DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Medical Devices; Quality System Regulation Amendments

Docket No. FDA-2021-N-0507

Preliminary Regulatory Impact Analysis
Initial Regulatory Flexibility Analysis
Unfunded Mandates Reform Act Analysis

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I. Introduction and Summary

A. Introduction

We have examined the impacts of the proposed rule under Executive Order 12866, Executive Order 13563, the Regulatory Flexibility Act (5 U.S.C. 601-612), and the Unfunded Mandates Reform Act of 1995 (Pub. L. 104-4). Executive Orders 12866 and 13563 direct us to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). We believe that this proposed rule is an economically significant regulatory action as defined by Executive Order 12866.

The Regulatory Flexibility Act requires us to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because the burden of the proposed rule on very small medical device establishment (as defined in the analysis), we propose to certify that the proposed rule will not have a significant economic impact on a substantial number of small entities.

The Unfunded Mandates Reform Act of 1995 (section 202(a)) requires us to prepare a written statement, which includes an assessment of anticipated costs and benefits, before proposing "any rule that includes any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more (adjusted annually for inflation) in any one year." The current threshold after adjustment for inflation is $158 million, using the most current (2020) Implicit Price Deflator for the Gross Domestic Product. This proposed rule would not result in an expenditure in any year that meets or exceeds this amount.

B. Summary of Costs and Benefits

Table 1 includes summary of estimated benefits (cost savings) and costs of the proposed rule. The benefit of the proposed rule is estimated in terms of reduction of compliance effort, and consequently cost savings, for medical device establishments that currently comply with both standards. The costs of the rule include initial training of personnel, and information technology and documentation update for the medical

device industry and the FDA. There is also a one-time cost of reading and learning the rule for the medical device establishments. We request comment on our benefits and costs estimates of the proposed rule.

Table 1: Summary of Benefits, Costs and Distributional Effects of Proposed Rule (Millions $)

Category		Primary Estimate	Low Estimate	High Estimate	Units			Notes
					Year Dollars	Discount Rate	Period Covered	
Benefits*	Annualized Monetized $M/year	$533	$267	$1,332	2020	7%	10 years	Benefits are cost savings
		$439	$220	$1,097	2020	3%	10 years	Benefits are cost savings
	Annualized Quantified					7%		
						3%		
	Qualitative							
Costs	Annualized Monetized $M/year	$6.96	$6.96	$6.96	2020	7%	10 years	
		$5.73	$5.73	$5.73	2020	3%	10 years	
	Annualized Quantified					7%		
						3%		
	Qualitative							
Transfers	Federal Annualized Monetized $M/year					7%		
						3%		
	From/ To	From:			To:			
	Other Annualized Monetized $M/year					7%		
						3%		
	From/To	From:			To:			
Effects	State, Local or Tribal Government: Small Business: Wages: Growth:							

* Estimated benefits are in terms of cost savings for medical device establishments that conform to the current Part 820 and ISO 13485. Other benefits that are not quantified potentially include quicker delivery and more efficient access to necessary devices for patients, leading to improvement of quality of life for consumers.
Note: All figures are in millions of dollars.

We have developed a comprehensive Preliminary Economic Analysis of Impacts that assesses the impacts of the proposed rule. The full analysis of economic impacts is available in the docket for this proposed rule (Ref. 11) and at http://www.fda.gov/AboutFDA/ReportsManualsForms/Reports/EconomicAnalyses/default.htm.

II. Preliminary Regulatory Impact Analysis

A. Background

Currently, FDA requires current Good Manufacturing Practices (CGMP) under the Quality System regulation (QSR) (21 CFR part 820) to ensure the required methods used in, and the facilities and controls used for, designing, manufacturing, packaging, labeling, storing, installing, and servicing of devices intended for human use. FDA proposes to converge the QSR with the quality management system requirements used by other regulatory authorities from other jurisdictions by amending current 21 CFR part 820 (Part 820) through incorporating by reference the International Organization for Standardization (ISO) requirements for medical devices under ISO 13485 (2016 edition). FDA is also proposing conforming edits to 21 CFR Part 4 to clarify medical device requirements for combination products, and to connect and align 21 CFR Part 4 with ISO 13485 and the proposed rule.

B. Market or Government Failure Requiring Federal Regulatory Action

Currently, establishments in the medical device industry registered with the FDA must comply with the current Part 820. In addition to the current Part 820, registered foreign establishments and domestic establishments that export their medical devices comply with ISO 13485, which is substantially similar to the current Part 820. The current Part 820 and ISO 13485 were concurrently implemented in 1996. In 2016, the International Organization for Standardization updated ISO 13485 in response to the latest quality management practices, including changes in technology and regulatory requirements and expectations. The current Part 820 has not been updated since its initial implementation in 1996. The buildup of competing standards over time leads to duplicative and sometimes obsolete constraints which, in turn, distorts the decision-making processes of establishments operating in the affected industry resulting in efficiency loss. As a result, some firms are overburdened by redundant effort in complying with both the current Part 820 and ISO 13485. The proposed rule intends to amend current Part 820 by incorporating ISO 13485 requirements so that compliance with ISO

13485 would satisfy requirements of the proposed rule; thereby, reducing regulatory burden of certain medical device manufacturers.

C. Purpose of the Proposed Rule

Many U.S. manufacturers are using two separate but similar requirements for quality system management of their medical devices – current Part 820 and ISO 13485. Although the current Part 820 requirements are effective to ensure that manufacturers of medical devices meet the applicable quality system requirements and specifications, FDA believes that proposing to apply ISO 13485 for all quality system requirements will reduce regulatory burden on device manufacturers and align common regulatory standards of the current Part 820 by harmonizing domestic and international requirements. When this rule is finalized, U.S. device manufacturers who distribute medical devices globally will have a harmonized quality management system to comply with requirements of regulating agencies/bodies. In addition, the transition to ISO for all medical devices has the potential to increase competitiveness of U.S. device manufacturers in a global market.

D. Baseline Conditions and Overview of Proposed Regulatory Changes

1. Comparison of the Current 21 CFR Part 820 and ISO 13485

We determined that the requirements in the current Part 820 are substantially similar to those of ISO 13485. The current Part 820 was compared to the ISO 13485 by FDA subject matter experts. FDA analyzed the comparison of the current Part 820 and ISO 13485 reached a consensus that the provisions are the same or substantially similar while some provisions of the FDA rule do not correlate to a single specific requirement in the ISO standard. In some instances, we found requirements need better clarification but are not intended to take a position on the matter of comparison; rather, these clarifications ensure implementation of a QMS is aligned with FDA expectations and regulations. In some instances, we determined that substituting a provision from the ISO 13485 instead of its counterpart in the current Part 820 in the proposed rule would reduce amount of regulatory effort.

While there was consensus that the proposed rule would decrease the regulatory burden of medical device establishments that comply with both standards, it was not possible to assess the provision-by-provision

increase or decrease of effort difference between the current Part 820 and the proposed rule. Some sources of costs savings for the industry include reduction of effort in:

- Preparation for inspections and audits. Given that the requirements of both standards would be aligned, FDA expects a reduction of effort in industry maintaining a state of preparedness for inspections and audits. With aligned requirements, the expectations for documentation to show conformity to requirements should reduce the duplication of effort by industry currently, in preparing for visits from regulators.
- Internal audits and management reviews. The proposed rule would result in establishments conducting internal audits and management reviews based on a single set of aligned requirements as opposed to auditing and assessing separately to the requirements of current Part 820 and ISO 13485 individually.
- Training costs: The harmonization of requirements would reduce training costs of industry in that there would only need to be internal training for a single set of aligned requirements. Maintaining multiple quality management systems requires training personnel on both the requirements of the current Part 820 and ISO 13485 in order to maintain a QMS that is in conformity with both standards.
- Documentation requirements. While the documentation requirements are substantively similar, there is a reduction of specific documentation types/files required in the proposed rule. The current 820 contains requirements for record types that are not specifically identified in ISO 13485, such as quality system record, device master record, design history file, and device history record. FDA has chosen to remove the requirements for specifically identified files, as we believe the elements that comprise those records are largely required to be documented by other ISO 13485 clauses, reducing burden on establishments to create separate files to meet those requirements.

In addition, the proposed rule would clarify some requirements in the current Part 820 that would lead to efficiency gains. For instance, in ISO 13485, there is a specific section requiring sterilization of medical device products, including validation; whereas, the current Part 820 requires that processes more generally be validated. For example, sterilization is specifically referenced as an example of a type of process that

must be validated in the preamble. The same is true of integrated risk management requirements. The current part 820 explicitly addresses risk management activities only in the risk analysis requirement within design validation in § 820.30(g); whereas, risk management requirements are more specifically listed throughout clauses in ISO 13485. FDA's current expectation that establishments integrate risk management activities across the total product lifecycle is discussed primarily within the preamble. This would require those to refer to the preamble to understand this expectation as opposed to have it clearly listed with the requirements of documents.

In lieu of estimating granular comparison of the two standards for establishment of different sizes, we decide on an overall decrease of regulatory burden for the affected establishment. FDA experts assess that the proposed rule would potentially, on average, result between 5% and 25% in reduction of compliance effort. In this analysis, we assume the effort of a medical device establishment that currently complies with both the current Part 820 and ISO 13485 would decrease by 10% by complying with the proposed rule. We use different reduction of burden rates of 5% and 25% in the Sensitivity Analysis section to measure the lower and upper bound estimates of these cost savings. We request comments on our assumption that establishments that currently comply with both standards would, on average, reduce their regulatory burden by 10%. We believe the effort of establishments that currently comply only with the current Part 820 is equal with the effort needed to comply with the proposed rule. We request comment on this assumption.

2. Affected Establishments

As of September 2020, there are 22,845 domestic and foreign medical device establishments registered with the FDA (see Table 2). FDA believes that initial importers would not be affected by the proposed rule. Therefore, the number of domestic establishments considered for the analysis is 8,631 (11,130 – 2,499). We request comment on how this rule, if finalized, will impact (change) decision to export products to U.S.

Table 2. Medical Device Establishments Registered with the FDA, 2020

Establishment Type	Domestic	Foreign	Total
Manufacturer/Complaint File Handler	5,291	8,720	14,011

Contract Manufacturer	959	1,417	2,376
Contract Sterilizer	63	124	187
Specification Developer	1,340	480	1,820
Re-processor of Single Use Devices	16	2	18
U.S. Manufacturer of Export Only Devices	90	0	90
Re-packager/Re-labeler	857	149	1,006
Remanufacturer	14	7	21
Foreign Exporter/Private Label Distributor		815	815
Initial Importer	2,499		2,499
Unknown	1	1	2
Total	**11,130**	**11,715**	**22,845**

***FDA, CDRH, September 2020**

3. Establishment Size

To determine the size demographics of medical device manufacturers, we use information from Department of Commerce's 2019 County Business Patterns (CBP) for the North American Industry Classification System (NAICS) codes typically used to identify medical device manufacturers (Table 3).

Table 3. NAICS Codes for Medical Device Manufacturers

NAICS Code	Establishment description	Number of Establishments
325413	In-vitro diagnostic substance manufacturing	250
334510	Electromedical and electrotherapeutic apparatus manufacturing	894
334517	Irradiation apparatus manufacturing	136
339112	Surgical and medical instrument manufacturing	1,283
339113	Surgical appliance and supplies manufacturing	1,786
339114	Dental equipment and supplies manufacturing	552
339115	Ophthalmic goods manufacturing	476
Total Establishments		**5,377**

Source: Department of Commerce, 2019 County Business Patterns, May 2021.

We distribute medical device establishments into five size categories: very small (1-9 employees), small (10-19 employees), medium (20-99 employees), large (100-249 employees), and very large (250+ employees). The 2019 CBP data for NAICS codes described in Table 3 indicates that approximately 51.5% of all manufacturing establishments are considered very small (1-9 employees), 12.5% are small establishments (10-19 employees), 21.4% are medium-sized establishments (20-99 employees), 8.2% are large (100-249 employees), and 6.3% are very large (250+ employees) (see Tables 4 and 7). We use these proportions to

estimate numbers of manufacturers of medical device registered with FDA by employment size. The CBP data indicates that the very small establishments defined as establishments that have a payroll of under $0.5 million.

Because we do not have robust data on the number of firms that currently comply with ISO 13485, we are using very small domestic medical device manufacturing establishments to represent those who will proportionally bear a greater burden of one-time costs by the proposed rule. As such, for the sake of this analysis we assume that very small medical device manufacturing establishments currently do not sell their products abroad and do not comply with ISO 13485. We request comment on this assumption.

Table 4. Size of Medical Device Manufacturing Establishments by Number of Employees for Selected NAICS Codes

NAICS Code	Establishment Size (no. of employees)					
	Very Small (1-9)	Small (10-19)	Medium (20-99)	Large (100-249)	Very large (250+)	Total
325413	87	28	78	24	33	250
334510	410	97	223	79	85	894
334517	55	20	35	15	11	136
339112	561	157	294	161	110	1,283
339113	1,019	234	354	107	72	1,786
339114	393	64	60	26	9	552
339115	244	73	108	31	20	476
Total	**2,769**	**673**	**1,152**	**443**	**340**	**5,377**
Proportion	**51.5%**	**12.5%**	**21.4%**	**8.2%**	**6.3%**	**100.0%**

Source: Department of Commerce, 2019 County Business Patterns, May 2021.

For the reasons stated, we assume that very small domestic manufacturers do not export their products and do not comply with ISO 13485. We also assume that very small foreign medical establishments do not export their products to the US. In addition, we assume that all foreign medical device establishments that currently exports to the U.S. comply with ISO 13485. To determine the proportions of small, medium, large, and very large foreign registered establishments, we extrapolate the proportions in Table 5 for those size categories. For example, the proportion of small foreign medical device establishments to all foreign establishments is 25.8% (12.5% ÷ (12.5% + 21.4% + 8.2% + 6.3%)). Similarly, the proportion of foreign companies that are medium, large, and very large are 44.2%, 17.0%, and 13.0% respectively (see Table 7). We

request comment on our assumptions regarding foreign medical device establishments exportation to the U.S and foreign facilities compliance with the ISO 13485 standard.

To determine the size demographics of importers of medical device products, we use information from CBP for the NAICS codes typically used to identify medical device importers (Table 5).

Table 5. NAICS Codes for Medical Device Importers

NAICS Code	Establishment description	No. of Ests.
423450	Medical, dental, and hospital equipment and supplies merchant wholesalers	10,494
423460	Ophthalmic goods merchant wholesalers	1,069
Total Establishments		**11,563**

Source: Department of Census, 2019 County Business Patterns, May 2021.

The 2019 CBP data for NAICS codes described in Table 3 indicates that there are approximately 72.5% of all medical device importers are considered very small (1-9 employees), 10.3% are small-sized establishments, 13.0% are medium sized establishments (20-99 employees), 2.7% are large (100-249 employees), and 1.4% are very large (250+ employees) (see Tables 6 and 7).

Table 6. Size of Medical Device Importers by Number of Employees for Selected NAICS Codes[1]

NAICS Code	Establishment Size (no. of employees)					
	Very Small (1-9)	Small (10-19)	Medium (20-99)	Large (100-249)	Very large (250+)	Total
423450	7,651	1,069	1,337	285	152	10,494
423460	735	119	171	31	13	1,069
Total	**8,386**	**1,188**	**1,508**	**316**	**165**	**11,563**
Proportion	**72.5%**	**10.3%**	**13.0%**	**2.7%**	**1.4%**	**100.0%**

[1] Department of Census, Bureau of Labor Statistics, 2019 County Business Patterns, May 2021.

Table 7. Proportion of Medical Device Establishments by Type and Establishment Size

Establishment Type	Establishment Size (no. of employees)				
	Very Small (1-9)	Small (10-19)	Medium (20-99)	Large (100-249)	Very Large (250+)
Domestic manufacturers	51.5%	12.5%	21.4%	8.2%	6.3%
Foreign manufacturers	N/A[1]	25.8%	44.2%	17.0%	13.0%
Importers	72.5%	10.3%	13.0%	2.7%	1.4%

[1] We assume that very small foreign medical device establishments do not export their products to the US.

We use the number of medical device establishments registered with FDA (Table 2) and proportion of medical device establishment by type and size (Table 7) to estimate the distribution of medical device establishments by type and employee size (see Tables 8a and 8b). The proposed rule increases the burden of very small domestic medical device manufacturers to switch their compliance from the current Part 820 to the proposed rule, while it decreases the burden of all other medical device establishments by moving from compliance with both standards to the proposed rule. Table 8a shows there are 4,445 very small domestic medical device establishments, establishments that we assume don't currently comply with ISO 13485 in addition to the current Part 820. These establishments incur a net cost as a result of the proposed rule. Other medical device establishments, 15,901 (4,186 domestic and 11,715 foreign establishments), experience net cost savings due to the proposed rule (see Tables 8a and 8b). The total number of medical device establishments that will be covered under the proposed rule is 20,346 (8,631 domestic establishments + 11,715 foreign establishments) (see Tables 8a and 8b).

Table 8a. Universe of Domestic Medical Device Establishments Affected by the Proposed Rule

Establishment Type	Domestic	Domestic			
	Very Small (1-9)	Small (10-19)	Medium (20-99)	Large (100-249)	Very Large (250+)
Manufacturer/Complaint File Handler	2,725	662	1,134	436	335
Contract Manufacturer	494	120	205	79	61
Contract Sterilizer	32	8	13	5	4
Specification Developer	690	168	287	110	85
Re-processor of Single Use Devices	8	2	3	1	1
U.S. Manufacturer of Export Only Devices	46	11	19	7	6
Re-packager/Re-labeler	441	107	184	71	54
Remanufacturer	7	2	3	1	1
Foreign Exporter/Private Label Distributor	0	0	0	0	0
Unknown	1	0	0	0	0
Total Manufacturers	**4,445**	**1,080**	**1,849**	**711**	**546**
Initial Importers	**1,812**	**257**	**326**	**68**	**36**
TOTAL	**6,257**	**1,337**	**2,175**	**779**	**581**
Very Small Manufacturers	**4,445**	**4,186**			
All Other Manufacturers					

Note: We multiply number of establishments (Table 2) by appropriate size proportion (Table 7) to derive the above numbers.

Table 8b. Universe of Foreign Medical Device Establishments Affected by the Proposed Rule

Establishment Type	Foreign			
	Small (10-19)	**Medium (20-99)**	**Large (100-249)**	**Very Large (250+)**
Manufacturer/ Complaint File Handler	2,250	3,852	1,481	1,137
Contract Manufacturer	366	626	241	185
Contract Sterilizer	32	55	21	16
Specification Developer	124	212	82	63
Re-processor of Single Use Devices	1	1	0	0
U.S. Manufacturer of Export Only Devices	0	0	0	0
Re-packager/Re-labeler	38	66	25	19
Remanufacturer	2	3	1	1
Foreign Exporter/Private Label Distributor	210	360	138	106
Unknown	0	0	0	0
Total Manufacturers	**3,023**	**5,175**	**1,990**	**1,527**
Initial Importers	**0**	**0**	**0**	**0**
TOTAL	**3,023**	**5,175**	**1,990**	**1,527**
All Foreign manufacturers	**11,715**			

Note: We multiply number of establishments (Table 2) by appropriate size proportion (Table 7) to derive the above numbers.

E. Cost Savings (Benefits) of the Proposed Rule

The primary benefit of the proposed rule is cost savings that come from the reduction of compliance effort by medical device establishments that currently follow both the current Part 820 and ISO 13485. In Section D, we estimated the number of small to very large medical device establishments that currently comply with both the current Part 820 and ISO 13485; these medical device establishments include 4,186 domestic manufacturing facilities (see Table 8a), and 11,715 foreign manufacturing facilities (see Table 8b). We assume the effort of a medical device establishment that complies with both the current Part 820 and ISO 13485 would decrease by 10% by complying with the proposed rule. We use different reduction of burden rates of 5% and 25% in the Sensitivity Analysis section to measure the lower and upper bound estimates of these benefits.

We use number of annual labor hours needed to comply with each provision of the current Part 820 final rule published in 1996 (21 CFR Parts 808, 812, and 820, Vol. 61, No. 195, October 7, 1996, pgs. 52602-62) and include the assumption of 10% reduction in burden to estimate annual labor hours saved for small to very large

medical device establishments for each provision. We then use information from the 1996 Part 820 final rule to determine proportion of types of labor needed to comply with each provision, and wage rates published by Department of Census's Bureau of Labor Statistics (BLS) (see Table 9) to estimate cost savings (reduction in burden) of complying with the proposed rule for certain establishments. Wage rates have been doubled to include overhead.

These annual cost savings are estimated by each subpart of the current Part 820, below. Table 10 presents summary annual cost savings for small to very large medical device establishments to comply with the proposed rule.

Table 9. Medical Device Industry Wage Rates for Selected Labor Categories

Labor Category	Wages (/hour)	NAICS	OCC Code
Vice president	$95.12	339100	11-1011
Upper management	$71.51	339100	11-2000
Middle management	$66.63	339100	11-3000
Technical	$40.44	339100	Multiple
Admin support	$31.36	339100	43-6011
Clerical	$17.38	339100	43-4070

Source: U.S. Bureau of Labor Statistics, May 2020 National Occupational Employment and Wage Estimates, United States.
Link: https://www.bls.gov/oes/current/oes_nat.htm#11-0000, Last accessed: June, 2021.
Note: All wage rates are doubled in calculation of costs and cost savings to account for overhead costs.

Table 10. Annual Cost Savings for Small to Very Large Medical Device Manufacturing Establishments

Part 820 Subpart	Cost Savings
Subpart A – General Provisions*	N/A
Subpart B – Quality System Requirements (see Table 14)	$6,614,627
Subpart C – Design Controls (see Table 18)	$396,781,551
Subpart D – Document Controls (see Table 21)	$484,520
Subpart E – Procurement (see Table 25)	$17,081,146
Subpart F – Identification and Traceability (see Table 28)	$173,429
Subpart G – Production and Process Controls (see Table 32)	$1,790,712
Subpart H – Acceptance Activities (see Table 35)	$259,190
Subpart I – Nonconforming Components and Devices (see Table 38)	$484,520
Subpart J – Corrective and Preventive Action (see Table 41)	$484,520
Subpart K – Labeling and Packaging Control*	$259,190
Subpart L – Handling, Storage, Distribution, and Installation (see Table 44)	$518,380
Subpart M – Records (see Table 47)	$484,520
Subpart N – Servicing (see Table 50)	$484,520
Subpart O – Statistical Techniques (see Table 53)	N/A
Total Annual Cost Savings	**$425,900,822**

Note: These are undiscounted annual cost savings.

Subpart A – General Provisions

Subpart A describes the scope, legal authority, and definitions of terms used in the current Part 820. It also states that manufacturers establish and maintain a quality system. FDA is not proposing to modify the scope of manufacturers and products which are subject to the current Part 820. To account for differences between definitions in current section 820.3 of the current Part 820 and Clause 3 of ISO 13485, FDA proposes to retain, revise, and/or withdraw certain definitions that are in the current section 820.3. The one-time cost of understanding how the proposed rule would modify the definitions in the current Part 820 are discussed in Section VIII.F, below. The annual cost savings associated with maintaining a quality system is estimated in Subpart B, below.

Subpart B – Quality System Requirements

Subpart B of the current Part 820 pertains to management's responsibility for assuring the existence and implementation of a quality system by documentation, and communication to employees of their quality policy and objectives. We assume that each medical device establishment that complies with both the current Part 820 and ISO 13485 would require 10% less annual labor hours to comply with the proposed rule for each provision of Subpart B, as explained in Section D.1. of this document. We request comment on this assumption. In the sensitivity analysis section, we compare the decrease in compliance effort by 5% and 25%. Table 11 shows the number of annual labor hours saved for each provision of the current Part 820, Subpart B, for a medical device establishment complying with the proposed rule.

Table 11. Number of Annual Labor Hours Saved by a Medical Device Establishment to Comply with the Proposed Rule, Subpart B

Part 820, Subpart B	**Establishment Size**			
	Small	**Medium**	**Large**	**Very Large**
Current 820.20(a) Quality Policy				
- Maintain Quality Policy[1]	1	1	2	2
Comply with NRPM[2]	0.9	0.9	1.8	1.8
Labor hours saved	**0.1**	**0.1**	**0.2**	**0.2**
Current 820.20(b) Organization				
- Maintain organizational structure	0	1	2	2
Comply with NRPM[2]	0	0.9	1.8	1.8
Labor hours saved	**0**	**0.1**	**0.2**	**0.2**

Current 820.20(c) Management Review				
- Review by management representative[1]	8	12	16	24
Comply with NRPM[2]	7.2	10.8	14.4	21.6
Labor hours saved	**0.8**	**1.2**	**1.6**	**2.4**
Current 820.20(d) Quality Planning				
- Maintain quality plan[1]	4	6	8	10
Comply with NRPM[2]	3.6	5.4	7.2	9
Labor hours saved	**0.4**	**0.6**	**0.8**	**1**
Current 820.20(e) Quality System Procedures				
- Maintain QSP[1]	4	6	8	10
Comply with NRPM[2]	3.6	5.4	7.2	9
Labor hours saved	**0.4**	**0.6**	**0.8**	**1**
Current 820.22 Quality Audit				
- Maintain procedures[1]	1	1	2	2
Comply with NRPM[2]	0.9	0.9	1.8	1.8
Labor hours saved	**0.1**	**0.1**	**0.2**	**0.2**
Current 820.25 Personnel				
- Maintain procedures[1]	1	1	2	2
Comply with NRPM[2]	0.9	0.9	1.8	1.8
Labor hours saved	**0.1**	**0.1**	**0.2**	**0.2**

1. Part 820 Final Rule, 1996.
2. Assume 10% decrease in effort in moving from complying with two similar standards to the proposed rule.

We use information from the 1996 Part 820 final rule to determine proportions of types of labor needed to comply with each section of Subpart B (see Table 12), and appropriate wage rates and overhead costs (see Table 9) to estimate benefits of complying with the proposed rule for affected establishments.

Table 12. Proportion of Annual Labor by Labor Category, Subpart B

Part 820, Subpart B	**Labor Category**					
	Vice President	**Upper Mgmt.**	**Middle Mgmt.**	**Technical**	**Admin Support**	**Clerical**
820.20(a) Quality Policy - Maintain Quality Policy	50%	50%	0%	0%	0%	0%
820.20(b) Organization - Maintain organizational structure	0%	80%	10%	0%	0%	10%
820.20(c) Management Review - Review by management representative	0%	100%	0%	0%	0%	0%
820.20(d) Quality Planning - Maintain quality plan 820.20(e) Quality System Procedures	0%	20%	70%	0%	0%	10%

- Maintain QSP	0%	20%	70%	0%	0%	10%
820.22 Quality Audit						
- Maintain procedures	0%	20%	70%	0%	0%	10%
820.25 Personnel						
- Maintain procedures	0%	20%	70%	0%	0%	10%

Source: Part 820 Final Rule, 1996

Using the number of hours saved in annual labor (Table 11) by proportion of labor category (Table 12), and by appropriate wage rate and overhead costs (Table 9), we determine the benefit of reduced annual labor burden to comply with Subpart B of the current Part 820 for affected entities (see Tables 13a and 13b). Benefits of complying with Subpart B of the current Part 820 by moving from compliance of both systems to the proposed rule results in a saving of approximately $6.7 million per year for the affected entities (see Table 14).

To illustrate estimated figures in Table 13a, as an example, we use estimated cost savings of $18,001 for small domestic medical device establishment to comply with the equivalent section of the proposed rule that pertains to Section 820.20(a) of the current Part 820: we expect that a small medical device establishment saves 0.1 hours as a result of the proposed rule (see Table 11). We use proportions of labor type to comply with the equivalent section of the proposed rule that pertains to section 820.20(a) of the current Part 820; namely, 50% for Vice President and 50% for Upper Management (see Tale 12) by their appropriate fully-loaded wage rates (hourly wage rates + benefits equaling 100% of wages). Fully-loaded wage rate for Vice President is calculated as $190.24 ($95.12/ hour (see Table 9) x 2), and $143.02/hour ($71.51/hour (see Table 9) x 2) for Upper Management.

Therefore, on average, a small medical device establishment would save approximately $17 when complying with the proposed rule: [0.1 hour x ($190.24/hour x 50%)] + [0.1 hour x ($143.02/hour x 50%)] = $16.66; rounded to $17 for presentation in Table 13a. We multiply the unit cost saving of $16.66 by number of small domestic medical device establishments (1,080.28; rounded to 1,080 for presentation in Table 13a) to obtain estimated cost savings of all small domestic medical device establishments: $16.66/establishment x 1,080.28 establishments = $18,000.70; rounded to $18,001 for presentation in Table 13a. The same process is repeated throughout the document.

Table 13a. Annual Cost Savings of Compliance with Only the Proposed Rule, Certain Domestic Establishments, Subpart B

Part 820, Subpart B	Establishment Size				Total
	Small	Medium	Large	Very large	
No. of Establishments	1,080	1,849	711	546	4,186
820.20(a) Quality Policy					
Unit cost saving	$17	$17	$33	$33	
Cost Saving	**$18,001**	**$30,812**	**$23,698**	**$18,188**	**$90,699**
820.20(b) Organization					
Unit cost saving	$0	$13	$26	$26	
Cost Saving	**$0**	**$24,264**	**$18,662**	**$14,323**	**$57,248**
820.20(c) Management Review					
Unit cost saving	$114	$172	$229	$343	
Cost Saving	**$123,601**	**$317,360**	**$162,720**	**$187,330**	**$791,011**
820.20(d) Quality Planning					
Unit cost saving	$50	$75	$100	$125	
Cost Saving	**$54,170**	**$139,088**	**$71,315**	**$68,417**	**$332,991**
820.20(e) Quality System Procedures					
Unit cost saving	$50	$75	$100	$125	
Cost Saving	**$54,170**	**$139,088**	**$71,315**	**$68,417**	**$332,991**
820.22 Quality Audit					
Unit cost saving	$13	$13	$25	$25	
Cost Saving	**$13,543**	**$23,181**	**$17,829**	**$13,683**	**$68,236**
820.25 Personnel					
Unit cost saving	$13	$13	$25	$25	
Cost Saving	**$13,543**	**$23,181**	**$17,829**	**$13,683**	**$68,236**
Total Cost Savings	**$277,028**	**$696,976**	**$383,367**	**$384,042**	**$1,741,413**

Note: Due to rounding, numbers presented in this table may not add up precisely to the totals provided.

Table 13b. Annual Cost Savings of Compliance with the Proposed Rule, Foreign Establishments, Subpart B

Part 820, Subpart B	Establishment Size				Total
	Small	Medium	Large	Very large	
No. of Establishments	3,023	5,175	1,990	1,527	**11,715**
820.20(a) Quality Policy					
Unit cost saving	$17	$17	$33	$33	
Cost Saving	**$50,374**	**$86,226**	**$66,317**	**$50,898**	**$253,814**
820.20(b) Organization					
Unit cost saving	$0	$13	$26	$26	
Cost Saving	**$0**	**$67,902**	**$52,223**	**$40,081**	**$160,206**
820.20(c) Management Review					
Unit cost saving	$114	$172	$229	$343	
Cost Saving	**$345,889**	**$888,107**	**$455,360**	**$524,230**	**$2,213,586**

820.20(d) Quality Planning					
Unit cost saving	$50	$75	$100	$125	
Cost Saving	**$151,592**	**$389,228**	**$199,570**	**$191,461**	**$931,850**
820.20(e) Quality System Procedures					
Unit cost saving	$50	$75	$100	$125	
Cost Saving	**$151,592**	**$389,228**	**$199,570**	**$191,461**	**$931,850**
820.22 Quality Audit					
Unit cost saving	$13	$13	$25	$25	
Cost Saving	**$37,898**	**$64,871**	**$49,892**	**$38,292**	**$190,954**
820.25 Personnel					
Unit cost saving	$13	$13	$25	$25	
Cost Saving	**$37,898**	**$64,871**	**$49,892**	**$38,292**	**$190,954**
Total Cost Savings	**$775,242**	**$1,950,434**	**$1,072,824**	**$1,074,714**	**$4,873,214**

Note: Due to rounding, numbers presented in this table may not add up precisely to the totals provided.

Table 14. Annual Cost Savings of Compliance with the Proposed Rule, Subpart B

Part 820, Subpart B Provision	Cost Savings
820.20(a) Quality Policy	$344,513
820.20(b) Organization	$217,454
820.20(c) Management Review	$3,004,597
820.20(d) Quality Planning	$1,264,841
820.20(e) Quality System Procedures	$1,264,841
820.22 Quality Audit	$259,190
820.25 Personnel	$259,190
Total Annual Cost Savings, Subpart B	**$6,614,627**

Note: These costs are the sum of costs in Tables 13a and 13b.

Subpart C – Design Controls

Subpart C of the current Part 820 requires each manufacturer to establish a formal, documented program for assuring that design requirements are properly established, verified, and translated into design specifications. The system employed by medical device establishments must address issues of design and development planning, design input, design review, design verification, design output, design transfer, and design changes. We assume that each medical device establishment that complies with both the current Part 820 and ISO 13485 would require 10% less annual labor hours to comply with the proposed rule for each provision of Subpart C, as explained in Section D.1. of this document. We request comment on this assumption. In the sensitivity analysis section, we compare the decrease in compliance effort by 5% and 25%. Table 15 shows the number of annual labor hours saved for each provision of the current Part 820, Subpart C, by complying with the proposed rule.

Table 15. Number of Annual Labor Hours Saved by a Medical Device Establishment to Comply with the Proposed Rule, Subpart C

Part 820, Subpart C	Establishment Size			
	Small	**Medium**	**Large**	**Very large**
Current 820.30(a) Design Controls, General				
- Maintain procedure[1]	3.0	6.0	15.0	56.0
Comply with NPRM[2]	2.7	5.4	13.5	50.4
Labor hours saved	**0.3**	**0.6**	**1.5**	**5.6**
Current 820.30(b) Design and Development Planning				
- Maintain standardized plan[1]	820.30(a)	820.30(a)	820.30(a)	820.30(a)
- Update and approve plan as design evolves[1]	32.0	104.0	208.0	520.0
Comply with NRPM[2]	28.8	93.6	187.2	468.0
Labor hours saved	**3.2**	**10.4**	**20.8**	**52.0**
Current 820.30(c) Design Input				
- Maintain procedure requirements[1]	820.30(a)	820.30(a)	820.30(a)	820.30(a)
Current 820.30(d) Design Output				
- Maintain procedures[1]	820.30(a)	820.30(a)	820.30(a)	820.30(a)
Current 820.30(e) Design Review				
- Maintain procedures[1]	820.30(a)	820.30(a)	820.30(a)	820.30(a)
- Conduct periodic design review meeting[1]	77.0	312.0	749.0	2,496.0
Comply with NRPM[2]	69.3	280.8	674.1	2,246.4
Labor hours saved	**7.7**	**31.2**	**74.9**	**249.6**
- Record minutes of design review meeting[1]	5.0	16.0	31.0	78.0
Comply with NRPM[2]	4.5	14.4	27.9	70.2
Labor hours saved	**0.5**	**1.6**	**3.1**	**7.8**
Current 820.30(f) Design Verification				
- Maintain procedures[1]	820.30(a)	820.30(a)	820.30(a)	820.30(a)
- Conduct periodic design review meeting[1]	249.0	809.0	1,619.0	4,047.0
Comply with NRPM[2]	224.1	728.1	1,457.1	3,642.3
Labor hours saved	**24.9**	**80.9**	**161.9**	**404.7**
Current 820.30(g) Design Validation				
- Maintain procedures[1]	820.30(a)	820.30(a)	820.30(a)	820.30(a)
- Test under actual or simulated use conditions[1]	820.30(f)	820.30(f)	820.30(f)	820.30(f)
- Document validation in DHF[1]	820.30(f)	820.30(f)	820.30(f)	820.30(f)

Current 820.30(h) Design Transfer				
- Maintain procedures[1]	820.30(a)	820.30(a)	820.30(a)	820.30(a)
- Review design before release[1]	6.0	21.0	42.0	104.0
Comply with NRPM[2]	5.4	18.9	37.8	93.6
Labor hours saved	**0.6**	**2.1**	**4.2**	**10.4**
Current 820.30(i) Design Changes				
- Maintain written procedures[1]	820.30(a)	820.30(a)	820.30(a)	820.30(a)
- Review and approve design changes[1]	56.0	182.0	364.0	910.0
Comply with NRPM[2]	50.4	163.8	327.6	819.0
Labor hours saved	**5.6**	**18.2**	**36.4**	**91.0**
Current 820.30(j) Design History File				
- Maintain procedures[1]	820.30(a)	820.30(a)	820.30(a)	820.30(a)
- Compile design history record[1]	3.0	10.0	21.0	52.0
Comply with NRPM[2]	2.7	9.0	18.9	46.8
Labor hours saved	**0.3**	**1.0**	**2.1**	**5.2**

1. Part 820 Final Rule, 1996.
2. Assume 10% decrease in effort in moving from complying with two similar standards to the proposed rule.

We use information from the 1996 Part 820 final rule to determine proportion of types of labor needed to comply with each provision of Subpart C (see Table 16), and appropriate wage rates and overhead costs (see Table 9) to estimate the burden reduction of complying with the proposed rule for affected establishments.

Table 16. Proportion of Annual Labor by Labor Category, Subpart C

Part 820, Subpart C	**Labor Category**					
	Vice President	**Upper Mgmt.**	**Middle Mgmt.**	**Technical**	**Admin Support**	**Clerical**
820.30(a) Design Controls, General						
- Maintain procedure	0%	20%	70%	0%	0%	10%
820.30(b) Design and Development Planning						
- Maintain standardized plan	820.30(a)	820.30(a)	820.30(a)	820.30(a)	820.30(a)	820.30(a)
- Update and approve plan as design evolves	0%	20%	40%	40%	0%	0%
820.30(c) Design Input						
- Maintain procedure requirements	820.30(a)	820.30(a)	820.30(a)	820.30(a)	820.30(a)	820.30(a)
820.30(d) Design Output						
- Maintain procedures	820.30(a)	820.30(a)	820.30(a)	820.30(a)	820.30(a)	820.30(a)
820.30(e) Design Review						
- Maintain procedures	820.30(a)	820.30(a)	820.30(a)	820.30(a)	820.30(a)	820.30(a)
- Conduct periodic design review meeting	10%	20%	20%	50%	0%	0%
- Record minutes of design review meeting	0%	0%	50%	0%	0%	50%

820.30(f) Design Verification						
- Maintain procedures	820.30(a)	820.30(a)	820.30(a)	820.30(a)	820.30(a)	820.30(a)
- Conduct periodic design review meeting	0%	0%	40%	60%	0%	0%
820.30(g) Design Validation						
- Maintain procedures	820.30(a)	820.30(a)	820.30(a)	820.30(a)	820.30(a)	820.30(a)
- Test under actual or simulated use conditions	820.30(f)	820.30(f)	820.30(f)	820.30(f)	820.30(f)	820.30(f)
- Document validation in DHF	820.30(f)	820.30(f)	820.30(f)	820.30(f)	820.30(f)	820.30(f)
820.30(h) Design Transfer						
- Maintain procedures	820.30(a)	820.30(a)	820.30(a)	820.30(a)	820.30(a)	820.30(a)
- Review design before release	0%	0%	100%	0%	0%	0%
820.30(i) Design Changes						
- Maintain written procedures	820.30(a)	820.30(a)	820.30(a)	820.30(a)	820.30(a)	820.30(a)
- Review and approve design changes	0%	0%	40%	60%	0%	0%
820.30(j) Design History File						
- Maintain procedures	820.30(a)	820.30(a)	820.30(a)	820.30(a)	820.30(a)	820.30(a)
- Compile design history record	0%	0%	0%	0%	100%	0%

Source: Part 820 Final Rule, 1996

Using the number of hours saved in annual labor (Table 15) by proportion of labor category (Table 16), and by appropriate wage rate and overhead costs (Table 9), we determine the cost savings from reduced annual labor burden to comply with Subpart C of the current Part 820 for affected establishments (see Tables 17a and 17b). Benefits of complying with Subpart C of the current Part 820 by moving from compliance of both systems to the proposed rule results in a cost saving of approximately $397 million per year for the affected entities (see Table 18).

Table 17a. Annual Cost Savings of Compliance with the Proposed Rule, Certain Domestic Establishments, Subpart C

Part 820, Subpart C	**Establishment Size**				**Totals**
	Small	**Medium**	**Large**	**Very Large**	
No. of Establishments	1,080	1,849	711	546	4,186
820.30(a) Design Controls, General					
- Maintain procedure					
Unit cost saving	$38	$75	$188	$702	
Cost Saving	**$40,628**	**$139,088**	**$133,716**	**$383,137**	**$696,569**
820.30(b) Design and Development Planning					
- Maintain standardized plan	820.30(a)	820.30(a)	820.30(a)	820.30(a)	
- Update and approve plan as design evolves					
Unit cost saving	$366	$1,188	$2,377	$5,942	
Cost Saving	**$394,987**	**$2,197,369**	**$1,689,991**	**$3,242,646**	**$7,524,992**
820.30(c) Design Input					
- Maintain procedure requirements	820.30(a)	820.30(a)	820.30(a)	820.30(a)	

820.30(d) Design Output - Maintain procedures	820.30(a)	820.30(a)	820.30(a)	820.30(a)	
820.30(e) Design Review - Maintain procedures - Conduct periodic design review meeting	820.30(a)	820.30(a)	820.30(a)	820.30(a)	
Unit cost saving	$883	$3,579	$8,593	$28,634	
Cost Saving	**$954,264**	**$6,618,654**	**$6,110,098**	**$15,627,378**	**$29,310,394**
- Record minutes of design review meeting					
Unit cost saving	$42	$134	$260	$655	
Cost Saving	**$45,377**	**$248,556**	**$185,190**	**$357,623**	**$836,746**
820.30(f) Design Verification - Maintain procedures - Conduct periodic design review meeting	820.30(a)	820.30(a)	820.30(a)	820.30(a)	
Unit cost saving	$2,536	$8,238	$16,487	$41,212	
Cost Saving	**$2,739,195**	**$15,233,847**	**$11,723,551**	**$22,491,619**	**$52,188,212**
820.30(g) Design Validation - Maintain procedures	820.30(a)	820.30(a)	820.30(a)	820.30(a)	
- Test under actual or simulated use conditions	820.30(f)	820.30(f)	820.30(f)	820.30(f)	
- Document validation in DHF	820.30(f)	820.30(f)	820.30(f)	820.30(f)	
820.30(h) Design Transfer - Maintain procedures - Review design before release	820.30(a)	820.30(a)	820.30(a)	820.30(a)	
Unit cost saving	$80	$280	$560	$1,386	
Cost Saving	**$86,375**	**$517,479**	**$397,992**	**$756,368**	**$1,758,213**
820.30(i) Design Changes - Maintain written procedures - Review and approve design changes	820.30(a)	820.30(a)	820.30(a)	820.30(a)	
Unit cost saving	$570	$1,853	$3,707	$9,267	
Cost Saving	**$616,044**	**$3,427,145**	**$2,635,808**	**$5,057,419**	**$11,736,415**
820.30(j) Design History File - Maintain procedures - Compile design history record	820.30(a)	820.30(a)	820.30(a)	820.30(a)	
Unit cost saving	$19	$63	$132	$326	
Cost Saving	**$20,327**	**$115,979**	**$93,659**	**$177,996**	**$407,960**
Total Cost Savings	**$4,897,196**	**$28,498,118**	**$22,970,003**	**$48,094,185**	**$104,459,502**

Note: Due to rounding, numbers presented in this table may not add up precisely to the totals provided.

Table 17b. Annual Cost Savings of Compliance with the Proposed Rule, Foreign Establishments, Subpart C

Part 820, Subpart C	Establishment Size				Totals
	Small	Medium	Large	Very Large	
No. of Establishments	3,023	5,175	1,990	1,527	11,715
820.30(a) Design Controls, General - Maintain procedure					

Unit cost saving	$38	$75	$188	$702	
Cost Saving	**$113,694**	**$389,228**	**$374,193**	**$1,072,180**	**$1,949,295**
820.30(b) Design and Development Planning					
- Maintain standardized plan	820.30(a)	820.30(a)	820.30(a)	820.30(a)	
- Update and approve plan as design evolves					
Unit cost saving	$366	$1,188	$2,377	$5,942	
Cost Saving	**$1,105,340**	**$6,149,172**	**$4,729,311**	**$9,074,300**	**$21,058,123**
820.30(c) Design Input					
- Maintain procedure requirements	820.30(a)	820.30(a)	820.30(a)	820.30(a)	
820.30(d) Design Output					
- Maintain procedures	820.30(a)	820.30(a)	820.30(a)	820.30(a)	
820.30(e) Design Review					
- Maintain procedures	820.30(a)	820.30(a)	820.30(a)	820.30(a)	
- Conduct periodic design review meeting					
Unit cost saving	$883	$3,579	$8,593	$28,634	
Cost Saving	**$2,670,435**	**$18,521,805**	**$17,098,649**	**$43,732,040**	**$82,022,929**
- Record minutes of design review meeting					
Unit cost saving	$42	$134	$260	$655	
Cost Saving	**$126,985**	**$695,566**	**$518,240**	**$1,000,781**	**$2,341,572**
820.30(f) Design Verification					
- Maintain procedures	820.30(a)	820.30(a)	820.30(a)	820.30(a)	
- Conduct periodic design review meeting					
Unit cost saving	$2,536	$8,238	$16,487	$41,212	
Cost Saving	**$7,665,432**	**$42,630,774**	**$32,807,474**	**$62,941,102**	**$146,044,782**
820.30(g) Design Validation					
- Maintain procedures	820.30(a)	820.30(a)	820.30(a)	820.30(a)	
- Test under actual or simulated use conditions	820.30(f)	820.30(f)	820.30(f)	820.30(f)	
- Document validation in DHF	820.30(f)	820.30(f)	820.30(f)	820.30(f)	
820.30(h) Design Transfer					
- Maintain procedures	820.30(a)	820.30(a)	820.30(a)	820.30(a)	
- Review design before release					
Unit cost saving	$80	$280	$560	$1,386	
Cost Saving	**$241,713**	**$1,448,126**	**$1,113,750**	**$2,116,639**	**$4,920,228**
820.30(i) Design Changes					
- Maintain written procedures	820.30(a)	820.30(a)	820.30(a)	820.30(a)	
- Review and approve design changes					
Unit cost saving	$570	$1,853	$3,707	$9,267	
Cost Saving	**$1,723,953**	**$9,590,607**	**$7,376,109**	**$14,152,805**	**$32,843,474**
820.30(j) Design History File					
- Maintain procedures	820.30(a)	820.30(a)	820.30(a)	820.30(a)	
- Compile design history record					
Unit cost saving	$19	$63	$132	$326	

Cost Saving	**$56,882**	**$324,559**	**$262,098**	**$498,107**	**$1,141,646**
Total Cost Savings	**$13,704,434**	**$79,749,837**	**$64,279,824**	**$134,587,954**	**$292,322,049**

Note: Due to rounding, numbers presented in this table may not add up precisely to the totals provided.

Table 18. Annual Cost Savings of Compliance with the Proposed Rule, Subpart C

Part 820, Subpart C Provision	Cost Savings
820.30(a) Design Controls, General	$2,645,863
820.30(b) Design and Development Planning	$28,583,115
820.30(c) Design Input	820.30(a)
820.30(d) Design Output	820.30(a)
820.30(e) Design Review	$114,511,641
820.30(f) Design Verification	$198,232,995
820.30(g) Design Validation	820.20(a), (f)
820.30(h) Design Transfer	$6,678,441
820.30(i) Design Changes	$44,579,889
820.30(j) Design History File	$1,549,607
Total Annual Cost Savings, Subpart C	**$396,781,551**

Note: These costs are the sum of costs in Tables 17a and 17b.

Subpart D – Document Controls

Subpart D of the current Part 820 requires manufacturers to establish and maintain procedures to control certain documents. The requirements include designation of individuals to manage review, approval, distribution, and modifications of documents. We assume that each medical device establishment that complies with both the current Part 820 and ISO 13485 would require 10% less annual labor hours to comply with the proposed rule for each provision of Subpart D, as explained in Section D.1. of this document. We request comment on this assumption. In the sensitivity analysis section, we compare the decrease in compliance effort by 5% and 25%. Table 19 shows the number of annual labor hours saved for each provision of the current Part 820, Subpart D, by complying with the proposed rule.

Table 19. Number of Annual Labor Hours Saved by a Medical Device Establishment to Comply with the Proposed Rule, Subpart D

Part 820, Subpart D	Establishment Size			
	Small	**Medium**	**Large**	**Very large**
Current 820.40 Document Controls				
- Maintain written procedures[1]	2	2	3	4
Comply with NPRM[2]	1.8	1.8	2.7	3.6
Labor hours saved	**0.2**	**0.2**	**0.3**	**0.4**

1. Part 820 Final Rule, 1996.
2. Assume 10% decrease in effort in moving from complying with two similar standards to the proposed rule.

We use information from the 1996 Part 820 final rule to determine proportion of types of labor needed to comply with each provision of Subpart D (see Table 20), and appropriate wage rates and overhead costs (see Table 9) to estimate cost savings of complying with the proposed rule for affected establishments.

Table 20. Proportion of Annual Labor by Labor Category, Subpart D

Part 820, Subpart D	Labor Category					
	Vice President	Upper Mgmt.	Middle Mgmt.	Technical	Admin Support	Clerical
820.40 Document Controls - Maintain written procedures	0%	20%	70%	0%	0%	10%

Source: Part 820 Final Rule, 1996

Using the number of hours saved in annual labor (Table 19) by proportion of labor category (Table 20), and by appropriate wage rate and overhead costs (Table 9), we determine the reduced annual labor burden to comply with the current Subpart D of Part 820 for affected entities (see Table 21). Cost savings of moving from compliance with both systems to the proposed rule results in a saving of approximately $485,000 per year for the affected entities (see Table 21).

Table 21. Annual Cost Savings of Compliance with the Proposed Rule, Subpart D

Part 820, Subpart D	**Establishment Size, Domestic**				**Totals**
	Small	**Medium**	**Large**	**Very Large**	
No. of Establishments	1,080	1,849	711	546	4,186
820.40 Document Controls - Maintain written procedures					
Unit cost saving	$25	$25	$38	$50	
Cost Saving	**$27,085**	**$46,363**	**$26,743**	**$27,367**	**$127,558**
Part 820 Provision	**Establishment Size, Foreign**				**Totals**
No. of Establishments	3,023	5,175	1,990	1,527	11,715
820.40 Document Controls - Maintain written procedures					
Unit cost saving	$25	$25	$38	$50	
Cost Saving	**$75,796**	**$129,743**	**$74,839**	**$76,584**	**$356,961**
Total Annual Cost Savings, Subpart D					**$484,520**

Note: Due to rounding, numbers presented in this table may not add up precisely to the totals provided.

Subpart E – Procurement

Subpart E of the current Part 820 requires each manufacturer to establish procedures to assess suppliers, provide clear specification of component requirements, and conduct inspections and tests of a supplier's quality system. The manufacturer must also establish controls to assure that specifications are properly described in

procurement documents. We assume that each medical device establishment that complies with both the current Part 820 and ISO 13485 would require 10% less annual labor hours to comply with the proposed rule for each provision of Subpart E, as explained in Section D.1. of this document. We request comment on this assumption. In the sensitivity analysis section, we compare the decrease in compliance effort by 5% and 25%. Table 22 shows the number of annual labor hours saved for each provision of the current Part 820, Subpart E, by complying with the proposed rule.

Table 22. Number of Annual Labor Hours Saved by a Medical Device Establishment to Comply with the Proposed Rule, Subpart E

Part 820, Subpart E	Establishment Size			
	Small	**Medium**	**Large**	**Very large**
Current 820.50(a) Evaluation of Suppliers, Contractors, and Consultants				
- Review quality of suppliers[1]	13	25	50	63
Comply with NPRM[2]	11.7	22.5	45	56.7
Labor hours saved	**1.3**	**2.5**	**5**	**6.3**
- Audit new suppliers[1]	10	20	40	80
Comply with NRPM[2]	9	18	36	72
Labor hours saved	**1**	**2**	**4**	**8**
Current 820.50(b) Purchasing Data				
- Review and approve purchasing documents[1]	5	39	129	60
Comply with NRPM[2]	4.5	35.1	116.1	54
Labor hours saved	**0.5**	**3.9**	**12.9**	**6**

1. Part 820 Final Rule, 1996.
2. Assume 10% decrease in effort in moving from complying with two similar standards to the proposed rule.

We use information from the 1996 Part 820 final rule to determine proportion of types of labor needed to comply with each provision of Subpart E (see Table 23), and appropriate wage rates and overhead costs (see Table 9) to estimate cost savings of complying with the proposed rule for affected establishments.

Table 23. Proportion of Annual Labor by Labor Category, Subpart E

Part 820, Subpart E	Labor Category					
	Vice President	**Upper Mgmt.**	**Middle Mgmt.**	**Technical**	**Admin Support**	**Clerical**
820.50(a) Evaluation of Suppliers, Contractors, and Consultants						
- Review quality of suppliers	0%	0%	0%	0%	100%	0%
- Audit new suppliers	0%	0%	100%	0%	0%	0%
820.50(b) Purchasing Data						
- Review and approve purchasing documents	0%	0%	0%	0%	100%	0%

Source: Part 820 Final Rule, 1996

Using the number of hours saved in annual labor (Table 22) by proportion of labor category (Table 23), and by appropriate wage rate and overhead costs (Table 9), we determine the reduced annual labor burden to comply with Subpart E of the current Part 820 for affected establishments (see Tables 24a and 24b). Cost savings of moving from compliance with both systems to the proposed rule results in a saving of approximately $17 million per year for the affected entities (see Table 25).

Table 24a. Annual Cost Savings of Compliance with the Proposed Rule, Certain Domestic Establishments, Subpart E

Part 820, Subpart E	**Establishment Size**				**Totals**
	Small	**Medium**	**Large**	**Very Large**	
No. of Establishments	1,080	1,849	711	546	4,186
820.50(a) Evaluation of Suppliers, Contractors, and Consultants - Review quality of suppliers					
Unit cost saving	$163	$313	$627	$790	
Cost Saving	**$176,054**	**$579,535**	**$445,719**	**$431,029**	**$1,632,336**
- Audit new suppliers					
Unit cost saving	$133	$267	$533	$1,066	
Cost Saving	**$143,958**	**$492,837**	**$379,040**	**$581,822**	**$1,597,656**
820.50(b) Purchasing Data - Review and approve purchasing documents					
Unit cost saving	$31	$245	$809	$376	
Cost Saving	**$33,878**	**$452,318**	**$575,335**	**$205,380**	**$1,266,910**
Total Cost Savings					**$4,496,903**

Note: Due to rounding, numbers presented in this table may not add up precisely to the totals provided.

Table 24b. Annual Cost Savings of Compliance with the Proposed Rule, Foreign Establishments, Subpart E

Part 820, Subpart E	**Establishment Size**				**Totals**
	Small	**Medium**	**Large**	**Very Large**	
No. of Establishments	3,023	5,175	1,990	1,527	11,715
820.50(a) Evaluation of Suppliers, Contractors, and Consultants - Review quality of suppliers					
Unit cost saving	$163	$313	$627	$790	
Cost Saving	**$492,673**	**$1,621,784**	**$1,247,310**	**$1,206,202**	**$4,567,970**
- Audit new suppliers					
Unit cost saving	$133	$267	$533	$1,066	
Cost Saving	**$402,856**	**$1,379,167**	**$1,060,714**	**$1,628,184**	**$4,470,921**

820.50(b) Purchasing Data - Review and approve purchasing documents					
Unit cost saving	$31	$245	$809	$376	
Cost Saving	**$94,804**	**$1,265,779**	**$1,610,031**	**$574,739**	**$3,545,353**
Total Cost Savings					**$12,584,243**

Note: Due to rounding, numbers presented in this table may not add up precisely to the totals provided.

Table 25. Annual Cost Savings of Compliance with the Proposed Rule, Subpart E

Part 820, Subpart E Provision	Cost Savings
820.50(a) Evaluation of Suppliers, Contractors, and Consultants	$12,268,883
820.50(b) Purchasing Data	$4,812,263
Total Annual Cost Savings, Subpart E	**$17,081,146**

Note: These costs are the sum of costs in Tables 24a and 24b.

Subpart F – Identification and Traceability

Subpart F of the current Part 820 requires manufacturers to establish and maintain procedures for identifying their products during all stages of receipt, production, distribution, and installation to prevent mix-ups. In addition, manufacturers are required to establish and maintain procedures for identifying with a control number each unit, lot, or batch of finished critical medical devices or components. We assume that each medical device establishment that complies with both the current Part 820 and ISO 13485 would require 10% less annual labor hours to comply with the proposed rule for each provision of Subpart F, as explained in Section D.1. of this document. We request comment on this assumption. In the sensitivity analysis section, we compare the decrease in compliance effort by 5% and 25%. Table 26 shows the number of annual labor hours saved for each provision of the current Part 820, Subpart F, by complying with the proposed rule.

Table 26. Number of Annual Labor Hours Saved by a Medical Device Establishment to Comply with the Proposed Rule, Subpart F

Part 820, Subpart F	Establishment Size			
	Small	Medium	Large	Very large
Current 820.60 Identification - Maintain written procedures[1]	1	1	2	2
Comply with NPRM[2]	0.9	0.9	1.8	1.8
Labor hours saved	**0.1**	**0.1**	**0.2**	**0.2**

1. Part 820 Final Rule, 1996.
2. Assume 10% decrease in effort in moving from complying with two similar standards to the proposed rule.

We use information from the 1996 Part 820 final rule to determine the proportion of types of labor needed to comply with each provision of Subpart F (see Table 27), and appropriate wage rates and overhead costs (see Table 9) to estimate cost savings of complying with the proposed rule for affected establishments.

Table 27. Proportion of Annual Labor by Labor Category, Subpart F

Part 820, Subpart F	Labor Category					
	Vice President	Upper Mgmt.	Middle Mgmt.	Technical	Admin Support	Clerical
820.60 Identification - Maintain written procedures	0%	0%	30%	0%	70%	0%

Source: Part 820 Final Rule, 1996

Using the number of hours saved in annual labor (Table 26) by proportion of labor category (Table 27), and by appropriate wage rate and overhead costs (Table 9), we determine the reduced annual labor burden to comply with Subpart F of the current Part 820 for affected entities (see Table 28). Cost savings from moving from compliance of both systems to the proposed rule results in a saving of approximately $174,000 per year for the affected entities (see Table 28).

Table 28. Annual Cost Savings of Compliance with the Proposed Rule, Subpart F

Part 820 Subpart F	Establishment Size, Domestic				Totals
	Small	Medium	Large	Very Large	
No. of Establishments	1,080	1,849	711	546	4,186
820.60 Identification - Maintain written procedures					
Unit cost saving	$8	$8	$17	$17	
Cost Saving	**$9,062**	**$15,511**	**$11,930**	**$9,156**	**$45,658**
Part 820 Subpart F	**Establishment Size, Foreign**				**Totals**
No. of Establishments	3,023	5,175	1,990	1,527	11,715
820.60 Identification - Maintain written procedures					
Unit cost saving	$8	$8	$17	$17	
Cost Saving	**$25,358**	**$43,407**	**$33,384**	**$25,622**	**$127,771**
Total Annual Cost Savings, Subpart F					**$173,429**

Note: Due to rounding, numbers presented in this table may not add up precisely to the totals provided.

Subpart G – Production and Process Controls

Subpart G of the current Part 820 requires manufacturers to establish and maintain procedures for processing controls, environmental control, and cleaning and sanitation. It also requires special processes to be validated and monitored. We assume that each medical device establishment that complies with both the current Part 820 and ISO 13485 would require 10% less annual labor hours to comply with the proposed rule for each provision of Subpart G, as explained in Section D.1. of this document. We request comment on this assumption. In the sensitivity analysis section, we compare the decrease in compliance effort by 5% and 25%. Table 29 shows the number of annual labor hours saved for each provision of the current Part 820, Subpart G of, by complying with the proposed rule.

Table 29. Number of Annual Labor Hours Saved to Comply with the Proposed Rule, Subpart G

Part 820, Subpart G	**Establishment Size**			
	Small	**Medium**	**Large**	**Very large**
Current 820.70(d) Personnel				
- Maintain and use procedures[1]	2	2	3	7
Comply with NPRM[2]	1.8	1.8	2.7	6.3
Labor hours saved	**0.2**	**0.2**	**0.3**	**0.7**
- Maintain written procedures[1]	2	2	3	4
Comply with NPRM[2]	1.8	1.8	2.7	3.6
Labor hours saved	**0.2**	**0.2**	**0.3**	**0.4**
Current 820.72(a) Control of Inspection, Measuring, and Test Equipment				
- Maintain and use procedure[1]	1	1	2	2
Comply with NPRM[2]	0.9	0.9	1.8	1.8
Labor hours saved	**0.1**	**0.1**	**0.2**	**0.2**
Current 820.75(b) Process Validation				
- Maintain procedure[1]	2	2	3	4
Comply with NPRM[2]	1.8	1.8	2.7	3.6
Labor hours saved	**0.2**	**0.2**	**0.3**	**0.4**

1. Part 820 Final Rule, 1996.
2. Assume 10% decrease in effort in moving from complying with two similar standards to the proposed rule.

We use information from the 1996 Part 820 final rule to determine proportion of types of labor needed to comply with each provision of Subpart G (see Table 30), and appropriate wage rates and overhead costs (see Table 9) to estimate cost savings from complying with the proposed rule for affected establishments.

Table 30. Proportion of Annual Labor by Labor Category, Subpart G

Subpart G	Labor Category					
	Vice President	Upper Mgmt.	Middle Mgmt.	Technical	Admin Support	Clerical
820.70(d) Personnel - Maintain and use procedures	0%	20%	70%	0%	0%	10%
820.70(i) Automated Processes - Maintain written procedures	0%	20%	70%	0%	0%	10%
820.72(a) Control of Inspection, Measuring, and Test Equipment - Maintain and use procedure	0%	20%	70%	0%	0%	10%
820.75(b) Process Validation - Maintain procedure	0%	20%	70%	0%	0%	10%

Source: Part 820 Final Rule, 1996

Using the number of hours saved in annual labor (Table 29) by proportion of labor category (Table 30), and by appropriate wage rate and overhead costs (Table 9), we determine the reduced annual labor burden to comply with Subpart F of the current Part 820 for affected domestic and foreign entities (see Tables 31a and 31b). Cost savings from complying with the proposed rule results in a saving of approximately $1.8 million per year for the affected entities (see Table 32).

Table 31a. Annual Cost Savings of Compliance with the Proposed Rule, Certain Domestic Establishments, Subpart G

Part 820, Subpart G	Establishment Size				Totals
	Small	Medium	Large	Very Large	
No. of Establishments	1,080	1,849	711	546	4,186
820.70(d) Personnel - Maintain and use procedures Unit cost saving	$25	$25	$38	$88	
Cost Saving	**$27,085**	**$46,363**	**$26,743**	**$47,892**	**$148,083**
- Maintain written procedures Unit cost saving					
Cost Saving	$25	$25	$38	$50	
820.72(a) Control of Inspection, Measuring, and Test Equipment - Maintain and use procedure Unit cost saving	**$27,085**	**$46,363**	**$26,743**	**$27,367**	**$127,558**
Cost Saving	$13	$13	$25	$25	
820.75(b) Process Validation - Maintain procedure Unit cost saving	**$13,543**	**$23,181**	**$17,829**	**$13,683**	**$68,236**
Cost Saving	$25	$25	$38	$50	

Total Cost Savings	**$471,435**

Note: Due to rounding, numbers presented in this table may not add up precisely to the totals provided.

Table 31b. Annual Cost Savings of Compliance with the Proposed Rule, Foreign Establishments, Subpart G

Part 820, Subpart G	Establishment Size				Totals
	Small	Medium	Large	Very Large	
No. of Establishments	3,023	5,175	1,990	1,527	**11,715**
820.70(d) Personnel - Maintain and use procedures					
Unit cost saving	$25	$25	$38	$88	
Cost Saving	**$75,796**	**$129,743**	**$74,839**	**$134,022**	**$414,400**
- Maintain written procedures					
Unit cost saving	$25	$25	$38	$50	
Cost Saving	**$75,796**	**$129,743**	**$74,839**	**$76,584**	**$356,961**
820.72(a) Control of Inspection, Measuring, and Test Equipment - Maintain and use procedure					
Unit cost saving	$13	$13	$25	$25	
Cost Saving	**$37,898**	**$64,871**	**$49,892**	**$38,292**	**$190,954**
820.75(b) Process Validation - Maintain procedure					
Unit cost saving	$25	$25	$38	$50	
Cost Saving	**$75,796**	**$129,743**	**$74,839**	**$76,584**	**$356,961**
Total Cost Savings					**$1,319,277**

Note: Due to rounding, numbers presented in this table may not add up precisely to the totals provided.

Table 32. Annual Cost Savings of Compliance with the Proposed Rule, Subpart G

Part 820 Provision	Cost Savings
820.70(d) Personnel	$1,047,002
820.72(a) Control of Inspection, Measuring, and Test Equipment	$259,190
820.75(b) Process Validation	$484,520
Total Annual Cost Savings, Subpart G	**$1,790,712**

Note: These costs are the sum of costs in Tables 31a and 31b.

Subpart H – Acceptance Activities

Subpart H of the current Part 820 requires manufacturers to establish and maintain procedures for acceptance activities including inspections, tests, or other verification activities. We assume that each medical device establishment that complies with both the current Part 820 and ISO 13485 would require 10% less annual labor hours to comply with the proposed rule for each provision of Subpart H, as explained in Section D.1. of this document. We request comment on this assumption. In the sensitivity analysis section, we compare

the decrease in compliance effort by 5% and 25%. Table 33 shows the number of annual labor hours saved for each provision of the current Part 820, Subpart H of, by complying with the proposed rule.

Table 33. Number of Annual Labor Hours Saved by a Medical Device Establishment to Comply with the Proposed Rule, Subpart H

Part 820, Subpart H	Establishment Size			
	Small	**Medium**	**Large**	**Very large**
Current 820.84 Inspection, Measuring and Testing Equipment				
- Maintain written procedures[1]	1	1	2	2
Comply with NPRM[2]	0.9	0.9	1.8	1.8
Labor hours saved	**0.1**	**0.1**	**0.2**	**0.2**

1. Part 820 Final Rule, 1996.
2. Assume 10% decrease in effort in moving from complying with two similar standards to the proposed rule.

We use information from the 1996 Part 820 final rule to determine the proportion of types of labor needed to comply with each provision of Subpart H (see Table 34), and appropriate wage rates and overhead costs (see Table 9) to estimate cost savings of complying with the proposed rule for affected establishments.

Table 34. Proportion of Annual Labor by Labor Category, Subpart H

Part 820, Subpart H	Labor Category					
	Vice President	**Upper Mgmt.**	**Middle Mgmt.**	**Technical**	**Admin Support**	**Clerical**
820.84 Inspection, Measuring and Testing Equipment						
- Maintain written procedures	0%	20%	70%	0%	0%	10%

Source: Part 820 Final Rule, 1996

Using the number of hours saved in annual labor (Table 33) by proportion of labor category (Table 34), and by appropriate wage rate and overhead costs (Table 9), we determine the reduced annual labor burden to comply with Subpart H of the current Part 820 for affected entities (see Table 35). Cost savings from moving from compliance of both systems to the proposed rule results in a saving of approximately $260,000 per year for the affected entities (see Table 35).

Table 35. Annual Cost Savings of Compliance with the Proposed Rule, Subpart H

Part 820 Subpart H	Establishment Size, Domestic				Totals
	Small	**Medium**	**Large**	**Very Large**	
No. of Establishments	1,080	1,849	711	546	**4,186**
820.84 Inspection, Measuring and Testing Equipment					

- Maintain written procedures					
Unit cost saving	$13	$13	$25	$25	
Cost Saving	$13,543	$23,181	$17,829	$13,683	$68,236
Part 820 Subpart H	**Establishment Size, Foreign**				**Totals**
No. of Establishments	3,023	5,175	1,990	1,527	11,715
820.84 Inspection, Measuring and Testing Equipment - Maintain written procedures					
Unit cost saving	$13	$13	$25	$25	
Cost Saving	$37,898	$64,871	$49,892	$38,292	$190,954
Total Annual Cost Savings, Subpart H					**$259,190**

Note: Due to rounding, numbers presented in this table may not add up precisely to the totals provided.

Subpart I – Nonconforming Components and Devices

Subpart I of the current Part 820 requires manufacturers to establish and maintain written procedures to control nonconforming products. The procedures are required to address the identification, documentation, evaluation, segregation, and disposition of nonconforming products. We assume that each medical device establishment that complies with both the current Part 820 and ISO 13485 would require 10% less annual labor hours to comply with the proposed rule for each provision of Subpart I, as explained in Section D.1. of this document. We request comment on this assumption. In the sensitivity analysis section, we compare the decrease in compliance effort by 5% and 25%. Table 36 shows the number of annual labor hours saved for each provision of Subpart I of the current Part 820, by complying with the proposed rule.

Table 36. Number of Annual Labor Hours Saved by a Medical Device Establishment to Comply with the Proposed Rule, Subpart I

Part 820, Subpart I	**Establishment Size**			
	Small	**Medium**	**Large**	**Very large**
Current 820.90(a) Control of Nonconforming Product				
- Maintain procedure[1]	2	2	3	4
Comply with NPRM[2]	1.8	1.8	2.7	3.6
Labor hours saved	**0.2**	**0.2**	**0.3**	**0.4**

1. Part 820 Final Rule, 1996.
2. Assume 10% decrease in effort in moving from complying with two similar standards to the proposed rule.

We use information from the 1996 Part 820 final rule to determine proportion of types of labor needed to comply with each provision of Subpart I (see Table 37), and appropriate wage rates and overhead costs (see Table 9) to estimate cost savings to complying with the proposed rule for affected establishments.

Table 37. Proportion of Annual Labor by Labor Category, Subpart I

Part 820, Subpart I	Labor Category					
	Vice President	Upper Mgmt.	Middle Mgmt.	Technical	Admin Support	Clerical
820.90(a) Control of Nonconforming Product - Maintain written procedures	0%	20%	70%	0%	0%	10%

Source: Part 820 Final Rule, 1996

Using the number of hours saved in annual labor (Table 36) by proportion of labor category (Table 37), and by appropriate wage rate and overhead costs (Table 9), we determine the reduced annual labor burden to comply with Subpart I of the current Part 820 for affected entities (see Table 38). Cost savings from moving from compliance with both systems to the proposed rule results in a saving of approximately $485,000 per year for the affected entities (see Table 38).

Table 38. Annual Cost Savings of Compliance with the Proposed Rule, Subpart I

Part 820, Subpart I	Establishment Size, Domestic				Totals
	Small	Medium	Large	Very Large	
No. of Establishments	1,080	1,849	711	546	4,186
820.90(a) Control of Nonconforming Product - Maintain written procedures					
Unit cost saving	$25	$25	$38	$50	
Cost Saving	**$27,085**	**$46,363**	**$26,743**	**$27,367**	**$127,558**
Part 820, Subpart I	**Establishment Size, Foreign**				**Totals**
No. of Establishments	3,023	5,175	1,990	1,527	11,715
820.90(a) Control of Nonconforming Product					

- Maintain written procedures					
Unit cost saving	$25	$25	$38	$50	
Cost Saving	**$75,796**	**$129,743**	**$74,839**	**$76,584**	**$356,961**
Total Annual Cost Savings, Subpart I					**$484,520**

Note: Due to rounding, numbers presented in this table may not add up precisely to the totals provided.

Subpart J – Corrective and Preventive Action

Subpart J of the current Part 820 requires manufacturers to establish a program and maintain written procedures to collect, correlate, and evaluate applicable internal and external quality control data for the purpose of detecting and preventing quality-issue problems. Manufacturers are also required to use obtained data from their program to determine possible solutions and document the corrective action selected and implemented. We assume that each medical device establishment that complies with both the current Part 820 and ISO 13485 would require 10% less annual labor hours to comply with the proposed rule for each provision of Subpart J, as explained in Section D.1. of this document. We request comment on this assumption. In the sensitivity analysis section, we compare the decrease in compliance effort by 5% and 25%. Table 39 shows the number of annual labor hours saved for each provision of the current Part 820, Subpart J, by complying with the proposed rule.

Table 39. Number of Annual Labor Hours Saved by a Medical Device Establishment to Comply with the Proposed Rule, Subpart J

Part 820, Subpart J Provision	**Establishment Size**			
	Small	**Medium**	**Large**	**Very large**
Current 820.100 Corrective and Preventive Action				
- Maintain written procedures[1]	2	2	3	4
Comply with NPRM[2]	1.8	1.8	2.7	3.6
Labor hours saved	**0.2**	**0.2**	**0.3**	**0.4**

1. Part 820 Final Rule, 1996.
2. Assume 10% decrease in effort in moving from complying with two similar standards to the proposed rule.

We use information from the 1996 Part 820 final rule to determine proportion of types of labor needed to comply with each provision of Subpart J (see Table 40), and appropriate wage rates and overhead costs (see Table 9) to estimate cost savings from complying with the proposed rule for affected establishments.

Table 40. Proportion of Annual Labor by Labor Category, Subpart J

Part 820, Subpart J Provision	Labor Category					
	Vice President	Upper Mgmt.	Middle Mgmt.	Technical	Admin Support	Clerical
820.100 Corrective and Preventive Action - Maintain written procedures	0%	20%	70%	0%	0%	10%

Source: Part 820 Final Rule, 1996

Using the number of hours saved in annual labor (Table 39) by proportion of labor category (Table 40), and by appropriate wage rate and overhead costs (Table 9), we determine the cost savings of the reduced annual labor burden to comply with Subpart J of the current Part 820 for affected entities (see Table 41). The move to the proposed rule results in a cost savings of approximately $1.3 million per year for the affected entities (see Table 41).

Table 41. Annual Cost Savings of Compliance with the Proposed Rule, Subpart J

Part 820, Subpart J	**Establishment Size, Domestic**				**Totals**
No. of Establishments	1,080	1,849	711	546	**4,186**
820.100 Corrective and Preventive Action - Maintain written procedures					
Unit cost saving	$25	$25	$38	$50	
Cost Saving	**$27,085**	**$46,363**	**$26,743**	**$27,367**	**$127,558**
Part 820, Subpart J	**Establishment Size, Foreign**				**Totals**
No. of Establishments	3,023	5,175	1,990	1,527	**11,715**
820.100 Corrective and Preventive Action - Maintain written procedures					
Unit cost saving	$25	$25	$38	$50	
Cost Saving	**$75,796**	**$129,743**	**$74,839**	**$76,584**	**$356,961**
Total Cost Savings, Subpart J					**$484,520**

Note: Due to rounding, numbers presented in this table may not add up precisely to the totals provided.

Subpart K – Labeling and Packaging Control

Subpart K of the current Part 820 requires medical device establishments to maintain a formal system for the safe and proper handling and storage of medical device and manufacturing materials. Controls must be established that prevent mix-ups, deterioration, and other adverse effects on medical devices and manufacturing materials. We assume that each medical device establishment that complies with both the current Part 820 and ISO 13485 would require 10% less annual labor hours to comply with the proposed rule for each provision of

Subpart K, as explained in Section D.1. of this document. We request comment on this assumption. In the sensitivity analysis section, we compare the decrease in compliance effort by 5% and 25%. Table 42 shows the number of annual labor hours saved for each provision of the current Part 820, Subpart K, by complying with the proposed rule.

Table 42. Number of Annual Labor Hours Saved by a Medical Device Establishment to Comply with the Proposed Rule, Subpart K

Part 820, Subpart K	Establishment Size			
	Small	**Medium**	**Large**	**Very large**
Current 820.120-820.122 Handling, Storage				
- Maintain written procedures[1]	1	1	2	2
Comply with NPRM[2]	0.9	0.9	1.8	1.8
Labor hours saved	**0.1**	**0.1**	**0.2**	**0.2**

1. Part 820 Final Rule, 1996.
2. Assume 10% decrease in effort in moving from complying with two similar standards to the proposed rule.

We use information from the 1996 Part 820 final rule to determine the proportion of types of labor needed to comply with each provision of Subpart K (see Table 43), and appropriate wage rates and overhead costs (see Table 9) to estimate cost savings of complying with the proposed rule for affected establishments.

Table 43. Proportion of Annual Labor by Labor Category, Subpart K

Part 820, Subpart K	Labor Category					
	Vice President	**Upper Mgmt.**	**Middle Mgmt.**	**Technical**	**Admin Support**	**Clerical**
820.120-820.122 Handling, Storage - Maintain written procedures	0%	20%	70%	0%	0%	10%

Source: Part 820 Final Rule, 1996

Using the number of hours saved in annual labor (Table 42) by proportion of labor category (Table 43), and by appropriate wage rate and overhead costs (Table 9), we determine the reduced annual labor burden to comply with Subpart K of the current Part 820 for affected entities (see Table 44). Cost savings from moving from compliance of both systems to the proposed rule results in a saving of approximately $260,000 per year for the affected entities (see Table 44).

Table 44. Annual Cost Savings of Compliance with the Proposed Rule, Subpart K

Part 820 Subpart K	Establishment Size, Domestic				Totals
	Small	**Medium**	**Large**	**Very Large**	
No. of Establishments	1,080	1,849	711	546	**4,186**

820.84 Inspection, Measuring and Testing Equipment - Maintain written procedures					
Unit cost saving	$13	$13	$25	$25	
Cost Saving	**$13,543**	**$23,181**	**$17,829**	**$13,683**	**$68,236**
Part 820 Subpart K	**Establishment Size, Foreign**				**Totals**
No. of Establishments	3,023	5,175	1,990	1,527	**11,715**
820.84 Inspection, Measuring and Testing Equipment - Maintain written procedures					
Unit cost saving	$13	$13	$25	$25	
Cost Saving	**$37,898**	**$64,871**	**$49,892**	**$38,292**	**$190,954**
Total Annual Cost Savings, Subpart K					**$259,190**

Note: Due to rounding, numbers presented in this table may not add up precisely to the totals provided.

Subpart L – Handling, Storage, Distribution, and Installation

Subpart L of the current Part 820 requires manufacturers to establish and maintain written procedures to ensure that mix-ups, damage, deterioration, contamination, or other adverse effects to the medical device product does not occur during handling, storage, distribution, or installation of the product. We assume that each medical device establishment that complies with both the current Part 820 and ISO 13485 would require 10% less annual labor hours to comply with the proposed rule for each provision of Subpart L, as explained in Section D.1. of this document. We request comment on this assumption. In the sensitivity analysis section, we compare the decrease in compliance effort by 5% and 25%. Table 45 shows the number of annual labor hours saved for each provision of Subpart L of the current Part 820, by complying with the proposed rule.

Table 45. Number of Annual Labor Hours Saved by a Medical Device Establishment to Comply with the Proposed Rule, Subpart L

Part 820, Subpart L Provision	**Establishment Size**			
	Small	**Medium**	**Large**	**Very large**
Current 820.140 Handling - Maintain written procedures[1]	1	1	2	2
Comply with NPRM[2]	0.9	0.9	1.8	1.8
Labor hours saved	**0.1**	**0.1**	**0.2**	**0.2**
Current 820.150 Storage(a) - Maintain written procedures[1]	1	1	2	2
Comply with NPRM[2]	0.9	0.9	1.8	1.8
Labor hours saved	**0.1**	**0.1**	**0.2**	**0.2**

1. Part 820 Final Rule, 1996.
2. Assume 10% decrease in effort in moving from complying with two similar standards to the proposed rule.

We use information from the 1996 Part 820 final rule to determine proportion of types of labor needed to comply with each provision of Subpart L (see Table 46), and appropriate wage rates and overhead costs (see Table 9) to estimate cost savings of complying with the proposed rule for affected establishments.

Table 46. Proportion of Annual Labor by Labor Category, Subpart L

Part 820, Subpart L Provision	Labor Category					
	Vice President	Upper Mgmt.	Middle Mgmt.	Technical	Admin Support	Clerical
820.140 Handling - Maintain written procedures	0%	20%	70%	0%	0%	10%
820.150 Storage(a) - Maintain written procedures	0%	20%	70%	0%	0%	10%

Source: Part 820 Final Rule, 1996

Using the number of hours saved in annual labor (Table 45) by proportion of labor category (Table 46), and by appropriate wage rate and overhead costs (Table 9), we determine the reduced annual labor burden to comply with Subpart L of the current Part 820 for affected entities (see Table 47). Cost savings from moving from compliance with both systems to the proposed rule results in a saving of approximately $520,000 per year for the affected entities (see Table 47).

Table 47. Annual Cost Savings of Compliance with the Proposed Rule, Subpart L

Part 820, Subpart L	Establishment Size, Domestic				Totals
	Small	Medium	Large	Very Large	
No. of Establishments	1,080	1,849	711	546	**4,186**
820.140 Handling - Maintain procedures Unit cost saving **Cost Saving**	 $13 **$13,543**	 $13 **$23,181**	 $25 **$17,829**	 $25 **$13,683**	 **$68,236**
820.150 Storage(a) - Maintain procedures Unit cost saving **Cost Saving**	 $13 **$13,543**	 $13 **$23,181**	 $25 **$17,829**	 $25 **$13,683**	 **$68,236**
Part 820, Subpart L	**Establishment Size, Foreign**				**Totals**
No. of Establishments	3,023	5,175	1,990	1,527	**11,715**
820.140 Handling - Maintain procedures Unit cost saving **Cost Saving**	 $13 **$37,898**	 $13 **$64,871**	 $25 **$49,892**	 $25 **$38,292**	 **$190,954**
820.150 Storage(a)					

- Maintain procedures					
Unit cost saving	$13	$13	$25	$25	
Cost Saving	**$37,898**	**$64,871**	**$49,892**	**$38,292**	**$190,954**
Total Cost Savings, Subpart L					**$518,380**

Note: Due to rounding, numbers presented in this table may not add up precisely to the totals provided.

Subpart M – Records

Subpart M of the current Part 820 requires manufacturers maintain all records to be legible, and stored in a manner to prevent deterioration, damage, or loss. Subpart M also requires including subcontractor quality records, if applicable. In addition to medical devices descriptions, complaint files are required to include the medical devices' packaging and labeling. Investigative records must include determination of if there was a device failure, whether the device failure resulted in death or injury, and description of corrective action. We assume that each medical device establishment that complies with both the current Part 820 and ISO 13485 would require 10% less annual labor hours to comply with the proposed rule for each provision of Subpart M, as explained in Section D.1. of this document. We request comment on this assumption. In the sensitivity analysis section, we compare the decrease in compliance effort by 5% and 25%. Table 48 shows the number of annual labor hours saved for each provision of the current Part 820, Subpart M, by complying with the proposed rule.

Table 48. Number of Annual Labor Hours Saved by a Medical Device Establishment to Comply with the Proposed Rule, Subpart M

Part 820, Subpart M Provision	**Establishment Size**			
	Small	**Medium**	**Large**	**Very large**
Current 820.198 Complaint Files				
- Maintain written procedures[1]	2	2	3	4
Comply with NPRM[2]	1.8	1.8	2.7	3.6
Labor hours saved	**0.2**	**0.2**	**0.3**	**0.4**

1. Part 820 Final Rule, 1996.
2. Assume 10% decrease in effort in moving from complying with two similar standards to the proposed rule.

We use information from the 1996 Part 820 final rule to determine proportion of types of labor needed to comply with each provision of Subpart M (see Table 49), and appropriate wage rates and overhead costs (see Table 9) to estimate cost savings from complying with the proposed rule for affected establishments.

Table 49. Proportion of Annual Labor by Labor Category, Subpart M

	Labor Category

Part 820, Subpart M Provision	Vice President	Upper Mgmt.	Middle Mgmt.	Technical	Admin Support	Clerical
820.198 Complaint Files - Maintain written procedures	0%	20%	70%	0%	0%	10%

Source: Part 820 Final Rule, 1996

Using the number of hours saved in annual labor (Table 48) by proportion of labor category (Table 49), and by appropriate wage rate and overhead costs (Table 9), we determine the reduced annual labor burden to comply with Subpart J of the current Part 820 for affected entities (see Table 50). Cost savings from moving from compliance with both systems to the proposed rule results in a saving of approximately $485,000 per year for the affected entities (see Table 50).

Table 50. Annual Cost Savings of Compliance with the Proposed Rule, Subpart M

Part 820, Subpart M	Establishment Size, Domestic				Totals
	Small	Medium	Large	Very Large	
No. of Establishments	1,080	1,849	711	546	**4,186**
820.198 Complaint Files - Maintain written procedures					
Unit cost saving	$25	$25	$38	$50	
Cost Saving	**$27,085**	**$46,363**	**$26,743**	**$27,367**	**$127,558**
Part 820, Subpart M	**Establishment Size, Foreign**				**Totals**
No. of Establishments	3,023	5,175	1,990	1,527	**11,715**
820.198 Complaint Files - Maintain written procedures					
Unit cost saving	$25	$25	$38	$50	
Cost Saving	**$75,796**	**$129,743**	**$74,839**	**$76,584**	**$356,961**
Total Annual Cost Savings, Subpart M					**$484,520**

Note: Due to rounding, numbers presented in this table may not add up precisely to the totals provided.

Subpart N – Servicing

Subpart N of the current Part 820 requires manufacturers to develop written procedures for managing servicing operations. The Subpart N requirements also mandate the maintenance of servicing records and the feedback of device problems detected during servicing into the corrective action system. We assume that each medical device establishment that complies with both the current Part 820 and ISO 13485 would require 10% less annual labor hours to comply with the proposed rule for each provision of Subpart N, as explained in Section D.1. of this document. We request comment on this assumption. In the sensitivity analysis section, we

compare the decrease in compliance effort by 5% and 25%. Table 51 shows the number of annual labor hours saved for each provision of Subpart N of the current Part 820, by complying with the proposed rule.

Table 51. Number of Annual Labor Hours Saved by a Medical Device Establishment to Comply with the Proposed Rule, Subpart N

Part 820, Subpart N Provision	Establishment Size			
	Small	Medium	Large	Very large
Current 820.200 Servicing				
- Maintain written procedures[1]	2	2	3	4
Comply with NPRM[2]	1.8	1.8	2.7	3.6
Labor hours saved	**0.2**	**0.2**	**0.3**	**0.4**

1. Part 820 Final Rule, 1996.
2. Assume 10% decrease in effort in moving from complying with two similar standards to the proposed rule.

We use information from the 1996 Part 820 final rule to determine proportion of types of labor needed to comply with each provision of Subpart N (see Table 52), and appropriate wage rates and overhead costs (see Table 9) to estimate benefits of complying with the proposed rule for affected establishments.

Table 52. Proportion of Annual Labor by Labor Category, Subpart N

Part 820, Subpart N Provision	Labor Category					
	Vice President	Upper Mgmt.	Middle Mgmt.	Technical	Admin Support	Clerical
820.200 Servicing						
- Maintain written procedures	0%	20%	70%	0%	0%	10%

Source: Part 820 Final Rule, 1996

Using the number of hours saved in annual labor (Table 51) by proportion of labor category (Table 52), and by appropriate wage rate and overhead costs (Table 9), we determine the reduced annual labor burden to comply with Subpart N of the current Part 820 for affected entities (see Table 53). Cost savings of moving from compliance with both systems to the proposed rule results in a saving of approximately $485,000 per year for the affected entities (see Table 53).

Table 53. Annual Cost Savings of Compliance with the Proposed Rule, Subpart N

Part 820, Subpart N	Establishment Size, Domestic				Totals
	Small	Medium	Large	Very Large	
No. of Establishments	1,080	1,849	711	546	**4,186**
820.200 Servicing - Maintain written procedures					
Unit cost saving	$25	$25	$38	$50	
Cost Saving	**$27,085**	**$46,363**	**$26,743**	**$27,367**	**$127,558**

Part 820, Subpart N	**Establishment Size, Foreign**				**Totals**
No. of Establishments	3,023	5,175	1,990	1,527	**11,715**
820.200 Servicing - Maintain written procedures					
Unit cost saving	$25	$25	$38	$50	
Cost Saving	**$75,796**	**$129,743**	**$74,839**	**$76,584**	**$356,961**
Total Cost Savings, Subpart N					**$484,520**

Note: Due to rounding, numbers presented in this table may not add up precisely to the totals provided.

Subpart O – Statistical Techniques

Subpart O of Part the current 820 requires manufacturers to establish and maintain appropriate statistical techniques and sampling plans to control the quality of processes and product characteristics. These requirements are consistent with usual practices throughout the medical device industry; therefore, there no annual compliance cost, or cost saving, is estimated for Subpart O. We request comment on this assumption.

Other Benefits of the Proposed Rule

The above analysis shows that there would be significant annual cost savings in regulatory compliance by the small to large firms within the medical device industry. A benefit that is not quantified in this analysis is quicker process for regulatory compliance for medical devices which would lead to timelier introduction of safe, effective, high-quality medical devices to patients. Quicker access to newly-developed medical devices potentially improves the life quality of the consumers; and alternatively, aid in avoiding illnesses, deaths, and costly medical treatments. Other benefits include reduced enforcement due to ease of compliance with one set of quality system management requirements and alignment of programs such as Medical Device Single Audit Program (MDSAP) with other regulations and standards.

F. Costs of the Proposed Rule

The proposed rule would impose costs both on the medical device establishments and FDA. All medical establishments undergo a one-time cost to learn the rule. In addition to learning the rule requirements, medical device establishments which are not in compliance with ISO 13485 when the proposed rule is implemented would undergo the following costs:

- One-time cost of initial training of regulatory compliance expert,
- One-time cost of initial updating of establishment's information technology, and
- One-time cost of initial update of establishment documents related to policy and procedures.

One-Time Costs to Learn the Rule

We model the one-time learning costs as the time required by medical device establishments' regulatory affairs expert to access and read the proposed rule. We estimate that a regulatory affairs expert would incur a burden between 15 and 30 minutes to access the rule and would read the provisions at a rate of 200 to 250 words per minute (wpm). The preamble and codified regulatory text are approximately 30,000 words. We estimate that it would take between 2 hours (30,000 words ÷ 250 wpm x 1 hour/60 mins), and 2.5 hours (30,000 words ÷ 200 wpm x 1 hour/60 mins) (average: 2.22 hours) for a regulatory affairs expert to read and understand the rule.

We estimate the mean hourly wage of a regulatory affairs expert using mean hourly wages reported in the Bureau of Labor Statistics, Occupational Employments Statistics, May 2020 for a lawyer (SOC 23-1011; $71.59) which is doubled ($143.18) to account for benefits and overhead costs. Applying the fully-loaded mean hourly wage to the hourly burdens described previously, we obtain a cost of between $344 and $415 (average: $372) for a regulatory affairs expert to access and read the final rule (i.e., (average of 15 and 30 minutes: 22.5 minutes or 0.375 hours + 2.22 hours) x $143.18per hour). The total access and learning cost for all affected entities (20,346) is between $7.0 million ($344/establishment x 20,346 establishments) and $8.5 million ($415/establishment x 20,346establishments) (average: $7.6 million). Table 54 breaks down the cost of learning the rule for the very small establishments (4,445; $5.92 million), and small to very large establishments (15,922; $5.66 million). We assume that each establishment would incur the access and reading costs the first year following publication of the rule. Consequently, over 10 years at a discount rate of 7 percent, we estimate the annualized one-time learning costs range from approximately $1 million to $1.2 million per year (average: $1.1 million per year). When we assume a discount rate of 3 percent, the annualized one-time costs range from approximately $820,000 to $990,000 per year (average: $888,000 per year) (see Table 54).

One-Time Cost of Initial Training of Regulatory Compliance Expert

We believe medical device establishments that currently comply with ISO 13485 already have a regulatory compliance expert who is familiar with the ISO standard. Therefore, these costs are attributed to the very small domestic medical device establishments (4,445). We expect that the person who directs regulatory compliance of a medical device establishment that currently is not in compliance with ISO 13485 would, at a minimum, attend a 3-day course to become knowledgeable of differences between Part 820 and ISO 13485. A compliance training organization offers a 3-day course for non-members at $2,435 per person.[1] A 3-day training on ISO 13485 for regulatory compliance experts of very small domestic medical device manufacturing establishments (4,445) who would transition to the proposed rule is approximately $10.9 million ($2,435/establishment x 4,445 establishments) (see Table 54). The training course includes a copy of the ISO 13485 for the participants. We assume that each establishment would incur this cost the first year following publication of the rule. Consequently, over 10 years at a discount rate of 7 percent, we estimate the annualized one-time document update is approximately $1.6 million per year (see Table 54). When we assume a discount rate of 3 percent, the annualized one-time cost is approximately $1.3 million per year (see Table 54).

One-Time Cost of Initial Updating of Medical Device Establishments' Information Technology

We believe medical device establishments that currently comply with ISO 13485 have already an updated information technology in order to comply with the ISO standard. Therefore, these costs are attributed to the very small domestic medical device establishments (4,445). We expect that a very small domestic medical device establishment that currently does not comply with ISO 13485 will update its compliance infrastructure, at a minimum, by purchasing specialized software that would guide the establishment in complying with the proposed rule. The least expensive option for ISO 13485 specialized software (1 user on 1 computer) is listed for $1,490.[2] The purchase of such software for all small medical device establishments

1 Design Control Requirements – Integrating the Quality System Regulation and ANSI/AAMI/ISO 13485. Source: http://university.aami.org/diweb/catalog/item/id/2283512/

2 IMSXPRESS online store. Source: http://www.imsxp.com/30OnlineStore/Store13QmsPkg.aspx?utm_source=Capterra13&utm_medium=Price&utm_campaign=Price13

(4,445) is approximately $6.7 million ($1,490/establishment x 4, 4,445establishments) (see Table 54). We assume that each establishment would incur this cost the first year following publication of the rule. Consequently, over 10 years at a discount rate of 7 percent, we estimate the annualized one-time document update is approximately $943,000 per year (see Table 54). When we assume a discount rate of 3 percent, the annualized one-time cost is approximately $777,000 per year (see Table 54).

One-Time Cost of Initial Update of Establishment Documents Related to Policy and Procedures

We believe medical device establishments that currently comply with ISO 13485 have already updated their establishments' documents related to policy and procedures associated with the ISO provisions. Therefore, these costs are attributed to the very small domestic medical device establishments (4,445). We expect that it would take 40 labor hours for the establishment's regulatory affairs expert to make changes and updates to the establishment's documents pertaining to policy and procedure changes as a result of the proposed rule. Using the fully-loaded mean hourly wage rate of $143.18 per hour (see above), we estimate that it would cost approximately $5,727 (40 hours x $143.18/hour) for a very small domestic medical device establishment to conduct this activity. Total cost of updating documents related to policy and procedures for small medical device establishments (4,445) is approximately $25.4 million ($5,727/establishment x 4,445establishments) (see Table 54). We assume that each establishment would incur this cost the first year following publication of the rule. Consequently, over 10 years at a discount rate of 7 percent, we estimate the annualized one-time document update is approximately $3.7 million per year (see Table 54). When we assume a discount rate of 3 percent, the annualized one-time cost is approximately $3.0 million per year (see Table 54).

Table 54. Summary of One-Time Costs for Medical Device Establishments

Activity	Affected Entities	One-Time Cost	Annualized Cost (10-year horizon)	
			3%	7%
Very Small Domestic Medical Device Establishments				
Learning the rule	4,445	$1,653,434	$193,833	$235,412
Initial training	4,445	$10,822,884	$1,268,772	$1,540,935
IT update	4,445	$6,622,627	$776,374	$942,913

Documents update	4,445	$25,454,890	$2,984,090	$3,624,204
Total cost, very small est.		**$44,553,835**	**$5,223,069**	**$6,343,464**
Small to Very Large Domestic and Foreign Medical Device Establishments				
Learning the rule	15,901	$5,915,278	$693,451	$842,202
Total cost, small to very large est.		**$5,915,278**	**$693,451**	**$842,202**
Total one-time costs		**$50,469,113**	**$5,916,520**	**$7,185,666**

Note: The criterion for "very small" is an establishment that has an annual revenue of less than $0.5 million. These establishments encompass categories of "establishments with less than 5 employees," and "establishments with 5 to 9 employees" in the 2019 County Business Pattern database.

FDA costs

As part of transitioning from managing the current Part 820 program to the proposed rule, FDA plans to provide initial training for its staff in the Office of Medical Device and Radiological Health Operations (OMDRHO), update its IT infrastructure, and update documents related to policies and procedures.

One-Time Cost of Initial training of OMDRHO staff

Initial training of the OMDRHO staff includes the following:

- A 5-day (40 hours) AAMI course on the QS regulation and ISO 13485 for 196 staff members: AAMI offers its training course (for maximum of 50 students/course) for $38,750. FDA would need 4 courses to accommodate its 196 staff members at a cost of $155,000 (4 courses x $38,750/course) (see Table 55). Average weighted hourly wage rate of OMDRHO staff is estimated at $50.76 per hour (see Table 56) which is doubled ($101.52) to account for benefits and overhead costs. Estimated cost of wages of OMDRHO staff to attend AAMI course is $795,947 (40 hours of training x 196 staff members/training x $101.52/hour) (see Table 55). In addition, OMDRHO estimates that travel and per diem cost to attend the AAMI Standard course at $1,600 per person assuming that in-person training is necessary. Therefore, the travel cost of 196 FDA staff members to attend the AAMI course is $313,000 (196 staff members x $1,600/staff member) (see Table 55). The total initial one-time cost of AAMI Standard course is estimated at $1,264,547 (see Tables 55 and 58).

Table 55. Initial One-Time Cost of AAMI Standard Course

Activity	Hours of Training	Number of staff/units	Average wage/unit price	Total
Training Time Cost	40	196	$101.52	$795,947
Training Instruction and Development	40	4	$38,750	$155,000
Travel Expenses ORA to Training	40	196	$1,600	$313,600
Total2.57]				**$1,264,547**

Table 56. OMDRHO Staff Number and Wages

Position/GS Level	Average Hourly Wage	Number of Staff
CSO GS-7	$26.69	20
CSO GS-9	$32.65	8
CSO GS-11	$39.51	20
CSO GS-12	$47.35	30
CSO GS-13	$56.31	70
CSO GS-14 (NE)	$66.54	2
CO GS-13	$56.31	14
PE GS-13	$56.31	2
SCSO GS-13/14	$61.43	17
GS 14 Managers	$66.54	8
GS 15+Managers	$78.27	5
Total		**196**
Mean Weighted Average	**$50.76**	

- A 4-day (32 hours) AAMI Audit course for 150 staff members (a subset of the 196 staff members): AAMI offers its Audit training course (for maximum of 50 students/course) for $35,000. FDA would need 3 courses to accommodate its 150 staff members at a cost of $105,000 (3 courses x $35,000/course) (see Table 57). OMDRHO estimates the average hourly wage rate of a participant of that of a GS-12 ($47.35/hour) (see Table 56) which is doubled ($94.70) to account for benefits and overhead costs. Estimated cost of wages of OMDRHO staff to attend AAMI Audit course is $455,000 (32 hours of training x 150 staff members/training x $94.70/hour) (see Table 57). In addition, OMDRHO estimates that travel and per diem cost to attend the AAMI course at $1,300 per person. Therefore, the travel cost of 150 FDA staff members to attend the AAMI Audit course is $195,000 (150 staff members x $1,300/staff member) (see Table 57). The total initial one-time cost of AAMI Audit course is estimated at $754,560 (see Tables 57 and 58).

Table 57. Initial One-Time Cost of AAMI Audit Course

Activity	Hrs of Training	Number of staff/units	Average wage/unit price	Total
Training Time Cost	32	150	$94.70	$454,560
Training Instruction and Development	32	3	$35,000	$105,000
Travel Expenses ORA to Training	32	150	$1,300	$195,000
Total				**$754,560**

- A 3-day (24 hours) training by FDA's Center for Devices and Radiological Health (CDRH) with FDA's Office of Regulatory Affairs (ORA) for 196 staff members: Using the fully-loaded weighted mean hourly wage of all OMDRHO staff member ($101.52), we estimate the cost of training 196 staff members for this in-house training at $477,568 (24 hours/staff member x $101.52/hour x 196 staff members) (see Table 58).
- A 3-day (24 hours) ORA Inspection Training for 175 staff members: Using the fully-loaded weighted mean hourly wage of OMDRHO staff member ($101.52), we estimate the cost of training 175 staff members for this in-house training at $426,400 (24 hours x $101.52/hour x 175 staff members) (see Table 58).
- 3-day (24 hours) ORA Enforcement/Compliance Training 17 staff members: We use the mean hourly wage of OMDRHO's COs and DCBs at the rate of GS-14, $66.54 per hour, and double it ($133.08 per hour) to account for benefits and overhead costs. We estimate the cost of training 17 staff members for this in-house training at $54,297 (24 hours/staff member x $133.08/hour x 17 staff members) (see Table 58).

Other One-Time Initial Training Costs

FDA estimates that it would cost $12,000 to conduct state contractor training for 7 inspectors in California and Texas (see Table 58).

Initial Cost of Updating FDA's Information Technology

Updating FDA's current software and other IT-related resources include the following:

- eNspect citation re-write and verification: The citation re-write and verification will be conducted by 3 FDA staff members for 800 labor hours at average hourly wage rate of a staff member between GS 13 and GS 14 pay levels, or at $61.43 per hour (see Table 56). Using the fully-loaded mean hourly wage rate ($122.85/hour = $61.43/hour x 2), we estimate that this IT activity costs $98,280 (3 staff members x 800 hours/3 staff members x $122.85/hour) (see Table 58).
- eNspect EIR re-write/formatting: The re-write/formatting of the eNspect EIR system requires 200 hours of one staff member at pay level of $61.43 per hour. Using the fully-loaded mean hourly wage rate ($122.85), we estimate that this IT activity costs $24,570 (1 staff member x 200 hours/staff member x $122.85/hour) (see Table 58).
- ORADSS report and data collection re-write: The re-write of ORADSS report and data is expected to require 200 hours of one staff member with a wage rate of $61.43 per hour. Using the fully-loaded mean hourly wage rate $122.85 per hour, we estimate that this IT activity costs $24,570 (1 staff member x 200 hours/staff member x $122.85/hour) (see Table 58).

One-Time Cost of Initial Update of FDA Documents Related to Policy and Procedures

We expect that it would take 300 labor hours for 3 staff members with a wage rate of $61.43 per hour to make changes and updates to FDA documents pertaining to policy and procedure changes as a result of the proposed rule. Using the fully-loaded mean hourly wage rate of $122.85 per hour, we estimate that it would cost $36,855 (300 staff hours x $122.85/hour) to conduct this one-time activity (see Table 58).

Summary of FDA Costs

Table 58 provides a summary of FDA costs described above. The total initial on-time cost for FDA to train its employees and update its IT infrastructure and documents and procedures related to the proposed rule are approximately $3.2 million. We assume that FDA would incur these initial costs the first year following publication of the rule. Consequently, over 10 years at a discount rate of 7 percent, we estimate the annualized initial FDA costs at approximately $452,000 per year. When we assume a discount rate of 3 percent, the annualized one-time costs are at approximately $373,000 per year.

Table 58. Summary of FDA Costs

Activity	Cost
Training	
AAMI Standards Course	$1,264,547
AAMI Audit Course	$754,560
CDRH Training with ORA	$477,568
ORA Inspection Training (CSO, SCSO & DIB)	$426,400
ORA Enforcement/Compliance Training (CO & DCB)	$54,297
State Contractors Training (CA & TX)	$12,000
IT Update	
eNSpect Citation Re-write (by GS 13/14s) & Verification	$98,280
eNSpect EIR Re-write/Formatting (by GS13/14s)	$24,570
ORADSS Report (data collection) Re-write (by GS 13/14)	$24,570
Documents Update	
IOM/CPGM/RPM/SOP Changes and Updates (review)	$36,855
Total	**$3,173,647**
Annualized 10-year, 7%	**$451,856**
Annualized 10-year, 3%	**$372,048**

G. Distributional Effects

There are no transfer payments or differential effects across income groups, ethnic groups, geographical regions, gender, and age groups.

H. International Effects

Throughout this PRIA, we assume that all foreign medical device establishments registered with the FDA and that are larger than very small (less than $500K) in size, currently comply with both the current Part 820 and ISO 13485. We request comments for these assumptions. Therefore, the proposed rule would benefit foreign medical device establishments through cost savings from reduced annual compliance effort to create and maintain a single quality system. For this analysis, we estimate 11,715 foreign medical device establishments by different employee size categories (see Table 8b) will experience these cost savings. In Section E, we estimate annual cost savings of approximately $315 million for foreign medical device establishments which currently comply with both the current Part 820 and ISO 13485. Cost savings estimated for foreign medical device

establishments in Section E are re-presented in Table 59. The annual cost savings to foreign establishments ($315M) is approximately 74% of total annual cost savings ($426M) of the proposed rule.

Table 59. Annual Cost Savings for Foreign Medical Device Establishments

Part 820 Subpart	Reference	Cost Savings
A	N/A	N/A
B	Table 13b	$4,873,214
C	Table 17b	$292,322,049
D	Table 21	$356,961
E	Table 24b	$12,584,243
F	Table 28	$1,319,277
G	Table 31b	$1,319,277
H	Table 35	$190,954
I	Table 38	$356,961
J	Table 41	$356,961
K	Table 44	$190,954
L	Table 47	$381,908
M	Table 50	$356,961
N	Table 53	$356,961
O	N/A	N/A
Annual Cost Savings, Foreign Establishments		**$314,966,682**
Annual Cost Savings, All Establishments		**$425,900,822**

The cost to foreign medical device establishments registered with the FDA is the labor cost of medical device establishments' regulatory affairs experts to access and read the proposed rule. In Section F, we estimated that, on average, it would cost a medical device establishment $372 to read and learn the proposed rule. Therefore, the cost of reading and learning the rule for all foreign establishments is approximately $4.36 million ($372/establishments x 11,715 establishments). We estimate the net cost savings to foreign medical device establishments registered with FDA at approximately $310 million ($315 million - $5 million).

I. Uncertainty and Sensitivity Analysis

In this section, we conduct sensitivity analyses of the assumption of decreased burden (cost savings) of establishments which are currently complying with both the current Part 820 and ISO 13485.

Decrease of Compliance Effort

In the above analysis, we assume the effort of a medical device establishment that complies with both the current Part 820 and ISO 13485 would decrease by 10% by moving to complying with the proposed rule. We now use different assumptions in proportion of reductions in burden rate, 5% and 25%, to measure the lower and upper bound estimates of these cost savings.

FDA costs under each burden rate (i.e., 5%, 10%, and 25%) remains the same. Comparison of effect of assumption rates shows that net savings of the proposed rule varies between $260M and $1,325M ($526M used in main analysis) (see Table 60). Industry costs, borne by very small establishments (revenue under $0.5M), are approximately $7 million (see Table 60).

Table 60 – Comparison of Effect of Assumption Rates for Increase (Annual Costs)/Decrease (Annual Cost Savings) Burden of Effort to Comply with the Proposed Rule

Cost	**Increase/Decrease Burden Effort**		
Saving/Cost	**5%**	**10%**	**25%**
Cost Savings - Industry	$266,389,091	$532,778,183	$1,331,945,457
Costs - Industry	$6,950,254	$6,950,254	$6,950,254
Costs - FDA	$451,856	$451,856	$451,856
Net Cost Savings	**$258,986,981**	**$525,376,073**	**$1,324,543,347**

Note: These annual costs are discounted at 7% for a 10-year horizon.

J. Analysis of Regulatory Alternatives to the Proposed Rule

1. Option One: Keep the Part 820 Standard as an Option for Entities who Prefer It

If the Part 820 standard were maintained as an option—though not a requirement—some, but not all, of the estimates appearing in the preceding analysis would change. Rule-induced cost savings would be the same, but the costs discussed above, incurred by entities not already complying with ISO 13485 requirements, would be avoided. Additionally, there would, relative to the rule as proposed, be unquantified costs to FDA, and potentially to some regulated entities, as a result of the incomplete streamlining and harmonization of standards being associated with greater scope for confusion. This regulatory option would be inconsistent with FDA's goal of harmonizing the current Part 820 and ISO 13485. No other dual systems are considered.

For analytic purposes, we request comment that would facilitate more thorough estimation of impacts associated with this regulatory approach.

2. Option Two: Take the Proposed Action

Under this option, we compare effect of postponement of implementation of the proposed rule by two years. We compare cost savings and costs of the proposed rule if the rule would be postponed by 2 years. Table 61 indicates that the net cost savings of a 2-year postponement of the proposed rule would be decreased from approximately $526M to $496M.

Table 61 – Postponement of Implementation Date of the Proposed Rule – Cost Savings and Costs

Cost/Cost Saving	**Implementation Date**	
	No Delay	**Two Year Delay**
Cost Savings – Industry	$532,778,183	$502,194,536
Costs – Industry	$6,950,254	$6,551,281
Costs - FDA	$451,856	$425,918
Net Cost Savings	**$525,376,073**	**$495,217,337**

Note: These annual costs are discounted at 7% for a 10-year horizon.

III. Initial Small Entity Analysis

The Regulatory Flexibility Act requires Agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. According to the Small Business Administration's (SBA's) standards for different sectors of medical device industry, the great majority of medical device establishments included in our analysis are considered 'small.' Table 62 includes examples of 'small business' criteria for different types of medical device establishments. We believe that most medical device establishments have fewer employees than SBA's thresholds allow (see Table 62). Therefore, considering SBA's standard for small business, the proposed rule would result in a net annual cost savings of over $400M (see Table 63).

In this analysis, we considered medical device establishments that are considered 'very small,' entities that have annual revenue of less than $0.5 and typically have 9 employees or less. We assumed that very small domestic medical establishments do not currently conform to the ISO 13485 standard. We ask for comments on

this assumption. Table 63 includes the estimated annual burden to medical device establishments based on whether they are very small or not. Annual burden of net costs for a very small establishment is estimated at approximately $1,500 (see Table 63). Cost savings for other medical device establishments is estimated, on average, at approximately $27,000 (see Table 63). As noted before, we believe that other benefits may accrue to medical device establishments as a result of the proposed rule. The harmonization of the current Part 820 and ISO 13485 as reflected in the proposed rule would result in less regulatory compliance burden and potentially quicker access for medical devices to the market. Considering the number (4,445) and annual burden ($1,427 cost) of very small establishments and those of small to very large establishments (15,901 establishments, $27,000 cost saving), we propose to certify that the proposed rule will not have a significant economic impact on a substantial number of small entities. This analysis, as well as other sections in this document, serves as the Initial Regulatory Flexibility Analysis, as required under the Regulatory Flexibility Act.

Table 62. Small Business Administration Threshold for a Small Business Designation

NAICS Code	Establishment description	Number of Employees
325413	In-vitro diagnostic substance manufacturing	1,250
334510	Electromedical and electrotherapeutic apparatus manufacturing	1,250
334517	Irradiation apparatus manufacturing	1,000
339112	Surgical and medical instrument manufacturing	1,000
339113	Surgical appliance and supplies manufacturing	750
339114	Dental equipment and supplies manufacturing	750
339115	Ophthalmic goods manufacturing	1,000

Source: Small Business Administration, Table of Small Business Size Standards.
Link: https://www.sba.gov/sites/default/files/2018-07/NAICS%202017%20Table%20of%20Size%20Standards.pdf
Last accessed: June, 2021

Table 63 – Annual Costs and Cost Savings of Medical Device Establishments Based on Size

Cost/Cost Saving	Size	
	Very Small	Small to Very Large
Total Costs	$6,343,464	$842,202
Total Cost Savings		$425,900,822
No. of Establishments	4,445	15,901
Cost/Establishment	**$1,427**	
Cost Saving/Establishment		**$26,731**

1. Costs are annualized for a 10-year period, 7% discount rate (see Table 54)
Note: Very small establishment has revenue of less than $0.5M per year.

Effect of Proposed Rule on Competitive Fairness in the Medical Device Industry

Potentially, foreign medical device establishments which currently do not export their products to the U.S. may choose to comply with the proposed rule, when finalized and implemented, and export their products to the U.S. These foreign medical device establishments will face the same one-time costs that all current foreign and domestic establishments face (including those designated 'very small'). In addition to prospective foreign medical device establishments, current domestic establishments (small to very large) may fill the void of medical device market share of the 'very small' domestic establishment who may choose to exit the industry. In face of new costly rulemaking, there is a potential for certain establishments deciding to exit the industry, new establishments entering the industry, or both. In the case where certain domestic establishments choose to exit the industry, there is a potential for existing domestic or foreign establishments to occupy the market of the exiting establishments or new establishments to enter the market. We request comments on potential change to the current industry demographics as a result of the proposed rule.

IV. References

1. Medical Devices; Current Good Manufacturing Practice (CGMP) Final Rule; Quality System Regulation, Food and Drug Administration, Federal Register Vol. 61 No.195, 10/7/1996, pgs. 52602-52662.
2. Economic Analysis of Proposed Revisions to the Good Manufacturing Practices Regulation for Medical Devices, Final Report, Eastern Research Group, Inc., November 1993.
3. Economic Analysis of Proposed Revisions to the Good Manufacturing Practices Regulation for Medical Devices, Addendum, Eastern Research Group, Inc., August 1996.