DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Radiological Health Regulations; Amendments to Records and Reports for Radiation Emitting Electronic Products; Amendments to Performance Standards for Diagnostic X-ray, Laser and Ultrasonic Products

Docket No. FDA- FDA-2018-N-3303

Final Regulatory Impact Analysis
Final Regulatory Flexibility Analysis
Unfunded Mandates Reform Act Analysis

Economics Staff
Office of Economics and Analysis
Office of Policy, Legislation, and International Affairs
Office of the Commissioner

Table of Contents

I. Introduction and Summary 3
A. Introduction 3
B. Summary of Costs and Benefits 4
C. Comments on the Preliminary Economic Analysis of Impacts and Our Responses 6
D. Summary of Changes 6
II. Final Economic Analysis of Impacts 6
A. Background 6
B. Need for Federal Regulatory Action 7
C. Purpose of the Rule 7
D. Baseline Conditions 8
E. Benefits of the Rule 9
F. Costs of the Rule 12
G. Distributional Effects 13
H. International Effects 13
I. Analysis of Regulatory Alternatives to the Rule 13
III. Final Small Entity Analysis 14
IV. References 14

I. Introduction and Summary

A. Introduction

We have examined the impacts of the final rule under Executive Order 12866, Executive Order 13563, the Regulatory Flexibility Act (5 U.S.C. 601-612), and the Unfunded Mandates Reform Act of 1995 (Pub. L. 104-4). Executive Orders 12866 and 13563 direct us to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). We believe that this final rule is not a significant regulatory action as defined by Executive Order 12866.

The Regulatory Flexibility Act requires us to analyze regulatory options that would minimize any significant impact of a rule on small entities. This rule will reduce regulations that are outdated and otherwise clarify existing requirements. Because this final rule does not impose any additional regulatory burdens, we certify that this 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 costs and benefits, 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 $165 million, using the most current (2021) Implicit Price Deflator for the Gross Domestic Product. This final rule will not result in an expenditure in any year that meets or exceeds this amount.

B. Summary of Costs and Benefits

We estimate the benefits of this rule in terms of cost savings. We derive the cost savings to industry from the reduction in labor associated with the reporting, recordkeeping, performance standards, and third-party disclosure requirements. Similarly, cost savings to FDA result from the reduction in labor hours required to review reports. The total present-value cost savings over a 20-year time period are $69.71 million at a 7 percent discount rate and $97.89 million at a 3 percent discount rate. Annualized total cost savings are $6.58 million. We estimate the costs to read the rule for all reporting respondents. The present value costs are $1.60 million, and the annualized costs calculated over a 20-year time period are $0.14 million at a 7 percent discount rate and $0.10 million at a 3 percent discount rate. A summary of the quantified cost savings and costs of the rule are presented in Table 1.

Table 1. Summary of Benefits, Costs and Distributional Effects of Final Rule

Category		Primary Estimate	Low Estimate	High Estimate	Units			Notes
					Year Dollars	Discount Rate	Period Covered	
Benefits	Annualized Monetized $millions/year	$6.58	$6.58	$6.58	2021	7%	20 years	
		$6.58	$6.58	$6.58	2021	3%	20 years	
	Annualized Quantified					7%		
						3%		
	Qualitative							
Costs	Annualized Monetized $millions/year	$0.14	$0.14	$0.14	2021	7%	20 years	
		$0.10	$0.10	$0.10	2021	3%	20 years	
	Annualized Quantified					7%		
						3%		
	Qualitative							
Transfers	Federal Annualized Monetized $millions/year					7%		
						3%		
	From/ To	From:			To:			
	Other Annualized Monetized $millions/year					7%		
						3%		
	From/To	From:			To:			
Effects	State, Local or Tribal Government: No effect Small Business: No effect Wages: No effect Growth: No effect							

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

FDA issued a proposed rule on April 1st, 2019. None of the comments addressed the preliminary regulatory impact analysis, provided data about the economic impact, or otherwise suggested that the economic analysis should be revised.

D. Summary of Changes

Aside from updating the data to provide estimates in 2021 dollars, the economic analysis of the final rule does not differ from the economic analysis of the proposed rule.

II. Final Economic Analysis of Impacts

A. Background

The Food and Drug Administration (FDA or Agency) is issuing a rule to amend and repeal parts of the radiological health regulations for recommendations for radiation protection during medical procedures, certain records and reporting for electronic products, and performance standards for diagnostic X-ray systems and their major components, laser products, and ultrasonic therapy products. This action intends to clarify and update the regulations to reduce regulatory requirements that are outdated and duplicative of other means to better protect the public health against harmful exposure to radiation-emitting electronic products and medical devices. These amendments will also decrease regulatory burdens and reduce or eliminate existing costs to manufacturers associated with the identified regulations.

B. Need for Federal Regulatory Action

The Agency believes the amendments in this final rule will help ensure that the requirements for radiation-emitting electronic products and devices will continue to protect the public health and safety while reducing unnecessary regulatory burdens. FDA has determined that some of the current reporting requirements are outdated and thus fail to reflect current practices. Furthermore, FDA has determined that some of the current reporting requirements are duplicative of other reporting requirements. Thus, these unnecessary or outdated reporting requirements do not correct the market failure for which they were adopted and instead yield an institutional failure, which this final rule attempts to correct.

C. Purpose of the Rule

This final rule updates FDA's radiological health regulations by amending parts of the general provisions that includes records and reporting requirements for electronic products. The radiation protection recommendations have become outdated and unnecessary due to current FDA safety communications and other mechanisms that can better protect patients and health professionals from unnecessary radiation exposure. The records and reporting requirements include annual reports and test records that depend upon the specific type of electronic products. FDA has determined upon review of the reports and recording requirements that some of the requirements are unnecessary or may be duplicative of other reporting requirements by FDA and State regulators. In addition, FDA is revising the timing for submissions of the reporting requirements for accidental radiation occurrences (AROs) to allow quarterly reporting for AROs that are not associated with a death or serious injury. FDA also amends the applications for variances process to no longer require a manufacturer to submit two additional copies with the

original documents. FDA also amends the reporting requirement for assemblers of components of diagnostic x-ray systems and the performance standard for laser products by clarifying provisions regarding the incorporation of certified and uncertified products. Lastly, this final rule repeals the performance standards for sonic, infrasonic, and ultrasonic products because they are limited to a subset of physical therapy devices with an outdated standard. The Agency considers the premarket medical device regulations to be sufficient to cover the safety of ultrasonic therapy products.

D. Baseline Conditions

These amendments will maintain protection of the public health while reducing regulatory burdens on manufacturers, dealers, and distributors of radiation emitting electronic products. Therefore, this final rule reduces recordkeeping and reporting requirements for some products and clarifies the applicability of certain requirements for other products. We estimate costs and benefits of this regulatory action in terms of the baseline reporting, recordkeeping, and third-party disclosure burden estimates. The baseline burden data come from the Information Collection for Electronic Products and include the number of respondents, the number of responses per respondent, and the average burden hours per response for each reporting category (Ref. 1). We derive the estimates by consultation with FDA and industry personnel, and from actual industry data, including recent product report submissions. At the baseline, there were a total of 23,040 respondents across all three reporting categories, with 472,804 total burden hours.

E. Benefits of the Rule

We estimate the benefits in terms of cost savings for industry and FDA. Industry cost savings are based on the number of respondents that, according to this rule, will be removed from (1) reporting, (2) recordkeeping, and (3) third-party disclosure requirements. Industry respondents include manufacturers and assemblers of electronic, laser, and ultrasonic therapy products. Annual reports are reviewed by FDA staff to determine product safety, conformance with performance standards, and adequacy of quality control testing. Thus, this final rule also generates cost savings to FDA from the reduction in labor hours required to review reports.

1. Industry Cost Savings

From discussions with subject matter experts at FDA, we collect information on the number of respondents for each form of recordkeeping and reporting requirements that this rule will remove. For each form, we multiply the number of eliminated respondents by the number of responses per respondent to obtain the total number of responses that this rule will eliminate. We then multiply the total eliminated responses by the average burden hours per response to arrive at the total hours that this rule will save for each affected form in the three reporting categories. Table 2 shows the number of hours saved for each reporting category. We estimate that 32,350 (23.9 percent) of the total annual reporting hours, 48,221 (14.4 percent) of the annual recordkeeping hours, and 72 (2.4 percent) of third-party disclosure hours will be reduced.

Table 2. Total Hours Saved

	Reporting Burden (1)	Recordkeeping Burden (2)	Third Party Disclosure Burden (3)	Total
Baseline Burden Hours	135,176	334,570	3,058	472,804
Total Hours Saved	32,350	48,221	72	80,643
Percent Hours Saved	23.9%	14.4%	2.4%	17.1%

To determine the savings from reduced labor, we use the 2021 mean base wages for regulatory affairs specialists, as reported by Payscale.com, to estimate the value associated with the information collection (Ref. 2). We account for employee benefits and other indirect costs by multiplying the mean base wage by 2, which gives us an adjusted mean hourly wage rate of $69.38 ($34.69[1] x 2). By multiplying the total number of hours saved by the adjusted wage, we estimate that the total annual cost savings to industry associated with this regulatory action is $5,595,341 (80,643 x $69.38). The present value of cost savings to industry over a 20-year time period is $59,277,121 at a 7 percent discount rate and $83,244,543 at a 3 percent discount rate. The annualized estimated cost savings to industry is $5,595,341. We summarize these costs in Table 3.

Table 3. Industry Cost Savings

	Present Value		Annualized Value	
	7%	3%	7%	3%
Estimated Cost Savings	$59,277,121	$83,244,543	$5,595,341	$5,595,341

[1] The base mean hourly wage was estimated by dividing the national average annual salary of $69,384 by 2,000 annual work hours.

2. FDA Cost Savings

The cost savings to FDA are based on the number of review hours associated with the reduction in reporting, recordkeeping, and third-party disclosure requirements. Since annual reporting refers to reports that are submitted to FDA for review, a reduction in reporting will also result in labor cost savings for FDA. Per the Information Collection for Electronic Products (Ref. 1), FDA estimates that 15 full time equivalent (FTE) positions participate in activities related to the information collection under the current regulations. An average FTE employee costs FDA's Center for Devices and Radiological Health $274,306. As in Table 2, we estimate that 23.9 percent of the total annual reporting burden hours will be reduced as a result of this final rule. Multiplying this percentage by the total number of FTEs, we estimate that a labor reduction equivalent to 3.59 FDA FTEs will result from the elimination of the specified annual reporting requirements (15 x 23.9 percent). Multiplying the annual FTE cost by the number of FTEs reduced yields an annual cost savings of $984,700 to FDA ($274,306 x 3.59). As in Table 4, the present value of cost savings to FDA over a 20-year time period are $10,431,926 at a 7 percent discount rate and $14,649,850 at a 3 percent discount rate; the annualized cost savings are $984,700.

Table 4. FDA Cost Savings

	Present Value		Annualized Value	
	7%	3%	7%	3%
Estimated Cost Savings	$10,431,926	$14,649,850	$984,700	$984,700

3. Total Cost Savings

Table 5 presents total cost savings, including cost savings to industry and FDA. The total present value of cost savings over a 20-year time period are $69,709,047 at 7 percent discount rate and $97,894,393 at a 3 percent discount rate. Annualized total cost savings are $6,580,041.

Table 5. Total Cost Savings

	Present Value		Annualized Value	
	7%	3%	7%	3%
Estimated Cost Savings	$69,709,047	$97,894,393	$6,580,041	$6,580,041

F. Costs of the Rule

We estimate the costs to read the rule for all respondents to the initial collection of information. We assume all baseline respondents will need to devote time to reading and understanding this regulation to determine whether this final rule applies to their firm. There are 23,040 initial respondents across all three reporting categories. At an adult average reading speed of 200-250 words per minute, we estimate that each reader will spend about 1 hour reading the rule. We assume one regulatory affairs specialist at each firm will read the rule. Using the adjusted hourly wage rate as calculated above, we value the time spent learning about the rule at a cost of $69.38 per respondent. Multiplying this estimate by the number of total respondents yields a total one-time cost for reading the rule of $1,598,607 ($69.38 x 23,040). As reported in Table 6, the present value costs are $1,598,607. The annualized costs calculated over a 20-year period are $141,025 at a 7 percent discount rate and $104,322 at a 3 percent discount rate.

Table 6. Costs to Read the Rule

	Present Value		Annualized Value	
	7%	3%	7%	3%
Estimated Costs	$1,598,607	$1,598,607	$141,025	$104,322

G. Distributional Effects

We do not expect any significant distributional effects from this rule.

H. International Effects

We do not expect there to be any significant quantifiable international economics effects of this rule because this rule will not impose any additional regulatory burdens on entities, including foreign entities.

I. Analysis of Regulatory Alternatives to the Rule

An alternative would be to extend the effective date of this rule for a 12-month period. Under this alternative, there will be minimal impacts on the costs but the impacts on the cost savings are more substantial due to delayed benefits. Table 7 presents the present values and annualized values under the alternative and the differences from this rule as proposed.

Table 7. Extending the Effective Date of the Rule for a 12-month Period

	Present Value		Annualized Value	
	7%	3%	7%	3%
Cost Savings				
Extending Effective Date	$65,148,642	$95,043,100	$6,149,571	$6,388,389
Difference from the Proposed Rule	$(4,560,405)	$(2,851,293)	$(430,470)	$(191,652)
Costs				
Extending Effective Date	$1,396,286	$1,506,841	$131,799	$101,283
Difference from the Proposed Rule	$(97,740)	$(45,205)	$(9,226)	$(3,039)

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. The rule does not impose any additional regulatory burdens. The only cost associated with this rule is the time for reading the rule, which is about 1 hour, and the cost is less than $100 per respondent. 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 and the Preamble of the final rule, serves as the Final Regulatory Flexibility Analysis, as required under the Regulatory Flexibility Act.

IV. References

1. Information Collection for Electronic Products (OMB control number 0910-0025)
2. https://www.payscale.com/research/US/Job=Regulatory_Affairs_Specialist/Salary (Accessed 12/21/21)