FEDERAL RAILROAD ADMINISTRATION
Post-Accident Toxicological Testing for Non-Controlled Substances (49 CFR 219)
SUPPORTING JUSTIFICATION
OMB No. 2130-XXXX

Summary of Submission

- The information collection associated with this proposed rule is a new. FRA is publishing a Notice of Proposed Rulemaking titled Control of Alcohol and Drug Use: Addition of Post-Accident Toxicological Testing for Non-Controlled Substances on May 17, 2012. See 77 FR 29307.

- The total number of burden hours requested for this submission is **five (5) hours.**

- The total number of responses requested for this submission is **32.**

- Total **program changes** amount to **five (5) hours**.

- There are no **adjustments**.

The answer to question **number 12 itemizes the hourly burden associated with each requirement of this rule (See pp. 8-10).

1. **Circumstances that make collection of the information necessary.**

Since 1985, as part of its accident investigation program, FRA has conducted post-accident alcohol and drug tests on railroad employees who have been involved in serious train accidents (50 FR 31508, August 2, 1985). If an accident meets FRA's criteria for post-accident testing (see 49 CFR 219.201), FRA conducts tests for alcohol and for certain drugs classified as controlled substances under the Controlled Substances Act (CSA), Title II of the Comprehensive Drug Abuse Prevention Substances Act of 1970 (CSA, 21 U.S.C. 801 et seq.). Controlled substances are drugs or chemicals that are prohibited or strictly regulated because of their potential for abuse or addiction. The Drug Enforcement Agency (DEA), which is primarily responsible for enforcing the CSA, oversees the classification of controlled substances into five schedules. Schedule I contains illicit drugs, such as marijuana and heroin, which have no legitimate medical use under Federal law. Currently, FRA routinely conducts post-accident tests for the following drugs: marijuana, cocaine, phencyclidine (PCP), and certain opiates, amphetamines, barbiturates, and benzodiazepines. Controlled substances are drugs or chemicals that are prohibited or strictly regulated because of their potential for abuse or addiction.

FRA research indicates that prescription and OTC drug use has become prevalent among railroad employees. For this reason, FRA is proposing to add certain non-controlled substances to its routine post-accident testing program, which currently routinely tests only for alcohol and controlled substances. At this time, FRA intends to add two types of non-controlled substances, tramadol (a synthetic opioid) and sedating antihistamines. Publication of this NPRM, however, in no way limits FRA's post-accident testing to the identified substances or in any way restricts FRA's ability to make routine amendments to its standard post-accident testing panel without prior notice. Furthermore, in addition to its standard post-accident testing panel, FRA always has the ability to test for "other impairing substances specified by FRA as necessary to the particular accident investigation." See 49 CFR 219.211(a). This flexibility is essential, since it allows FRA to conduct post-accident tests for any substance (e.g., carbon monoxide) that its preliminary investigation shows may have played a role in an accident.

FRA is proposing to add tests for certain non-controlled substances to respond to the significant rise in prescription and OTC drug use in the more than 25 years since FRA began post-accident testing. In 2006, an ongoing telephone survey about the use of medications by U.S. adults found that 82 percent took at least one prescription or OTC drug, dietary supplement, or herbal remedy, each week. See SLONE EPIDEMIOLOGY CENTER AT BOSTON UNIVERSITY, PATTERNS OF MEDICATIONS USE IN THE UNITED STATES (2006). Also in 2006, a study commissioned by the National Community Pharmacists Association (NCPA) found that up to 75 percent of Americans reported not always taking their prescription medication as directed, 49 percent reported forgetting to take a prescribed medication, 31 percent reported not filling a prescription, 29 percent reported stopping use of a medication before its supply ran out, and 24 percent reported taking less than the recommended dosage. See NATIONAL COMMUNITY PHARMACISTS ASSOCIATION, TAKE AS DIRECTED: A PRESCRIPTION NOT FOLLOWED (2006). Today, the Physician's Desk Reference contains over 13,000 prescription drugs, most of which are non-controlled substances.

In 1998, FRA first expressed concerns that § 219.103, which addresses the use of Schedule II-V controlled substances by safety-sensitive employees, may be too narrow to cover the use of prescription and OTC drugs since most of these drugs are not controlled substances. To supplement § 219.103, FRA issued Safety Advisory 98-3 (Advisory), Recommended practices for the safe use of prescription and over-the-counter drugs by safety-sensitive railroad employees, which made recommendations to railroads on how to handle prescription and OTC drug use by their safety-sensitive employees. See 63 FR 71334, December 24, 1998).

After issuing this Advisory, FRA initiated two projects to research whether the prevalence of prescription drugs should be more closely evaluated and monitored as a possible safety concern in the rail industry. As detailed below, both projects found that

prescription and OTC drug use was prevalent among railroad employees involved in reportable accidents.

In the first project, which lasted from April 2002 to April 2009, FRA asked railroad employees who had been involved in human-factor accidents that were reportable under FRA's accident reporting regulations at 49 CFR Part 225 to complete FRA surveys on their recent prescription and OTC drug use. Of the 294 human-factor accidents surveyed, only 20 percent had no employee self-reports of drug use (this 20 percent also included accidents where employees would not complete questionnaires or could not be located). In the 80 percent of surveyed accidents where prescription or OTC drug use, or both, had been self-reported, employees listed a wide variety of generic and brand name drugs, with many employees listing multiple prescription and OTC drugs, as well as dietary supplements and herbal preparations.

In 2005, FRA began a second research project that partially responded to one in a series of recommendations to FRA made by the National Transportation Safety Board (NTSB) concerning the use of prescription and OTC drugs by safety-sensitive employees. (The NTSB made similar recommendations to DOT and other DOT agencies.)

R-00-004: Establish in coordination with the U.S. Department of Transportation, the Federal Motor Carrier Safety Administration, the Federal Transit Administration, and the U.S. Coast Guard, comprehensive toxicological testing requirements for an appropriate sample of fatal highway, railroad, transit, and marine accidents to ensure the identification of the role played by common prescription and over-the-counter medications. Review and analyze the results of such testing at intervals not to exceed 5 years.

In this project, FRA re-tested a sample of 150 frozen post-accident testing urine specimens that had previously been reported as negative for the substances in the agency's standard post-accident drug testing panel. After redacting any identifying employee information, FRA used a commercially available medical professional drug testing panel to re-test these specimens for commonly used prescription and OTC drugs with known risks of adverse side effects, such as pain relievers, anti-depressants, and sedating antihistamines. Of the 150 re-tested samples, 14 (9.3 percent) tested positive for at least one potentially impairing prescription or OTC drug. These post-accident re-testing results confirmed those of FRA's human-factor accident survey, by also showing that prescription and OTC drug use was prevalent among railroad employees.

Because FRA's post-accident testing program predates both DOT's testing procedures (49 CFR part 40) and the Omnibus Transportation Employee Testing Act of 1991, neither part 40 nor Department of Health and Human Services (HHS) guidelines apply to post-accident testing procedures and protocols. See 49 CFR 40.1. All post-accident tests are conducted on behalf of FRA by a single laboratory (FRA is revising appendix B to 49 CFR Part 219 to designate Quest Diagnostics as its post-accident testing laboratory) in

accordance with FRA specifications. FRA conducts compliance and quality audits of the laboratory each quarter.

As explained above, FRA intends to add testing for two types of non-controlled substances (tramadol , a synthetic opioid and sedating antihistamines) to its standard post-accident testing program to address the widespread use of prescription and OTC drugs by railroad employees. Both tramadol and the drugs in the sedating antihistamine category have potential side effects that could impair an employee's cognitive abilities (such as the ability to stay awake and alert or the ability to recognize and take appropriate emergency action) or cause impairing conditions (such as dizziness, agitation, and loss of coordination). These drugs are discussed below:

***** Tramadol. Tramadol is a semi-synthetic opioid. Opioids can be natural (e.g., codeine and morphine), semi-synthetic (e.g., oxycodone and hydromorphone), or wholly synthetic in origin (e.g., methadone). All opioids, regardless of origin, pose risks of sedation, and can cause abuse and dependence with prolonged use.

*****Sedating antihistamines. This widely used category of drugs includes, but is not limited to, diphenhydramine, chlorpheniramine, brompheniramine, and doxylamine. Sedating antihistamines are used primarily to treat allergy and cold symptoms, but may also be used as sleep aids or as treatment for allergic reactions such as itching and swelling. As their name implies, sedating antihistamines (as opposed to non-sedating antihistamines such as loratadine) have a known tendency to cause drowsiness. Because of this tendency, the manufacturer's instructions on the packaging and labeling of sedating antihistamines caution against use while driving, operating machinery, or performing tasks where alertness is required. Although these drugs are available at both prescription and OTC dosages, sedating anithistamines are usually taken as OTC drugs.

Adding testing for these types of non-controlled substances to its post-accident testing program will enable FRA to detect a broader range of potentially impairing drugs that may contribute to the cause or severity of accidents. As FRA has done for the controlled substances in its standard post-accident panel, FRA would consult with forensic toxicologists to establish screening and confirmation limits and administrative cut-offs for these non-controlled substances.

Although FRA is not proposing any change in its handling of post-accident test results for controlled substances in accordance with 49 CFR 219.211, FRA is proposing to handle the post-accident results for non-controlled substances differently. Specifically, as mentioned earlier, while sedating antihistamines are available at both prescription and OTC dosages, they are usually taken as OTC drugs. Since by definition these drugs can cause sedation, in 2009 FRA began post-accident testing for sedating antihistamines to determine whether their use is becoming a safety issue in the rail industry. This testing has been for research and accident investigation purposes only, and FRA has not reported

any sedating antihistamine test results to railroads or employees. FRA intends to continue its research testing without reporting any sedating antihistamines and in this NPRM proposed to keep the testing results confidential and not report to the relevant railroad or employee any sedating antihistamine post-accident test results.

The proposed addition of these non-controlled substances to FRA's standard post-accident tests would not create new direct costs for employers since FRA would bear the costs of the additional post-accident tests. Any additional costs to employers would be minimal and indirect, such as the cost of responding to an increased number of positive post-accident test results should FRA decide to report tramadol or sedating antihistamine results, or both.

2. <u>How, by whom, and for what purpose the information is to be used</u>.

The information collected under the proposed rule will be reported to Medical Review Officers (MROs) and railroad employees to inform them of the results of post-accident toxicological tests for additional controlled substances (drugs) screened by FRA approved laboratories. Under section 219.211 of the proposed rule, FRA is making a routine adjustment/amendment to controlled substances tested after serious train accidents to add the following synthetic narcotics: Hydrocodone (Vicodin, Lorcet, others), Oxycodone (Oxycontin, Percocet, Percodan, others), Hydromorphone (Dilaudid, others), Oxymorphone (Numorphane,others), Fetanyl (Sublimaze, Actiq, others), Methadone (Dolophine, others), and Propoxyphene (Darvon, Darvocet, others). MROs will use the information reported to them to determine whether employees involved in train accidents are abusing any of these additional controlled drugs and whether changes need to be made in the railroads' drug/alcohol program to prevent such abuse and eliminate train accidents caused by such use/abuse. [*Note: FRA is also adding certain non-controlled substances –tramadol and sedating antihistamines – to its standard post-accident testing program. Under the proposed rule, the tests results for these non-controlled substances will not be reported to railroad MROs or to railroad employees. However, FRA has invited comment on whether MROs should receive these results as well.*]

3. <u>How, by whom, and for what purpose the information is to be used</u>.

Over the years, FRA has strongly supported and highly encouraged the use of advanced automated technology, particularly electronic recordkeeping, to reduce burden on railroads and other entities that submit or retain information required by the agency. However, with the exception of the MIS reports, the types of information collected – either for reporting or recordkeeping purposes – are not conducive to electronic collection techniques. Nevertheless, FRA has no objection if test results for controlled substances are transmitted from the laboratories to a railroad's Medical Review Officer (MRO) by various electronic means (e.g., teleprinters, facsimile, or computer).

It should be noted that the burden for this collection of information is minuscule (five (5) hours).

4. Efforts to identify duplication.

The source of the information collection requirements is unique for each separate occurrence and, therefore, there is no known duplication of this material.

Data collected are not available from any other source.

5. Efforts to minimize the burden on small businesses.

The regulation only applies to railroads and, accordingly, has no direct impact on small units of governments, business, or other organizations. FRA has not found any costs associated with this NPRM for the regulated industry. Any associated costs for conducting post-accident testing for non-controlled substances would be nominal and assumed by the Federal government in their entirety. Railroads would not be required to change their collection process, and would have to follow the same collection, shipping, and handling processes they currently follow. This means that individuals subject to post-accident testing would provide the same specimens currently required, which would then be tested for tramadol and sedating antihistamines at FRA's expense. Since FRA would use these results for research and accident investigation purposes only, tramadol and sedating antihistamines test results would not be reported directly to either the employee or the employing railroad. This reporting process would apply to both surviving and fatally injured employees. No monetary costs would be imposed on the industry as a result of this addition. Thus, FRA certifies that this proposed rule will not have a significant economic impact on a substantial number of small entities.

6. Impact of less frequent collection of information.

If this collection of information were not conducted, or conducted less frequently, rail safety in the U.S. might be seriously jeopardized. Specifically, without the results of post-accident toxicological tests being reported to Medical Review Officers (MROs), railroads would have no way to determine whether specific controlled substances were being abused by their employees and causing serious train accidents/incidents. In particular, without testing for the additional controlled substances (synthetic narcotics -- hydrocodone, oxycodone, hydormorphone, oxymorphone, fentanyl, methadone, propoxyphene, tramadol) that are being added as a routine part of FRA's standard testing panel under section 219.211, railroads would have no idea that these other controlled substances are being used/abused by their employees. Further, without this information being reported to MROs, railroads would be unable to assess/determine whether their alcohol and drug misuse prevention programs are effective and whether these additional

controlled substances need to be added to their misuse programs. If railroads did not have effective alcohol and drug misuse prevention programs and if these programs were not carefully monitored, railroad employees working in safety-sensitive positions might abuse/continue to abuse alcohol and drugs while on-duty, or just prior to coming on-duty. This could lead to greater numbers of – and perhaps more severe – accident/incidents where train crews, other railroad employees, passengers, and innocent bystanders are injured or killed. Particularly in the case of a catastrophic accident or an accident involving the release of radioactive or other hazardous materials, the number of casualties and harm to the environment and surrounding communities might be great.

To be effective, a safety program requires timely information. Collection of this information less frequently would render the information obsolete and meaningless, and would impair FRA's and railroads safety programs. If future experience indicates a lesser frequency is warranted, the agency would carefully review this part of its regulatory safety program and make necessary revisions accordingly.

In sum, this collection aids FRA and railroads in promoting and maintaining a safe rail environment. As such, it makes furthers FRA's main mission.

7. Special circumstances.

All reporting and recordkeeping requirements are within these guidelines.

8. Compliance with 5 CFR 1320.8.

As required by the Paperwork Reduction Act of 1995, FRA is publishing this Notice of Proposed Rulemaking in the Federal Register on May 17, 2012, soliciting comment from the public, interested parties, and the regulated community on the proposed rule and associated information collection. *See 77 FR XXXX*.

FRA will respond to any comments received relating to the proposed rule and associated information collection in the final rule and associated information collection submission.

Background

FRA's post-accident testing program has been in existence since 1985. FRA has received suggestions from railroad representatives, collectors, and others on how to make the program's requirements easier to understand and follow.

In this proposed rulemaking, FRA is seeking comment on whether it should continue to keep post-accident test results for sedating antihistamines confidential. Also, FRA is seeking specific comments on how it should handle tramadol post-accident test results. Should FRA release post-accident test results for tramadol as it does for other opioids that

are controlled substances? Should FRA keep post-accident results for tramadol confidential as it proposes to continue doing for sedating antihistamines? Is there another approach that would better handle tramadol test results?

9. Payments or gifts to respondents.

There are no monetary payments or gifts made to respondents associated with the information collection requirements contained in this regulation.

10. Assurance of confidentiality.

No assurances of confidentiality have been provided to affected respondents. FRA maintains a set of accident investigation files. FRA will not maintain a system of records that will permit the identification of records by an individual name. FRA does hold in confidence information concerning medically authorized use of controlled substances, pursuant to 5 U.S.C. 552 (b)(6), except where the information is deemed material to determination of accident causation. The random testing programs for alcohol and drugs require that results of random tests and related medical information be held in confidence, except as necessary to effect discipline and/or referral for rehabilitation.

11. Justification for any questions of a sensitive nature.

These requirements have nothing to do with sensitive matters such as sexual behavior and attitudes, religious beliefs, and other matters commonly considered private.

12. Estimate of burden hours for information collected.

Note: Although there are currently 754 railroads currently operating, the number of railroads affected by this proposed rulemaking is 698.

SUBPART C – POST-ACCIDENT TOXICOLOGICAL TESTING

Analysis and follow-up - MRO [219.211(a), (b), & (c)]

(a) The laboratory designated in appendix B to this part undertakes prompt analysis of specimens provided under this subpart, consistent with the need to develop all relevant information and produce a complete report. Specimens are analyzed for alcohol, controlled substances, and non-controlled substances specified by FRA under protocols specified by FRA. These substances may be tested for in any form, whether naturally or synthetically derived. Specimens may be analyzed for other impairing substances specified by FRA as necessary to the particular accident investigation. [*Note: The burden for alcohol and drug testing of railroad employees is included under DOT's Part 40*

information collection submission. Consequently, there is no additional burden associated with this requirement.] (**Revised requirement**)

(b) Results of post-accident toxicological testing for controlled substances conducted under this subpart are reported to the railroad's Medical Review Officer and the employee. * * *

Results of post-accident toxicological testing under this subpart are reported to the railroad's Medical Review Officer (MRO) and the employee. The MRO and the railroad must treat the test results and any information concerning medical use or administration of drugs provided under this subpart in the same confidential manner as if subject to subpart H of this part, except where publicly disclosed by FRA or the National Transportation Safety Board.

(c) With respect to a surviving employee, a test reported as positive for alcohol or a controlled substance by the designated laboratory must be reviewed by the railroad's Medical Review Officer with respect to any claim of use or administration of medications (consistent with § 219.103) that could account for the laboratory findings. The Medical Review Officer must promptly report the results of each review to the Associate Administrator for Safety, FRA, Washington, DC, 20590. Such report must be in writing and must reference the employing railroad, accident/incident date, and location, and the envelope must be marked "**ADMINISTRATIVELY CONFIDENTIAL: ATTENTION ALCOHOL/DRUG PROGRAM MANAGER**." The report must state whether the MRO reported the test result to the employing railroad as positive or negative and the basis of any determination that analytes detected by the laboratory derived from authorized use (including a statement of the compound prescribed, dosage/frequency, and any restrictions imposed by the authorized medical practitioner). Unless specifically requested by FRA in writing, the Medical Review Officer must not disclose to FRA the underlying physical condition for which any medication was authorized or administered.

As a result of the proposed rule, FRA will be testing additional controlled substances. Consequently, FRA estimates that the number of MRO reports will increase. Approximately 16 reports will be prepared annually by MROs and 16 copies of the report will be sent to railroad employees. It is estimated that it will take approximately 15 minutes to prepare the report and forward it to FRA and another five minutes to make a copy of the report and send it to the railroad employee. Total annual burden for this requirement is two (2) hours.

Respondent Universe:

698 railroads

Burden time per response: 15 minutes + 5 minutes

Frequency of Response: On occasion

Annual number of Responses: 16 reports + 16 report copies
Annual Burden: 5 hours

Calculation: 16 reports x 15 min. + 16 report copies x 5 min. = 5 hours

Total annual burden for this entire requirement is five (5) hours.

Total annual burden for this entire information collection is five (5) hours.

13. Estimate of total annual costs to respondents.

Respondent Costs

There are no other costs to respondents other than the ones reflected in the response to question 12 above. [*Note: The costs for the Custody and Control Forms (CCFs) are the responsibility of the Department of Health and Human Services (DHHS*).]

14. Estimate of Cost to Federal Government.

There is an additional cost to FRA resulting from the additional controlled substances (synthetic opioids) included in the standard testing panel of railroad employees that will undergo laboratory testing post-accident.

FRA estimates the annual cost for the additional controlled substances post-accident toxicological testing of railroad employees as follows:

$112 per test 196 tests per year

$ 21,985 TOTAL

15. Explanation of program changes and adjustments.

This is a new collection of information. By definition, the entire burden of five (5) hours is a **program change**.

There are no additional costs to respondents regarding this proposed rule other than the burden hours specified in the answer to question number of this document.

16. Publication of results of data collection.

The information concerning impairment in an accident setting, which is received pursuant to this program, will be published in a subset of data contained in FRA's annual Accident/Incident Bulletin. All of the remaining information obtained under this program is intended for use by the Office of Safety technical staff in its ongoing accident prevention activities or will be used by railroads in monitoring compliance by their employees with the prohibitions on alcohol and drug use.

17. Approval for not displaying the expiration date for OMB approval.

Once OMB approval is received, FRA will publish the approval number for these information collection requirements in the Federal Register.

18. Exception to certification statement.

No exceptions are taken at this time.

Meeting Department of Transportation (DOT) Strategic Goals

This information collection supports the top DOT strategic goal, namely transportation safety. Without this collection of information, rail safety in the U.S. would be seriously jeopardized. Specifically, without the results of post-accident toxicological tests being reported to Medical Review Officers (MROs), railroads would have no way to determine whether specific controlled substances were being abused by their employees and causing serious train accidents/incidents. In particular, without testing for the additional controlled substances (synthetic narcotics -- hydrocodone, oxycodone, hydormorphone, oxymorphone, fentanyl, methadone, propoxyphene, tramadol) that are being added as a routine part of FRA's standard testing panel under section 219.211, railroads would have no idea that these other controlled substances are being used/abused by their employees. Further, without this information being reported to MROs, railroads would be unable to assess/determine whether their alcohol and drug misuse prevention programs are effective and whether these additional controlled substances need to be added to their misuse programs. If railroads did not have effective alcohol and drug misuse prevention programs and if these programs were not carefully monitored, railroad employees working in safety-sensitive positions might abuse/continue to abuse alcohol and drugs while on-duty, or just prior to coming on-duty. This could lead to greater numbers of – and perhaps more severe – accident/incidents where train crews, other railroad employees, passengers, and innocent bystanders are injured or killed. Particularly in the case of a catastrophic accident or an accident involving the release of radioactive or other hazardous materials, the number of casualties and harm to the environment and surrounding communities might be great.

In this information collection, as in all its information collection activities, FRA seeks to do its utmost to fulfill DOT Strategic Goals and to be an integral part of One DOT.