CENTER FOR DEVICES AND RADIOLOGICAL HEALTH
RESOURCE SUMMARY
FY 2018

PPS NO.	PROJECT TITLE	INSPECTIONAL FTES		ANALYTICAL FTES		TOTAL OPERATIONAL FTEs
		DOMESTIC	FOREIGN	DOMESTIC	FOREIGN	
		117.06	56.54	14.02	1.63	
	TOTAL	173.60		15.65		189.25
81	POSTMARKET ASSURANCE: DEVICES	2.40		0.05		2.45
82	COMPLIANCE: DEVICES	80.09	51.24	1.94		133.27
83	PRODUCT EVALUATION: DEVICES	6.41	4.16			10.57
84	SCIENCE: DEVICES			9.05		9.05
85	MAMMOGRAPHY QUALITY STANDARDS ACT (MQSA) AUTHORITY	16.91	0.09			17.00
86	RADIATION CONTROL AND HEALTH SAFETY ACT (RCHSA) AUTHORITY	11.25	1.05	2.98	1.63	16.91

PROJECT SUMMARY SHEET

FY 2018

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	FOREIGN		
	TOTAL		**2.45**		**2.45**	
1	Medical Device Problem Reporting- MDR Follow- up	81010	0.60		**0.60**	81-2
2	Enforcement Of The Medical Device Reporting (MDR) Regulation	81011	1.85		**1.85**	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	**0.60**

	6. ORGANIZATION	DOMESTIC INSPEC-TIONS (1)	DOMESTIC SAMPLE COLL STER	DOMESTIC SAMPLE COLL ENG	DOMESTIC SAMPLE ANALYSIS ENG	DOMESTIC SAMPLE ANALYSIS STER				
	TOTAL ORA	**84**	**1**	**1**	**1**	**1**				
ORAHQ	Office of Regulatory Affairs (National Experts)	(b) (5), (b) (7)(E) [redacted]								
IOG-MPT	International Operations - Medical Products and Tobacco (Foreign Cadre)									
OMDRHO	**OFFICE OF MED. DEV. & RAD HLTH OPR (TOTAL DIVISIONS)**									
MDRHE	Division of Medical Device & Rad Health Operations East									
MDRHC	Division of Medical Device & Rad Health Operations Central									
MDRHW	Division of Medical Device & Rad Health Operations West									
OMPTSLO	**TOTAL LABORATORY**									
FCC	Forensic Chemistry Center									
WEAC	Winchester Engineering and Analytical Center									
ESTIMATED HOURS PER OPERATION		6.00	8.20	8.20	37.00	20.00				
TOTAL HOURS		504.00	8.20	8.20	37.00	20.00				
CONVERSION FACTOR		950.00	950.00	950.00	1180.00	1180.00				
TOTAL OPERATIONAL FTEs		0.53	0.01	0.01	0.03	0.02				

9. 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.

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	**1.85**

	6. ORGANIZATION	**DOMESTIC INSPEC-TIONS**								
	TOTAL ORA	**585**								
ORAHQ	Office of Regulatory Affairs (National Experts)	(b) (5), (b) (7)(E) [redacted]								
IOG-MPT	International Operations - Medical Products and Tobacco (Foreign Cadre)									
OMDRHO	**OFFICE OF MED. DEV. & RAD HLTH OPR (TOTAL DIVISIONS)**									
MDRHE	Division of Medical Device & Rad Health Operations East									
MDRHC	Division of Medical Device & Rad Health Operations Central									
MDRHW	Division of Medical Device & Rad Health Operations West									
OMPTSLO	**TOTAL LABORATORY**									
FCC	Forensic Chemistry Center									
WEAC	Winchester Engineering and Analytical Center									
ESTIMATED HOURS PER OPERATION		3.00								
TOTAL HOURS		1755.00								
CONVERSION FACTOR		950.00								
TOTAL OPERATIONAL FTEs		1.85								

9. REMARKS

PROJECT SUMMARY SHEET

FY 2018

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	FOREIGN		
	TOTAL		**82.03**	**51.24**	**133.27**	
1	Inspection of Medical Device Manufacturers	82845, A- S	81.09	51.24	**132.33**	82-5-6
2	Center Initiated Assignments	82Z800	0.64		**0.64**	82-7
3	Forensic Evaluation and Sample Analysis	82R838	0.30		**0.30**	82-8

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

FY 2018 ORA WORK PLAN — October 1, 2017

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 ☐ CENTER	**132.33** [122.67]

	6. ORGANIZATION	DOMESTIC INSPECTIONS CLASS 2, 3 & UNCLASSIFIED LEVEL 1 82845A	DOMESTIC INSPECTIONS CLASS 2, 3 & UNCLASSIFIED LEVEL I 82845A (1)	DOMESTIC INSPECTIONS Class 2, 3 & UNCLASSIFIED LEVEL II 82845B	FOREIGN INSPEC-TIONS LEVEL II 82845B	DOMESTIC COMPLIANCE INSPEC-TIONS LEVEL III 82845C	FOREIGN COMPLIANCE INSPEC-TIONS LEVEL III 82845C	DOMESTIC FOR CAUSE INSPEC-TIONS 82845G	FOREIGN FOR CAUSE INSPEC-TIONS 82845G	DOMESTIC FOR CAUSE HIGH RISK INSPEC-TIONS 82845H
	TOTAL ORA	**982**	**737**	**134**	**679**	**181**	**14**	**164**	**11**	**96**
ORAHQ	Office of Regulatory Affairs (National Experts)	(b) (5), (b) (7)(E) [redacted]								
IOG-MPT	International Operations - Medical Products and Tobacco (Foreign Cadre)									
OMDRHO	**OFFICE OF MED. DEV. & RAD HLTH OPR (TOTAL DIVISIONS)**									
MDRHE	Division of Medical Device & Rad Health Operations East									
MDRHC	Division of Medical Device & Rad Health Operations Central									
MDRHW	Division of Medical Device & Rad Health Operations West									
OMPTSLO	**TOTAL LABORATORY**									
FCC	Forensic Chemistry Center									
WEAC	Winchester Engineering and Analytical Center									
ESTIMATED HOURS PER OPERATION		36.00		50.00	60.00	84.25	66.00	66.00	80.00	61.25
TOTAL HOURS		35352.00		6700.00	40740.00	15249.25	924.00	10824.00	880.00	5880.00
CONVERSION FACTOR		950.00		950.00	950.00	950.00	950.00	950.00	950.00	950.00
TOTAL OPERATIONAL FTEs		37.21		7.05	42.88	16.05	0.97	11.39	0.93	6.19

9. REMARKS

(1) Please use the Risk Based Prioritized list provided by CDRH to conduct these inspections.The inspections listed in this column are approximately 75% of the Level 1 (Class 2, 3 and unclassified firms) target. The risk based prioritized list is posted with the work plan on the WPB website. These operations have been planned using planning PAC 82845A. Please report all accomplishments using PAC 82845A.

FY 2018 ORA WORK PLAN — October 1, 2017

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 [ ] CENTER	**132.33** [9.66]

	6. ORGANIZATION	FOREIGN FOR CAUSE HIGH RISK INSPEC-TIONS 82845H	DOMESTIC STERIL-IZATION INSPEC-TIONS 82845S	FOREIGN STERIL-IZATION INSPEC-TIONS 82845S	DOMESTIC INVESTI-GATIONS INSPEC-(Hours) 82845B	AUDITS/ INVESTI-GATIONS MDSAP (Hours) 82845L	AUDITS/ INVESTI -GATIONS MDSAP (Hours) 82845M	DOMESTIC SAMPLE COLLEC-TIONS 82845 (2)	DOMESTIC SAMPLE ANALYSIS MICRO 82845 (3)	DOMESTIC SAMPLE ANALYSIS ENG 82845 (4)
	TOTAL ORA	**74**	**20**	**120**	**710**	**479**	**479**	**29**	**14**	**15**
ORAHQ	Office of Regulatory Affairs (National Experts)	(b) (5), (b) (7)(E) [redacted]								
IOG-MPT	International Operations - Medical Products and Tobacco (Foreign Cadre)									
OMDRHO	**OFFICE OF MED. DEV. & RAD HLTH OPR (TOTAL DIVISIONS)**									
MDRHE	Division of Medical Device & Rad Health Operations East									
MDRHC	Division of Medical Device & Rad Health Operations Central									
MDRHW	Division of Medical Device & Rad Health Operations West									
OMPTSLO	**TOTAL LABORATORY**									
FCC	Forensic Chemistry Center									
WEAC	Winchester Engineering and Analytical Center									
ESTIMATED HOURS PER OPERATION		70.00	10.00	8.00				7.74	15.92	63.38
TOTAL HOURS		5180.00	200.00	960.00	710.00	479.00	479.00	224.46	222.88	950.70
CONVERSION FACTOR		950.00	950.00	950.00	950.00	950.00	950.00	950.00	1180.00	1180.00
TOTAL OPERATIONAL FTEs		5.45	0.21	1.01	0.75	0.50	0.50	0.24	0.19	0.81

9. 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.
(4) 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	0.64

	6. ORGANIZATION	METHOD DEVELOP-MENT ENG (Hours)								
	TOTAL ORA	**750**								
ORAHQ	Office of Regulatory Affairs (National Experts)	(b) (5), (b) (7) (E)								
IOG-MPT	International Operations - Medical Products and Tobacco (Foreign Cadre)									
OMDRHO	**OFFICE OF MED. DEV. & RAD HLTH OPR (TOTAL DIVISIONS)**									
MDRHE	Division of Medical Device & Rad Health Operations East									
MDRHC	Division of Medical Device & Rad Health Operations Central									
MDRHW	Division of Medical Device & Rad Health Operations West									
OMPTSLO	**TOTAL LABORATORY**									
FCC	Forensic Chemistry Center									
WEAC	Winchester Engineering and Analytical Center									
ESTIMATED HOURS PER OPERATION										
TOTAL HOURS		750.00								
CONVERSION FACTOR		1180.00								
TOTAL OPERATIONAL FTEs		0.64								

9. REMARKS

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	0.30

	6. ORGANIZATION	FORENSIC ANALYSIS CHEM (Hours)								
	TOTAL ORA	**365**								
ORAHQ	Office of Regulatory Affairs (National Experts)	(b) (5), (b) (7)(E) [redacted]								
IOG-MPT	International Operations - Medical Products and Tobacco (Foreign Cadre)									
OMDRHO	**OFFICE OF MED. DEV. & RAD HLTH OPR (TOTAL DIVISIONS)**									
MDRHE	Division of Medical Device & Rad Health Operations East									
MDRHC	Division of Medical Device & Rad Health Operations Central									
MDRHW	Division of Medical Device & Rad Health Operations West									
OMPTSLO	**TOTAL LABORATORY**									
FCC	Forensic Chemistry Center									
WEAC	Winchester Engineering and Analytical Center									
ESTIMATED HOURS PER OPERATION										
TOTAL HOURS		365.00								
CONVERSION FACTOR		1205.00								
TOTAL OPERATIONAL FTEs		0.30								

9. REMARKS

PROJECT SUMMARY SHEET

FY 2018

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	FOREIGN		
	TOTAL		**6.41**	**4.16**	**10.57**	
1	Medical Device Premarket Approval and Postmarket Inspections:					
	Premarket Approval Inspections	83001	4.42	2.90	**7.32**	83-10
	Postmarket Approval Inspections	83001A	1.99	1.26	**3.25**	83-10

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	10.57

	6. ORGANIZATION	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	**95**	**52**	**45**	**23**					
ORAHQ	Office of Regulatory Affairs (National Experts)	(b) (5), (b) (7)(E) [redacted]								
IOG-MPT	International Operations - Medical Products and Tobacco (Foreign Cadre)									
OMDRHO	**OFFICE OF MED. DEV. & RAD HLTH OPR (TOTAL DIVISIONS)**									
MDRHE	Division of Medical Device & Rad Health Operations East									
MDRHC	Division of Medical Device & Rad Health Operations Central									
MDRHW	Division of Medical Device & Rad Health Operations West									
OMPTSLO	**TOTAL LABORATORY**									
FCC	Forensic Chemistry Center									
WEAC	Winchester Engineering and Analytical Center									
ESTIMATED HOURS PER OPERATION		44.20	53.00	42.00	52.00					
TOTAL HOURS		4199.00	2756.00	1890.00	1196.00					
CONVERSION FACTOR		950.00	950.00	950.00	950.00					
TOTAL OPERATIONAL FTEs		4.42	2.90	1.99	1.26					

9. REMARKS

PROJECT SUMMARY SHEET

FY 2018

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	FOREIGN		
	TOTAL		**9.05**		**9.05**	
1	Test Method Development and Evaluation	84Z002	5.05		**5.05**	84-12
2	Methods Validation/Development Program	84R816	4.00		**4.00**	84-13

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	[X] ORA [ ] CENTER	5.05

	6. ORGANIZATION	METHOD DEVELOP-MENT ENG (Hours) (1)								
	TOTAL ORA	**5960**								
ORAHQ	Office of Regulatory Affairs (National Experts)	(b) (5), (b) (7) (E)								
IOG-MPT	International Operations - Medical Products and Tobacco (Foreign Cadre)									
OMDRHO	**OFFICE OF MED. DEV. & RAD HLTH OPR (TOTAL DIVISIONS)**									
MDRHE	Division of Medical Device & Rad Health Operations East									
MDRHC	Division of Medical Device & Rad Health Operations Central									
MDRHW	Division of Medical Device & Rad Health Operations West									
OMPTSLO	**TOTAL LABORATORY**									
FCC	Forensic Chemistry Center									
WEAC	Winchester Engineering and Analytical Center									
ESTIMATED HOURS PER OPERATION										
TOTAL HOURS		5960								
CONVERSION FACTOR		1180								
TOTAL OPERATIONAL FTEs		5.05								

9. 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	4.00

	6. ORGANIZATION	APPLIED TECHNOLOGY CENTER METHOD DEVELOPMENT MIC (Hours)	METHOD DEVELOP-MENT/ VALID-ATION MIC (Hours)							
	TOTAL ORA	**2360**	**2410**							
ORAHQ	Office of Regulatory Affairs (National Experts)	(b) (5), (b) (7)(E) [redacted]								
IOG-MPT	International Operations - Medical Products and Tobacco (Foreign Cadre)									
OMDRHO	**OFFICE OF MED. DEV. & RAD HLTH OPR (TOTAL DIVISIONS)**									
MDRHE	Division of Medical Device & Rad Health Operations East									
MDRHC	Division of Medical Device & Rad Health Operations Central									
MDRHW	Division of Medical Device & Rad Health Operations West									
OMPTSLO	**TOTAL LABORATORY**									
FCC	Forensic Chemistry Center									
WEAC	Winchester Engineering and Analytical Center									
ESTIMATED HOURS PER OPERATION										
TOTAL HOURS		2360	2410							
CONVERSION FACTOR		1180	1205							
TOTAL OPERATIONAL FTEs		2.00	2.00							

9. REMARKS

PROJECT SUMMARY SHEET

FY 2018

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	FOREIGN		
	TOTAL		**16.91**	**0.09**	**17.00**	
1	Mammography Facilities Inspection Program	85014 A,C,F	16.91	0.09	**17.00**	85-15

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 ☐ CENTER	17.00

	6. ORGANIZATION	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	DOMESTIC INVESTI-GATIONS (Hours) 85014 (2)	TECHNICAL ASSITANCE NON-RRHR (Hours) 85014 (3)	TECHNICAL ASSISTANCE RRHR (Hours) 85014 (4)
	TOTAL ORA	**658**	**12**	**121**	**60**	**1**	**1528**	**2728**	**7480**	**1200**
ORAHQ	Office of Regulatory Affairs (National Experts)	(b) (5), (b) (7)(E) [redacted]								
IOG-MPT	International Operations - Medical Products and Tobacco (Foreign Cadre)									
OMDRHO	**OFFICE OF MED. DEV. & RAD HLTH OPR (TOTAL DIVISIONS)**									
MDRHE	Division of Medical Device & Rad Health Operations East									
MDRHC	Division of Medical Device & Rad Health Operations Central									
MDRHW	Division of Medical Device & Rad Health Operations West									
OMPTSLO	**TOTAL LABORATORY**									
FCC	Forensic Chemistry Center									
WEAC	Winchester Engineering and Analytical Center									
ESTIMATED HOURS PER OPERATION		8.00	9.00	8.00	8.00	13.00				
TOTAL HOURS		5264.00	108.00	968.00	480.00	13.00	1528.00	2728.00	7480.00	1200.00
CONVERSION FACTOR		1160.00	1160.00	1160.00	1160.00	1160.00	1160.00	1160.00	1160.00	1200.00
TOTAL OPERATIONAL FTEs		4.54	0.09	0.83	0.41	0.01	1.32	2.35	6.45	1.00

9. REMARKS

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) Inspection Follow-Up Activities. Resources planned as OP 13 (Domestic Investigations).

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

(4) Techical Assistance and Coordination Activities: RRHRs.

RRHRs SHOULD REPORT ALL TECHNICAL ASSISTANCE & COORDINATION HOURS

PROJECT SUMMARY SHEET

FY 2018

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	FOREIGN		
	TOTAL		**14.23**	**2.68**	**16.91**	
1	Inspection of Manufacturers of Laser Products	86001	2.42	0.85	**3.27**	86-17
2	Field Implementation of Sunlamp Regs	86002	0.35	0.19	**0.54**	86-18
3	Field Compliance Testing of Diagnostic X-Ray Equipment	86003	2.25	0.86	**3.11**	86-19
4	Compliance Testing of Electronic Products at WEAC	86006 (A, D, E)	2.27	0.78	**3.05**	86-20
5	Medical Device and Radiological Health Use Control Policy	86008	3.00		**3.00**	86-21
6	Emergency Planning and Response Activities	86009	2.00		**2.00**	86-21
7	Center Initiated Assignments- EPRC	86Z800	1.24		**1.24**	86-22
8	OEI Improvement Program- Rad Health	86R876	0.70		**0.70**	86-23

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
Laser Products Laser Product Manufacturer Compliance	Radiation Control and Health Safety Act (RCHSA)

3. PROGRAM/ASSIGNMENT CODE(S)	4. WORK ALLOCATION PLANNED BY	5. OPERATIONAL FTE POSITIONS
86001	[X] ORA [ ] CENTER	3.27

	6. ORGANIZATION	DOMESTIC INSPEC-TIONS (1)	FOREIGN INSPEC-TIONS (ENG) (2)	DOMESTIC INVESTI-GATIONS (Hours)	DOMESTIC SAMPLE COLLECTION DOC	FIELD EXAMS/ TESTS (3)	TECHNICAL ASSISTANCE/ TRAINING (Hours) (4)			
	TOTAL ORA	**95**	**25**	**285**	**17**	**74**	**751**			
ORAHQ	Office of Regulatory Affairs (National Experts)	(b) (5), (b) (7)(E) [redacted]								
IOG-MPT	International Operations - Medical Products and Tobacco (Foreign Cadre)									
OMDRHO	**OFFICE OF MED. DEV. & RAD HLTH OPR (TOTAL DIVISIONS)**									
MDRHE	Division of Medical Device & Rad Health Operations East									
MDRHC	Division of Medical Device & Rad Health Operations Central									
MDRHW	Division of Medical Device & Rad Health Operations West									
OMPTSLO	**TOTAL LABORATORY**									
FCC	Forensic Chemistry Center									
WEAC	Winchester Engineering and Analytical Center									
ESTIMATED HOURS PER OPERATION		10.00	40.00		5.50	3.00				
TOTAL HOURS		950.00	1000.00	285.00	93.50	222.00	751.00			
CONVERSION FACTOR		950.00	1180.00	950.00	950.00	950.00	950.00			
TOTAL OPERATIONAL FTEs		1.00	0.85	0.30	0.10	0.23	0.79			

9. 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
Sunlamp Regs Sunlamp Product Manufacturer Compliance	Radiation Control and Health Safety Act (RCHSA)

3. PROGRAM/ASSIGNMENT CODE(S)	4. WORK ALLOCATION PLANNED BY	5. OPERATIONAL FTE POSITIONS
86002	[X] ORA [ ] CENTER	0.54

	6. ORGANIZATION	DOMESTIC INSPEC-TIONS (1)	FOREIGN INSPEC TIONS	FIELD EXAMS/ TESTS (2)	TECHNICAL ASSIST-ANCE (Hours) (3)					
	TOTAL ORA	**10**	**9**	**28**	**66**					
ORAHQ	Office of Regulatory Affairs (National Experts)	(b) (5), (b) (7)(E) [redacted]								
IOG-MPT	International Operations - Medical Products and Tobacco (Foreign Cadre)									
OMDRHO	**OFFICE OF MED. DEV. & RAD HLTH OPR (TOTAL DIVISIONS)**									
MDRHE	Division of Medical Device & Rad Health Operations East									
MDRHC	Division of Medical Device & Rad Health Operations Central									
MDRHW	Division of Medical Device & Rad Health Operations West									
OMPTSLO	**TOTAL LABORATORY**									
FCC	Forensic Chemistry Center									
WEAC	Winchester Engineering and Analytical Center									
ESTIMATED HOURS PER OPERATION		20.00	20.00	2.40						
TOTAL HOURS		200.00	180.00	67.20	66.00					
CONVERSION FACTOR		950.00	950.00	950.00	950.00					
TOTAL OPERATIONAL FTEs		0.21	0.19	0.07	0.07					

9. 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
Diagnostic X-Ray Equipment Diagnostic X-Ray Manufacturer Compliance	Radiation Control and Health Safety Act (RCHSA)

3. PROGRAM/ASSIGNMENT CODE(S)	4. WORK ALLOCATION PLANNED BY	5. OPERATIONAL FTE POSITIONS
86003	[X] ORA [ ] CENTER	3.11

	6. ORGANIZATION	DOMESTIC INSPEC-TIONS	FOREIGN INSPEC-TIONS	DOMESTIC INVESTI-GATIONS (Hours)	METHOD DEVELOP-MENT (Hours)					
	TOTAL ORA	**75**	**22**	**738**	**248**					
ORAHQ	Office of Regulatory Affairs (National Experts)	(b) (5), (b) (7)(E) [redacted]								
IOG-MPT	International Operations - Medical Products and Tobacco (Foreign Cadre)									
OMDRHO	**OFFICE OF MED. DEV. & RAD HLTH OPR (TOTAL DIVISIONS)**									
MDRHE	Division of Medical Device & Rad Health Operations East									
MDRHC	Division of Medical Device & Rad Health Operations Central									
MDRHW	Division of Medical Device & Rad Health Operations West									
OMPTSLO	**TOTAL LABORATORY**									
FCC	Forensic Chemistry Center									
WEAC	Winchester Engineering and Analytical Center									
ESTIMATED HOURS PER OPERATION		16.00	37.00							
TOTAL HOURS		1200.00	814.00	738.00	248.00					
CONVERSION FACTOR		950.00	950.00	950.00	1180.00					
TOTAL OPERATIONAL FTEs		1.26	0.86	0.78	0.21					

9. REMARKS

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

3. PROGRAM/ASSIGNMENT CODE(S)	4. WORK ALLOCATION PLANNED BY	5. OPERATIONAL FTE POSITIONS
86006 A,D,E	[X] ORA [ ] CENTER	3.05

	6 ORGANIZATION	FOREIGN INSPEC-TIONS (ENG) (1)	DOMESTIC SAMPLE COLLECTION MICROWAVE 86006A	DOMESTIC SAMPLE COLLECTION NON-MED LASERS 86006E	DOMESTIC SAMPLE COLLECTION SUN LAMPS 86006G (2)	DOMESTIC SAMPLE ANALYSIS MICROWAVE 86006A	DOMESTIC SAMPLE ANALYSIS X-RAY 86006D	DOMESTIC SAMPLE ANALYSIS NON-MED LASERS 86006E	DOMESTIC SAMPLE ANALYSIS SUN LAMPS 86006G (3)
	TOTAL ORA	**10**	**66**	**49**	**20**	**66**	**1**	**49**	**20**
ORAHQ	Office of Regulatory Affairs (National Experts)	(b) (5), (b) (7)(E) [redacted]							
IOG-MPT	International Operations - Medical Products and Tobacco (Foreign Cadre)								
OMDRHO	**OFFICE OF MED. DEV. & RAD HLTH OPR (TOTAL DIVISIONS)**								
MDRHE	Division of Medical Device & Rad Health Operations East								
MDRHC	Division of Medical Device & Rad Health Operations Central								
MDRHW	Division of Medical Device & Rad Health Operations West								
OMPTSLO	**TOTAL LABORATORY**								
FCC	Forensic Chemistry Center								
WEAC	Winchester Engineering and Analytical Center								
ESTIMATED HOURS PER OPERATION		92.00	1.00	4.00	2.00	11.24	248.41	20.07	19.80
TOTAL HOURS		920.00	66.00	196.00	40.00	741.84	248.41	983.43	396.00
CONVERSION FACTOR		1180.00	1180.00	1180.00	1180.00	1180.00	1180.00	1180.00	1180.00
TOTAL OPERATIONAL FTEs		0.78	0.06	0.17	0.03	0.63	0.21	0.83	0.34

9. 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
Radiological Health Control Activities	Radiation Control and Health Safety Act (RCHSA)

3. PROGRAM/ASSIGNMENT CODE(S)	4. WORK ALLOCATION PLANNED BY	5. OPERATIONAL FTE POSITIONS
86008, 86009	[X] ORA [ ] CENTER	5.00

	6. ORGANIZATION	TECHNICAL ASSIST-ANCE (Hours) RRHR 86008 (1)	EMER-GENCY RESPONSE (Hours) RRHR 86009 (2)							
	TOTAL ORA	**3600**	**2400**							
ORAHQ	Office of Regulatory Affairs (National Experts)	(b) (5), (b) (7)(E) [redacted]								
IOG-MPT	International Operations - Medical Products and Tobacco (Foreign Cadre)									
OMDRHO	**OFFICE OF MED. DEV. & RAD HLTH OPR (TOTAL DIVISIONS)**									
MDRHE	Division of Medical Device & Rad Health Operations East									
MDRHC	Division of Medical Device & Rad Health Operations Central									
MDRHW	Division of Medical Device & Rad Health Operations West									
OMPTSLO	**TOTAL LABORATORY**									
FCC	Forensic Chemistry Center									
WEAC	Winchester Engineering and Analytical Center									
ESTIMATED HOURS PER OPERATION										
TOTAL HOURS		3600.00	2400.00							
CONVERSION FACTOR		1200.00	1200.00							
TOTAL OPERATIONAL FTEs		3.00	2.00							

9. 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)

3. PROGRAM/ASSIGNMENT CODE(S)	4. WORK ALLOCATION PLANNED BY	5. OPERATIONAL FTE POSITIONS
86Z800	[X] ORA [ ] CENTER	1.24

	6. ORGANIZATION	DOMESTIC INSPEC-TIONS 86Z800 (1)	TECHNICAL ASSISTANCE (OP 92) (Analytical) Hours (2)							
	TOTAL ORA	**10**	**590**							
ORAHQ	Office of Regulatory Affairs (National Experts)	(b) (5), (b) (7)(E) [redacted]								
IOG-MPT	International Operations - Medical Products and Tobacco (Foreign Cadre)									
OMDRHO	**OFFICE OF MED. DEV. & RAD HLTH OPR (TOTAL DIVISIONS)**									
MDRHE	Division of Medical Device & Rad Health Operations East									
MDRHC	Division of Medical Device & Rad Health Operations Central									
MDRHW	Division of Medical Device & Rad Health Operations West									
OMPTSLO	**TOTAL LABORATORY**									
FCC	Forensic Chemistry Center									
WEAC	Winchester Engineering and Analytical Center									
ESTIMATED HOURS PER OPERATION		70.00								
TOTAL HOURS		700.00	590							
CONVERSION FACTOR		950.00	1180							
TOTAL OPERATIONAL FTEs		0.74	0.50							

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.

(2) Hours will be used for providing training (developing training materials) and technical assistance by ORA lab analysts.

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
OEI Improvement Program- Rad Health	Radiation Control and Health Safety Act (RCHSA)

3. PROGRAM/ASSIGNMENT CODE(S)	4. WORK ALLOCATION PLANNED BY	5. OPERATIONAL FTE POSITIONS
86R876	[X] ORA [ ] CENTER	0.70

	6. ORGANIZATION	OEI IMPROVE-MENT (Hours) 86R876								
	TOTAL ORA	**663**								
ORAHQ	Office of Regulatory Affairs (National Experts)	(b) (5), (b) (7) (E)								
IOG-MPT	International Operations - Medical Products and Tobacco (Foreign Cadre)									
OMDRHO	**OFFICE OF MED. DEV. & RAD HLTH OPR (TOTAL DIVISIONS)**									
MDRHE	Division of Medical Device & Rad Health Operations East									
MDRHC	Division of Medical Device & Rad Health Operations Central									
MDRHW	Division of Medical Device & Rad Health Operations West									
OMPTSLO	**TOTAL LABORATORY**									
FCC	Forensic Chemistry Center									
WEAC	Winchester Engineering and Analytical Center									
ESTIMATED HOURS PER OPERATION										
TOTAL HOURS		663.00								
CONVERSION FACTOR		950.00								
TOTAL OPERATIONAL FTEs		0.70								

9. REMARKS