

data in such a way that the data do not represent what actually occurred. Examples of falsification of data include, but are not limited to, the following:

(A) Creating data that were never obtained (e.g., making up data or results and recording or reporting them; reporting enrollment in a study of a subject who did not exist; forging the signature on an informed consent form);

(B) Altering data by replacing original data with something different that does not accurately reflect study conduct or results (e.g., changing a laboratory measurement to a less extreme deviation from normal);

(C) Recording or obtaining data from a specimen, sample, or test whose origin is not accurately described or in a way that does not accurately reflect the data (e.g., changing the date of a specimen, sample, or test; adding a substance not called for in the study to a specimen or sample; identifying a specimen, sample, or test as coming from a specific subject when it came from a source other than the subject);

(D) Omitting data that were obtained and would be appropriate for recording based on study design and conduct (e.g., not recording exclusionary medical history or prohibited concomitant medications or treatments; omitting data so that a statistical analysis yields a result that would not have been obtained had all data been analyzed).

(ii) The term *data* includes, but is not limited to, individual facts, tests, specimens, samples, results, statistics, items of information, or statements made by individuals.

(2) Sponsors should not report errors (e.g., typographical errors, transposed numbers or characters) to FDA under paragraph (d) of this section.

Dated: February 12, 2010.

**Leslie Kux,**

*Acting Assistant Commissioner for Policy.*

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**BILLING CODE 4160-01-S**

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## POSTAL REGULATORY COMMISSION

### 39 CFR Part 3050

[Docket No. RM2010-8; Order No. 406]

#### Periodic Reporting

**AGENCY:** Postal Regulatory Commission.

**ACTION:** Advance notice of proposed rulemaking; availability of rulemaking petition.

**SUMMARY:** The Commission is noticing a Postal Service petition proposing a change in transportation cost system

sampling. The proposal involves distributing rail costs using inter-BMC highway distribution factors. This notice briefly describes the Postal Service's rationale for proposing this change and addresses procedural steps associated with the petition.

**DATES:** Comments are due: February 24, 2010.

**ADDRESSES:** Submit comments electronically via the Commission's Filing Online system at <http://www.prc.gov>. Commenters who cannot submit their views electronically should contact the person identified in **FOR FURTHER INFORMATION CONTACT** by telephone for advice on alternatives to electronic filing.

**FOR FURTHER INFORMATION CONTACT:** Stephen L. Sharfman, General Counsel, 202-789-6820 or [stephen.sharfman@prc.gov](mailto:stephen.sharfman@prc.gov).

**SUPPLEMENTARY INFORMATION:**

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#### I. Background

On February 9, 2010, the Postal Service filed a petition to initiate an informal rulemaking proceeding to consider a change in the analytical methods approved for use in periodic reporting.<sup>1</sup> The Postal Service labels its proposal "Proposal One" because it intends that it relate to the FY 2010 rather than the FY 2009 compliance reporting cycle. Proposal One seeks authorization from the Commission to immediately eliminate the rail portion of the Transportation Cost System (TRACS) sampling, and proposes instead to distribute rail costs using the Inter-BC highway distribution factors.

The Postal Service states that as part of a realignment of its transportation and distribution systems, it is shifting much of its transportation needs from rail to truck. Because rail costs are rapidly dwindling, it proposes to eliminate TRACS rail sampling, and to use the TRACS inter-BMC distribution in place of the Rail distribution key in Cost Segment 14. Table 1 of the supporting material accompanying the Petition (Proposal One) shows that Freight Rail and Rail Plant Load costs are expected to decline by 75 percent from FY 2009 to FY 2010, when they will amount to less than \$15 million. *Id.*, Proposal One, at 1. Table 2 shows that substituting the inter-BMC distribution key for the Rail

distribution key in FY 2009 would have had a small impact on the share of Segment 14 costs borne by each market dominant product. *Id.* at 2. The Postal Service comments that the impact will be *de minimis* in FY 2010 when Rail costs will make up a much smaller share of Segment 14 costs. The Postal Service states its desire to make the change before Quarter 3 of FY 2010 makes more efficient use of its data collection resources. *Id.*

#### II. Procedural Matters

The Commission sets February 24, 2010 as the due date for public comments. The Commission will determine the need for reply comments after reviewing the initial comments received.

Kenneth Moeller is designated as the Public Representative to represent the interests of the general public in this proceeding.

#### III. Ordering Paragraphs

*It is ordered:*

1. The Petition of the United States Postal Service Requesting Initiation of a Proceeding to Consider a Proposed Change in Analytic Principles (Proposal One), filed February 9, 2010, is granted.

2. The Commission establishes Docket No. RM2010-8 to consider the matters raised by the Postal Service's Petition.

3. Interested persons may submit comments on Proposal One no later than February 24, 2010.

4. Pursuant to 39 U.S.C. 505, Kenneth Moeller is appointed to serve as the Public Representative representing the interests of the general public.

5. The Secretary shall arrange for publication of this notice in the **Federal Register**.

By the Commission.

**Shoshana M. Grove,**  
*Secretary.*

[FR Doc. 2010-3225 Filed 2-18-E8; 8:45 am]

**BILLING CODE 7710-FW-S**

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## ENVIRONMENTAL PROTECTION AGENCY

### 40 CFR Parts 80, 85, and 86

[EPA-HQ-OAR-2010-0052; FRL-9113-8]

RIN 2060-AI23; 2060-AQ12

#### Tier 2 Light-Duty Vehicle and Light-Duty Truck Emission Standards and Gasoline Sulfur Control Requirements (Section 610 Review)

**AGENCY:** Environmental Protection Agency (EPA).

<sup>1</sup> Petition of the United States Postal Service Requesting Initiation of a Proceeding to Consider a Proposed Change in Analytic Principles (Proposal One), February 9, 2010 (Petition).