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-2018-X-XXXX

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

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Contents

I. Introduction and Summary

A. Introduction

We have examined the impacts of the proposed rule under Executive Order 12866, Executive Order 13563, Executive Order 13771, 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). Executive Order 13771 requires that the costs associated with significant new regulations "shall, to the extent permitted by law, be offset by the elimination of existing costs associated with at least two prior regulations." We believe that this proposed 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 This proposed rule will reduce regulations that are outdated and otherwise clarify existing requirements. Because the proposed rule does not impose any additional regulatory burdens, we certify that the proposed rule will not have a significant economic impact on a substantial number of small entities.

The Unfunded Mandates Reform Act of 1995 (section 202(a)) requires us to prepare a written statement, which includes an assessment of anticipated costs and benefits, before 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 $150 million, using the most current (2017) Implicit Price Deflator for the Gross

Domestic Product. This proposed rule would not result in an expenditure in any year that meets or exceeds this amount.

B. Summary of Costs and Benefits

Benefits are estimated in terms of cost savings. Industry cost savings are derived by estimating the savings in reduced labor resulting from the reduction in reporting, recordkeeping, performance standards, and third party disclosure requirements. 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 $62.8 million at a 7 percent discount rate and $88.2 million at a 3 percent discount rate. Annualized total cost savings are $5.93 million. We estimate the costs to read the rule, if finalized, for all reporting respondents. The present value costs are $1.47 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.

Table 1. Summary of Benefits and Costs

Category	Primary Estimate	Low Estimate	High Estimate	Year Dollars	Discount Rate	Period Covered	Notes
Benefits							
Annualized Monetized $millions/year	$5.93 million	$5.93 million	$5.93 million	2016	7%	20 years	
	$5.93 million	$5.93 million	$5.93 million	2016	3%	20 years	
Annualized Quantified					7%		None
					3%		
Qualitative							None

Costs							
Annualized Monetized $millions/year	$0.14 million	$0.14 million	$0.14 million	2016	7%	20 years	
	$0.10 million	$0.10 million	$0.10 million	2016	3%	20 years	
Annualized Quantified					7%		
					3%		
Qualitative							
				Units			
Category	Primary Estimate	Low Estimate	High Estimate	Year Dollars	Discount Rate	Period Covered	Notes
Transfers							
Federal Annualized Monetized $millions/year					7%		None
					3%		
From/To	From:			To:			
Other Annualized Monetized $millions/year					7%		None
					3%		
From/To	From:			To:			

Effects	
State, Local, or Tribal Government	
No estimated effect.	
Small Business	
No estimated effect.	
Wages: No estimated effect.	
Growth: No estimated effect.	

In line with Executive Order 13771, in Table 2 we estimate present and annualized values of costs and cost savings over an infinite time horizon. Based on these cost-savings this proposed rule would be considered a deregulatory action under EO 13771.

Table 2 EO 13771 Summary Tables (in $ Millions 2016 dollars, over a perpetual time horizon)

	Primary (7%)	Lower Bound (7%)	Upper Bound (7%)	Primary (3%)	Lower Bound (3%)	Upper Bound (3%)
Present Value of Costs	$1.47	$1.47	$1.47	$1.47	$1.47	$1.47
Present Value of Cost Savings	$84.65	$84.65	$84.65	$197.52	$197.52	$197.52
Present Value of Net Costs	-$83.18	-$83.18	-$83.18	-$196.05	-$196.05	-$196.05
Annualized Costs	$0.10	$0.10	$0.10	$0.04	$0.04	$0.04
Annualized Cost Savings	$5.93	$5.93	$5.93	$5.93	$5.93	$5.93
Annualized Net Costs	-$5.82	-$5.82	-$5.82	-$5.88	-$5.88	-$5.88

II. Preliminary Regulatory Impact Analysis

A. Background

The Food and Drug Administration (FDA or Agency) is issuing a proposed 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. The Agency is proposing this action to clarify and update the regulations to reduce regulatory requirements that are outdated and duplicate 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.

If finalized, this proposed rule will update FDA's radiological health regulations by amending parts of the general provisions including 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 depending upon the specific type of electronic product. 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 proposes to revise the timing for submissions of 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 proposes to amend the applications for variances process to no longer require a manufacturer to submit two additional copies with the original documents. FDA also proposes to amend 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, FDA proposes to repeal 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.

B. Market Failure Requiring Federal Regulatory Action

The Agency believes the amendments in this proposed 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 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 the proposed rule attempts to correct.

C. Benefits and Costs

1. Baseline

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

2. Benefits

Benefits are estimated as cost savings. We estimate cost savings for industry and FDA. Industry cost savings are based on the number of respondents eliminated for reporting, recordkeeping, and third party disclosure requirements. The 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, FDA cost savings result from the reduction in labor hours required to review reports.

A. Industry Cost Savings

The number of respondents eliminated for each form that will be affected by this deregulatory action were generated from discussions with subject matter experts at FDA. For each affected form, the number of eliminated respondents was multiplied by the number of responses per respondent to yield the total number of eliminated responses. We then multiplied the total responses eliminated by the average burden hours per response to arrive at the total hours eliminated for each affected form in the three reporting categories. Table 3 shows the number of hours eliminated for each reporting category. We estimate that 32,350 (23.9 percent) of the total the 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 eliminated.

Table 3--Total Hours Eliminated

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

To determine the estimated savings in reduced labor, activities associated with this information collection are valued using 2016 mean base wages for regulatory affairs specialists as reported by Payscale.com (Ref. 2). After accounting for benefits and overhead by multiplying the mean base wage by 2, the adjusted mean hourly wage rate is $63.96 ($31.98[1] x 2). By multiplying the total number of hours eliminated by the adjusted wage, we estimate that the total annual cost savings to industry associated with this proposed regulatory action is $5,157,610 (80,643 x $63.96). The present value cost savings to industry over a 20-year time period is $54,639,795 at a 7 percent discount rate and $76,732,215 at a 3 percent discount rate, and the annualized estimated cost savings to industry is $5,157,610. These costs are summarized in Table 4.

Table 4--Industry Cost Savings

	Present Value		**Annualized Values**	
	7%	3%	7%	3%
Estimated Cost Savings	$54,639,795	$76,732,215	$5,157,610	$5,157,610

B. FDA Cost Savings

The cost savings to FDA are based on the number of hours eliminated for the annual reporting requirement. Since annual reporting refers to reports that are submitted to FDA for review, a reduction in reporting would 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 is projected to cost FDA's Center for Devices and

[1] The base mean hourly wage was estimated by dividing the national average annual salary of $63,956 by 2,000 annual work hours.

Radiological Health $213,944. As reported in Table 3, we estimate that 23.9 percent of the total annual reporting burden hours will be eliminated as a result of this proposed rule if finalized. Multiplying this percentage by the total number of FTEs, we estimate a labor reduction equivalent to 3.59 FDA FTEs would 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 to FDA of $768,013 ($213,944 x 3.59). As summarized in Table 5, the present value cost savings to FDA over a 20-year time period of $8,136,344 at a 7 percent discount rate and $11,426,099 at a 3 percent discount rate, and the annualized cost savings are $768,013.

Table 5--FDA Cost Savings

	Present Value		**Annualized Values**	
	7%	3%	7%	3%
Estimated Cost Savings	$8,136,344	$11,426,099	$768,013	$768,013

C. Total Cost Savings

Total cost savings include cost savings to industry and FDA, and are presented in Table 6. The total present value cost savings over a 20-year time period are $62,776,139 at 7 percent discount rate and $88,158,313 at a 3 percent discount rate. Annualized total cost savings are $5,925,623.

Table 6--Total Cost Savings

	Present Value		Annualized Values	
	7%	3%	7%	3%
Industry Cost Savings	$54,639,795	$76,732,215	$5,157,610	$5,157,610

FDA Cost Savings	$8,136,344	$11,426,099	$768,013	$768,013
Total Cost Savings	$62,776,139	$88,158,313	$5,925,623	$5,925,623

3. Costs

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 the proposed rule applies to their firm. There are 23,040 initial respondents across all three reporting categories[2]. 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 specialists 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 $63.96 per respondent. Multiplying this estimate by the number of total respondents yields a total one-time cost for reading the rule of $1,473,546 ($63.96 x 23,040). As reported in Table 7, the present value costs are $1,473,546 and the annualized costs calculated over a 20-year time period are $139,092 at a 7 percent discount rate and $99,045 at a 3 percent discount rate.

Table 7--Costs to Read the Rule

	Present Value		**Annualized Values**	
	7%	3%	7%	3%
Costs to Read the Rule	$1,473,546	$1,473,546	$139,092	$99,045

[2] This number is an upper bound. We assume each respondent represents one firm. There is a possibility that the total is overstated if there are overlapping respondents. However, we currently do not have the data to make this determination.

III. Initial Regulatory Flexibility Analysis

FDA has examined the economic implications of the proposed rule as required by the Regulatory Flexibility Act. If a rule will have a significant economic impact on a substantial number of small entities, the Regulatory Flexibility Act requires agencies to analyze regulatory options that would lessen the economic effect of the rule on small entities. Because the proposed rule does not impose any additional regulatory burdens, we certify that the proposed rule will not have a significant economic impact on a substantial number of small entities.

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 11/8/2017)