



*The Affordable Care Act:  
An Improved Strategy Is Needed to  
Ensure Accurate Reporting and Payment  
of the Medical Device Excise Tax*

**July 17, 2014**

**Reference Number: 2014-43-043**

This report has cleared the Treasury Inspector General for Tax Administration disclosure review process and information determined to be restricted from public release has been redacted from this document.

**Redaction Legend:**

1 = Tax Return/Return Information

2 = Risk Circumvention of Agency Regulation or Statute

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## HIGHLIGHTS

### **THE AFFORDABLE CARE ACT: AN IMPROVED STRATEGY IS NEEDED TO ENSURE ACCURATE REPORTING AND PAYMENT OF THE MEDICAL DEVICE EXCISE TAX**

## Highlights

**Final Report issued on July 17, 2014**

Highlights of Reference Number: 2014-43-043 to the Internal Revenue Service Commissioners for the Small Business/Self-Employed Division and the Wage and Investment Division.

### **IMPACT ON TAXPAYERS**

The Affordable Care Act includes a tax provision that provides for an excise tax equal to 2.3 percent of the sales price for medical devices sold beginning January 1, 2013. Manufacturers, producers, and importers are responsible for collecting the medical device excise tax and must file a Form 720, *Quarterly Federal Excise Tax Return*. The Joint Committee on Taxation estimated revenues from the medical device excise tax of \$20 billion for Fiscal Years 2013 through 2019.

### **WHY TIGTA DID THE AUDIT**

This audit was initiated as part of our continued coverage of the IRS's implementation of key Affordable Care Act tax provisions. The overall objective of this review was to assess the IRS processing of tax returns reporting the medical device excise tax and efforts to identify taxpayer noncompliance.

### **WHAT TIGTA FOUND**

Our review found that both the number of Forms 720 filed reporting the medical device excise tax and the amount of the associated revenue reported are lower than estimated. The IRS is attempting to develop a compliance strategy to ensure that businesses are compliant with medical device excise tax filing and payment requirements and has taken several measures to advise medical device manufacturers of the new excise tax. However, the IRS cannot identify the population of medical

device manufacturers registered with the Food and Drug Administration that are required to file a Form 720 and pay the excise tax.

In addition, processing controls do not ensure the accuracy of medical device excise tax figures reported on paper-filed Forms 720. Our analysis of 5,107 Forms 720 processed for the quarters ending March 31 and June 30, 2013, identified discrepancies in the amount of the medical device excise tax and/or taxable sales amount captured from 276 paper-filed tax returns. TIGTA identified medical device excise tax discrepancies totaling almost \$117.8 million when comparing the excise tax amount captured by the IRS from the Form 720 to the excise tax amount TIGTA calculated.

Finally, the IRS erroneously assessed 219 failure to deposit penalties totaling \$706,753 against businesses filing a Form 720 for the quarters ending March 31 and June 30, 2013, which was designated a penalty relief period. The IRS had reversed 133 of the 219 penalty assessments. When TIGTA alerted the IRS of the remaining 86 penalties, IRS management reversed the penalties and issued apology letters to the affected taxpayers.

### **WHAT TIGTA RECOMMENDED**

TIGTA recommended that the IRS continue refining its compliance strategy to include actions that can be taken to identify noncompliant manufacturers. TIGTA also recommended that the IRS conduct a review of the 276 tax returns TIGTA identified to determine the proper excise tax owed, establish a process to verify the accuracy of the medical device excise tax amount for paper-filed Forms 720, and initiate a process to correspond with taxpayers to obtain missing taxable sales or tax amounts.

The IRS agreed with our recommendations and plans to consider alternative strategies for identifying noncompliant manufacturers, identify programming changes needed to improve the math verification for paper-filed Forms 720, and implement procedures for corresponding with taxpayers if the changes can be accomplished within budgetary constraints. The IRS also indicated that about two-thirds of the paper-filed tax returns TIGTA identified were reviewed.



TREASURY INSPECTOR GENERAL  
FOR TAX ADMINISTRATION

DEPARTMENT OF THE TREASURY  
WASHINGTON, D.C. 20220

July 17, 2014

**MEMORANDUM FOR** COMMISSIONER, SMALL BUSINESS/SELF-EMPLOYED  
DIVISION  
COMMISSIONER, WAGE AND INVESTMENT DIVISION

**FROM:** Michael E. McKenney  
Acting Deputy Inspector General for Audit

**SUBJECT:** Final Audit Report – The Affordable Care Act: An Improved Strategy  
Is Needed to Ensure Accurate Reporting and Payment of the Medical  
Device Excise Tax (Audit # 201340332)

This report presents the results of our review to assess the Internal Revenue Service's processing of tax returns reporting the medical device excise tax and efforts to identify taxpayer noncompliance. This audit is included in the Treasury Inspector General for Tax Administration's Fiscal Year 2014 Annual Audit Plan and addresses the major management challenge of Implementing the Affordable Care Act and Other Tax Law Changes.

Management's complete response to the draft report is included as Appendix V.

Copies of this report are also being sent to the Internal Revenue Service managers affected by the report recommendations. If you have any questions, please contact me or Russell P. Martin, Acting Assistant Inspector General for Audit (Returns Processing and Account Services).



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## *Abbreviations*

BRTF	Business Return Transaction File
CY	Calendar Year
e-filed	Electronically filed
FDA	Food and Drug Administration
FTD	Failure to Deposit
IRS	Internal Revenue Service
NAICS	North American Industry Classification System
TIGTA	Treasury Inspector General for Tax Administration



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## *Background*

The Patient Protection and Affordable Care Act of 2010<sup>1</sup> and the Health Care and Education Reconciliation Act of 2010<sup>2</sup> that made amendments to it (collectively referred to as the Affordable Care Act hereafter) were both signed into law in March 2010. The Affordable Care Act revenue provisions are expected to generate \$438 billion between Fiscal Years 2010 and 2019.<sup>3</sup> One such provision is Section 1405 that provides for an excise tax equal to 2.3 percent of the sales price for medical devices sold beginning January 1, 2013. The Joint Committee on Taxation estimated revenues from the medical device excise tax of \$20 billion for Fiscal Years 2013 through 2019.

***Medical devices are devices intended for humans, including any instrument, machine, or implant intended for the diagnosis, cure, treatment, or prevention of disease.***

In general, a taxable medical device is a device intended for humans that is listed with the Food and Drug Administration (FDA) under section 510(j) of the Federal Food, Drug, and Cosmetic Act<sup>4</sup> and 21 Code of Federal Regulations part 807. Exclusions include eyeglasses, contact lenses, hearing aids, and medical devices purchased by the general public at retail for individual use<sup>5</sup> as well as medical devices exported outside of the United States.

Manufacturers, producers, and importers (commonly referred to as “manufacturers” or “businesses” throughout the report) are responsible for collecting the medical device excise tax and must file a Form 720, *Quarterly Federal Excise Tax Return*. The medical device excise tax is reported on Part 1 of Form 720. Manufacturers are required to enter the total sales price (referred throughout as taxable sales) of all taxable medical devices sold during the quarter and the total tax due (2.3 percent of the taxable sales). The first quarterly tax returns reporting the

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<sup>1</sup> Pub. L. No. 111-148, 124 Stat. 119 (2010) (codified as amended in scattered sections of the U.S. Code), as amended by the Health Care and Education Reconciliation Act of 2010, Pub. L. No. 111-152, 124 Stat. 1029.

<sup>2</sup> Pub. L. No. 111-152, 124 Stat. 1029. (See Affordable Care Act, *infra*).

<sup>3</sup> Joint Committee on Taxation, JCX-17-10, Estimated Revenue Effects of the Amendment in the Nature of a Substitute to H.R. 4872, the “Reconciliation Act of 2010,” as Amended, in Combination With the Revenue Effects of H.R. 3590, the “Patient Protection and Affordable Care Act,” as Passed by the Senate and Scheduled for Consideration by the House Committee on Rules on March 20, 2010 (March 20, 2010).

<sup>4</sup> Pub. L. No. 75-717, 52 Stat. 1040 (1938).

<sup>5</sup> This is known as the retail exemption. This exemption includes devices of a type generally purchased by the general public at retail for individual use; regularly available for purchase and use by individuals who are not medical professionals; and not primarily intended for use in a medical institution or office or by a medical professional. The evaluation of whether the retail exemption applies is based on all the relevant facts and circumstances.



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medical device excise tax were due April 30, 2013. Figure 1 shows where the medical device excise tax is reported on Form 720.

**Figure 1: Reporting of the Medical Device Excise Tax on Form 720**

IRS No.	Manufacturers Taxes	Number of tons	Sales price	Rate	Tax	IRS No.
36	Coal— Underground mined			\$1.10 per ton		36
37				4.4% of sales price		37
38	Coal— Surface mined			\$.55 per ton		38
39				4.4% of sales price		39
				Number of tires	Tax	IRS No.
108	Taxable tires other than bias ply or super single tires					108
109	Taxable bias ply or super single tires (other than super single tires designed for steering)					109
113	Taxable tires, super single tires designed for steering					113
40	Gas guzzler tax. Attach Form 6197. Check if one-time filing <input type="checkbox"/>					40
97	Vaccines (see instructions)					97
136	<b>Taxable medical devices</b>		Sales price	2.3% of sales price		<b>136</b>

Source: Form 720 for Tax Year<sup>6</sup> 2013.

Manufacturers are required to submit semimonthly<sup>7</sup> payments of excise tax either by the Electronic Federal Tax Payment System<sup>8</sup> or an approved alternative method<sup>9</sup> when the tax liability is \$2,500 or more for the quarter. However, if the tax liability is less than \$2,500 for the quarter, then the tax is payable by the tax return due date. Manufacturers are subject to a failure to deposit (FTD) penalty if 95 percent of the net tax liability is not timely deposited for the semimonthly period.

<sup>6</sup> A 12-month accounting period for keeping records on income and expenses used as the basis for calculating the annual taxes due.

<sup>7</sup> A semimonthly period is the first 15 days of a month (which would be the first semimonthly period) or the 16<sup>th</sup> day of the month to the last day of the month (which would be the second semimonthly period).

<sup>8</sup> The system designed to process Federal tax deposits and other types of business and individual payments.

<sup>9</sup> Alternative methods include tax professional, financial institution, payroll service, or other trusted third party.



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This review was performed at the IRS Submission Processing Site in Covington, Kentucky, and with information obtained from the Small Business/Self-Employed Division Headquarters in Washington, D.C., and the Wage and Investment Division Headquarters in Atlanta, Georgia, during the period June 2013 through March 2014. We conducted this performance audit in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objective. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objective. Detailed information on our audit objective, scope, and methodology is presented in Appendix I. Major contributors to the report are listed in Appendix II.





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## *Results of Review*

### **Development of a Compliance Strategy to Identify Medical Device Excise Tax Nonfilers Continues to Be a Challenge**

The IRS is attempting to develop a compliance strategy to ensure that businesses are compliant with medical device excise tax filing and payment requirements. Specifically, the IRS has taken several measures to advise medical device manufacturers of the new excise tax during implementation, including:

- Developed a communication and outreach plan for taxpayers that might owe the new tax on medical device sales.
- Disseminated information regarding the new filing requirements in many different forms, including adding information to the IRS website and giving seminars at IRS Nationwide Tax Forums.
- Prepared high-level talking points for executives and phone scripts for telephone assistants responding to taxpayer questions.
- Revised Form 720 to reflect the tax and updated the associated Form 720 instructions, which included adding a paragraph describing the tax in the ‘What’s New’ section on the first page and referencing the statute and regulations associated with the new tax filing requirements.

However, the IRS still cannot identify the population of medical device manufacturers registered with the FDA that are required to file a Form 720 and pay the medical device excise tax. Businesses involved in the production and distribution of medical devices intended for commercial distribution in the United States are required to register annually with the FDA.<sup>10</sup> The IRS has analyzed medical device registration data obtained from the FDA. However, this data cannot be used to definitively identify manufacturers subject to the medical device excise tax reporting and payment requirements. Specific exemptions, other safe harbors,<sup>11</sup> and retail exemptions apply, and therefore not all businesses registered with the FDA are engaged in taxable sales of medical devices. For example, the IRS evaluated the FDA’s registration data as of May 21, 2013, and identified 16,370 businesses with registered medical devices but estimated

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<sup>10</sup> 21 Code of Federal Regulations part 807.

<sup>11</sup> Devices or classes of devices that are considered to be of a type generally purchased by the general public at retail for individual use. For example, devices that qualify as durable medical equipment, prosthetics, orthotics, or supplies for which payment is available on a purchase basis under Medicare Part B payment rules.



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that only 4,500 to 7,800 of these businesses may sell taxable medical devices. The IRS concluded that a more precise estimate of businesses selling taxable devices could not be made because the FDA's requirements for registering are much different than requirements for paying the excise tax. In addition, the Employer Identification Number<sup>12</sup> is not captured as part of the FDA's registration process. This increases the difficulty for the IRS to compare tax returns filed with the FDA's registration data to identify the population of potential nonfilers.

**The North American Industry Classification System code is unreliable for use to identify businesses that may be subject to excise tax reporting and payment**

The North American Industry Classification System (NAICS) is a system for classifying business establishments by type of economic activity. The NAICS is the standard used by Federal agencies in classifying business establishments for the purpose of collecting, analyzing, and publishing statistical data related to the U.S. business economy. Businesses are required to select from a list of principal business activities and enter the associated NAICS code on the business income tax returns (*e.g.*, Form 1120, *U.S. Corporation Income Tax Return*). For example, businesses that are engaged in the manufacturing of medical equipment and supplies are supposed to enter NAICS Code 339110 (*Medical Equipment and Supplies Manufacturing*) on their tax return. However, our testing found that the use of the NAICS code does not accurately identify businesses engaged in the sale of medical devices. For example:

- **The NAICS Code 339110 is not the only NAICS code used by manufacturers of medical devices.** We identified 2,007 of 2,965 businesses filing a Form 720 during quarters ending March 31 and June 30, 2013, for the medical device excise tax reported a NAICS code other than 339110. For example, the other NAICS codes reported by the manufacturers included NAICS Code 454390 (*Other Direct Selling Establishments*); NAICS Code 423990 (*Other Miscellaneous Durable Goods*); and NAICS Code 339900 (*Other Miscellaneous Manufacturing*).
- **The NAICS code does not always signify a business that is engaged in taxable sales of medical devices.** We identified 5,443 businesses filing Tax Year 2012 income tax returns reporting NAICS Code 339110 that did not file a Form 720 in Tax Year 2013 reporting the medical device excise tax.

Furthermore, a prior Treasury Inspector General for Tax Administration (TIGTA) report on the excise tax on indoor tanning services<sup>13</sup> cited concerns about the reliability of NAICS codes. These concerns included that the IRS does not require entry of the NAICS code on filed tax returns and that the codes cannot be relied upon as being correct. This report further concluded

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<sup>12</sup> The Employer Identification Number is a unique nine-digit number issued by the IRS to identify a taxpayer's business account.

<sup>13</sup> TIGTA, Ref. No. 2011-40-115, *Affordable Care Act: The Number of Taxpayers Filing Tanning Excise Tax Returns Is Lower Than Expected* (Sept. 2011).



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that the IRS faced difficulties in identifying the population of businesses subject to the tanning excise tax. With regard to nonfiling of the required Forms 720, the IRS recognized that some taxpayers that had not filed required returns may have simply been unaware of the new tax rather than willfully ignoring the law. In June 2011, the IRS issued notices to approximately 14,000 taxpayers that were identified through various data sources as potentially owing the tanning excise tax but had not filed a Form 720 during the third or fourth quarters of Calendar Year (CY) 2010.

The IRS indicated that the experience realized with the indoor tanning tax is not relevant to the medical device excise tax due to the dissimilarity of the industries and taxpayers involved. IRS management indicated that they are pursuing the use of the FDA registration database, Form 637, *Application for Registration (For Certain Excise Tax Activities)*, registration information, and other information to identify and perfect information on potential medical device nonfilers. Once the population of nonfilers is identified, the IRS will evaluate alternatives, which may include the issuance of a notice.

**Tax returns filed and taxes reported are lower than original estimates**

Our review found that both the number of Forms 720 filed and the amount of the medical device excise tax revenue being reported are lower than estimated. Figure 2 shows that the IRS processed 5,107 Forms 720 with reported excise taxes of \$913.4 million for the quarters ending March 31 and June 30, 2013. The IRS estimated between 9,000 and 15,600 quarterly Forms 720 tax returns with excise tax revenue of \$1.2 billion for this same period.

**Figure 2: Quarterly Return Filings  
and Medical Device Excise Tax Revenues**

Quarter (period ended)	Returns Filed	Taxes Reported
March 31, 2013	2,729	\$478.6 million
June 30, 2013	2,378	\$434.8 million
<b>Total</b>	<b>5,107</b>	<b>\$913.4 million</b>

Source: TIGTA's analysis of the Business Return Transaction File (BRTF)<sup>14</sup> as of September 5, 2013.

**Recommendation**

**Recommendation 1:** The Commissioner, Small Business/Self-Employed Division, should continue refining its compliance strategy to include actions that can be taken to identify noncompliant manufacturers. This should include an assessment of the benefit of issuing notices

<sup>14</sup> IRS database that contains tax return information originally filed by the taxpayer and transcribed from Forms 720.



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to potential nonfilers of the medical device excise tax identified from the manufacturers registered with the FDA.

**Management’s Response:** The IRS agreed with this recommendation. The IRS is considering alternative strategies for identifying noncompliant medical device manufacturers and may issue notices to potential nonfilers if there appears to be a benefit to future tax administration.

***Processing Controls Do Not Ensure the Accuracy of Medical Device Excise Tax Figures Reported on Paper-Filed Forms 720***

Our analysis of 5,107 Forms 720 processed for the quarters ending March 31 and June 30, 2013, identified discrepancies in the amount of the medical device excise tax and/or taxable sales amount captured from 276 paper-filed tax returns. We identified medical device excise tax discrepancies totaling almost \$117.8 million when comparing the excise tax amount captured by the IRS from the Form 720 to the excise tax amount we calculated. Our calculated excise tax amount was computed by taking the taxable sales amount captured by the IRS from the Form 720 and multiplying this amount by the tax rate (*i.e.*, 2.3 percent).

The discrepancies we identified included instances in which our calculated excise tax amount was less than the amount of tax captured from the Form 720 (potential overstated tax amount) and more than the amount of tax captured from the Form 720 (potential understated tax amount). Figure 3 details the 276 paper-filed Forms 720 for which the tax amount was either overstated or understated by \$100 or more based upon the amount reported or captured for taxable sales.

***Figure 3: Discrepancies on Forms 720 Reporting Medical Device Excise Tax Amounts for Quarters Ending March 31 and June 30, 2013***

Description	Potential Overstated Tax Amount	Potential Understated Tax Amount	Total
Number of Tax Returns	225	51	276
Reported Tax Amount on Forms 720	\$43.3 million	\$2.9 million	\$46.1 million <sup>15</sup>
TIGTA’s Calculated Tax Amount	\$1.7 million	\$79.1 million	\$80.8 million
Total Discrepancy	\$41.6 million	\$76.2 million <sup>16</sup>	\$117.8 million

Source: TIGTA’s analysis of the BRTF as of September 5, 2013.

<sup>15</sup> Total does not equal sum of overstated and understated tax amounts due to rounding.

<sup>16</sup> \*\*\*\*\*1\*\*\*\*\*.



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**The IRS does not systemically verify tax calculations on paper-filed Forms 720**

IRS instructions for Form 720 require taxpayers to enter the total sales price of all taxable medical devices sold during the quarter and the total tax due. The IRS systemically rejects electronically filed (e-filed) Forms 720 when the medical device excise tax amount does not equal the sum of taxable sales multiplied by the 2.3 percent tax rate. However, a similar control is not in place for paper-filed Forms 720. Discrepancies can result from taxpayer errors or tax examiner errors when inputting data from the paper-filed Forms 720 into IRS computers. Our analysis of the 276 paper-filed Forms 720 with discrepancies found that:

- 106 (38 percent) Forms 720 contained a sales price amount with a decimal that was likely excluded, misplaced, or missed during the processing of these tax returns. The IRS indicated that during post-processing actions it identified a transcription problem with the taxable sales recorded during processing that involved a missing or excluded decimal point. For example,

*Taxpayer A enters taxable sales as \$1234567 without a comma or decimal point. During tax return processing, an IRS tax examiner enters this amount as \$12,345.67; however, the actual taxable sales was \$1,234,567.*

The IRS indicated that this type of discrepancy occurred because the Tax Year 2013 Form 720 did not contain a cents column for the taxable sales. The IRS revised Form 720 for Tax Year 2014 to include a cents column to encourage taxpayers to report the taxable sales amount in a dollar and cents format.

- 88 (32 percent) Forms 720 contained an excise tax amount that was the same as the taxable sales amount.
- 82 (30 percent) Forms 720 had no specific pattern in the discrepancy.

IRS management explained that the discrepancies included inaccurate decimal point placement and transcription errors of the taxable sales amount and not errors resulting in actual lost revenue. \*\*\*\*\*2\*\*\*\*\*

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\*\*2\*\*. Otherwise, implementing the changes would result in system downtime and processing delays. However, we noted that the IRS has programmed a systemic check for e-filed returns received through the Modernized e-File system<sup>17</sup> to identify and reject tax returns with discrepancies in tax amounts reported on Form 720.

<sup>17</sup> The Modernized e-File system is the IRS's electronic filing system that enables real-time processing of tax returns while improving error detection, standardizing business rules, and expediting acknowledgements to taxpayers.



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**The IRS calculates tax amount or taxable sales when missing on paper-filed returns**

In addition to the discrepancies in tax amounts, we also found that when a filer does not include the taxable sales or tax amount on a paper-filed Form 720 reporting the medical device excise tax, the IRS identifies these tax returns for correction during the processing of the tax return. Contrary to the processing of e-filed Forms 720, which are systemically rejected when the taxable sales or tax amount is missing, for paper-filed returns the IRS will calculate the missing amount using whichever amount is present (*i.e.*, taxable sales or tax amount). For example, if the tax amount is missing, the IRS calculates it by multiplying the taxable sales amount by 2.3 percent. As of September 4, 2013, the IRS's systemic check for missing medical device sales price or tax amount identified 261 paper-filed returns requiring correction.

The process the IRS follows in calculating missing amounts for the medical device excise tax is not consistent with the IRS's processing procedures for another excise tax. For example, when taxpayers file a Form 720 to report excise tax on tires,<sup>18</sup> the IRS will correspond with the taxpayer to obtain missing information such as the number of tires. When we brought this to IRS management's attention, they explained that paper-filed tax returns are perfected according to taxpayer intent in the IRS's Submission Processing Document Perfection Operation. IRS management also indicated that the IRS has the authority to correspond for missing information. However, if the taxpayer failed to reply, the IRS would ultimately have to calculate the tax based on the information provided on the return and follow the taxpayer's intent.

When the taxable sales or tax amount is missing or the tax return contains potential discrepancies in tax amount, the IRS cannot ensure the accuracy of the tax return information and may post an incorrect tax amount to the taxpayer's account. This could lead to erroneously issued refunds or erroneous tax assessments.

***Recommendations***

**Recommendation 2:** The Commissioner, Small Business/Self-Employed Division, should conduct a review of the 276 paper-filed tax returns we identified with a discrepancy between the excise tax amount captured by the IRS from the Form 720 and the excise tax amount we calculated as being owed to determine the proper excise tax owed.

**Management's Response:** The IRS agreed with this recommendation. The IRS indicated that it completed a review of approximately two-thirds of the 276 paper-filed returns identified by TIGTA as having a discrepancy. The review included returns with both overstatements and understatements; however, these discrepancies had no tax consequence. The payments and deposits on those returns equaled the amount of

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<sup>18</sup> A taxable tire is any tire of the type used on highway vehicles if wholly or partially made of rubber and if marked according to Federal regulations for highway use.



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reported tax. The IRS indicated that since two-thirds of the 276 identified returns were reviewed and no change to the reported tax was found, no further action will be taken with regard to those returns.

The Commissioner, Wage and Investment Division, should:

**Recommendation 3:** Establish a process for paper-filed Forms 720 to math verify the accuracy of the medical device excise tax amount and correspond with taxpayers on the corrected taxable amount.

**Management's Response:** The IRS agreed with this recommendation. The IRS will identify the programming changes needed to improve math verification for paper-filed Forms 720 and will determine if those changes can be accomplished within budgetary and resource constraints. Dependent on the deployment of the programming changes, the IRS will identify those returns with errors and correspond with the taxpayers to correct them. In the event the requested programming changes are not funded, the IRS will consider this action closed upon completion of the cost analysis and funding decision.

**Recommendation 4:** Initiate a process to correspond with taxpayers to obtain missing taxable sales or tax amounts during the processing of paper-filed Forms 720 reporting the medical device excise tax.

**Management's Response:** The IRS agreed with this recommendation. Dependent on the deployment of programming changes discussed above, the IRS will implement procedures for corresponding with taxpayers to obtain missing information needed to accurately process paper-filed Forms 720. In the event the requested programming changes are not funded, the IRS will consider this action closed upon completion of the cost analysis and funding decision.

### ***Taxpayers Were Erroneously Assessed Failure to Deposit Penalties During the Penalty Relief Period***

The IRS erroneously assessed 219 FTD penalties during the period July 8 to December 9, 2013, totaling \$706,753 against businesses filing a Form 720 for the quarters ending March 31 and June 30, 2013, which was designated as part of the penalty relief period. The IRS and the U.S. Department of the Treasury recognized that many medical device manufacturers would still be preparing their systems to comply with the medical device excise tax when the tax went into effect on January 1, 2013, including the requirement to make semimonthly deposits. As a result, the IRS issued Notice 2012-77, *Interim Guidance and Request for Comments; Medical Device Excise Tax; Manufacturers Excise Taxes; Constructive Sale Price; Deposit Penalties*, on December 5, 2012, which provided temporary relief from the penalty for manufacturers who fail to make timely deposits during the first three quarters of CY 2013 so long as the taxpayer shows a good faith effort to comply.



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As of January 8, 2014, the IRS reversed 133 of the 219 penalty assessments. The IRS advised us that these penalty reversals may have occurred due to taxpayer responses to assessment notices. When we alerted the IRS of the 86 unreversed penalty assessments, it agreed that the penalties were assessed in error because of employee error and the fact that the Internal Revenue Manual<sup>19</sup> was not properly updated. As a result, IRS management reversed the penalties and issued apology letters to the 86 affected taxpayers we identified. In addition, IRS management reminded employees working the FTD penalty assessments of the temporary FTD penalty relief and updated the Internal Revenue Manual to reflect that penalties would not be assessed in the first three quarters of CY 2013 so long as the taxpayer shows a good faith effort to comply. Finally, the IRS obtained an extract from the Master File<sup>20</sup> listing accounts that contained an FTD penalty associated with the medical device excise tax for the first three quarters of CY 2013, reversed erroneous penalty assessments, and issued apology letters to the affected taxpayers.

***Processes Were Timely Developed to Review Applications for Medical Device Excise Tax-Exempt Registrations***

As of December 5, 2013, the IRS had approved Forms 637 for 1,823 of the 2,295 manufacturers applying for tax-exempt status. The IRS timely ensured that the manufacturers applying for tax-exempt status were engaged in the manufacturing and/or distribution of medical devices and had a satisfactory tax filing history. Our review of a statistically valid sample of 77 manufacturers<sup>21</sup> with approved Forms 637 found that the IRS reviewed the exempt registrations within the required 60-day time frame.<sup>22</sup> In addition, the IRS correctly ensured that the businesses were engaged in the manufacturing and/or distribution of medical devices and had a satisfactory tax filing history.<sup>23</sup>

Under certain conditions, manufacturers may engage in a nontaxed sale of medical devices that would otherwise be taxed. Tax-free sales include medical devices sold to a buyer for the purpose of further manufacture or resale to a buyer for further manufacture as well as sales to a buyer with a place of business in the United States for export or for resale to a second purchaser for

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<sup>19</sup> The IRS's official policies and procedures.

<sup>20</sup> The IRS database that stores various types of taxpayer account information. This database includes individual, business, and employee plans and exempt organizations data.

<sup>21</sup> We used attribute sampling to calculate the minimum sample size of 77 approved Forms 637 based on a confidence level of 90 percent, an expected rate of occurrence of 5 percent, and a precision rate of  $\pm 4$  percent.

<sup>22</sup> Only \*\*\*\*\*] \*\*\*\*\*; therefore, based on a one-sided 90 percent confidence level, we are 90 percent confident that at most 90 Forms 637 were not timely processed.

<sup>23</sup> We did not identify any exceptions from a sample of 77 approved Forms 637; therefore, based on a one-sided 90 percent confidence level, we are 90 percent confident that at most 54 Forms 637 have invalid application approvals.





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export. To qualify as a tax-free sale, both parties must be registered with the IRS using Form 637.

In anticipation of an influx of manufacturers applying for tax-exempt registrations, the IRS developed a provisional registration approval process to expedite evaluation of the tax-exempt status applications. This process included revising Form 637 and updating the associated instructions to permit businesses to use Form 637 to request a registration for nontaxed sales of medical devices. For the provisional registration, the IRS review process did not include a field visit or inspection of taxpayer records. The IRS included an addendum to the registration letter to the manufacturer to advise that IRS approval was conditional and subject to further review.

Furthermore, IRS guidance requires a revenue agent or tax examiner within the Small Business/Self-Employed Division to complete evaluations of Form 637 applications within 60 days from the date of assignment. The two primary factors, whether provisional or not, considered during the application review process include the “Activity Test” and the “Satisfactory Tax History Test.”

- **Activity Test:** The taxpayer’s business operations show that the applicant is regularly engaged in the activity for which the registration is requested.
- **Satisfactory Tax History Test:** The taxpayer has a satisfactory tax filing history including deposit, payment, reporting, and claims for all Federal taxes.

Accurately processing approvals for tax-exempt registration provides the IRS a reasonable basis for entrusting these manufacturers to engage in nontaxed sales of medical devices that would otherwise be taxed.



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## Appendix I

### *Detailed Objective, Scope, and Methodology*

Our overall objective was to assess the effectiveness of IRS processing of tax returns reporting the medical device excise tax and efforts to identify taxpayer noncompliance. To accomplish this objective, we:

- I. Evaluated the effectiveness of IRS controls to verify the accuracy of the medical device excise tax amount reported by manufacturers on Form 720, *Quarterly Federal Excise Tax Return*.
  - A. Reviewed the IRS's Internal Revenue Manual<sup>1</sup> and Modernized e-File system<sup>2</sup> business rules and met with IRS personnel to identify processing controls to ensure the accuracy of the medical device excise tax amount reported on Form 720.
  - B. Compared the filing requirements between paper- and e-filed Forms 720 to identify inconsistencies between the two filing methods.
  - C. Conducted a walkthrough at the IRS Submission Processing Site in Covington, Kentucky, to observe measures taken by the Error Resolution and Document Perfection Operation functions to ensure the accuracy of the medical device excise tax amounts reported on Forms 720 during processing.
  - D. Reviewed management information reports to identify the volume of error conditions associated with Forms 720 reporting the medical device excise tax.
  - E. Assessed the accuracy of the medical device excise tax amount reported on Form 720.
    1. Identified 5,107 Forms 720 processed for the quarters ending March 31 and June 30, 2013, reporting medical device excise taxes from the BRTF<sup>3</sup> as of September 5, 2013.
    2. Evaluated the accuracy of the tax amount recorded on the BRTF.
      - a) Calculated the medical device excise tax based on the taxable sales recorded on the BRTF multiplied by the tax rate of 2.3 percent.

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<sup>1</sup> The IRS's official policies and procedures.

<sup>2</sup> The Modernized e-File system is the IRS's electronic filing system that enables real-time processing of tax returns while improving error detection, standardizing business rules, and expediting acknowledgements to taxpayers.

<sup>3</sup> IRS database that contains tax return information originally filed by the taxpayer and transcribed from Forms 720.



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- b) Compared the excise tax amount calculated in Step I.E.2.a to the medical device excise tax recorded on the BRTF and posted to the Master File.<sup>4</sup>
  - c) Identified 276 Forms 720 for which the medical device excise tax amount was either overstated or understated by \$100 or more based upon the reported taxable sales amount, resulting in a potential difference of \$117.8 million in excise taxes.
- II. Assessed the effectiveness of IRS efforts to promote taxpayer compliance and identify nonfilers.
- A. Identified IRS communication materials available to inform the business community about the medical device excise tax and return filing and reporting requirements.
  - B. Discussed with IRS management the post-processing compliance measures as planned for the medical device excise tax.
  - C. Discussed with IRS management their efforts to identify nonfilers.
  - D. Assessed the use of NAICS<sup>5</sup> codes to identify nonfilers.
    - 1. Identified 6,266 Tax Year<sup>6</sup> 2012 tax returns with gross receipts greater than \$0 reporting NAICS Code 339110 (*Medical Equipment and Supplies Manufacturing*).
    - 2. Of the 6,266 Tax Year 2012 tax returns identified in Step II.D.1, determined that 5,575 Tax Year 2012 tax returns did not report the medical device excise tax on a Form 720 for the quarters ending March 31 and June 30, 2013, processed through September 5, 2013.
    - 3. Of the 5,575 Tax Year 2012 tax returns identified in Step II.D.2, determined that 5,443 Tax Year 2012 tax returns were not associated with a business approved by the IRS for tax-free sales (*i.e.*, the IRS had no record of Form 637, *Application for Registration (For Certain Excise Tax Activities)*, for these taxpayers).

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<sup>4</sup> The IRS database that stores various types of taxpayer account information. This database includes individual, business, and employee plans and exempt organizations data.

<sup>5</sup> The Office of Management and Budget's NAICS is a system for classifying business establishments by type of economic activity. The NAICS is the standard used by Federal statistical agencies in classifying business establishments for the purpose of collecting, analyzing, and publishing statistical data related to the U.S. business economy.

<sup>6</sup> A 12-month accounting period for keeping records on income and expenses used as the basis for calculating the annual taxes due.



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- III. Evaluated the effectiveness of IRS procedures to assess eligibility requirements for manufacturers requesting exemption to the excise tax and to ensure that the applications were timely processed.
- A. Reviewed the Internal Revenue Manual to identify the criteria for determining whether a business should be granted tax-exempt status during the Form 637 review and approval process.
  - B. Discussed with IRS management the provisional Form 637 application approval measures to determine whether it lessened the review process required by the Internal Revenue Manual.
  - C. Obtained from the IRS a listing of 2,295 businesses filing a Form 637 requesting a Letter of Registration for tax-free sales and selected a statistically valid random sample of 77 manufacturers<sup>7</sup> from the 1,823 businesses receiving an approved registration for tax-exempt medical device excise tax sales during the period January 1 through December 5, 2013.
    - 1. Reviewed IRS documentation of the Form 637 registration review and determined whether the manufacturer met the activity requirement<sup>8</sup> for the registration and had a satisfactory tax filing, deposit, payment, and claim history for all Federal taxes of the applicant/registrant.
    - 2. Determined that all 77 application approvals for tax-free sales were supported by a review of the business activity and tax filing history. Based on a one-sided 90 percent confidence level, we are 90 percent confident that at most 54 Forms 637 in the population have invalid application approvals.
    - 3. Compared the completion date to the assignment date and determined that \*\*\*\*\*1\*\*\*\*\*. Based on a one-sided 90 percent confidence level, we are 90 percent confident that at most 90 Forms 637 in the population were not timely processed.

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<sup>7</sup> We used attribute sampling to calculate the minimum sample size of 77 approved Forms 637 based on a confidence level of 90 percent, an expected rate of occurrence of 5 percent, and a precision rate of  $\pm 4$  percent. We selected a statistically valid random sample to help quantify the extent of the problem over the entire population. A contract statistician assisted with developing our sampling projections.

<sup>8</sup> The taxpayer is regularly engaged, or will be regularly engaged, within a reasonable time, in the activity for which the registration is being requested (*i.e.*, tax-free sales of medical devices).



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- IV. Determined if the IRS had effective processes and procedures to prevent erroneous assessments of the FTD penalty.
- A. Identified from the Business Master File<sup>9</sup> 221 FTD penalties totaling \$707,203 assessed through December 28, 2013, on Forms 720 reporting the medical device excise tax for the quarters ending March 31 and June 30, 2013, processed through September 5, 2013.
- B. Of the 221 FTD penalties identified in Step IV.A, determined that 219 FTD penalties totaling \$706,753 were erroneously assessed.

**Data validation methodology**

During this review, we relied on Tax Year 2013 Form 720 data extracted from the BRTF for Processing Year<sup>10</sup> 2013 as of September 5, 2013, and taxpayer account transaction data extracted from the Business Master File through the end of Processing Year 2013 that were provided by the TIGTA Office of Investigations' Strategic Data Services. To assess the reliability of computer-processed data, programmers within Strategic Data Services validated the data extract files, while we ensured that each data extract contained the specific data elements we requested and that the data elements were accurate. For example, we reviewed judgmental samples<sup>11</sup> of the data extracts and verified that the data in the extracts were the same as the data captured in the IRS's Integrated Data Retrieval System.<sup>12</sup> We also validated the IRS's listing of Form 637 applications for the medical device excise tax by comparing selected data fields for our statistically valid sample of records to the case file information obtained from the Issue Management System.<sup>13</sup> As a result of our testing, we determined the data used in our review were reliable.

**Internal controls methodology**

Internal controls relate to management's plans, methods, and procedures used to meet their mission, goals, and objectives. Internal controls include the processes and procedures for planning, organizing, directing, and controlling program operations. They include the systems for measuring, reporting, and monitoring program performance. We determined that the following internal controls were relevant to our audit objective: IRS communication and outreach efforts to ensure that tax returns were accurately and timely filed, policies and

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<sup>9</sup> The IRS database that consists of Federal tax-related transactions and accounts for businesses. These include employment taxes, income taxes on businesses, and excise taxes.

<sup>10</sup> The calendar year in which the tax return or document is processed by the IRS.

<sup>11</sup> A judgmental sample is a nonstatistical sample, the results of which cannot be used to project to the population.

<sup>12</sup> IRS computer system capable of retrieving or updating stored information. It works in conjunction with a taxpayer's account records.

<sup>13</sup> The Issue Management System is designed to be used by revenue agents and specialists during the process of performing reviews of Form 637 applications. It supports issue identification, tracking, and management through a suite of automated tools.



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procedures to ensure that taxpayers are filing required returns and paying the correct amount of tax, and actions taken to ensure that approved applications for exemption to the tax are properly processed. TIGTA's contract statistician assisted with developing projections of potentially invalid and untimely Form 637 application approvals.



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**Appendix II**

*Major Contributors to This Report*

Russell P. Martin, Acting Assistant Inspector General for Audit (Returns Processing and Account Services)  
Diana M. Tengesdal, Acting Director  
Darryl Roth, Audit Manager  
Van Warmke, Lead Auditor  
Kyle Bambrough, Senior Auditor  
Jack Laney Jr., Auditor  
Kevin O’Gallagher, Information Technology Specialist  
Steven Vandigriff, Information Technology Specialist



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## **Appendix III**

### *Report Distribution List*

Commissioner C  
Office of the Commissioner – Attn: Chief of Staff C  
Deputy Commissioner for Services and Enforcement SE  
Deputy Commissioner, Wage and Investment Division SE:W  
Deputy Commissioner, Small Business/Self-Employed Division SE:S  
Director, Affordable Care Act Office SE:ACA  
Director, Customer Account Services, Wage and Investment Division SE:W:CAS  
Director, Specialty Programs SE:S:SP  
Director, Submission Processing, Wage and Investment Division SE:W:CAS:SP  
Chief Counsel CC  
National Taxpayer Advocate TA  
Director, Office of Legislative Affairs CL:LA  
Director, Office of Program Evaluation and Risk Analysis RAS:O  
Office of Internal Control OS:CFO:CPIC:IC  
Audit Liaisons:  
    Commissioner, Small Business/Self-Employed Division SE:S  
    Chief, Program Evaluation and Improvement, Wage and Investment Division  
    SE:W:S:PEI





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## Appendix IV

### *Outcome Measures*

This appendix presents detailed information on the measurable impact that our recommended corrective actions will have on tax administration. These benefits will be incorporated into our Semiannual Report to Congress.

#### **Type and Value of Outcome Measure:**

- Reliability of Information – Potential; \$117.8 million<sup>1</sup> in excise taxes on 276 taxpayer accounts that are incorrectly recorded on the IRS's BRTF<sup>2</sup> for Tax Year<sup>3</sup> 2013 (see page 7).

#### **Methodology Used to Measure the Reported Benefit:**

We conducted reliability testing of the 5,107 Forms 720, *Quarterly Federal Excise Tax Return*, reporting the medical device excise tax as part of our evaluation of IRS controls to verify the accuracy of the medical device excise tax amount on the IRS's BRTF. We identified 276 paper-filed Forms 720 for the quarters ending March 31 and June 30, 2013, processed through September 5, 2013, that contained discrepancies in the amount of the medical device excise tax or taxable sales amount. We identified total discrepancies, in terms of the medical device excise tax amount, of almost \$117.8 million by comparing the excise tax amount captured by the IRS from the Form 720 to the excise tax amount we calculated. We based our calculated excise tax amount on the taxable sales amount captured by IRS from the Form 720 and multiplied this amount by the tax rate (*i.e.*, 2.3 percent).

For these 276 returns, the calculated tax amount was either overstated or understated by \$100 or more. This includes 225 returns for which our calculated excise tax amount was less than the amount of tax captured from the Form 720 (potential overstated tax amount) with a total difference of \$41.6 million and 51 returns for which our calculated excise tax amount was more than the amount of tax captured from the Form 720 (potential understated tax amount) with a total difference of \$76.2 million. We added the \$41.6 million to the \$76.2 million to arrive at the \$117.8 million.

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<sup>1</sup> \*\*\*\*\* ] \*\*\*\*\*

<sup>2</sup> IRS database that contains tax return information originally filed by the taxpayer and transcribed from Forms 720.

<sup>3</sup> A 12-month accounting period for keeping records on income and expenses used as the basis for calculating the annual taxes due.



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**Type and Value of Outcome Measure:**

- Taxpayer Rights and Entitlements – Actual; \$378,835 in erroneous FTD penalty assessments on 86 taxpayer accounts in Tax Year 2013 (see page 11).

**Methodology Used to Measure the Reported Benefit:**

The IRS processed 5,107 Forms 720 reporting the medical device excise tax for quarters ending March 31 and June 30, 2013, through September 5, 2013. We identified 221 FTD penalties totaling \$707,203 that were assessed on the Forms 720 through December 28, 2013. From this population, we determined that 219 FTD penalties totaling \$706,753 were assessed erroneously since the taxpayers were provided temporary relief from the penalty if they failed to make timely deposits during the first three quarters of CY 2013. We found that 133 of the 219 penalty assessments had been reversed. However, 86 (39 percent) of the 219 erroneous FTD penalties totaling \$378,835 remained on the taxpayer accounts as of January 8, 2014.



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**Appendix V**

*Management's Response to the Draft Report*



COMMISSIONER  
SMALL BUSINESS/SELF-EMPLOYED DIVISION

DEPARTMENT OF THE TREASURY  
INTERNAL REVENUE SERVICE  
WASHINGTON, D.C. 20224

JUN 20 2014

MEMORANDUM FOR MICHAEL E. MCKENNEY  
ACTING DEPUTY INSPECTOR GENERAL FOR AUDIT

FROM: Karen Schiller  
Commissioner, Small Business/Self-Employed Division

SUBJECT: Draft Audit Report – The Affordable Care Act: An Improved  
Strategy is Needed to Ensure Accurate Reporting and Payment  
of the Medical Device Excise Tax (Audit # 201340332)

Thank you for the opportunity to review your draft report. We agree with your recommendations and appreciate your acknowledgement of the efforts we have already made to implement this provision. These efforts include developing a comprehensive implementation plan, revising forms and instructions, delivering education and outreach, and training personnel. As a result, we were prepared for the initial filing year challenges associated with the new excise tax on medical devices.

As your report notes, the IRS took prompt action to address nearly 2,000 Forms 637, "Application for Registration", for medical device manufacturers. We modified existing procedures to expedite the registration process. As a result, medical device businesses continued operation without delays or burden due to implementation of the new tax.

We appreciate the audit team bringing to our attention some Failure to Pay penalties erroneously assessed during the penalty relief period. As you pointed out in your report, we have already taken appropriate steps to remedy the situation. We have also updated our procedures and guidance to help prevent future occurrences.

Your report acknowledges the difficulty in identifying the population of medical device manufacturers registered with the Food and Drug Administration (FDA) that may be required to file a Form 720 and pay the medical device excise tax. While differing formats make it very difficult to match FDA data to IRS data, we are currently working on innovative approaches for using this data to identify potential non-filers.



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Your report also identifies discrepancies in the medical device excise tax and/or taxable sales amount captured from the paper-filed Forms 720. IRS reviewed these discrepancies and found that they did not result in any lost tax revenue. However, we have already taken action to change Form 720 entry fields to address this problem in the future.

We are in agreement with the outcome measures mentioned in your report.

If you have any questions, please contact me, or a member of your staff may contact John H. Imhoff, Director, Specialty Programs, Small Business/Self-Employed Division at (215) 861-1176.

Attachment



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Attachment

**RECOMMENDATION 1:**

The Commissioner, Small Business/Self-Employed Division, should continue refining its compliance strategy to include actions that can be taken to identify noncompliant manufacturers. This should include an assessment of the benefit of issuing notices to potential non-filers of the medical device excise tax identified from the manufacturers registered with the FDA.

**CORRECTIVE ACTION:**

IRS is considering alternative strategies for identifying noncompliant medical device manufacturers. IRS may issue notices to potential non-filers if there appears to be a benefit to future tax administration.

**IMPLEMENTATION DATE:**

December 15, 2015

**RESPONSIBLE OFFICIAL(S):**

Director, Specialty Programs, Excise Tax Office, Small Business/Self-Employed Division

**CORRECTIVE ACTION MONITORING PLAN:**

The IRS will monitor this corrective action as part of our internal management system of controls.

**RECOMMENDATION 2:**

The Commissioner, Small Business/Self-Employed Division, should conduct a review of the 276 paper-filed tax returns we identified with a discrepancy between the excise tax amount captured by the IRS from the Form 720 to the excise tax amount we calculated as being owed to determine the proper excise tax owed.

**CORRECTIVE ACTION:**

SB/SE Excise Tax and W&I completed a joint review of approximately two-thirds of the 276 paper-filed returns identified by TIGTA as having a discrepancy. The review included returns with both overstatements and understatements. Using similar review methodologies, SB/SE Excise Tax and W&I found the same discrepancies; however, these discrepancies had no tax consequence. The payments and deposits on those returns equaled the amount of reported tax. Since two-thirds of the 276 identified returns were reviewed and no change to the reported tax was found, no further action will be taken with regard to those returns.

**IMPLEMENTATION DATE:**

Completed



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**RESPONSIBLE OFFICIAL(S):**

N/A

**CORRECTIVE ACTION MONITORING PLAN:**

N/A

**RECOMMENDATION 3:**

The Commissioner, Wage and Investment Division, should establish a process for paper-filed Forms 720 to math verify the accuracy of the medical device excise tax amount and correspond with taxpayers on the corrected taxable amount.

**CORRECTIVE ACTION:**

We will identify the programming changes needed to improve the math verification for paper-filed Forms 720, Quarterly Federal Excise Tax Return, and will determine if those changes can be accomplished within budgetary and resource constraints. Dependent on deployment of the programming changes, we will identify those returns with errors and correspond with the taxpayers to correct them. In the event the requested programming changes are not funded, we will consider this action closed upon completion of the cost analysis and funding decision.

**IMPLEMENTATION DATE:**

February 15, 2016

**RESPONSIBLE OFFICIAL:**

Director, Submission Processing, Customer Account Services, Wage & Investment Division

**CORRECTIVE ACTION MONITORING PLAN:**

The IRS will monitor this corrective action as part of our internal management system of controls.

**RECOMMENDATION 4:**

The Commissioner, Wage and Investment Division should initiate a process to correspond with taxpayers to obtain missing taxable sales or tax amounts during the processing of paper-filed Forms 720 reporting the medical device excise tax.

**CORRECTIVE ACTION:**

Dependent on the deployment of programming changes discussed in the previous corrective action, we will implement procedures for corresponding with taxpayers to obtain missing information needed to accurately process paper-filed Forms 720. In the event the requested programming changes are not funded, we will consider this action closed upon completion of the cost analysis and funding decision.



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**IMPLEMENTATION DATE:**

February 15, 2016

**RESPONSIBLE OFFICIAL:**

Director, Submission Processing, Customer Account Services, Wage and Investment  
Division

**CORRECTIVE ACTION MONITORING PLAN:**

The IRS will monitor this corrective action as part of our internal management system of  
controls.