DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Medical Devices; Quality System Regulation Amendments

Docket No. FDA-2021-N-0507

Final Regulatory Impact Analysis
Final 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 final rule under Executive Order 12866, Executive Order 13563, Executive Order 14094, the Regulatory Flexibility Act (5 U.S.C. 601-612), the Congressional Review Act/Small Business Regulatory Enforcement Fairness Act (5 U.S.C. 801, Pub. L. 104-121), and the Unfunded Mandates Reform Act of 1995 (Pub. L. 104-4).

Executive Orders 12866,13563, and 14094 direct us to assess all benefits, costs, and transfers 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). Rules are "significant" under Executive Order 12866 Section 3(f)(1) (as amended by Executive Order 14094) if they "have an annual effect on the economy of $200 million or more (adjusted every 3 years by the Administrator of the Office of Information and Regulatory Affairs (OIRA) for changes in gross domestic product); or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, territorial, or tribal governments or communities. OIRA has determined that this final rule is a significant regulatory action under Executive Order 12866 section 3(f)(1)).

A rule is "major" under the Congressional Review Act/Small Business Regulatory Enforcement Fairness Act if it has resulted or is likely to result in an annual effect on the economy of $100 million or more or meets other criteria specified in the Congressional Review Act (5 U.S.C. 804(2)). OIRA has determined that this final rule is a major rule under the Congressional Review Act/Small Business Regulatory Enforcement Fairness Act.

The Regulatory Flexibility Act requires us to analyze regulatory options that would minimize any significant impact of a rule on small entities. Our small entities analysis (see Part III) indicates that the final rule would result in net cost savings of over $500 million for medical device establishments deemed as small entities by the Small Business Administration. Therefore, we certify that the final 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 impacts, before issuing "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 $177 million, using the most current (2022) Implicit Price Deflator for the Gross Domestic Product. This final rule would not result in an expenditure in any year that meets or exceeds this amount.

B. Summary of Costs and Benefits and Transfers

Table 1 includes summary of estimated benefits (cost savings) and costs of the final rule. The benefit of the final rule is estimated in terms of reduction of compliance effort, and consequently cost savings, for medical device establishments that previously complied with both the QS regulation and ISO 13485. The costs of the rule include initial training of personnel, and information technology and documentation updates 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.

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

Category		Primary Estimate	Low Estimate	High Estimate	Units			Notes
					Year Dollars	Discount Rate	Period Covered	
Benefits*	Annualized Monetized $M/year	$540	$270	$1,349	2022	7%	10 years	Benefits are cost savings
		$561	$280	$1,401	2022	3%	10 years	Benefits are cost savings
	Annualized Quantified					7%		
						3%		
	Qualitative							
Costs	Annualized Monetized $M/year	$8.20	$8.20	$8.20	2022	7%	10 years	
		$7.29	$7.29	$7.29	2022	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 Economic Analysis of Impacts that assesses the impacts of the final rule. The full analysis of economic impacts is available in the docket for this final rule (Ref. 11) and at http://www.fda.gov/AboutFDA/ReportsManualsForms/Reports/EconomicAnalyses/default.htm.

C. Comments on the Preliminary Economic Analysis of Impacts and Our Responses

On February 23, 2022, FDA published a proposed rule to amend Part 820 (87 Federal Register 10119).

In the paragraphs below, we describe and respond to the comments received on the Preliminary Economic Analysis of Impacts (PRIA). The number assigned to each comment is purely for organizational purposes and does not signify the comment's value, importance, or the order in which it was received.

(Comment 1) A commenter inquired how will FDA "certify" that the proposed rule will not have a significant economic impact on a substantial number of small entities. In addition, the commenter inquired whether the "certification" refers to certification issued by medical device Notification Bodies.

(Response) The Regulatory Flexibility Act requires us to analyze regulatory options that would minimize any significant impact of a rule on small entities. When it is determined that a proposed or final rule

will not have a significant impact on a substantial number of small entities, FDA certifies the proposed or final rule to that effect. In this FRIA, we assess that the final rule does not have an adverse impact on a substantial number of small entities by showing that the final rule would result in a net annual cost savings of over $500 million for small businesses, as defined by the Small Business Administration (see Section III).

(Comment 2) A Commenter noted that ISO 13485 is a copyrighted document that may be associated with a fee, and thus may not be accessible to all entities, and suggested that FDA make the standard available and cost-free.

(Response) FDA agrees with the portion of the comment that notes that ISO 13485 is a copyrighted document, but advises that a mechanism exists to enable any entity to access standards incorporated by reference in the National Institute of Standards and Technology website, through its Standards Incorporated By Reference portal at no cost. The website for the portal is located here: https://www.nist.gov/standardsgov/accessing-standards-incorporated-reference#:~:text=The%20American%20National%20Standards%20Institute,of%20Federal%20Regulations%20(CFR)

(Comment 3) A commenter stated that only initial training of FDA personnel is considered in the PRIA. In addition, the commenter inquires on ongoing training of FDA personnel on other areas (e.g., combination products, radiation-specific products).

(Response) Ongoing training of existing personnel and initial training of new personnel is a standard work practice at the CDRH. CDRH personnel are trained in appropriate areas to be able to assess and support regulatory effort of the medical device establishments. In this FRIA, we assess the costs of initial training of the FDA on the final rule. Costs of future ongoing trainings (e.g., refreshers, technology updates) are offset or accounted for by activities included in the baseline and are a continuation of our previous training practices.

(Comment 4) A commenter indicated that the annualized costs savings ($540M at 7% discount rate; $561M at 3% discount rate) “would be negatable in the near term, and minor in the long term based on standardization.”

(Response) In the FRIA, we demonstrate that the final rule decreases the regulatory burden of certain medical device establishments. However, it is expected that the regulatory burden of some medical device establishments will remain unchanged as a result of the final rule; therefore, the cost savings would be negatable in the near term or long term for these establishments. The cost-benefit analysis in the FRIA indicates that the annual benefit ($540M at 7% discount rate) of the final rule significantly outweighs the annual cost ($8.20M at 7% discount rate).

D. Summary of Changes

We have made edits to the analysis based on changes applied to the final rulemaking. Specifically, we updated data we previously used in the Preliminary Regulatory Impact Analysis of the proposed rule. The updated data include:

- Medical device establishments registered with the FDA. The number of establishments currently registered with the FDA increased from 22,845 in the PRIA to 28,303. However, for this FRIA, we excluded establishments registered as "initial importers" (3,009 establishments; see Table 2) as we believe they would not be affected by the final rule. We believe that compliance effort by initial importers would remain the same before and after the implementation of the final rule. The number of domestic medical device establishments used in the FRIA increased to 10,269 (13,278 domestic establishments – 3,009 initial importers) (PRIA: 8,631) while the number of foreign medical device establishments increased to 15,025 (PRIA: 11,715) (see Table 2).
- Size demographics of medical device establishments. We used the latest available (2021) U.S. Bureau of Census County Business Pattern datasets to estimate the number of medical device establishments in different size categories. Changes in size demographic of medical device establishments were not significant.
- Wage Rates. We used the latest available (May 2022) U.S. Bureau of Labor Statistics datasets to determine labor costs and cost savings by the medical device industry as a result of the final rule. Across

all labor categories, wages in the medical device industry increased, on average, by 10.05% between 2020 and 2022. We also used the 2022 GS pay scale to determine FDA labor costs.

- Other Costs. We updated the costs for specialized software to assist very small medical device establishments to conform to the final rule, and professional courses designed to train FDA personnel.

Pursuant to FDA's response to public comments, the effective date of the final rule will be 2 years from the publication of the final rule in the Federal Register. The scheduled effective date affects annualizations of costs and cost savings. We estimate that the 2-year effective date decreases annual cost savings by approximately $75M (from $590M to $515M) and decreases annual costs by approximately $1.1M (from $8.9M to $7.8M) over a 10-year period (7% discount rate).

Overall, stakeholders did not raise concerns regarding the PRIA through the public comments that would warrant structural changes to the analysis. Public comments are discussed above.

II. Final Regulatory Impact Analysis

A. Background

FDA has authority to promulgate regulations governing current Good Manufacturing Practices (CGMP) under section 520(f) of the FD&C Act to ensure that the required methods are used in, and the facilities and controls are used for, designing, manufacturing, packaging, labeling, storing, installing, and servicing of devices intended for human use. The CGMP regulation is codified at 21 CFR part 820 (Part 820) and was previously referred to as the Quality System (QS) regulation. In this final rule, FDA is amending Part 820 to harmonize device CGMP requirements in Part 820 with the International Organization for Standardization (ISO) requirements for medical devices under ISO 13485: 2016 (ISO 13485) by incorporating ISO 13485 by reference in Part 820. The amended Part 820 is referred to as the Quality Management System Regulation (QMSR). ISO 13485 is used by regulatory authorities from other jurisdictions to govern quality management system

requirements. FDA is also making 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 final rule.

B. Market or Government Failure Requiring Federal Regulatory Action

Establishments in the medical device industry registered with the FDA must comply with the CGMP requirements in Part 820. In addition, registered foreign establishments and domestic establishments that export their medical devices comply with ISO 13485, which FDA considers to be substantially similar to the QS regulation. The QS regulation 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. Part 820 has not been updated since a significant revision in 1996. The buildup of competing expectations for quality management systems over time leads to duplicative and sometimes obsolete constraints which, in turn, results in increased regulatory compliance cost to the industry potentially without concomitant added benefits to the consumers. As a result, some firms are overburdened by redundant effort in complying with both the QS regulation and ISO 13485. The final rule amends Part 820 by incorporating by reference ISO 13485 requirements thereby harmonizing Quality System expectations across regulatory jurisdictions and reducing the regulatory burden for certain medical device manufacturers.

C. Purpose of the Final Rule

Many U.S. manufacturers have historically used two separate but similar requirements for quality system management of their medical devices – the QS regulation and ISO 13485. While the QS regulation requirements have been effective in ensuring that manufacturers of medical devices meet the applicable quality system requirements for the U.S., harmonizing CGMP requirements with ISO 13485 will reduce the regulatory burden on device manufacturers and align domestic and international requirements. 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, incorporating ISO 13485 requirements into CGMP

requirements for the U.S. has the potential to increase competitiveness of U.S. device manufacturers in a global market.

D. Baseline Conditions and Overview of Final Regulatory Changes

1. Comparison of the QS regulation and ISO 13485

FDA considers the previous QS regulation and ISO 13485 to be the same or substantially similar, although some provisions of the QS regulation did not correlate to a single specific requirement in ISO 13485. In some instances, we found requirements needed better clarification, but we do not intend to take a position on the matter of comparison; rather, these clarifications are intended to ensure that implementation of a QMS is aligned with FDA expectations and regulations. In some instances, we determined that substituting a provision from ISO 13485 instead of its counterpart in the QS regulation would reduce the amount of regulatory effort on the regulated industry.

The requirements of the new QMSR are substantively similar to those of the previous QS regulation, but organization of the QMSR differs from that of the QS regulation and it was not possible to assess the provision-by-provision increase or decrease of effort difference between the previous QS regulation and the new QMSR. There is consensus that the final rule will decrease the regulatory burden of medical device establishments that complied with both ISO 13485 and the previous QS regulation; some sources of costs savings for the industry include reduction of effort in:

- Preparation for inspections and audits. Given that the requirements of both ISO 13485 and the QMSR will be aligned, FDA expects a reduction of industry effort to maintain 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 in preparing for visits from regulators.
- Internal audits and management reviews. The final rule will result in establishments conducting internal audits and management reviews based on aligned requirements as opposed to auditing and assessing separately to comply with the requirements of the previous QS regulation and ISO 13485 individually.

- Training costs: The harmonization of requirements will reduce training costs of industry in that internal training can now cover an aligned set of requirements. Maintaining multiple quality management systems required training personnel on the requirements of both the QS regulation and ISO 13485 in order to maintain a QMS that is in conformity with both.
- Documentation requirements. While documentation requirements are substantively similar between the previous QS regulation and ISO 13485, amending Part 820 through this final rule will lead to a reduction of specific documentation types/files. The QS regulation contained requirements for certain record types that are not specifically identified in ISO 13485, such as the quality system record, device master record, design history file, and device history record. In the QMSR, FDA has removed requirements for these record types, as we believe the elements that comprise these records are largely required to be documented by other ISO 13485 clauses, with the result being a reduced burden on establishments that no longer need to create separate files to maintain QS regulation-specific record types.

In addition, the final rule clarifies some requirements compared to the previous QS regulation and will lead to efficiency gains. For instance, in ISO 13485, there is a specific section requiring sterilization of medical device products, including validation; whereas, the previous QS regulation required that processes more generally be validated. The previous QS regulation specifically referenced sterilization 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 QS regulation explicitly addressed risk management activities only in the risk analysis requirement within design validation in previous Part 820.30(g) whereas risk management requirements are more specifically listed throughout clauses in ISO 13485. FDA's expectation that establishments integrate risk management activities across the total product lifecycle was discussed primarily within the preamble of the rulemaking finalizing the QS regulation, which required entities to refer to the preamble to understand the expectation as opposed to having it clearly listed with the requirements of documents.

In lieu of estimating granular comparison of ISO 13485 and the QS regulation for establishments of different sizes, we decide on an overall decrease of regulatory burden for the affected establishment. FDA experts assess that the final rule would potentially result in, on average, between a 5% and 25% reduction of compliance effort. In this analysis, we assume the effort of a medical device establishment that would have complied with both the QS regulation and ISO 13485 would decrease by 10% by complying with the QMSR in the final 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.

Affected Establishments

As of March 2023, there are 28,303 domestic and foreign medical device establishments registered with the FDA (see Table 2). FDA believes that initial importers would not be affected by the final rule. Therefore, the number of domestic establishments considered for the analysis is 10,269 (13,278 – 3,009).

Table 2. Medical Device Establishments Registered with the FDA, 2023

Establishment Type	**Domestic**	**Foreign**	**Total**
Manufacturer/Complaint File Handler	6,320	11,376	17,696
Contract Manufacturer	1,158	1,732	2,890
Contract Sterilizer	68	166	234
Specification Developer	1,537	514	2,051
Re-processor of Single Use Devices	26	4	30
U.S. Manufacturer of Export Only Devices	120	0	120
Re-packager/Re-labeler	1,020	191	1,211
Remanufacturer	15	8	23
Foreign Exporter/Private Label Distributor		1,024	1,024
Initial Importer	3,009		3,009
Unknown	5	10	15
Total	**13,278**	**15,025**	**28,303**

***FDA, CDRH, March 2023.**

2. Establishment Size

To determine the size demographics of medical device manufacturers, we use information from United States Census Bureau's 2020 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	254
334510	Electromedical and electrotherapeutic apparatus manufacturing	919
334517	Irradiation apparatus manufacturing	134
339112	Surgical and medical instrument manufacturing	1,291
339113	Surgical appliance and supplies manufacturing	1,854
339114	Dental equipment and supplies manufacturing	544
339115	Ophthalmic goods manufacturing	461
Total Establishments		**5,457**

Source: United States Census Bureau, 2020 County Business Patterns, Link: https://data.census.gov, Accessed: March 2023.

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 2020 CBP data for NAICS codes described in Table 3 indicates that approximately 52.12% of all manufacturing establishments are considered very small (1-9 employees), 12.35% are small establishments (10-19 employees), 21.39% are medium-sized establishments (20-99 employees), 7.75% are large (100-249 employees), and 6.40% are very large (250+ employees) (see Tables 4 and 7). We use these proportions to estimate numbers of manufacturers of medical devices registered with FDA by employment size. The CBP data indicates that the very small establishments are 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 final 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.

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	88	33	72	23	38	254

334510	434	92	230	73	90	919
334517	50	20	38	14	12	134
339112	581	155	289	156	110	1,291
339113	1,083	229	366	101	75	1,854
339114	381	63	68	21	11	544
339115	227	82	104	35	13	461
Total	**2,844**	**674**	**1,167**	**423**	**349**	**5,457**
Proportion	**52.12%**	**12.35%**	**21.39%**	**7.75%**	**6.40%**	**100.00%**

Source: United States Census Bureau, 2020 County Business Patterns, https://data.census.gov, March 2023.

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 export 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 25.79% (12.35% ÷ (12.35% + 21.39% + 7.75% + 6.40%)). Similarly, the proportion of foreign companies that are medium, large, and very large are 44.66%, 16.19%, and 13.36% respectively (see Table 7).

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	10,761
423460	Ophthalmic goods merchant wholesalers	1,020
Total Establishments		**11,781**

Source: United States Census Bureau, 2020 County Business Patterns, Link: https://data.census.gov, Accessed: March 2023.

The 2020 CBP data for NAICS codes described in Table 3 indicates that approximately 73.25% of all medical device importers are considered very small (1-9 employees), 9.77% are small-sized establishments, 12.57% are medium sized establishments (20-99 employees), 2.76% are large (100-249 employees), and 1.66% 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

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	7,936	1,035	1,313	291	186	10,761
423460	693	116	168	34	9	1020
Total	**8,629**	**1,151**	**1,481**	**325**	**195**	**11,781**
Proportion	**73.25%**	**9.77%**	**12.57%**	**2.76%**	**1.66%**	**100.00%**

Source: United States Census Bureau, 2020 County Business Patterns, Link: https://data.census.gov, Accessed: March 2023.

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	52.12%	12.35%	21.39%	7.75%	6.40%
Foreign manufacturers	N/A*	25.79%	44.66%	16.19%	13.36%
Importers	73.25%	9.77%	12.57%	2.76%	1.66%

* 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 the 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 final rule increases the burden of very small domestic medical device manufacturers to switch their compliance from the previous QS regulation to the QMSR, while it decreases the burden of all other medical device establishments by moving from compliance with both the QS regulation and ISO 13485 to the QMSR. Table 8a shows that there are 5,352 very small domestic medical device establishments, which are establishments that we assume have not previously complied with ISO 13485 in addition to the previous QS regulation. These establishments incur a net cost as a result of the final rule. Other medical device establishments, 19,942 (4,917 domestic and 15,025 foreign establishments), experience net cost savings due to the final rule (see Tables 8a and 8b). The total number of medical device establishments that will be covered under the final rule is 25,294 (10,269 domestic establishments + 15,025 foreign establishments) (see Tables 8a and 8b).

Table 8a. Universe of Domestic Medical Device Establishments Affected by the Final 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	3,294	781	1,352	490	404
Contract Manufacturer	604	143	248	90	74
Contract Sterilizer	35	8	15	5	4
Specification Developer	801	190	329	119	98
Re-processor of Single Use Devices	14	3	6	2	2
U.S. Manufacturer of Export Only Devices	63	15	26	9	8
Re-packager/Re-labeler	532	126	218	79	65
Remanufacturer	8	2	3	1	1
Foreign Exporter/Private Label Distributor	0	0	0	0	0
Unknown	3	1	1	0	0
Total Manufacturers	**5,352**	**1,268**	**2,196**	**796**	**657**
Initial Importers	2,204	294	378	83	50
TOTAL	7,556	1,562	2,574	879	707
Very Small Manufacturers	**5,352**				
All Other Manufacturers		**4,917**			

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 Final Rule

Establishment Type	Foreign			
	Small (10-19)	Medium (20-99)	Large (100-249)	Very Large (250+)
Manufacturer/ Complaint File Handler	2,934	5,081	1,842	1,519
Contract Manufacturer	447	774	280	231
Contract Sterilizer	43	74	27	22
Specification Developer	133	230	83	69
Re-processor of Single Use Devices	1	2	1	1
U.S. Manufacturer of Export Only Devices	0	0	0	0
Re-packager/Re-labeler	49	85	31	26
Remanufacturer	2	4	1	1
Foreign Exporter/Private Label Distributor	264	457	166	137
Unknown	3	4	2	1
Total Manufacturers	**3,876**	**6,710**	**2,432**	**2,007**
Initial Importers	0	0	0	0
TOTAL	**3,876**	**6,710**	**2,432**	**2,007**
All Foreign Manufacturers	**15,025**			

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 Final Rule

The primary benefit of the final rule is cost savings, which come from the reduction of demonstrating compliance with both the previous QS regulation and ISO 13485. In Section D, we estimated the number of small to very large medical device establishments that complied with both the QS regulation and ISO 13485; these medical device establishments include 4,917 domestic manufacturing facilities (see Table 8a), and 15,025 foreign manufacturing facilities (see Table 8b). We assume the effort of a medical device establishment that complied with both the previous QS regulation and ISO 13485 will decrease by 10% by complying with the QMSR in this final 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 previous QS regulation based on information from the QS regulation final rule which was published in 1996 (21 CFR Parts 808, 812, and 820, Vol. 61, No. 195, October 7, 1996, pgs. 52602-62). We include the assumption of 10% reduction in burden to estimate annual labor hours saved for small to very large medical device establishments for complying with the QMSR in this final rule compared to complying with both the previous QS regulation and ISO 13485 for each provision of the previous QS regulation. We then use information from the QS regulation 1996 final rule to determine the proportion of types of labor needed to comply with each provision of that regulation, and wage rates published by U.S. Bureau of Labor Statistics (BLS) (see Table 9) to estimate cost savings (reduction in burden) of complying with this QMSR final rule for certain establishments. Wage rates have been doubled to include overhead.

These annual cost savings are estimated by each subpart of the previous QS regulation, below. Table 10 presents summary annual cost savings for small to very large medical device establishments to comply with the QMSR in this final rule.

Table 9. Medical Device Industry Wage Rates for Selected Labor Categories – NAICS 339100

Labor Category	Wages (/hour) 2022*	Category Code
Vice president	$118.48	11-1011
Upper management	$73.23	11-2000

Middle management	$71.25	11-3000
Technical	$43.68	Multiple
Admin support	$34.16	43-6011
Clerical	$19.02	43-4070

*Source: May 2022 National Occupational Employment and Wage Estimates. U.S. Bureau of Labor Statistics.
Link: https://www.bls.gov/oes/current/oes_nat.htm#11-0000, Last accessed: November 2023.
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

Previous Part 820 Subpart	**Cost Savings**
Subpart A – General Provisions*	N/A
Subpart B – Quality System Requirements (see Table 14)	$8,682,559
Subpart C – Design Controls (see Table 18)	$538,590,471
Subpart D – Document Controls (see Table 21)	$643,502
Subpart E – Purchasing Controls (see Table 25)	$22,853,554
Subpart F – Identification and Traceability (see Table 28)	$233,989
Subpart G – Production and Process Controls (see Table 32)	$2,379,851
Subpart H – Acceptance Activities (see Table 35)	$343,194
Subpart I – Nonconforming Product (see Table 38)	$643,502
Subpart J – Corrective and Preventive Action (see Table 41)	$643,502
Subpart K – Labeling and Packaging Control*	$343,194
Subpart L – Handling, Storage, Distribution, and Installation (see Table 44)	$686,388
Subpart M – Records (see Table 47)	$643,502
Subpart N – Servicing (see Table 50)	$643,502
Subpart O – Statistical Techniques (see Table 53)	N/A
Total Annual Cost Savings	**$577,330,707**

Note: These are undiscounted annual cost savings.

Subpart A – General Provisions

Subpart A of the previous QS regulation describes the scope, legal authority, and definitions of terms used in the previous QS regulation. It also states that manufacturers must establish and maintain a quality system. In this final rule for the QMSR, FDA is not modifying the scope of manufacturers and products subject to Part 820. Because there are differences between definitions for terms in the previous QS regulation and in Clause 3 of ISO 13485 and its normative reference, ISO 9000, FDA is modifying Part 820.3 to retain, revise, and withdraw certain definitions previously found in the QS regulation. The one-time cost of understanding how the final rule modifies the definitions in Part 820.3 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 previous QS regulation pertained 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. This final rule replaces the previous requirements with substantially similar requirements in ISO 13845. We assume that each medical device establishment that complied with both the previous QS regulation and ISO 13485 will require 10% fewer annual labor hours to comply with the provisions of the final rule that correspond to provision(s) found in Subpart B of the previous QS regulation, as explained in Section D.1. of this document. 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 a medical device establishment complying with the QMSR in this final rule organized by each provision of Subpart B of the previous QS regulation.

Table 11. Number of Annual Labor Hours Saved by a Medical Device Establishment to Comply with Provisions of the Final Rule that Correspond to Subpart B of the Previous QS Regulation

QS Regulation, Subpart B (Part 820.20 - 820.25)	Establishment Size			
	Small	**Medium**	**Large**	**Very Large**
Previous 820.20(a) Quality Policy				
- Maintain Quality Policy[1]	1	1	2	2
Comply with Final Rule[2]	0.9	0.9	1.8	1.8
Labor hours saved	**0.1**	**0.1**	**0.2**	**0.2**
Previous 820.20(b) Organization				
- Maintain organizational structure	0	1	2	2
Comply with Final Rule[2]	0	0.9	1.8	1.8
Labor hours saved	**0**	**0.1**	**0.2**	**0.2**
Previous 820.20(c) Management Review				
- Review by management representative[1]	8	12	16	24
Comply with Final Rule[2]	7.2	10.8	14.4	21.6
Labor hours saved	**0.8**	**1.2**	**1.6**	**2.4**
Previous 820.20(d) Quality Planning				
- Maintain quality plan[1]	4	6	8	10
Comply with Final Rule[2]	3.6	5.4	7.2	9
Labor hours saved	**0.4**	**0.6**	**0.8**	**1**
Previous 820.20(e) Quality System Procedures				
- Maintain QSP[1]	4	6	8	10
Comply with Final Rule[2]	3.6	5.4	7.2	9
Labor hours saved	**0.4**	**0.6**	**0.8**	**1**
Previous 820.22 Quality Audit				
- Maintain procedures[1]	1	1	2	2
Comply with Final Rule[2]	0.9	0.9	1.8	1.8

Labor hours saved	**0.1**	**0.1**	**0.2**	**0.2**
Previous 820.25 Personnel				
- Maintain procedures[1]	1	1	2	2
Comply with Final Rule[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 sets of QS requirements to complying with the QMSR in the final rule.

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

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

QS Regulation, Subpart B (820.20 - 820.25)	**Labor Category**					
	Vice President	**Upper Mgmt.**	**Middle Mgmt.**	**Technical**	**Admin Support**	**Clerical**
Previous 820.20(a) Quality Policy - Maintain Quality Policy	50%	50%	0%	0%	0%	0%
Previous 820.20(b) Organization - Maintain organizational structure	0%	80%	10%	0%	0%	10%
Previous 820.20(c) Management Review - Review by management representative	0%	100%	0%	0%	0%	0%
Previous 820.20(d) Quality Planning - Maintain quality plan	0%	20%	70%	0%	0%	10%
Previous 820.20(e) Quality System Procedures - Maintain QSP	0%	20%	70%	0%	0%	10%
Previous 820.22 Quality Audit - Maintain procedures	0%	20%	70%	0%	0%	10%
Previous 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 provisions of the QMSR corresponding to Subpart B of the previous QS regulation for affected entities (see Tables 13a and 13b). Benefits of complying with the QMSR will result in a cost savings of approximately $8.7 million per year for the affected entities by moving from compliance with both ISO 13485 and the previous QS regulation to the final rule (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 establishments to comply with the section of the QMSR that corresponds to Section 820.20(a) of the previous QS regulation. We expect that a small medical device establishment saves 0.1 hours as a result of the final rule (see Table 11). We use proportions of labor type to comply with the section of the QMSR that corresponds to section 820.20(a) of the previous QS regulation; 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 $236.96 ($118.48/ hour (see Table 9) x 2), and $146.46/hour ($73.23/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 QMSR in this final rule: [0.1 hour x ($236.96/hour x 50%)] + [0.1 hour x ($146.46/hour x 50%)] = $19.17; rounded to $19 for presentation in Table 13a. We multiply the unit cost savings of $19.17by number of small domestic medical device establishments (1,268.34; rounded to 1,268 for presentation in Table 13a) to obtain estimated cost savings of all small domestic medical device establishments: $19.17/establishment x 1,268.34 establishments = $24,315.26; rounded to $24,315for presentation in Table 13a. The same process is repeated throughout the document.

Table 13a. Annual Cost Savings of Compliance with the QMSR in the Final Rule Using Corresponding Provisions of Subpart B of the QS Regulation

QS Regulation, Subpart B (820.20 - 820.25)	Establishment Size				Total
	Small	Medium	Large	Very large	
No. of Establishments	1,268	2,196	796	657	4,917
Previous 820.20(a) Quality Policy					
Unit cost saving	$19	$19	$38	$38	
Cost Savings	**$24,315**	**$42,101**	**$30,520**	**$25,181**	**$122,117**
Previous 820.20(b) Organization					
Unit cost saving	$0	$14	$27	$27	

Cost Savings	**$0**	**$29,696**	**$21,527**	**$17,761**	**$68,984**
Previous 820.20(c) Management Review					
Unit cost saving	$117	$176	$234	$352	
Cost Savings	**$148,608**	**$385,963**	**$186,532**	**$230,850**	**$951,953**
Previous 820.20(d) Quality Planning					
Unit cost saving	$53	$80	$106	$133	
Cost Savings	**$67,397**	**$175,043**	**$84,597**	**$87,247**	**$414,283**
Previous 820.20(e) Quality System Procedures					
Unit cost saving	$53	$80	$106	$133	
Cost Savings	**$67,397**	**$175,043**	**$84,597**	**$87,247**	**$414,283**
Previous 820.22 Quality Audit					
Unit cost saving	$13	$13	$27	$27	
Cost Savings	**$16,849**	**$29,174**	**$21,149**	**$17,449**	**$84,622**
Previous 820.25 Personnel					
Unit cost saving	$13	$13	$27	$27	
Cost Savings	**$16,849**	**$29,174**	**$21,149**	**$17,449**	**$84,622**
Total Cost Savings	**$341,417**	**$866,193**	**$450,071**	**$483,184**	**$2,140,865**

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 QMSR in the Final Rule Using Corresponding Provisions of Subpart B of the QS Regulation, Foreign Establishments

QS Regulation, Subpart B (820.20 - 820.25)	**Establishment Size**				**Total**
	Small	**Medium**	**Large**	**Very large**	
No. of Establishments	3,876	6,710	2,432	2,007	15,025
Previous 820.20(a) Quality Policy					
Unit cost saving	$19	$19	$38	$38	
Cost Savings	**$74,298**	**$128,644**	**$93,259**	**$76,944**	**$373,146**
Previous 820.20(b) Organization					
Unit cost saving	$0	$14	$27	$27	
Cost Savings	**$0**	**$90,739**	**$65,780**	**$54,272**	**$210,791**
Previous 820.20(c) Management Review					
Unit cost saving	$117	$176	$234	$352	
Cost Savings	**$454,092**	**$1,179,359**	**$569,973**	**$705,392**	**$2,908,817**
Previous 820.20(d) Quality Planning					
Unit cost saving	$53	$80	$106	$133	
Cost Savings	**$205,941**	**$534,867**	**$258,496**	**$266,593**	**$1,265,897**
Previous 820.20(e) Quality System Procedures					

Unit cost saving	$53	$80	$106	$133	
Cost Savings	**$205,941**	**$534,867**	**$258,496**	**$266,593**	**$1,265,897**
Previous 820.22 Quality Audit					
Unit cost saving	$13	$13	$27	$27	
Cost Savings	**$51,485**	**$89,144**	**$64,624**	**$53,319**	**$258,572**
Previous 820.25 Personnel					
Unit cost saving	$13	$13	$27	$27	
Cost Savings	**$51,485**	**$89,144**	**$64,624**	**$53,319**	**$258,572**
Total Cost Savings	**$1,043,244**	**$2,646,765**	**$1,375,252**	**$1,476,432**	**$6,541,693**

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 QMSR in the Final Rule Using Corresponding Provisions of Subpart B of the QS Regulation

QS Regulation, Subpart B (820.20 - 820.25)	Cost Savings
Previous 820.20(a) Quality Policy	$495,263
Previous 820.20(b) Organization	$279,775
Previous 820.20(c) Management Review	$3,860,770
Previous 820.20(d) Quality Planning	$1,680,181
Previous 820.20(e) Quality System Procedures	$1,680,181
Previous 820.22 Quality Audit	$343,194
Previous 820.25 Personnel	$343,194
Total Annual Cost Savings, Subpart B	**$8,682,559**

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

Subpart C – Design Controls

Subpart C of the previous QS regulation required each manufacturer to establish a formal, documented program for assuring that design requirements were properly established, verified, and translated into design specifications. This final rule replaces the previous requirements with substantially similar requirements in ISO 13845. The system employed by medical device establishments was required to 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 complied with both the previous QS regulation and ISO 13485 will require 10% fewer annual labor hours to comply with the provisions of the final rule that correspond to provisions found in Subpart C of the previous QS regulation, as explained in Section D.1. of this document. 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 a medical device establishment complying with the final rule, organized by each provision of Subpart C of the previous QS regulation.

Table 15. Number of Annual Labor Hours Saved by a Medical Device Establishment to Comply with Provisions of the Final Rule that Correspond to Subpart C of the Previous QS Regulation

QS Regulation, Subpart C (Part 820.30)	Establishment Size			
	Small	**Medium**	**Large**	**Very large**
Previous 820.30(a) Design Controls, General				
- Maintain procedure[1]	3.0	6.0	15.0	56.0
Comply with Final Rule[2]	2.7	5.4	13.5	50.4
Labor hours saved	**0.3**	**0.6**	**1.5**	**5.6**
Previous 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 Final Rule[2]	28.8	93.6	187.2	468.0
Labor hours saved	**3.2**	**10.4**	**20.8**	**52.0**
Previous 820.30(c) Design Input				
- Maintain procedure requirements[1]	820.30(a)	820.30(a)	820.30(a)	820.30(a)
Previous 820.30(d) Design Output				
- Maintain procedures[1]	820.30(a)	820.30(a)	820.30(a)	820.30(a)
Previous 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 Final Rule[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 Final Rule[2]	4.5	14.4	27.9	70.2
Labor hours saved	**0.5**	**1.6**	**3.1**	**7.8**
Previous 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 Final Rule[2]	224.1	728.1	1,457.1	3,642.3
Labor hours saved	**24.9**	**80.9**	**161.9**	**404.7**
Previous 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)

Previous 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 Final Rule[2]	5.4	18.9	37.8	93.6
Labor hours saved	**0.6**	**2.1**	**4.2**	**10.4**
Previous 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 Final Rule[2]	50.4	163.8	327.6	819.0
Labor hours saved	**5.6**	**18.2**	**36.4**	**91.0**
Previous 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 Final Rule[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 sets of QS requirements to the QMSR in this final rule.

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

Table 16. Proportion of Annual Labor by Labor Category, Subpart C of the Previous QS Regulation

QS Regulation, Subpart C (Part 820.30)	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 provisions of the QMSR corresponding to Subpart C of the previous QS regulation for affected establishments (see Tables 17a and 17b). Benefits of complying with the QMSR will result in cost savings of approximately $539 million per year for the affected entities by moving from compliance with both ISO 13485 and the previous QS regulation to the final rule (see Table 18).

Table 17a. Annual Cost Savings of Compliance with the QMSR in the Final Rule Using Corresponding Provisions of Subpart C of the QS Regulation, Certain Domestic Establishments

QS Regulation, Subpart C (Part 820.30)	**Establishment Size**				**Totals**
	Small	**Medium**	**Large**	**Very Large**	
No. of Establishments	1,268	2,196	796	657	4,917
820.30(a) Design Controls, General					
- Maintain procedure					
Unit cost saving	$40	$80	$199	$744	
Cost Savings	**$50,548**	**$175,043**	**$158,619**	**$488,581**	**$872,790**
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	$388	$1,261	$2,522	$6,304	

Cost Savings	**$492,071**	**$2,768,993**	**$2,007,342**	**$4,140,439**	**$9,408,845**
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	$964	$3,905	$9,375	$31,243	
Cost Savings	**$1,222,454**	**$8,576,445**	**$7,462,839**	**$20,518,796**	**$37,780,533**
- Record minutes of design review meeting					
Unit cost saving	$45	$144	$280	$704	
Cost Savings	**$57,246**	**$317,182**	**$222,751**	**$462,421**	**$1,059,600**
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	$2,725	$8,852	$17,715	$44,283	
Cost Savings	**$3,455,684**	**$19,439,904**	**$14,101,391**	**$29,082,609**	**$66,079,587**
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	$85	$299	$598	$1,482	
Cost Savings	**$108,443**	**$657,172**	**$476,408**	**$973,302**	**$2,215,325**
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	$613	$1,991	$3,983	$9,957	
Cost Savings	**$777,182**	**$4,373,378**	**$3,170,418**	**$6,539,455**	**$14,860,432**
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	$20	$68	$143	$355	
Cost Savings	**$25,996**	**$150,035**	**$114,204**	**$233,319**	**$523,554**
Total Cost Savings	**$6,189,623**	**$36,458,152**	**$27,713,970**	**$62,438,923**	**$132,800,668**

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 QMSR in the Final Rule Using Corresponding Provisions of Subpart C of the QS Regulation, Foreign Establishments

	Establishment Size	

QS Regulation, Subpart C (Part 820.30)	Small	Medium	Large	Very Large	Totals
No. of Establishments	3,876	6,710	2,432	2,007	15,025
820.30(a) Design Controls, General					
- Maintain procedure					
Unit cost saving	$40	$80	$199	$744	
Cost Savings	**$154,456**	**$534,867**	**$484,680**	**$1,492,922**	**$2,666,925**
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	$388	$1,261	$2,522	$6,304	
Cost Savings	**$1,503,586**	**$8,461,020**	**$6,133,696**	**$12,651,654**	**$28,749,956**
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	$964	$3,905	$9,375	$31,243	
Cost Savings	**$3,735,368**	**$26,206,449**	**$22,803,679**	**$62,697,864**	**$115,443,360**
- Record minutes of design review meeting					
Unit cost saving	$45	$144	$280	$704	
Cost Savings	**$174,924**	**$969,191**	**$680,645**	**$1,412,988**	**$3,237,748**
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	$2,725	$8,852	$17,715	$44,283	
Cost Savings	**$10,559,293**	**$59,401,168**	**$43,088,643**	**$88,865,714**	**$201,914,818**
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	$85	$299	$598	$1,482	
Cost Savings	**$331,361**	**$2,008,076**	**$1,455,726**	**$2,974,053**	**$6,769,215**
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	$613	$1,991	$3,983	$9,957	
Cost Savings	**$2,374,781**	**$13,363,427**	**$9,687,626**	**$19,982,160**	**$45,407,993**

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	$20	$68	$143	$355	
Cost Savings	**$79,434**	**$458,452**	**$348,966**	**$712,938**	**$1,599,789**
Total Cost Savings	**$18,913,202**	**$111,402,649**	**$84,683,660**	**$190,790,292**	**$405,789,803**

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 QMSR in the Final Rule Using Corresponding Provisions of Subpart C of the QS Regulation

QS Regulation, Subpart C (Part 820.30)	Cost Savings
Previous 820.30(a) Design Controls, General	$3,539,715
Previous 820.30(b) Design and Development Planning	$38,158,801
Previous 820.30(c) Design Input	820.30(a)
Previous 820.30(d) Design Output	820.30(a)
Previous 820.30(e) Design Review	$157,521,241
Previous 820.30(f) Design Verification	$267,994,406
Previous 820.30(g) Design Validation	820.20(a), (f)
Previous 820.30(h) Design Transfer	$8,984,540
Previous 820.30(i) Design Changes	$60,268,425
Previous 820.30(j) Design History File	$2,123,343
Total Annual Cost Savings, Subpart C	**$538,590,471**

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

Subpart D – Document Controls

Subpart D of the current previous QS regulation required manufacturers to establish and maintain procedures to control certain documents. The requirements included designation of individuals to manage review, approval, distribution, and modifications of documents. This final rule replaces the previous requirements with substantially similar requirements in ISO 13845. We assume that each medical device establishment that complied with both the previous QS regulation and ISO 13485 will require 10% fewer annual labor hours to comply with the provisions of the final rule that correspond to provisions found in Subpart D of the previous QS regulation, as explained in Section D.1. of this document. 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 a medical device establishment complying with the QMSR in this final rule organized by each provision of Subpart D of the previous QS regulation.

Table 19. Number of Annual Labor Hours Saved by a Medical Device Establishment to Comply with Provisions of the Final Rule that Correspond to Subpart D of the Previous QS Regulation

	Establishment Size

QS Regulation, Subpart D (Part 820.40)	Small	Medium	Large	Very large
Previous 820.40 Document Controls				
- Maintain written procedures[1]	2	2	3	4
Comply with Final Rule[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 final rule.

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

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

QS Regulation, Subpart D (820.40)	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 provisions of the QMSR corresponding to Subpart D of the previous QS regulation for affected entities (see Table 21). Benefits of complying with the QMSR will result in a cost savings of approximately $644,000 per year for the affected entities by moving from compliance with both ISO 13485 and the previous QS regulation to the final rule (see Table 21).

Table 21. Annual Cost Savings of Compliance with the QMSR in the Final Rule Using Corresponding Provisions of Subpart D of the QS Regulation

QS Regulation, Subpart D (Part 820.40)	Establishment Size, Domestic				Totals
	Small	Medium	Large	Very Large	
No. of Establishments	1,268	2,196	796	657	4,917
820.40 Document Controls					

- Maintain written procedures					
Unit cost saving	$27	$27	$40	$53	
Cost Savings	**$33,699**	**$58,348**	**$31,724**	**$34,899**	**$158,669**
Part 820 Provision	**Establishment Size, Foreign**				**Totals**
No. of Establishments	3,876	6,710	2,432	2,007	15,025
820.40 Document Controls - Maintain written procedures					
Unit cost saving	$27	$27	$40	$53	
Cost Savings	**$102,971**	**$178,289**	**$96,936**	**$106,637**	**$484,833**
Total Annual Cost Savings, Subpart D					**$643,502**

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

Subpart E – Purchasing Controls

Subpart E of the current previous QS regulation required 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 was required to also establish controls to assure that specifications were properly described in procurement documents. This final rule replaces the previous requirements with substantially similar requirements in ISO 13845. We assume that each medical device establishment that complied with both the previous QS regulation and ISO 13485 will require 10% fewer annual labor hours to comply with the provisions of the final rule that correspond to provisions found in Subpart E of the previous QS regulation, as explained in Section D.1. of this document. 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 a medical device establishment complying with the QMSR in this final rule organized by each provision of Subpart E of the previous QS regulation.

Table 22. Number of Annual Labor Hours Saved by a Medical Device Establishment to Comply with Provisions of the Final Rule that Correspond to Subpart E of the Previous QS Regulation

QS Regulation, Subpart E (Part 820.50)	**Establishment Size**			
	Small	**Medium**	**Large**	**Very large**
Previous 820.50(a) Evaluation of Suppliers, Contractors, and Consultants				
- Review quality of suppliers[1]	13	25	50	63
Comply with Final Rule[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 Final Rule[2]	9	18	36	72
Labor hours saved	**1**	**2**	**4**	**8**
Previous 820.50(b) Purchasing Data				
- Review and approve purchasing documents[1]	5	39	129	60
Comply with Final Rule[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 sets of QS requirements to the QMSR in the final rule.

We use information from the 1996 final rule codifying the QS regulation in Part 820 to determine proportions of types of labor needed to comply with each section of Subpart E of the previous QS regulation (see Table 23), and appropriate wage rates and overhead costs (see Table 9) to estimate cost savings of complying with the QMSR in this final rule for affected establishments.

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

QS Regulation, Subpart E (Part 820.50)	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 provisions of the QMSR corresponding to Subpart E of the previous QS regulation for affected establishments (see Tables 24a and 24b). Benefits of complying with the QMSR will result in cost savings of approximately $23 million per year for the affected entities by moving from compliance with both ISO 13485 and the previous QS regulation to the final rule (see Table 25).

Table 24a. Annual Cost Savings of Compliance with the QMSR in the Final Rule Using Corresponding Provisions of Subpart E of the QS Regulation, Certain Domestic Establishments

Part 820, Subpart E	Establishment Size				Totals
	Small	Medium	Large	Very Large	
No. of Establishments	1,268	2,196	796	657	4,917

820.50(a) Evaluation of Suppliers, Contractors, and Consultants - Review quality of suppliers Unit cost saving **Cost Savings** - Audit new suppliers Unit cost saving **Cost Savings**	 $173 **$219,041** $143 **$180,738**	 $332 **$729,346** $285 **$625,878**	 $664 **$528,729** $570 **$453,722**	 $837 **$549,653** $1,140 **$748,694**	 **$2,026,769** **$2,009,032**
820.50(b) Purchasing Data - Review and approve purchasing documents Unit Cost Saving **Cost Savings**	 $34 **$43,326**	 $266 **$585,137**	 $881 **$701,540**	 $410 **$269,215**	 **$1,599,217**
Total					**$5,635,019**

Table 24b. Annual Cost Savings of Compliance with the QMSR in the Final Rule Using Corresponding Provisions of Subpart E of the QS Regulation, Foreign Establishments

Part 820, Subpart E	**Establishment Size**				**Totals**
	Small	**Medium**	**Large**	**Very Large**	
No. of Establishments	3,876	6,710	2,432	2,007	15,025
820.50(a) Evaluation of Suppliers, Contractors, and Consultants - Review quality of suppliers Unit cost saving **Cost Savings** - Audit new suppliers Unit cost saving **Cost Savings**	 $173 **$669,309** $143 **$552,268**	 $332 **$2,228,612** $285 **$1,912,453**	 $664 **$1,615,600** $570 **$1,386,406**	 $837 **$1,679,537** $1,140 **$2,287,733**	 **$6,193,058** **$6,138,860**
820.50(b) Purchasing Data - Review and approve purchasing documents Unit Cost Saving **Cost Savings**	 $34 **$132,389**	 $266 **$1,787,962**	 $881 **$2,143,646**	 $410 **$822,621**	 **$4,886,618**
Total					**$17,218,536**

Table 25. Annual Cost Savings of Compliance with the QMSR in the Final Rule Using Corresponding Provisions of Subpart E of the QS Regulation

Part 820, Subpart E Provision	**Cost Savings**
820.50(a) Evaluation of Suppliers, Contractors, and Consultants	$16,367,719
820.50(b) Purchasing Data	$6,485,836
Total Annual Cost Savings, Subpart E	**$22,853,554**

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

Subpart F – Identification and Traceability

Subpart F of the previous QS regulation required 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 were also required to establish and maintain procedures for identifying with a control number each unit, lot, or batch of finished critical medical devices or components. This final rule replaces the previous requirements with substantially similar requirements in ISO 13845. We assume that each medical device establishment that complied with both the previous QS regulation and ISO 13485 will require 10% fewer annual labor hours to comply with the provisions of the final rule that correspond to provisions found in Subpart F of the previous QS regulation, as explained in Section D.1. of this document. 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 a medical device establishment complying with the QMSR in this final rule organized by each provision of Subpart F of the previous QS regulation.

Table 26. Number of Annual Labor Hours Saved by a Medical Device Establishment to Comply with Provisions of the Final Rule that Correspond to Subpart F of the Previous QS Regulation

QS Regulation, Subpart F (Part 820.60)	Establishment Size			
	Small	**Medium**	**Large**	**Very large**
Previous 820.60 Identification - Maintain written procedures[1]	1	1	2	2
Comply with Final Rule[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 sets of QS requirements to the QMSR in this final rule.

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

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

QS Regulation, Subpart F (Part 820.60)	Labor Category					
	Vice President	**Upper Mgmt.**	**Middle Mgmt.**	**Technical**	**Admin Support**	**Clerical**
Previous 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 provisions of the QMSR corresponding to Subpart F of the previous QS regulation for affected entities (see Table 28). Benefits of complying with the QMSR will result in a cost saving of approximately $234,000 per year for the affected entities by moving from compliance with both ISO 13485 and the previous QS regulation to the final rule (see Table 28).

Table 28. Annual Cost Savings of Compliance with the QMSR in the Final Rule Using Corresponding Provisions of Subpart F of the QS Regulation

QS Regulation, Subpart F (Part 820.60)	**Establishment Size, Domestic**				**Totals**
	Small	**Medium**	**Large**	**Very Large**	
No. of Establishments	1,268	2,196	796	657	4,917
820.60 Identification - Maintain written procedures					
Unit cost saving	$9	$9	$18	$18	
Cost Savings	**$11,488**	**$19,891**	**$14,419**	**$11,897**	**$57,695**
Part 820 Subpart F	**Establishment Size, Foreign**				**Totals**
No. of Establishments	3,876	6,710	2,432	2,007	15,025
820.60 Identification - Maintain written procedures					
Unit cost saving	$9	$9	$18	$18	
Cost Savings	**$35,103**	**$60,778**	**$44,060**	**$36,352**	**$176,294**
Total Annual Cost Savings, Subpart F					**$233,989**

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 previous QS regulation required manufacturers to establish and maintain procedures for processing controls, environmental control, and cleaning and sanitation. It also required special processes to be validated and monitored. This final rule replaces the previous requirements with substantially similar requirements in ISO 13845. We assume that each medical device establishment that complied with both the

previous QS regulation and ISO 13485 will require 10% fewer annual labor hours to comply with the provisions of the final rule that correspond to provisions found in Subpart G of the previous QS regulation, as explained in Section D.1. of this document. 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 a medical device establishment complying with the QMSR in this final rule, organized by each provision of Subpart G of the previous QS regulation.

Table 29. Number of Annual Labor Hours Saved by a Medical Device Establishment to Comply with Provisions of the Final Rule that Correspond to Subpart G of the Previous QS Regulation

QS Regulation, Subpart G (Part 820.70 – 820.75)	Establishment Size			
	Small	**Medium**	**Large**	**Very large**
Previous 820.70(d) Personnel				
- Maintain and use procedures[1]	2	2	3	7
Comply with Final Rule [2]	1.8	1.8	2.7	6.3
Labor hours saved	**0.2**	**0.2**	**0.3**	**0.7**
Previous 820.70(i) Automated Processes				
- Maintain written procedures[1]	2	2	3	4
Comply with Final Rule [2]	1.8	1.8	2.7	3.6
Labor hours saved	**0.2**	**0.2**	**0.3**	**0.4**
Previous 820.72(a) Control of Inspection, Measuring, and Test Equipment				
- Maintain and use procedure[1]	1	1	2	2
Comply with Final Rule [2]	0.9	0.9	1.8	1.8
Labor hours saved	**0.1**	**0.1**	**0.2**	**0.2**
Previous 820.75(b) Process Validation				
- Maintain procedure[1]	2	2	3	4
Comply with Final Rule [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 sets of QS requirements to complying with the QMSR in the final rule.

We use information from the 1996 final rule codifying the QS regulation in Part 820 to determine proportions of types of labor needed to comply with each section of Subpart G of the previous QS regulation (see Table 30), and appropriate wage rates and overhead costs (see Table 9) to estimate cost savings from complying with the QMSR in this final rule for affected establishments.

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

	Labor Category

QS Regulation, Subpart G (820.70 – 820.75)	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 provisions of the QMSR corresponding to Subpart G of the previous QS regulation for affected domestic and foreign entities (see Tables 31a and 31b). Benefits of complying with the QMSR will result in cost savings of approximately $2.4 million per year for the affected entities by moving from compliance with both ISO 13485 and the previous QS regulation to the final rule (see Table 32).

Table 31a. Annual Cost Savings of Compliance with the QMSR in the Final Rule Using Corresponding Provisions of Subpart G of the QS Regulation, Certain Domestic Establishments

QS Regulation, Subpart G (Part 820.70 – 820.75)	Establishment Size				Totals
	Small	Medium	Large	Very Large	
No. of Establishments	1,268	2,196	796	657	4,917
820.70(d) Personnel - Maintain and use procedures					
Unit cost saving	$27	$27	$40	$93	
Cost Savings	**$33,699**	**$58,348**	**$31,724**	**$61,073**	**$184,843**
- Maintain written procedures					
Unit cost saving	$27	$27	$40	$53	
Cost Savings	**$33,699**	**$58,348**	**$31,724**	**$34,899**	**$158,669**
820.72(a) Control of Inspection,					

Measuring, and Test Equipment - Maintain and use procedure					
Unit cost saving	$13	$13	$27	$27	
Cost Savings	**$16,849**	**$29,174**	**$21,149**	**$17,449**	**$84,622**
820.75(b) Process Validation - Maintain procedure					
Unit cost saving	$27	$27	$40	$53	
Cost Savings	**$33,699**	**$58,348**	**$31,724**	**$34,899**	**$158,669**
Total Cost Savings					**$586,802**

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 QMSR in the Final Rule Using Corresponding Provisions of Subpart G of the QS Regulation, Foreign Establishments

QS Regulation, Subpart B (820.70 - 820.75)	**Establishment Size**				**Totals**
	Small	**Medium**	**Large**	**Very Large**	
No. of Establishments	3,876	6,710	2,432	2,007	**15,025**
820.70(d) Personnel - Maintain and use procedures					
Unit cost saving	$27	$27	$40	$93	
Cost Savings	**$102,971**	**$178,289**	**$96,936**	**$186,615**	**$564,811**
- Maintain written procedures					
Unit cost saving	$27	$27	$40	$53	
Cost Savings	**$102,971**	**$178,289**	**$96,936**	**$106,637**	**$484,833**
820.72(a) Control of Inspection, Measuring, and Test Equipment - Maintain and use procedure					
Unit cost saving	$13	$13	$27	$27	

Cost Savings	**$51,485**	**$89,144**	**$64,624**	**$53,319**	**$258,572**
820.75(b) Process Validation - Maintain procedure					
Unit cost saving	$27	$27	$40	$53	
Cost Savings	**$102,971**	**$178,289**	**$96,936**	**$106,637**	**$484,833**
Total Cost Savings					**$1,793,049**

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 QMSR in the Final Rule Using Corresponding Provisions of Subpart G of the QS Regulation

Part 820 Provision	Cost Savings
820.70(d) Personnel	$1,393,155
820.72(a) Control of Inspection, Measuring, and Test Equipment	$343,194
820.75(b) Process Validation	$643,502
Total Annual Cost Savings, Subpart G	**$2,379,851**

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

Subpart H – Acceptance Activities

Subpart H of the previous QS regulation required manufacturers to establish and maintain procedures for acceptance activities including inspections, tests, or other verification activities. This final rule replaces the previous requirements with substantially similar requirements in ISO 13845. We assume that each medical device establishment that complied with both the previous QS regulation and ISO 13485 will require 10% fewer annual labor hours to comply with the provisions of the final rule that correspond to provisions found in Subpart H of the previous QS regulation, as explained in Section D.1. of this document. 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 a medical device establishment complying with the QMSR in this final rule, organized by each provision Subpart H of the previous QS regulation.

Table 33. Number of Annual Labor Hours Saved by a Medical Device Establishment to Comply with Provisions of the Final Rule that Correspond to Subpart H of the Previous QS Regulation

QS Regulation, Subpart H (Part 820.84)	Establishment Size			
	Small	Medium	Large	Very large
Previous820.84 Inspection, Measuring and Testing Equipment				
- Maintain written procedures[1]	1	1	2	2
Comply with Final Rule [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 sets of QS requirements to the QMSR in this final rule.

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

Table 34. Proportion of Annual Labor by Labor Category, Subpart H of the Previous QS Regulation

QS Regulation, Subpart H (Part 820.84)	**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 provisions of the QMSR corresponding to Subpart H of the previous QS regulation for affected establishments (see Table 35). Benefits of complying with the QMSR will result in cost savings of approximately $344,000 per year for the affected entities by moving from compliance with both ISO 13485 and the previous QS regulation to the final rule (see Table 35).

Table 35. Annual Cost Savings of Compliance with the QMSR in the Final Rule Using Corresponding Provisions of Subpart H of the QS Regulation

QS Regulation, Subpart H (Part 820.84)	**Establishment Size, Domestic**				**Totals**
	Small	**Medium**	**Large**	**Very Large**	
No. of Establishments	1,268	2,196	796	657	**4,917**
820.84 Inspection, Measuring and Testing Equipment - Maintain written procedures					
Unit cost saving	$13	$13	$27	$27	
Cost Savings	**$16,849**	**$29,174**	**$21,149**	**$17,449**	**$84,622**
Part 820 Subpart H	**Establishment Size, Foreign**				**Totals**
No. of Establishments	3,876	6,710	2,432	2,007	**15,025**

820.84 Inspection, Measuring and Testing Equipment - Maintain written procedures					
Unit cost saving	$13	$13	$27	$27	
Cost Savings	**$51,485**	**$89,144**	**$64,624**	**$53,319**	**$258,572**
Total Annual Cost Savings, Subpart H					**$343,194**

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

Subpart I – Nonconforming Product

Subpart I of the previous QS regulation required manufacturers to establish and maintain written procedures to control nonconforming products. The procedures were required to address the identification, documentation, evaluation, segregation, and disposition of nonconforming products. This final rule replaces the previous requirements with substantially similar requirements in ISO 13845. We assume that each medical device establishment that complied with both the previous QS regulation and ISO 13485 will require 10% fewer annual labor hours to comply with the provisions of the final rule that correspond to provisions found in Subpart I of the previous QS regulation, as explained in Section D.1. of this document. 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 a medical device establishment complying with the QMSR in this final rule, organized by each provision of Subpart I of the previous QS regulation.

Table 36. Number of Annual Labor Hours Saved by a Medical Device Establishment to Comply with Provisions of the Final Rule that Correspond to Subpart I of the Previous QS Regulation

QS Regulation, Subpart I (Part 820.90)	**Establishment Size**			
	Small	**Medium**	**Large**	**Very large**
Previous 820.90(a) Nonconforming Product				
- Maintain procedure[1]	2	2	3	4
Comply with Final Rule [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 final rule.

We use information from the 1996 final rule codifying the QS regulation in Part 820 to determine proportion of types of labor needed to comply with each section of Subpart I of the previous QS regulation (see

Table 37), and appropriate wage rates and overhead costs (see Table 9) to estimate cost savings to complying with the QMSR in this final rule for affected establishments.

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

QS Regulation, Subpart I (Part 820.90)	Labor Category					
	Vice President	Upper Mgmt.	Middle Mgmt.	Technical	Admin Support	Clerical
820.90(a) 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 provisions of the QMSR corresponding to Subpart I of the previous QS regulation for affected entities (see Table 38). Benefits of complying with the QMSR will result in cost savings of approximately $644,000 per year for the affected entities by moving from compliance with both ISO 13485 and the previous QS regulation to the final rule (see Table 38).

Table 38. Annual Cost Savings of Compliance with the QMSR in the Final Rule Using Corresponding Provisions of Subpart I of the QS Regulation

Part 820, Subpart I	**Establishment Size, Domestic**				**Totals**
	Small	**Medium**	**Large**	**Very Large**	
No. of Establishments	1,268	2,196	796	657	4,917
820.90(a) Control of Nonconforming Product - Maintain written procedures Unit cost saving	$27	$27	$40	$53	
Cost Savings	**$33,699**	**$58,348**	**$31,724**	**$34,899**	**$158,669**
Part 820, Subpart I	**Establishment Size, Foreign**				**Totals**
No. of Establishments	3,876	6,710	2,432	2,007	15,025
820.90(a) Control of Nonconforming Product					

- Maintain written procedures					
Unit cost saving	$27	$27	$40	$53	
Cost Savings	**$102,971**	**$178,289**	**$96,936**	**$106,637**	**$484,833**
Total Annual Cost Savings, Subpart I					**$643,502**

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 previous QS regulation required 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 were also required to use obtained data from their program to determine possible solutions and document the corrective action selected and implemented. This final rule replaces the previous requirements with substantially similar requirements in ISO 13845. We assume that each medical device establishment that complied with both the previous QS regulation and ISO 13485 will require 10% fewer annual labor hours to comply with the provisions of the final rule that correspond to provisions found in Subpart J of the previous QS regulation, as explained in Section D.1. of this document. 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 a medical device establishment complying with the QMSR in this final rule, organized by each provision of Subpart J of the previous QS regulation.

Table 39. Number of Annual Labor Hours Saved by a Medical Device Establishment to Comply with Provisions of the Final Rule that Correspond to Subpart J of the Previous QS Regulation

QS Regulation, Subpart J (Part 820.100)	**Establishment Size**			
	Small	**Medium**	**Large**	**Very large**
Previous 820.100 Corrective and Preventive Action				
- Maintain written procedures[1]	2	2	3	4
Comply with Final Rule[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 sets of QS requirements to the QMSR in the final rule.

We use information from the 1996 final rule codifying the QS regulation in Part 820 to determine proportions of types of labor needed to comply with each section of Subpart J of the previous QS regulation

(see Table 40), and appropriate wage rates and overhead costs (see Table 9) to estimate cost savings from complying with the QMSR in this final rule for affected establishments.

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

QS Regulation, Subpart J (Part 820.100)	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 provisions of the QMSR corresponding to Subpart J of the previous QS regulation for affected entities (see Table 41). Benefits of complying with the QMSR will result in a cost savings of approximately $644,000 per year for the affected entities by moving from compliance with both ISO 13485 and the previous QS regulation to the final rule (see Table 41).

Table 41. Annual Cost Savings of Compliance with the QMSR in the Final Rule Using Corresponding Provisions of Subpart J of the QS Regulation

QS Regulation, Subpart J (Part 820.100)	**Establishment Size, Domestic**				**Totals**
No. of Establishments	1,268	2,196	796	657	**4,917**
820.100 Corrective and Preventive Action - Maintain written procedures					
Unit cost saving	$27	$27	$40	$53	
Cost Savings	**$33,699**	**$58,348**	**$31,724**	**$34,899**	**$158,669**
Part 820, Subpart J	**Establishment Size, Foreign**				**Totals**
No. of Establishments	3,876	6,710	2,432	2,007	**15,025**
820.100 Corrective and Preventive Action - Maintain written procedures					
Unit cost saving	$27	$27	$40	$53	
Cost Savings	**$102,971**	**$178,289**	**$96,936**	**$106,637**	**$484,833**
Total Cost Savings, Subpart J					**$643,502**

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 previous QS regulation required medical device establishments to maintain a formal system for the safe and proper handling and storage of medical device and manufacturing materials. Controls that prevent mix-ups, deterioration, and other adverse effects on medical devices and manufacturing materials

were also required to be established. This final rule replaces the previous requirements with substantially similar requirements in ISO 13845. We assume that each medical device establishment that complied with both the previous QS regulation and ISO 13485 will require 10% fewer annual labor hours to comply with the provisions of the final rule that correspond to provisions found in Subpart K of the previous QS regulation, as explained in Section D.1. of this document. 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 a medical device establishment complying with the QMSR in this final rule organized by each provision of Subpart K of the previous QS regulation.

Table 42. Number of Annual Labor Hours Saved by a Medical Device Establishment to Comply with Provisions of the Final Rule that Correspond to Subpart K of the Previous QS Regulation

QS Regulation, Subpart K, (Part 820.120 – 820.130)	Establishment Size			
	Small	**Medium**	**Large**	**Very large**
820.120-820.122 Handling, Storage - Maintain written procedures[1]	1	1	2	2
Comply with Final Rule [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 sets of QS requirements to the QMSR in this final rule .

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

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

QS Regulation, Subpart K (Part 820.120 – 820.130)	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 provisions of the QMSR corresponding to Subpart K of the previous QS regulation for affected

entities (see Table 44). Benefits of complying with the QMSR will result in cost savings of approximately $344,000 per year for the affected entities by moving from compliance with both ISO 13485 and the previous QS regulation to the final rule (see Table 44).

Table 44. Annual Cost Savings of Compliance with the QMSR in the Final Rule Using Corresponding Provisions of Subpart K of the QS Regulation

QS Regulation, Subpart K (Part 820.120 – 820.130))	**Establishment Size, Domestic**				**Totals**
	Small	**Medium**	**Large**	**Very Large**	
No. of Establishments	1,268	2,196	796	657	
820.84 Inspection, Measuring and Testing Equipment - Maintain written procedures					
Unit cost saving	$13	$13	$27	$27	
Cost Savings	**$16,849**	**$29,174**	**$21,149**	**$17,449**	**$8**
QS Regulation, Subpart K (Part 820.120 – 820.130))	**Establishment Size, Foreign**				**Totals**
No. of Establishments	3,876	6,710	2,432	2,007	**1**
820.84 Inspection, Measuring and Testing Equipment - Maintain written procedures					
Unit cost saving	$13	$13	$27	$27	
Cost Savings	**$51,485**	**$89,144**	**$64,624**	**$53,319**	**$25**
Total Annual Cost Savings, Subpart K					**$34**

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 previous QS regulation required manufacturers to establish and maintain written procedures to ensure that mix-ups, damage, deterioration, contamination, or other adverse effects to the medical device product did not occur during handling, storage, distribution, or installation of the product. This final rule replaces the previous requirements with substantially similar requirements in ISO 13845. We assume that each medical device establishment that complied with both the previous QS regulation and ISO 13485 will require 10% fewer annual labor hours to comply with the provisions of the final rule that correspond to provisions found in Subpart L of the previous QS regulation, as explained in Section D.1. of this document. 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 a medical device establishment complying with the QMSR in this final rule, organized by each provision of Subpart L of the previous QS regulation.

Table 45. Number of Annual Labor Hours Saved by a Medical Device Establishment to Comply with Provisions of the Final Rule that Correspond to Subpart L of the Previous QS Regulation

QS Regulation, Subpart L (Part 820.140, 820.150)	Establishment Size			
	Small	**Medium**	**Large**	**Very large**
Previous820.140 Handling				
- Maintain written procedures[1]	1	1	2	2
Comply with Final Rule [2]	0.9	0.9	1.8	1.8
Labor hours saved	**0.1**	**0.1**	**0.2**	**0.2**
Previous 820.150 Storage(a)				
- Maintain written procedures[1]	1	1	2	2
Comply with Final Rule [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 sets of QS requirements to complying with the QMSR in the final rule.

We use information from the 1996 final rule codifying the QS regulation in Part 820 to determine proportions of types of labor needed to comply with each section of Subpart L of the previous QS regulation (see Table 46), and appropriate wage rates and overhead costs (see Table 9) to estimate cost savings of complying with the QMSR in this final rule for affected establishments.

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

Part 820, Subpart L (Part 820.140, 820.150)	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 provisions of the QMSR corresponding to Subpart L of the previous QS regulation (see Table 47). Benefits of complying with the QMSR will result in a cost savings of approximately $687,000 per year for the affected entities by moving from compliance with both ISO 13485 and the previous QS regulation to the final rule (see Table 47).

Table 47. Annual Cost Savings of Compliance with the QMSR in the Final Rule Using Corresponding Provisions of Subpart L of the QS Regulation

Part 820, Subpart L (Part 820.140, 820.150)	**Establishment Size, Domestic**				**Totals**
	Small	**Medium**	**Large**	**Very Large**	
No. of Establishments	1,268	2,196	796	657	**4,917**
820.140 Handling - Maintain procedures					
Unit cost saving	$13	$13	$27	$27	
Cost Savings	**$16,849**	**$29,174**	**$21,149**	**$17,449**	**$84,622**
820.150 Storage(a) - Maintain procedures					
Unit cost saving	$13	$13	$27	$27	
Cost Savings	**$16,849**	**$29,174**	**$21,149**	**$17,449**	**$84,622**
Part 820, Subpart L	**Establishment Size, Foreign**				**Totals**
No. of Establishments	3,876	6,710	2,432	2,007	**15,025**
820.140 Handling - Maintain procedures					
Unit cost saving	$13	$13	$27	$27	
Cost Savings	**$51,485**	**$89,144**	**$64,624**	**$53,319**	**$258,572**
820.150 Storage(a) - Maintain procedures					
Unit cost saving	$13	$13	$27	$27	
Cost Savings	**$51,485**	**$89,144**	**$64,624**	**$53,319**	**$258,572**
Total Cost Savings, Subpart L					**$686,388**

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 previous QS regulation required that manufacturers maintain all records to be legible, and stored in a manner to prevent deterioration, damage, or loss. Subpart M also required including subcontractor quality records, if applicable. In addition to medical devices descriptions, complaint files were required to include the medical devices' packaging and labeling. Investigative records were also required to determine of whether there was a device failure, whether the device failure resulted in death or injury, and a description of corrective action. This final rule replaces the previous requirements with substantially similar requirements in ISO 13845. We assume that each medical device establishment that complied with both the previous QS

regulation and ISO 13485 will require 10% fewer annual labor hours to comply with the provisions of the final rule that correspond to provisions found in Subpart M of the previous QS regulation, as explained in Section D.1. of this document. 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 a medical device establishment complying with the QMSR in this final rule, organized by each provision of Subpart G of the previous QS regulation.

Table 48. Number of Annual Labor Hours Saved by a Medical Device Establishment to Comply with Provisions of the Final Rule that Correspond to Subpart G of the Previous QS Regulation

QS Regulation, Subpart M (Part 820.198)	Establishment Size			
	Small	**Medium**	**Large**	**Very large**
820.198 Complaint Files				
- Maintain written procedures[1]	2	2	3	4
Comply with Final Rule [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 sets of QS requirements to complying with the QMSR in the final rule.

We use information from the 1996 final rule codifying the QS regulation in Part 820 to determine proportions of types of labor needed to comply with each section of Subpart M of the previous QS regulation (see Table 49), and appropriate wage rates and overhead costs (see Table 9) to estimate cost savings from complying with the QMSR in this final rule for affected establishments.

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

Part 820, Subpart M Provision (Part 820.198)	Labor Category					
	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 provisions of the QMSR corresponding to Subpart G of the previous QS regulation for affected entities (see Table 50). Benefits of complying with the QMSR will result in cost savings of approximately

$644,000 per year for the affected entities by moving from compliance with both ISO 13485 and the previous QS regulation to the final rule (see Table 50).

Table 50. Annual Cost Savings of Compliance with the QMSR in the Final Rule Using Corresponding Provisions of Subpart M of the QS Regulation

Part 820, Subpart M (Part 820.198)	**Establishment Size, Domestic**				**Totals**
	Small	**Medium**	**Large**	**Very Large**	
No. of Establishments	1,268	2,196	796	657	**4,917**
820.198 Complaint Files - Maintain written procedures					
Unit cost saving	$27	$27	$40	$53	
Cost Savings	**$33,699**	**$58,348**	**$31,724**	**$34,899**	**$158,669**
Part 820, Subpart M	**Establishment Size, Foreign**				**Totals**
No. of Establishments	3,876	6,710	2,432	2,007	**15,025**
820.198 Complaint Files - Maintain written procedures					
Unit cost saving	$27	$27	$40	$53	
Cost Savings	**$102,971**	**$178,289**	**$96,936**	**$106,637**	**$484,833**
Total Annual Cost Savings, Subpart M					**$643,502**

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 previous QS regulation required manufacturers to develop written procedures for managing servicing operations. The Subpart N requirements also mandated the maintenance of servicing records and the feedback of device problems detected during servicing into the corrective action system. This final rule replaces the previous requirements with substantially similar requirements in ISO 13845. We assume that each medical device establishment that complied with both the previous QS regulation and ISO 13485 will require 10% fewer annual labor hours to comply with the provisions of the final rule that correspond to provisions found in Subpart N of the previous QS regulation, as explained in Section D.1. of this document. 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 a medical device establishment complying with the QMSR in this final rule, organized by each provision of Subpart N of the previous QS regulation.

Table 51. Number of Annual Labor Hours Saved by a Medical Device Establishment to Comply with Provisions of the Final Rule that Correspond to Subpart N of the Previous QS Regulation

QS Regulation, Subpart N (Part 820.200)	Establishment Size			
	Small	Medium	Large	Very large
Previous820.200 Servicing				
- Maintain written procedures[1]	2	2	3	4
Comply with Final Rule [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 sets of QS requirements to complying with the QMSR in the final rule.

We use information from the 1996 final rule codifying the QS regulation in Part 820 to determine proportions of types of labor needed to comply with each section of Subpart N of the previous QS regulation (see Table 52), and appropriate wage rates and overhead costs (see Table 9) to estimate benefits of complying with the QMSR in this final rule for affected establishments.

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

QS Regulation, Subpart N (Part 820.200)	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 provisions of the QMSR corresponding to Subpart N of the previous QS regulation for affected entities (see Table 53). Benefits of complying with the QMSR will result in cost savings of approximately $644,000 per year for the affected entities by moving from compliance with both ISO 13485 and the previous QS regulation to the final rule (see Table 53).

Table 53. Annual Cost Savings of Compliance with the QMSR in the Final Rule Using Corresponding Provisions of Subpart N of the QS Regulation

QS Regulation, Subpart N (Part 820.200)	Establishment Size, Domestic				Totals
	Small	Medium	Large	Very Large	
No. of Establishments	1,268	2,196	796	657	**4,917**
820.200 Servicing					

- Maintain written procedures					
Unit cost saving	$27	$27	$40	$53	
Cost Savings	**$33,699**	**$58,348**	**$31,724**	**$34,899**	**$158,669**
QS Regulation, Subpart N (Part 820.200)	**Establishment Size, Foreign**				**Totals**
No. of Establishments	3,876	6,710	2,432	2,007	**15,025**
820.200 Servicing - Maintain written procedures					
Unit cost saving	$27	$27	$40	$53	
Cost Savings	**$102,971**	**$178,289**	**$96,936**	**$106,637**	**$484,833**
Total Cost Savings, Subpart N					**$643,502**

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 previous QS regulation required 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 savings, is estimated for Subpart O.

Other Benefits of the Final Rule

The above analysis shows that there would be significant annual cost savings in regulatory compliance by small to large firms within the medical device industry. A benefit that is not quantified in this analysis is a quicker process for regulatory compliance for medical devices, which would lead to timelier introduction of safe, effective, high-quality medical devices to patients. More timely access to newly-developed medical devices has the potential to help patients avoid illnesses, deaths, and costly medical treatments, as well as improving the quality of life of the consumers. 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 Final Rule

The final rule will 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's requirements, medical device establishments that are not in compliance with ISO 13485 when the final rule is implemented will 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 final 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 2022 for a lawyer (SOC 23-1011; $78.74) which is doubled ($157.48) 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 $378 and $457 (average: $409) 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 $157.48 per hour). The total access and learning cost for all affected entities (25,294) is between $9.57 million ($378/establishment x 25,294 establishments) and $11.56 million ($457/establishment x 25,294 establishments) (average: $10.35 million). Table 54 breaks down the cost of learning the rule for th very small establishments (5,352; $2.19 million), and small to very large establishments (19,942; $8.16 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 cost for all establishments (25,294 = 5,352 + 19,942) is approximately $1.29 million per year ($272,208 + $1,104,306). When we assume a discount rate of 3 percent, the annualized one-time cost is approximately $1.15 per year ($241,876 + $901,284) (see Table 54). The 10-year horizon period of the one-time cost annualizations considers that the final rule will become effective 2 years following its publication date.

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 (5,352). 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 $2,796 per person.[1] A 3-day training on ISO 13485 for regulatory compliance experts of very small domestic medical device manufacturing establishments (5,352) who would transition to the final rule is approximately $15 million ($2,796/establishment x 5,352 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 $1.86 million per year (see Table 54). When we assume a discount rate of 3 percent, the annualized one-time cost is approximately $1.66 million per year over 10 years (see Table 54). The 10-year horizon period of the one-time cost annualizations considers that the final rule will be implemented 2 years following its publication date.

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

1 Design Control Requirements – Integrating the Quality System Regulation. Source: http:// aami.org/, March 2023. Priced at $2,935; deflated to March 2022 prices at $2,795.64 to for consistency with cost saving estimates which are calculated in 2022 dollars.

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 (5,352). 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 final rule. The least expensive option for ISO 13485 specialized software which requires a one-time payment is listed for $690.[2] The purchase of such software for all small medical device establishments (5,352) is approximately $3.7 million ($690/establishment x 5,352 establishments) (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 $460,000 per year (see Table 54). When we assume a discount rate of 3 percent, the annualized one-time cost is approximately $408,000 per year over 10 years (see Table 54). The 10-year horizon period of the one-time cost annualizations considers that the final will be implemented 2 years following its publication.

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 (5,352). 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 final rule. Using the fully-loaded mean hourly wage rate of $157.48 per hour (see above), we estimate that it would cost approximately $6,300 (40 hours x $157.48/hour) for a very small domestic medical device establishment to conduct this activity. The total cost of updating documents related to policy and procedures for small medical device establishments (5,352) is approximately $33.7 million ($6,300/establishment x 5,352 establishments) (see Table 54). We assume that each establishment would incur this cost the first year following publication of

2 Pre-loaded ISO 13485:2016 & 21 CFR 820 template documentation, IMSXPRESS. Source: http://www.imsxp.com/

the rule. Consequently, over 10 years at a discount rate of 7 percent, we estimate the annualized one-time document update is approximately $4.2 million per year (see Table 54). When we assume a discount rate of 3 percent, the annualized one-time cost is approximately $3.8 million per year over 10 years (see Table 54). The 10-year horizon period of the one-time cost annualizations considers that the final rule will be implemented 2 years following its publication.

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	5,352	$2,188,906	$241,876	$272,208
Initial training	5,352	$14,963,768	$1,653,511	$1,860,865
IT update	5,352	$3,692,775	$408,055	$459,226
Documents update	5,352	$33,712,363	$3,725,250	$4,192,403
Total cost, very small est.		**$54,557,812**	**$6,028,693**	**$6,784,702**
Small to Very Large Domestic and Foreign Medical Device Establishments				
Learning the rule	19,942	$8,156,340	$901,284	$1,014,306
Total cost, small to very large est.		**$8,156,340**	**$901,284**	**$1,014,306**
Total one-time costs		**$62,714,152**	**$6,929,976**	**$7,799,008**

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 2020 County Business Pattern database.

FDA costs

As part of transitioning from managing the QS regulation program to the QMSR as described in the final 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 $52.46 per hour (see Table 56) which is doubled ($104.92) to account for benefits and overhead costs. Estimated cost of wages of OMDRHO staff to attend AAMI course is $822,542 (40 hours of training x 196 staff members/training x $104.92/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 approximately $1.3 million (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	$104.92	$822,542
Training Instruction and Development	40	4	$38,750	$155,000
Travel Expenses ORA to Training	40	196	$1,600	$313,600
Total				**$1,291,142**

Table 56. OMDRHO Staff Number and Wages

Position/GS Level	Average Hourly Wage	Number of Staff
CSO GS-7	$27.50	20
CSO GS-9	$33.64	8
CSO GS-11	$40.70	20
CSO GS-12	$48.78	30
CSO GS-13	$58.01	70
CSO GS-14 (NE)	$68.55	2
CO GS-13	$58.01	14
PE GS-13	$60.83	2
SCSO GS-13/14	$64.83	17
GS 14 Managers	$68.55	8
GS 15+Managers	$80.63	5
Total		**196**
Mean Weighted Average	**$52.46**	
Mean Wage + Benefits	**$104.92**	

- 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 ($48.78/hour) (see Table 56) which is doubled ($97.56) to account for benefits and overhead costs. Estimated cost of wages of OMDRHO staff to attend AAMI Audit course is $468,288 (32 hours of training x 150 staff members/training x $97.56/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 $768,288 (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	$97.56	$468,288
Training Instruction and Development	32	3	$35,000	$105,000
Travel Expenses ORA to Training	32	150	$1,300	$195,000
Total				**$768,288**

- 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 ($104.92), we estimate the cost of training 196 staff members for this in-house training at $493,525 (24 hours/staff member x $104.92/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 ($104.92), we estimate the cost of training 175 staff

members for this in-house training at $440,648 (24 hours x $104.92/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, $68.55 per hour, and double it ($137.10 per hour) to account for benefits and overhead costs. We estimate the cost of training 17 staff members for this in-house training at $55,937 (24 hours/staff member x $137.10/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 $64.83 per hour (see Table 56). Using the fully-loaded mean hourly wage rate ($129.66/hour = $64.83/hour x 2), we estimate that this IT activity costs $103,728 (3 staff members x 800 hours/3 staff members x $129.66/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 $67.98 per hour. Using the fully-loaded mean hourly wage rate ($129.66), we estimate that this IT activity costs $25,932 (1 staff member x 200 hours/staff member x $129.66/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 $64.83 per hour. Using the fully-loaded mean hourly wage rate $129.66 per hour, we estimate that this IT activity costs $25,932 (1 staff member x 200 hours/staff member x $129.66/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 $64.83 per hour to make changes and updates to FDA documents pertaining to policy and procedure changes as a result of the final rule. Using the fully-loaded mean hourly wage rate of $129.66 per hour, we estimate that it would cost $38,898 (300 staff hours x $129.66/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 final rule are approximately $3.3 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 $404,000 per year. When we assume a discount rate of 3 percent, the annualized one-time costs are at approximately $360,000 per year over 10 years. The 10-year horizon period of the one-time FDA cost annualizations considers that the final will be implemented 2 years following its publication date.

Table 58. Summary of FDA Costs

Activity	Cost
Training	
AAMI Standards Course	$1,291,142
AAMI Audit Course	$768,288
CDRH Training with ORA	$493,525
ORA Inspection Training (CSO, SCSO & DIB)	$440,648
ORA Enforcement/Compliance Training (CO & DCB)	$55,937
State Contractors Training (CA & TX)	$12,000
IT Update	
eNSpect Citation Re-write (by GS 13/14s) & Verification	$103,728
eNSpect EIR Re-write/Formatting (by GS13/14s)	$25,932
ORADSS Report (data collection) Re-write (by GS 13/14)	$25,932
Documents Update	
IOM/CPGM/RPM/SOP Changes and Updates (review)	$38,898
Total	**$3,256,030**
Annualized 10-year, 7%	**$404,914**
Annualized 10-year, 3%	**$359,795**

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 FRIA, we assume that all foreign medical device establishments registered with the FDA that are larger than very small (less than $500K) in size, currently comply with both the current Part 820 and ISO 13485. Therefore, the final rule would benefit foreign medical device establishments through cost savings from the reduced annual compliance effort to create and maintain a single quality system. For this analysis, we estimate 15,025 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 $435 million for foreign medical device establishments that 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 ($435M) is approximately 75% of total annual cost savings ($578M) of the final 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	$6,541,693
C	Table 17b	$405,789,803
D	Table 21	$484,833
E	Table 24b	$17,218,536
F	Table 28	$176,294
G	Table 31b	$1,793,049
H	Table 35	$258,572
I	Table 38	$484,833
J	Table 41	$484,833
K	Table 44	$258,572
L	Table 47	$517,145
M	Table 50	$484,833
N	Table 53	$484,833

O	N/A	N/A
Annual Cost Savings, Foreign Establishments		**$434,977,829**
Annual Cost Savings, All Establishments		**$577,330,707**

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 final rule. In Section F, we estimated that, on average, it would cost a medical device establishment $370 to read and learn the final rule. Therefore, the cost of reading and learning the rule for all foreign establishments is approximately $6.15 million ($409/establishments x 15,025 establishments). We estimate the net cost savings to foreign medical device establishments registered with FDA at approximately $429 million ($435 million - $6 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 final 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.

Industry costs and 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 final rule varies between approximately $262 million and approximately $1,341 million ($532M used as the primary estimate in main analysis) (see Table 60).

Table 60 – Comparison of Effect of Assumption Rates for Increase/Decrease of Burden of Effort to Comply with the Final Rule

Cost Saving/Cost	**Increase/Decrease Burden Effort**		
	5%	**10%**	**25%**
	Lower Estimate	Primary Estimate	Upper Estimate
Cost Savings – Industry	$269,780,704	$539,561,409	$1,348,903,521

Costs - Industry	$7,799,008	$7,799,008	$7,799,008
Costs – FDA	$404,914	$404,914	$404,914
Net Cost Savings	**$261,576,783**	**$531,357,487**	**$1,340,699,600**

Note: These annual costs are discounted at 7% for a 10-year horizon. The 10-year horizon period of the cost annualizations considers that the final rule will be implemented 2 years following its publication date.

J. Analysis of Regulatory Alternatives to the Final Rule

1. Option One: Keep the QS Regulation as an Option for Entities who Prefer It

If the QS regulation were maintained as an option—though not a requirement— for compliance with FDA's CGMP requirements for medical devices 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 incurred by entities not already complying with ISO 13485 requirements would be avoided, as discussed above. Additionally, there would be unquantified costs to FDA relative to the rule as written, and potentially to some regulated entities, as a result of incomplete streamlining and harmonization of expectations being associated with greater scope for confusion. This regulatory option would be inconsistent with FDA's goal of harmonizing the medical device CGMP requirements with ISO 13485. No other dual systems are considered.

2. Option Two: Finalize the Proposed Action

The final rule will have an effective date 2 years from the date of its publication in the Federal Register. Under this option, we compare effect of postponement of the effective date of the final rule by an additional two years. We compare cost savings and costs of the final rule if the rule would extend its effective date by 2 additional years. Table 61 indicates that the net cost savings of a 2-year postponement of the effective date of the final rule would be decreased from approximately $532 million to approximately $465 million.

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

Cost/Cost Saving	**Implementation Date**	
	No Delay	**Two Year Delay**
Cost Savings – Industry	$539,561,409	$471,273,830
Costs – Industry	$7,799,008	$6,811,956

Costs - FDA	$404,914	$353,667
Net Cost Savings	**$531,357,487**	**$464,108,208**

Note: These annual costs are discounted at 7% for a 10-year horizon. The 10-year horizon period of the cost annualizations considers that the final rule will be implemented 2 years following its publication date.

III. Final 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 entities.' Based on data provided by the U.S. Census Bureau for selected medical device establishments (see Table 3), approximately 99% of all medical device establishments would be considered small entities by the SBA. 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 final rule would result in a net annual cost savings of over $500 million (see Table 63).

In this analysis, we considered medical device establishments that are considered 'very small,' entities that have annual revenue of less than $0.5M and typically have 9 employees or less. We assumed that very small domestic medical establishments do not currently conform to the ISO 13485 standard. Table 63 includes the estimated annualized burden to medical device establishments based on whether they are very small or not. Annualized burden of costs for a very small establishment is estimated at approximately $1,200 (see Table 63). Net annualized 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 final rule. The harmonization of medical device CGMP requirements with ISO 13485 as reflected in the final rule will result in a smaller regulatory compliance burden and potentially quicker access for medical devices to enter the market. Considering the number (5,352) and annual burden ($1,268 cost) of very small establishments and those of small to very large establishments (19,942 establishments, $27,005

cost saving), we certify that the final 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 Final 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	1,200
339112	Surgical and medical instrument manufacturing	1,000
339113	Surgical appliance and supplies manufacturing	800
339114	Dental equipment and supplies manufacturing	750
339115	Ophthalmic goods manufacturing	1,000

Source: Small Business Administration, Table of Small Business Size Standards.
Link: Table of Small Business Size Standards. U.S. Small Business Administration. March 17, 2023.
Last accessed: November 2023

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

Cost/Cost Saving	Size	
	Very Small	Small to Very Large
Total Costs	$6,784,702	$1,014,306
Total Cost Savings		$539,561,409
No. of Establishments	5,352	19,942
Cost/Establishment	**$1,268**	
Cost Saving/Establishment		**$27,005**

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 Final Rule on Competitive Fairness in the Medical Device Industry

Potentially, foreign medical device establishments that currently do not export their products to the U.S. may choose to comply with the final rule, when 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 the ‘very small’ domestic establishments who may choose to exit the industry. In the face of new costly rulemaking, there is a potential for certain establishments to decide to exit the industry, new establishments to enter 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.

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.