FED FACIL INSPEC-TIONS 85014	DOMESTIC VHA INSPEC-TIONS 85014	DOMESTIC INSPEC-TIONS FOLLOW-UP 85014F	AUDIT INVESTI-GATIONS (Hours) 85014A	OTHER OPERA-TIONS (Hours) 85014C (2)	TECHNICAL ASSITANCE NON-RRHR (Hours) 85014C (4)	TECHNICAL ASSISTANCE RRHR (Hours) 85014C (5)
	TOTAL ORA	**759**	**14**	**105**	**58**	**5**	**3185**	**1210**	**3880**	**1200**
HQ	*HEADQUARTERS*	(b) (5), (b) (7)(E) [redacted]								
	TOTAL FIELD									
NE	*REGIONAL STAFF*									
	NEW ENGLAND									
	NEW YORK									
CE	*REGIONAL STAFF*									
	BALTIMORE									
	CHICAGO									
	CINCINNATI									
	DETROIT									
	MINNEAPOLIS									
	NEW JERSEY									
	PHILADELPHIA									
SE	*REGIONAL STAFF*									
	ATLANTA									
	FLORIDA									
	NEW ORLEANS									
	SAN JUAN									
SW	*REGIONAL STAFF*									
	DALLAS									
	DENVER									
	KANSAS CITY									
	SOUTHWEST IMPORT DISTRICT									
PA	*REGIONAL STAFF*									
	LOS ANGELES									
	SAN FRANCISCO									
	SEATTLE									
LABS	**TOTAL LABORATORY**									
	ARKANSAS REGIONAL LAB									
	DENVER LAB									
	DETROIT LAB									
	FORENSIC CHEM. CTR									
	KANSAS LAB									
	NORTHEAST REGIONAL LAB									
	PACIFIC REGIONAL LAB-NW									
	PACIFIC REGIONAL LAB-SW									
	PHILADELPHIA LAB									
	SAN FRANCISCO LAB									
	SOUTHEAST REGIONAL LAB									
	SAN JUAN LAB									
	WEAC									
ESTIMATED HOURS PER OPERATION		8.0	10.0	8.0	8.0	7.0				
TOTAL HOURS		6072	140	840	464	35	3185	1210	3880	1200
CONVERSION FACTOR		1160	1160	1160	1160	1160	1160	1160	1160	1200
TOTAL OPERATIONAL FTEs		5.23	0.12	0.72	0.40	0.03	2.75	1.04	3.34	1.00

7. REMARKS

Regional Radiological Health Representatives (RRHR) should report all technical assistance and coordination hours

(1) Certified non-federal Mammography Facility not covered by state contracts

(2) Compliance Activities: Inspection Follow-Up Activities (Non-Warning Letter).

(3) Compliance Activities: Warning Letters.

(4) Technical Assistance and Coordination Activities: Non-RRHRs.

(5) Techical Assistance and Coordination Activities: RRHRs.

RRHRs SHOULD REPORT ALL TECHNICAL ASSISTANCE & COORDINATION HOURS

PROJECT SUMMARY SHEET

FY 2017

1. PROGRAM CATEGORY	2. PPS PROJECT NAME/NUMBER
Medical Devices and Radiological Health	Radiation Control and Health Safety Act (RCHSA) Authority - 86

3. NO.	4. FDA COMPLIANCE PROGRAMS AND ASSIGNMENTS	5. PROGRAM ASSIGNMENT CODE	6. OPERATIONAL FTE			7. TOTAL OPERATIONAL FTEs	8. PAGE
			DOMESTIC	IMPORT	FOREIGN		
	TOTAL		**18.8**	**8.3**	**2.6**	**29.7**	
1	Inspection of Manufacturers of Laser Products	86001	3.3		0.8	4.1	86-19
2	Field Implementation of Sunlamp Regs	86002	0.4		0.2	0.6	86-20
3	Field Compliance Testing of Diagnostic X-Ray Equipment	86003	5.2		0.8	6.0	86-21
4	Compliance Testing of Electronic Products at WEAC	86006 (A, D, E)	3.3		0.8	4.1	86-22
5	Imported Electronic Products	86007	0.9	8.3		9.2	86-23
6	Medical Device and Radiological Health Use Control Policy	86008	3.0			3.0	86-24
7	Emergency Planning and Response Activities	86009	2.0			2.0	86--24
8	Center Initiated Assignments- EPRC	86Z800	0.7			0.7	86-25

CENTER PROJECT MANAGER/TELEPHONE	ORA PLANNER/TELEPHONE
Deniz Mackey 301-796-5908	Archana Mathur 301-796-4393

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
Inspection of Manufacturers of Laser Products	Radiation Control and Health Safety Act (RCHSA) Authority - 86

3. PROGRAM/ASSIGNMENT CODE(S)	4. WORK ALLOCATION PLANNED BY	5. OPERATIONAL FTE POSITIONS
86001	[X] ORA [ ] CENTER	4.1

REGION	6. DISTRICT/ SPECIALIZED LABORATORY	DOMESTIC INSPEC-TIONS (1)	FOREIGN INSPEC-TIONS (ENG) (2)	DOMESTIC INVESTI-GATIONS (Hours)	DOMESTIC SAMPLE COLL DOC	FIELD EXAMS/ TESTS (3)	TECHNICAL ASSISTANCE/ TRAINING (Hours) (4)	OEI IMPROVE-MENT (Hours) 86R876		
	TOTAL ORA	**95**	**30**	**352**	**17**	**74**	**751**	**760**		
HQ	*HEADQUARTERS*	(b) (5), (b) (7)(E) [redacted]								
NE	**TOTAL FIELD**									
	REGIONAL STAFF									
	NEW ENGLAND									
	NEW YORK									
CE	*REGIONAL STAFF*									
	BALTIMORE									
	CHICAGO									
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	MINNEAPOLIS									
	NEW JERSEY									
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	ATLANTA									
	FLORIDA									
	NEW ORLEANS									
	SAN JUAN									
SW	*REGIONAL STAFF*									
	DALLAS									
	DENVER									
	KANSAS CITY									
	SOUTHWEST IMPORT DISTRICT									
PA	*REGIONAL STAFF*									
	LOS ANGELES									
	SAN FRANCISCO									
	SEATTLE									
LABS	**TOTAL LABORATORY**									
	ARKANSAS REGIONAL LAB									
	DENVER LAB									
	DETROIT LAB									
	FORENSIC CHEM. CTR									
	KANSAS LAB									
	NORTHEAST REGIONAL LAB									
	PACIFIC REGIONAL LAB-NW									
	PACIFIC REGIONAL LAB-SW									
	PHILADELPHIA LAB									
	SAN FRANCISCO LAB									
	SOUTHEAST REGIONAL LAB									
	SAN JUAN LAB									
	WEAC									
ESTIMATED HOURS PER OPERATION		10.00	31.00		5.50	3.00				
TOTAL HOURS		950	930	352	94	222	751	760		
CONVERSION FACTOR		950	1180	950	950	950	950	950		
TOTAL OPERATIONAL FTEs		1.00	0.79	0.37	0.10	0.23	0.79	0.80		

7. REMARKS

(1) Inspections should be conducted on manufacturers of Class IIIb and Class IV products. For medical lasers, a joint QSIT and electronic product radiation control inspection should be conducted.

(2) Foreign inspections to be conducted by WEAC Analysts and other EOS Specialists.

(3) Field tests may be conducted for any laser products located at a user facility. (Class IIIb or IV medical, industrial and commercial lasers, including laser light show projectors). Field testing refers to testing at a fixed installation, while an inspection (1) of a non-fixed laser light show would be considered an inspection.

(4) To include all other activities such as technical assistance, coordination, and training.

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
Field Implementation of Sunlamp Regs	Radiation Control and Health Safety Act (RCHSA) Authority - 86

3. PROGRAM/ASSIGNMENT CODE(S)	4. WORK ALLOCATION PLANNED BY	5. OPERATIONAL FTE POSITIONS
86002	[X] ORA [ ] CENTER	0.6

REGION	6. DISTRICT/ SPECIALIZED LABORATORY	DOMESTIC INSPEC-TIONS (1)	FOREIGN INSPEC TIONS	FIELD EXAMS/ TESTS (2)	TECHNICAL ASSIST-ANCE (Hours) (3)					
	TOTAL ORA	**12**	**5**	**30**	**76**					
HQ	*HEADQUARTERS*	(b) (5), (b) (7)(E) [redacted]								
	TOTAL FIELD									
	REGIONAL STAFF									
NE	NEW ENGLAND									
	NEW YORK									
	REGIONAL STAFF									
	BALTIMORE									
	CHICAGO									
CE	CINCINNATI									
	DETROIT									
	MINNEAPOLIS									
	NEW JERSEY									
	PHILADELPHIA									
	REGIONAL STAFF									
	ATLANTA									
SE	FLORIDA									
	NEW ORLEANS									
	SAN JUAN									
	REGIONAL STAFF									
	DALLAS									
SW	DENVER									
	KANSAS CITY									
	SOUTHWEST IMPORT DISTRICT									
	REGIONAL STAFF									
PA	LOS ANGELES									
	SAN FRANCISCO									
	SEATTLE									
	TOTAL LABORATORY									
	ARKANSAS REGIONAL LAB									
	DENVER LAB									
	DETROIT LAB									
	FORENSIC CHEM. CTR									
	KANSAS LAB									
LABS	NORTHEAST REGIONAL LAB									
	PACIFIC REGIONAL LAB-NW									
	PACIFIC REGIONAL LAB-SW									
	PHILADELPHIA LAB									
	SAN FRANCISCO LAB									
	SOUTHEAST REGIONAL LAB									
	SAN JUAN LAB									
	WEAC									
ESTIMATED HOURS PER OPERATION		16.05	36.00	4.40						
TOTAL HOURS		193	180	132	76					
CONVERSION FACTOR		950	950	950	950					
TOTAL OPERATIONAL FTEs		0.20	0.19	0.14	0.08					

7. REMARKS

(1) Inspectional figures are only for biennial or for cause inspections of manufactures of sunlamp products (e.g. sunlamps, booths, or beds). A joint QSIT and electronic productradiation control inspection should be conducted. Examination of sunlamp products at a user facility (e.g. tanning parlor, athletic club) are NOT counted as inspections because they are field tests.

(2) Each sunlamp product tested may be counted as a field test, even if located in a single facility.

(3) To include all other activities such as technical assistance, coordination and training

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
Field Compliance Testing of Diagnostic X-Ray Equipment	Radiation Control and Health Safety Act (RCHSA) Authority - 86

3. PROGRAM/ASSIGNMENT CODE(S)	4. WORK ALLOCATION PLANNED BY	5. OPERATIONAL FTE POSITIONS
86003	[X] ORA [ ] CENTER	6.0

REGION	6 DISTRICT/ SPECIALIZED LABORATORY	DOMESTIC INSPECTIONS (1)	FOREIGN INSPECTIONS	DOMESTIC INVESTIGATIONS (Hours)	OEI IMPROVEMENT (Hours) 86R876	METHOD DEVELOPMENT (Hours)	TECHNICAL ASSISTANCE (Hours)			
	TOTAL ORA	**122**	**19**	**1986**	**760**	**248**	**100**			
HQ	*HEADQUARTERS*	(b) (5), (b) (7)(E) [redacted]								
	TOTAL FIELD									
NE	*REGIONAL STAFF*									
	NEW ENGLAND									
	NEW YORK									
CE	*REGIONAL STAFF*									
	BALTIMORE									
	CHICAGO									
	CINCINNATI									
	DETROIT									
	MINNEAPOLIS									
	NEW JERSEY									
	PHILADELPHIA									
SE	*REGIONAL STAFF*									
	ATLANTA									
	FLORIDA									
	NEW ORLEANS									
	SAN JUAN									
SW	*REGIONAL STAFF*									
	DALLAS									
	DENVER									
	KANSAS CITY									
	SOUTHWEST IMPORT DISTRICT									
PA	*REGIONAL STAFF*									
	LOS ANGELES									
	SAN FRANCISCO									
	SEATTLE									
LABS	**TOTAL LABORATORY**									
	ARKANSAS REGIONAL LAB									
	DENVER LAB									
	DETROIT LAB									
	FORENSIC CHEM. CTR									
	KANSAS LAB									
	NORTHEAST REGIONAL LAB									
	PACIFIC REGIONAL LAB-NW									
	PACIFIC REGIONAL LAB-SW									
	PHILADELPHIA LAB									
	SAN FRANCISCO LAB									
	SOUTHEAST REGIONAL LAB									
	SAN JUAN LAB									
	WEAC									
ESTIMATED HOURS PER OPERATION		15.5	39.0							
TOTAL HOURS		1891	741	1986	760	248	100			
CONVERSION FACTOR		950	950	950	950	1180	950			
TOTAL OPERATIONAL FTEs		1.99	0.78	2.09	0.80	0.21	0.11			

7. REMARKS

(1) - Domestic inspections allocated as per firm listing received from CDRH.

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
Compliance Testing of Electronic Products at WEAC	Radiation Control and Health Safety Act (RCHSA) Authority - 86

3. PROGRAM/ASSIGNMENT CODE(S)	4. WORK ALLOCATION PLANNED BY	5. OPERATIONAL FTE POSITIONS
86006 A,D,E	[ ] ORA [X] CENTER	4.1

REGION	6. DISTRICT/ SPECIALIZED LABORATORY	FOREIGN INSPEC-TIONS (ENG) (1)	DOMESTIC SAMPLE COLLECTION MICROWAVE 86006A	DOMESTIC SAMPLE COLLECTION X-RAY 86006D	DOMESTIC SAMPLE COLLECTION NON-MED LASERS 86006E	DOMESTIC SAMPLE COLLECTION SUN LAMPS 86006G	DOMESTIC SAMPLE ANALYSIS MICROWAVE 86006A (2)	DOMESTIC SAMPLE ANALYSIS X-RAY 86006D	DOMESTIC SAMPLE ANALYSIS NON-MED LASERS 86006E	DOMESTIC SAMPLE ANALYSIS SUN LAMPS 86006G (3)
	TOTAL ORA	**10**	**70**	**4**	**50**	**20**	**70**	**4**	**50**	**20**
HQ	*HEADQUARTERS*	(b) (5), (b) (7)(E) [redacted]								
NE	**TOTAL FIELD**									
	REGIONAL STAFF									
	NEW ENGLAND									
	NEW YORK									
CE	*REGIONAL STAFF*									
	BALTIMORE									
	CHICAGO									
	CINCINNATI									
	DETROIT									
	MINNEAPOLIS									
	NEW JERSEY									
	PHILADELPHIA									
SE	*REGIONAL STAFF*									
	ATLANTA									
	FLORIDA									
	NEW ORLEANS									
	SAN JUAN									
SW	*REGIONAL STAFF*									
	DALLAS									
	DENVER									
	KANSAS CITY									
	SOUTHWEST IMPORT DISTRICT									
PA	*REGIONAL STAFF*									
	LOS ANGELES									
	SAN FRANCISCO									
	SEATTLE									
LABS	**TOTAL LABORATORY**									
	ARKANSAS REGIONAL LAB									
	DENVER LAB									
	DETROIT LAB									
	FORENSIC CHEM. CTR									
	KANSAS LAB									
	NORTHEAST REGIONAL LAB									
	PACIFIC REGIONAL LAB-NW									
	PACIFIC REGIONAL LAB-SW									
	PHILADELPHIA LAB									
	SAN FRANCISCO LAB									
	SOUTHEAST REGIONAL LAB									
	SAN JUAN LAB									
	WEAC									
ESTIMATED HOURS PER OPERATION		88.07	2.00	2.00	4.00	4.00	13.5	287.8	19.8	19.8
TOTAL HOURS		881	140	8	200	80	944	1151	989	396
CONVERSION FACTOR		1180	1180	1180	1180	1180	1180	1180	1180	1180
TOTAL OPERATIONAL FTEs		0.75	0.12	0.01	0.17	0.07	0.80	0.98	0.84	0.34

7. REMARKS

(1) Foreign inspections should be conducted at electronic product manufacturers. For any inspections of radiation- emitting medical device manufacturers, a joint QSIT and electronic product radiation control inspection should be conducted.

(2) Domestic Sample Collection of Sunlamps (WEAC) should be conducted under newly created PAC, 86006G.

(3) Domestic Sample Analysis of Sunlamps (WEAC) should be conducted under newly created PAC, 86006G.

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
Imported Electronic Products	Radiation Control and Health Safety Act (RCHSA) Authority - 86

3. PROGRAM/ASSIGNMENT CODE(S)	4. WORK ALLOCATION PLANNED BY	5. OPERATIONAL FTE POSITIONS
86007, 86R824, 86R833, 99R833	[X] ORA [ ] CENTER	9.3

REGION	6. DISTRICT/ SPECIALIZED LABORATORY	IMPORT ENTRY REVIEW (Hours) 86R833	IMPORT INVEST-IGATIONS (Hours) (1)	IMPORT FIELD EXAMS	IMPORT SAMPLE COLL	IMPORT LABEL EXAMS (Hours) (2)	IMPORT SAMPLE ANALYSIS ENG			
	TOTAL ORA	**7000**	**1600**	**750**	**110**	**200**	**110**			
HQ	*HEADQUARTERS*	(b) (5), (b) (7)(E) [redacted]								
NE	**TOTAL FIELD**									
	REGIONAL STAFF									
	NEW ENGLAND									
	NEW YORK									
CE	*REGIONAL STAFF*									
	BALTIMORE									
	CHICAGO									
	CINCINNATI									
	DETROIT									
	MINNEAPOLIS									
	NEW JERSEY									
	PHILADELPHIA									
SE	*REGIONAL STAFF*									
	ATLANTA									
	FLORIDA									
	NEW ORLEANS									
	SAN JUAN									
SW	*REGIONAL STAFF*									
	DALLAS									
	DENVER									
	KANSAS CITY									
	SOUTHWEST IMPORT DISTRICT									
PA	*REGIONAL STAFF*									
	LOS ANGELES									
	SAN FRANCISCO									
	SEATTLE									
LABS	**TOTAL LABORATORY**									
	ARKANSAS REGIONAL LAB									
	DENVER LAB									
	DETROIT LAB									
	FORENSIC CHEM. CTR									
	KANSAS LAB									
	NORTHEAST REGIONAL LAB									
	PACIFIC REGIONAL LAB-NW									
	PACIFIC REGIONAL LAB-SW									
	PHILADELPHIA LAB									
	SAN FRANCISCO LAB									
	SOUTHEAST REGIONAL LAB									
	SAN JUAN LAB									
	WEAC									
ESTIMATED HOURS PER OPERATION				0.50	2.00		9.88			
TOTAL HOURS		7000	1600	375	220	200	1087			
CONVERSION FACTOR		1200	950	950	950	950	1180			
TOTAL OPERATIONAL FTEs		5.83	1.68	0.39	0.23	0.21	0.92			

7. REMARKS

(1) Import investigation hours are for filer evaluations, follow-up to refusals, and other operations.
(2) Import label exams (LEX) should be reported using OP code 52.

- Filer Evaluations (OP code 95, PAC 99R833)
- Follow-up to Refusals (PAC 86R824)

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
Radiological Health Control Activities	Radiation Control and Health Safety Act (RCHSA) Authority - 86

3. PROGRAM/ASSIGNMENT CODE(S)	4. WORK ALLOCATION PLANNED BY	5. OPERATIONAL FTE POSITIONS
86008, 86009	[ ] ORA [X] CENTER	5.0

REGION	6. DISTRICT/ SPECIALIZED LABORATORY	TECHNICAL ASSIST-ANCE (Hours) RRHR 86008 (1)	EMER-GENCY RESPONSE (Hours) RRHR 86009 (2)							
	TOTAL ORA	**3600**	**2400**							
HQ	*HEADQUARTERS*	(b) (5), (b) (7)(E)								
NE	**TOTAL FIELD**									
	REGIONAL STAFF									
	NEW ENGLAND									
	NEW YORK									
CE	*REGIONAL STAFF*									
	BALTIMORE									
	CHICAGO									
	CINCINNATI									
	DETROIT									
	MINNEAPOLIS									
	NEW JERSEY									
	PHILADELPHIA									
SE	*REGIONAL STAFF*									
	ATLANTA									
	FLORIDA									
	NEW ORLEANS									
	SAN JUAN									
SW	*REGIONAL STAFF*									
	DALLAS									
	DENVER									
	KANSAS CITY									
	SOUTHWEST IMPORT DISTRICT									
PA	*REGIONAL STAFF*									
	LOS ANGELES									
	SAN FRANCISCO									
	SEATTLE									
LABS	**TOTAL LABORATORY**									
	ARKANSAS REGIONAL LAB									
	DENVER LAB									
	DETROIT LAB									
	FORENSIC CHEM. CTR									
	KANSAS LAB									
	NORTHEAST REGIONAL LAB									
	PACIFIC REGIONAL LAB-NW									
	PACIFIC REGIONAL LAB-SW									
	PHILADELPHIA LAB									
	SAN FRANCISCO LAB									
	SOUTHEAST REGIONAL LAB									
	SAN JUAN LAB									
	WEAC									
ESTIMATED HOURS PER OPERATION										
TOTAL HOURS		3600	2400							
CONVERSION FACTOR		1200	1200							
TOTAL OPERATIONAL FTEs		3.00	2.00							

7. REMARKS

(1) Miscellaneous hours for Regional Radiological Health Representatives (RRHR) for federal/state liaison activities includes coordination, technical assistance, and other activities for following PAC codes: 86002, 86003, 86004, 86008 and 86009.

(2) Regional Radiological Health Representatives (RRHR) for technical assistance to state and local agencies regarding emergency response planning, reviewing, and evaluating emergency plans related to nuclear power plant.

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
Center Initiated Assignments - EPRC	Radiation Control and Health Safety Act (RCHSA) Authority- 86

3. PROGRAM/ASSIGNMENT CODE(S)	4. WORK ALLOCATION PLANNED BY	5. OPERATIONAL FTE POSITIONS
86Z800	[X] ORA [X] CENTER	0.7

REGION	6. DISTRICT/ SPECIALIZED LABORATORY	DOMESTIC INSPEC-TIONS 86Z800 (1)								
	TOTAL ORA	**10**								
HQ	*HEADQUARTERS*	(b) (5), (b) (7)(E)								
	TOTAL FIELD									
	REGIONAL STAFF									
NE	NEW ENGLAND									
	NEW YORK									
	REGIONAL STAFF									
	BALTIMORE									
	CHICAGO									
CE	CINCINNATI									
	DETROIT									
	MINNEAPOLIS									
	NEW JERSEY									
	PHILADELPHIA									
	REGIONAL STAFF									
	ATLANTA									
SE	FLORIDA									
	NEW ORLEANS									
	SAN JUAN									
	REGIONAL STAFF									
	DALLAS									
SW	DENVER									
	KANSAS CITY									
	SOUTHWEST IMPORT DISTRICT									
	REGIONAL STAFF									
PA	LOS ANGELES									
	SAN FRANCISCO									
	SEATTLE									
	TOTAL LABORATORY									
	ARKANSAS REGIONAL LAB									
	DENVER LAB									
	DETROIT LAB									
	FORENSIC CHEM. CTR									
	KANSAS LAB									
LABS	NORTHEAST REGIONAL LAB									
	PACIFIC REGIONAL LAB-NW									
	PACIFIC REGIONAL LAB-SW									
	PHILADELPHIA LAB									
	SAN FRANCISCO LAB									
	SOUTHEAST REGIONAL LAB									
	SAN JUAN LAB									
	WEAC									
ESTIMATED HOURS PER OPERATION		70.00								
TOTAL HOURS		700								
CONVERSION FACTOR		950								
TOTAL OPERATIONAL FTEs		0.74								

9. REMARKS

(1) Inspections will only cover Electronic Product and Radiation Control (EPRC) requirements under existing compliance programs, with additional guidance to be provided by CDRH.

- Inspectional resources have been planned at the national level in order to provide greater flexibility for the center to assign inspections to any district.
- Districts may utilize resources as needed to perform inspections assigned by the Center.