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[4910-06-P]

**DEPARTMENT OF TRANSPORTATION**

**Federal Railroad Administration**

**49 CFR Part 219**

**[Docket No. FRA-2010-0155]**

**RIN 2130-AC24**

**Control of Alcohol and Drug Use: Addition of Post-Accident Toxicological Testing for Non-Controlled Substances**

**AGENCY:** Federal Railroad Administration (FRA), Department of Transportation

(DOT)

**ACTION:** Final Rule.

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**SUMMARY:** In 1985, FRA implemented a post-accident toxicological testing (post-accident testing) program to test railroad employees who had been involved in serious train accidents for alcohol and certain controlled substances (marijuana, cocaine, phencyclidine (PCP), and selected opiates, amphetamines, barbiturates, and benzodiazepines). This final rule adds certain non-controlled substances with potentially impairing side effects to its standard post-accident testing panel. The non-controlled substances include tramadol and sedating antihistamines. This final rule makes clear that FRA intends to keep the post-accident test results for these non-controlled substances confidential while it continues to obtain and analyze data on the extent to which prescription and over-the-counter (OTC) drug use by railroad employees potentially affects rail safety.

**DATES:** This rule is effective on [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]. Petitions for reconsideration must be received on or before [INSERT DATE 60 DAYS FROM DATE OF PUBLICATION]. Petitions for reconsideration will be posted in the docket for this proceeding. Comments on any submitted petition for reconsideration must be received on or before [INSERT DATE 105 DAYS FROM DATE OF PUBLICATION].

**ADDRESSES:** Petitions for reconsideration or comments on such petitions: Any petitions and any comments to petitions related to Docket No. FRA-2010-0155, may be submitted by any of the following methods:

- Online: Comments should be filed at the Federal eRulemaking Portal, <http://www.regulations.gov>. Follow the online instructions for submitting comments.
- Fax: 202-493-2251.
- Mail: Docket Management Facility, U.S. DOT, 1200 New Jersey Avenue SE, W12-140, Washington, DC 20590.
- Hand Delivery: Room W12-140 on the Ground level of the West Building, 1200 New Jersey Avenue SE, Washington, DC between 9 a.m. and 5 p.m. Monday through Friday, except federal holidays.

**Instructions:** All submissions must include the agency name and docket number or Regulatory Identification Number (RIN) for this rulemaking. All petitions and comments received will be posted without change to <http://www.regulations.gov>; this includes any personal information. Please see the Privacy Act heading in the “Supplementary Information” section of this document for Privacy Act information related to any submitted petitions or materials.

Docket: For access to the docket to read background documents or comments received, go to <http://www.regulations.gov> at any time or to Room W12-140 on the Ground level of the West Building, 1200 New Jersey Avenue, SE, Washington, DC between 9 a.m. and 5 p.m. Monday through Friday, except Federal holidays.

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**SUPPLEMENTARY INFORMATION:**

**The NPRM**

In 1985, to further its accident investigation program, FRA began conducting alcohol and drug tests on railroad employees who had been involved in serious train accidents that met its specified criteria for post-accident testing (see 49 CFR 219.201). Since the program's inception, FRA has routinely conducted post-accident tests for alcohol and for certain drugs classified by the Drug Enforcement Administration (DEA) as controlled substances because of their potential for abuse or addiction. See 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.). As noted in the NPRM, FRA has historically conducted post-accident tests for alcohol and marijuana, cocaine, phencyclidine (PCP), and certain opiates, amphetamines, barbiturates, and benzodiazepines. The purpose of these tests is to determine if alcohol misuse or drug abuse played a role in the occurrence or severity of an accident.

On May 17, 2012, FRA proposed to add routine post-accident tests for certain non-controlled substances with potentially impairing side effects (77 FR 29307). As

discussed in the NPRM, studies have shown a significant increase in the daily use of prescription drugs, OTC drugs, vitamins, and herbal and dietary supplements by both railroad workers and the general population. Although most prescription drugs and all OTC drugs are non-controlled substances, many commonly used ones, such as antihistamines and muscle relaxants (e.g., tramadol), carry warning labels against driving or moving heavy machinery because of their potential sedating effects. Furthermore, even prescription and OTC drugs that do not carry such warnings can have unintended side effects when taken in combination with other drugs, when not used in accordance with directions, or when a user has an unusual reaction.

In the NPRM, FRA discussed testing for two non-controlled substances: (1) tramadol, which is available only by prescription, and (2) sedating antihistamines, which are available at both prescription and OTC dosages. FRA asked for comment on how the agency should handle test results for these first non-controlled substances to be tested for routinely in its post-accident testing program. In the NPRM, FRA proposed to continue its research testing related to sedating antihistamines and keep the test results confidential and not report to the relevant railroad or employee any sedating antihistamine post-accident test results. In the NPRM, FRA noted that although tramadol is a non-controlled substance, it is a prescription-only semi-synthetic opioid that can cause dizziness, and sought comment on how it should handle tramadol post-accident test results. FRA specifically requested comment as to whether the agency should release post-accident test results for tramadol as it does for other opioids that are controlled substances.

The NPRM also contained two announcements. To make its post-accident testing requirements and procedures easier to understand, FRA announced that its standard post-accident testing box would include new information and an updated and simplified form and instructions. FRA also announced that it was amending Appendix B to 49 CFR part 219 to designate Quest Diagnostics in Tucker, Georgia as its post-accident testing laboratory.

### **Comments on the NPRM**

FRA received seven comments on the NPRM. FRA received comments from the Association of American Railroads (AAR), the American College of Occupational and Environmental Medicine (ACOEM), and a joint submission from the American Train Dispatchers Association, the Brotherhood of Locomotive Engineers and Trainmen, the Brotherhood of Maintenance of Way Employes Division, the Brotherhood of Railroad Signalmen, and the United Transportation Union (collectively referred to as “Rail Labor”); with the Transportation Trades Division, AFL-CIO filing a comment in support. FRA also received individual comments from three health care professionals (HCPs). FRA addresses the common issues raised by the commentators below instead of addressing each comment separately.

#### **The addition of post-accident tests for tramadol and sedating antihistamines**

Comment was divided on FRA’s proposal to add routine post-accident tests for non-controlled substances such as tramadol and sedating antihistamines. Rail Labor representatives, who were uniformly opposed, asserted that conducting post-accident tests for legal drugs would discourage railroad employees from using necessary prescription and OTC drugs, and that the resulting risks from untreated medical

conditions could outweigh the possible adverse effects from the medications used to treat them. Rail Labor representatives also stressed the privacy interests employees have in their medical information and expressed concerns that the release of positive test results for sedating antihistamines could cause an employee to suffer discipline or dismissal for the use of a legal substance. The AAR supported FRA's proposal, and the ACOEM was strongly in favor of post-accident testing for non-controlled substances as a necessary first step in increasing employee and employer awareness of the risks of unintended drug interactions from polypharmacy (the use of multiple prescription and OTC drugs). The HCPs who submitted comments had varied views. One HCP supported the addition of sedating antihistamines, but not tramadol, because the HCP considered it to be a "mild opioid." Another HCP supported the addition of both substances because of their tendency to induce drowsiness, but added that FRA needed to address the issue of fatigue among railroad workers. A third HCP, noting that any substance, including water, can be problematic if taken incorrectly or in too large amounts, questioned how FRA had selected tramadol and the four sedating antihistamines mentioned in the NPRM for post-accident testing.

Some commentators questioned whether FRA had proven that post-accident testing for non-controlled substances was necessary. Rail Labor pointed out that the independent studies FRA cited in the NPRM (SLOANE EPIDEMIOLOGY CENTER AT BOSTON UNIVERSITY, PATTERNS OF MEDICATIONS USE IN THE UNITED STATES (2006), and NATIONAL COMMUNITY PHARMACISTS ASSOCIATION, TAKE AS DIRECTED: A PRESCRIPTION NOT FOLLOWED (2006)) concerned the prevalence of prescription and OTC drug use among the population in general, and not railroad workers in particular.

An HCP also expressed the view that FRA had not shown that medication use was prevalent in the rail industry.

FRA notes that commenters provided no evidence that the use of prescription and OTC drugs by the railroad employee population is different than that of the general population studied in Slone and National Community. In 2006, FRA published a study that it had commissioned from Foster-Miller, Inc. (GERTLER, J., HARTENBAUM, N., MD, VIALE, A., WITTELS, E., MD, S. ELLIS, ESQ. (2005) MEDICAL STANDARDS FOR RAILROAD WORKERS), which found over 60 percent of U.S. railroad workers to be males between 45-64 years of age. That same year, Slone found that 30 percent of men between 45-64 years old self-reported using five or more prescription and OTC drugs in a week, while the corresponding figure for men between 18-44 years old was only eight percent. Slone concluded that the nearly one third of older men who use at least five drugs a week are at greater risk for unintended drug interactions.

Moreover, FRA's own research studies provided anecdotal evidence of multiple drug use among railroad employees. As discussed in the NPRM, from April 2002 to April 2009, FRA asked railroad employees who had been involved in reportable (see FRA's accident reporting regulations at 49 CFR part 225) human-factor accidents to complete surveys on their recent prescription and OTC drug use. In eighty percent of the 294 railroad accidents at least partially attributed to human error during this period, one or more of the employees involved reported using at least one generic or brand name drug, and many employees reporting the use of multiple substances, including not only prescription and OTC drugs, but also herbal remedies and dietary supplements. FRA believes the actual use of prescription and OTC drugs by railroad employees is likely

higher than that indicated in these self-reports, since some survey respondents may have omitted or forgotten drugs that they had used.

Rail Labor representatives commented that FRA had no data linking the use of tramadol or sedating antihistamines to an increased risk of rail accidents, whether due to an adverse side effect of the drug or an employee's failure to comply with HCP or manufacturer directions. This is correct. As FRA noted in the NPRM, FRA proposes to conduct post-accident testing for tramadol and sedating antihistamines for research purposes only to obtain such data and to determine whether their use presents a safety issue in the railroad industry. While the addition of any drug to FRA's post-accident testing panel indicates that the drug is of safety concern to FRA, FRA's purpose in adding routine post-accident tests for non-controlled substances is to obtain data, not to deter the use of legal drugs by railroad employees. FRA would not be fulfilling its accident investigation mission if it did not research the impact of legal drugs on the occurrence or severity of significant rail accidents, including the potential risks of using drugs with known adverse effects and the potential risks of using multiple prescription and OTC drugs which may cause unintended drug interactions.

One HCP cited several studies on the sedating effects of various antihistamines and asked how FRA decided to select diphenhydramine, chlorpheniramine, bromenphiramine, and doxylamine for post-accident testing. To clarify, FRA listed these drugs simply as examples, and not as an exhaustive list, of the sedating antihistamines that would be added to FRA's drug panel. As stated in the NPRM, the sedating antihistamines category "includes, but is not limited to, diphenhydramine, chlorpheniramine, bromenphiramine, and doxylamine" (77 FR at 29308, emphasis

added). As explained below, the purpose of FRA post-accident testing is to obtain data on the potential causes of major railroad accidents. FRA's ability to do so would be hampered if it could only post-accident test for four of the drugs in the sedating antihistamine class.

FRA is selecting tramadol and sedating antihistamines, both of which can cause drowsiness, as the initial non-controlled substances to be added to its standard post-accident testing panel. The widely used painkiller tramadol is a synthetic opioid similar to other synthetic opioids such as the controlled substances oxycodone and methadone. The use of sedating antihistamines, which is even more common, has been studied by the National Highway Traffic Safety Administration (NHTSA), which expressed concerns that "first generation antihistamines produce objective signs of skills performance impairment as well as subjective symptoms of sedation." See MOSKOWITZ AND WILKINSON, ANTIHISTAMINE AND DRIVING-RELATED BEHAVIOR: A REVIEW OF THE EVIDENCE FOR IMPAIRMENT (2004). As explained in the NPRM, the addition of tramadol and sedating antihistamines to FRA's standard post-accident drug panel does not limit FRA's ability to conduct post-accident tests for other non-controlled substances, whether to investigate an individual accident or to conduct additional research.

### **The Reporting of post-accident test results for non-controlled substances**

As noted above, in the NPRM, FRA asked for comment on how it should handle post-accident test results for non-controlled substances such as sedating antihistamines and tramadol. Comment was divided on the issue of whether FRA should report tramadol post-accident test results. Rail Labor representatives and one HCP objected to

the release of results for tramadol, on the grounds that it is a mild opioid that is not a controlled substance. Conversely, the AAR argued that as the primary guardians of rail safety, railroads had a need to know both tramadol and sedating antihistamines results to be able to address any concerns that could affect safe operations. With the exception of the AAR, all commentators supported FRA's proposal to continue the practice of not reporting post-accident test results for sedating antihistamines.

After reviewing the comments, FRA has decided to maintain its proposal to treat post-accident test results for non-controlled substances (including sedating antihistamines and tramadol) confidential. To this end, FRA is revising the regulatory text of § 219.211(b) as proposed in the NPRM to limit the reporting of post-accident testing results to results for controlled substances only. An employee's use of a non-controlled substance is legal and generally subject to few restrictions, and FRA is not convinced at this time that a railroad has a safety need to know whether an employee is using a non-controlled substance while subject to performing covered service. Thus, FRA will not report non-controlled substance post-accident test results to the railroads. FRA will report a post-accident test result for a non-controlled substance to an employer or a third party only if an employee has provided specific written consent for release of his or her test result to the employer or third party. (As has been its standard practice, FRA may also provide post-accident test results and post-mortem specimens to the National Transportation Safety Board upon request. See § 219.211(f) and (h).) Except for these limited circumstances, all post-accident test results for non-controlled substances will be kept confidential. FRA will, however, continue to monitor its post-accident test results and other data to see if changes in policy or additional action are needed.

## **The nature of FRA post-accident testing**

Several comments concerned both the addition of non-controlled substances to post-accident tests and FRA post-accident testing in general. An HCP commented that since the purpose of post-accident testing is to prevent accidents, FRA would better address non-controlled substance use by expanding the scope of its prohibitions instead of its post-accident testing program. Rail Labor representatives commented that FRA post-accident testing was exempt from DOT testing procedures (see Procedures for Transportation Workplace Drug and Alcohol Testing Programs (49 CFR part 40)) only by “dint of history,” and that the proposed addition of non-controlled substances would make FRA’s post-accident testing panel inconsistent with the drug panels used by other DOT programs. To address these comments, some of which reflect misperceptions of the nature and history of the program, FRA is providing an overview of the program’s fundamentals.

While the purpose of other DOT agency workplace testing programs is to detect or deter drug abuse, the purpose of FRA post-accident testing is not to prevent, but to investigate the causes of significant railroad accidents and incidents; this is why the FRA’s post-accident testing program has always tested for more controlled substances (e.g., barbiturates and benzodiazepines) than do other DOT agency testing programs. Furthermore, an examination of the history of FRA post-accident testing reveals that the program’s exemption from part 40 coverage was deliberate. FRA pioneered transportation workplace testing (see Final Rule implementing FRA reasonable suspicion and post-accident testing, 50 FR 31508, August 2, 1985), and the Supreme Court upheld the Constitutionality of both programs in Skinner v. RLEA, 489 U.S. 602, 109 S. Ct.

1402 (1989). Congress took notice of this Court decision two years later when it enacted the Omnibus Transportation Employee Testing Act of 1991 (“Omnibus Act,” Pub. L 102-143, Oct. 28, 1991), by specifically exempting FRA post-accident testing from the Act, which required DOT and six of its operating administrations to implement transportation workplace testing programs in accordance with standards set by the Department of Health and Human Services (HHS). DOT in turn exempted FRA post-accident testing from its part 40 procedures (see § 40.1(c)), which implemented the Omnibus Act’s mandates and govern all other types of FRA and DOT testing.

Although FRA encourages railroad employees to seek drugs with fewer potential side effects, FRA does not believe the addition of non-controlled substances to post-accident tests will discourage employees from seeking necessary treatment. As stated above, FRA will not report post-accident test results for non-controlled substances except with the permission of the employee. Moreover, the average employee will finish his or her railroad career without ever being required to provide post-accident test specimens. The number of post-accident tests conducted annually is only a fraction of the total number of FRA drug and alcohol tests conducted each year, because post-accident tests are conducted only on employees involved in rail accidents or incidents that meet FRA’s criteria for a “qualifying event” (see the four types of qualifying events described in § 219.201). In 2011, for example, there were only 87 qualifying events in which a total of 195 railroad employees were post-accident tested. This means that 195 post-accident drug tests and 195 post-accident alcohol tests were administered in 2011, while during that same year a total of 34,093 random drug tests and 42,289 random alcohol tests were administered to railroad employees. As previously mentioned, FRA has designated

Quest Diagnostics as its post-accident testing laboratory. Again unlike other workplace testing programs, FRA post-accident testing specimens are analyzed only at a single laboratory. To be awarded the contract as FRA's designated post-accident testing laboratory, a laboratory must be able to meet not only the technical qualifications for HHS laboratory certification but also qualifications set by FRA specifically for its post-accident testing program. These include the capability to analyze a wider variety of specimens (unique among DOT testing programs, FRA post-accident tests blood from surviving employees and tissue and fluid specimens from fatalities), for a wider variety of substances (e.g., barbiturates, carbon monoxide) at lower levels of detection than other HHS-certified laboratories. FRA audits the post-accident laboratory's compliance and quality each quarter.

Rail Labor representatives also expressed misgivings related to railroad availability policies, unpredictable work schedules, and FRA post-accident testing cutoffs. Their concern was that a railroad employee could test above the cutoff for tramadol or a sedating antihistamine if the employee used the substance, received an unexpected call for duty, and was later involved in an accident or incident that qualified for post-accident testing. For the reasons outlined below, FRA believes this misgiving is unfounded.

FRA has consulted with forensic toxicologists to establish post-accident screening and confirmation cut-offs for tramadol and sedating antihistamines, as appropriate for purposes of accident investigation. The purpose of random and other types of workplace tests is to detect whether a substance or its metabolite is present in an employee's system, with the ultimate goal of deterring or detecting substance abuse. This is not the case with

FRA post-accident testing. With the exception of major train accidents, where all crew members involved must be tested, a railroad supervisor on the scene must make a good faith determination that an employee may have played a role in the cause or severity of an accident before the employee is post-accident tested. When a significant accident occurs, the special features of the program – the requirement to collect blood from surviving employees, the requirement to collect and test specimens from fatalities, the requirement to use only FRA-issued specimen collection kits and forms, the requirement to follow FRA-only collection procedures, the requirement that all specimens be shipped to a single laboratory for analysis, the requirement that this laboratory exceed the qualifications for HHS certification, and the requirement that all test results be reviewed by FRA, which has sole control over whether they are reported to employees and employers – enable FRA to collect data as one part of its investigation of the cause of the accident. (See Appendix C to 49 CFR part 219.) Because the ultimate purpose of FRA’s post-accident testing program is to determine the cause of an accident, an employee’s post-accident test result is just one of the many things FRA investigates. The mere presence of a substance or metabolite in an employee’s system is never considered in isolation and FRA retains control of all post-accident specimens and results to ensure that a post-accident test result is interpreted in the context of the overall investigation.

Accidents can occur at any time, under different circumstances, and for a variety of reasons. For this reason FRA will maintain its practice of adjusting the substances, cutoffs and protocols in its post-accident testing program without notice and as it has done since the program’s inception. When a major accident happens, FRA cannot wait

for notice and comment before deciding whether to test for a substance that is not on its routine post-accident testing panel if preliminary investigation shows the substance may have played a role in the accident's occurrence or severity. Publication of this final rule provides notice that FRA will routinely conduct post-accident tests for non-controlled substances but does not provide precedent that FRA will publish notice of future changes to its post-accident testing program.

Rail Labor representatives also questioned why FRA was proposing to add post-accident tests for prescription and OTC drugs, given the conclusions of a Working Group tasked by the Railroad Safety Advisory Committee (RSAC) to develop Medical Standards (Task Number 2006-03, Medical Standards for Safety-Critical Personnel). According to these commentators, the Working Group had concluded “that regulatory treatment of such usage [of prescription drugs, OTC drugs, dietary supplements, and herbal remedies] is inappropriate . . . and that FRA’s current Safety Advisory [Safety Advisory 98-3, Recommended practices for the safe use of prescription and over-the-counter drugs by safety-sensitive railroad employees, 63 FR 71334, December 24, 1998] continues to sufficiently address recommended practices for safe use of prescription and OTC drugs.” FRA believes that this characterization by these commentators is incorrect since the Medical Standards Working Group has made no consensus recommendations to the RSAC about the use of medications by safety-sensitive employees and Task 2006-03 remains open.

Finally, with regard to Safety Advisory 98-3, FRA notes that the stated purpose of that Advisory remains as important today as it was when the Advisory was issued – i.e., the recommendations in that Advisory are intended to ensure that transportation

employees safely use prescription and OTC drugs. In that Advisory, FRA specifically noted that “FRA does not have a clear picture of the extent to which the performance of safety-sensitive employees is adversely affected by legal drug use.” FRA’s promulgation of this final rule adding certain non-controlled substances to its standard post-accident testing panel is one step toward FRA’s longstanding goal of determining whether the performance of safety-sensitive employees is adversely affected by the use of prescription and OTC drugs.

### **Contents of Standard Post-Accident Testing Box**

As announced in the NPRM, FRA is amending the contents of its standard post-accident testing box. FRA is adding guidance on the basis, purpose, and requirements of its post-accident testing program and updating the information requests in FRA F 6180.74, Post-Accident Testing Blood/Urine Custody and Control Form. These amendments should make FRA’s post-accident testing collection and shipping requirements easier to understand and follow. (FRA is not changing the contents of its fatalities post-accident testing box or changing the other form in its standard post-accident testing box, Form FRA F 6180.73, Accident Information Required for Post-Accident Toxicological Testing.)

### **Section-by-Section Analysis**

#### Section 219.5 - Definitions

FRA received no comment on its proposed definition of a non-controlled substance and is adding the definition as proposed.

#### Section 219.13 – Preemptive effect

FRA received one comment from an HCP who supported removal and reservation of this section. As proposed, FRA is removing the preemption language in paragraph (a) of this section because part 219 has preemptive effect by operation of law under the Federal Rail Safety Act (FRSA). See 49 U.S.C. 20106. Also as proposed, FRA is moving the language in paragraph (b) of this section to a new paragraph (c) of § 219.17.

#### Section 219.17 - Construction

As discussed in the paragraph above and as proposed in the NPRM, FRA is adding a new paragraph (c) to this section to replace the language formerly contained in § 219.13(b). This new paragraph states that part 219 does not impact State criminal laws imposing sanctions for reckless conduct that leads to actual loss of life, injury, or damage to property, whether such provisions apply specifically to railroad employees or the public at large.

#### Section 219.211 – Analysis and follow-up

As proposed in the NPRM, in the second sentence of paragraph (a), FRA is replacing the phrase “alcohol and controlled substances specified by FRA” with “alcohol, controlled substances, and non-controlled substances specified by FRA” to accommodate the addition of routine testing for non-controlled substances to its post-accident testing program. As also proposed in the NPRM, FRA is deleting the reference to submittal of FRA post-accident testing protocols to HHS, since as detailed above, HHS standards do not apply to FRA post-accident testing and FRA is adopting language from the DEA by adding a sentence stating that substances may be tested for in any form, whether naturally or synthetically derived, since controlled substances can be derived from many sources (e.g., opiates can be natural, synthetic, or semi-synthetic in origin).

As discussed above, FRA will keep all non-controlled substance post-accident test results confidential. FRA is therefore amending the first sentence of paragraph (b) as proposed in the NPRM.—This change is intended to make clear that FRA will report post-accident test results for controlled substances only.

Although not discussed in the NPRM, FRA is also amending the first sentence of paragraph (f)(1) of this section to state that post-accident test results for non-controlled substances will not be in the final toxicology report included in each FRA accident investigation report. In the NPRM, FRA asked for comment on whether non-controlled substance results should be reported to employers and employees; most commentators favored keeping these post-accident test results confidential. While FRA did not raise the issue of whether non-controlled substance post-accident test results should be included in FRA accident investigation reports, keeping these results confidential from employers and employees would be meaningless if FRA published them in its official reports. FRA will therefore redact non-controlled substance test results from a post-accident toxicology testing report before that report is published as part of an FRA accident investigation report. This amendment is necessary to ensure the complete confidentiality of non-controlled substance post-accident test results.

## **Appendix B**

As announced in the NPRM, FRA is revising Appendix B to this part to designate Quest Diagnostics in Tucker, Georgia as its post-accident testing laboratory.

### **Regulatory Impact and Notices**

- A. Executive Order 12866 and 13563 and DOT Regulatory Policies and Procedures

This final rule has been evaluated in accordance with existing policies and procedures under both Executive Order 12866 and 13563 and DOT policies and procedures. See 44 FR 11034; February 26, 1979. FRA has prepared and placed in the docket (FRA-2010-0155) a regulatory impact analysis addressing the economic impact of this final rule.

As part of the regulatory impact analysis, FRA has assessed pertinent costs expected from the implementation of this rulemaking. FRA has not found any costs associated with this final rule. Additional costs are assumed by the Federal government in their entirety. Railroads will not be required to change their collection process and will have to follow the same collection, shipping, and handling processes they currently follow. This means that individuals subject to post-accident testing will provide the same specimens currently required, which will then be tested for tramadol and sedating antihistamines at FRA's expense. Since FRA will use these results for research and accident investigation purposes only, tramadol and sedating antihistamines test results will not be reported directly to either the employee or the employing railroad. This reporting process will apply to both surviving and fatally injured employees. No monetary costs will be imposed on the industry as a result of this addition.

As part of the regulatory impact analysis, FRA has explained what the likely benefits for this final rule will be, and provided numerical assessments of the potential value of such benefits. The inclusion of tramadol and sedating antihistamines will generate safety benefits. Qualitative benefits will be generated with the inclusion of sedating antihistamines and tramadol in the post-accident testing panel by providing FRA with the data necessary to carry out research to inform future policy on this topic. The

final rule will generate quantifiable benefits upon the addition of sedating antihistamines to the post-accident testing panel by creating a small deterring effect on the use of sedating antihistamines by railroad workers and encouraging the use of alternative medications for allergic relief. A deterring effect will be generated by the regulatory signal FRA is sending to the regulated community about the safety concern related to these non-controlled substances. FRA expects some individuals to alter their usage of these substances and improve safety. Thus, in general, the final rule will reduce railroad accidents and their associated casualties and damages. FRA believes the value of the anticipated safety benefits will exceed the cost of implementing the final rule. Over a 10-year period, this analysis finds that \$2.3 million in benefits will accrue through accident prevention. The discounted value of this is \$1.9 million (PV, 7 percent). The table below presents the estimated benefits associated with the final rule.

<b>10-Year Estimated Benefits of the Final Rule (<i>in millions</i>)</b>		
	Benefits	PV, 7%
Tramadol	\$0	\$0
Sedating Antihistamines	\$2.3	\$1.9
<b>Total</b>	<b>\$2.3</b>	<b>\$1.9</b>

Dollars are discounted at a Present value rate of 7 percent.

Regulatory Flexibility Act - Certification of No Significant Economic Impact on a Substantial Number of Small Entities

FRA developed the final rule in accordance with Executive Order 13272 (“Proper Consideration of Small Entities in Agency Rulemaking”) and DOT’s procedures and

policies to promote compliance with the Regulatory Flexibility Act (5 U.S.C. 601 et seq.) to ensure potential impacts of rules on small entities are properly considered. FRA certified pursuant to the Regulatory Flexibility Act (5 U.S.C. 605(b)) in the NPRM. Furthermore, FRA invited all interested parties to submit data and information regarding this certification and did not receive any comments about it during the public comment period.

The Regulatory Flexibility Act requires an agency to review regulations to assess their impact on small entities. An agency must conduct a regulatory flexibility analysis unless it determines and certifies that a rule is not expected to have a significant economic impact on a substantial number of small entities.

Consistent with societal trends, FRA is concerned about the increasing use of non-controlled drugs in the railroads labor force. With this final rule FRA will learn about the impact of some of these non-controlled substances on railroad safety by updating the definition of non-controlled substances, changing the reporting requirements related to the drug panel change, and including more drugs in the current post-accident testing panel. This Regulatory Flexibility Impact Analysis is presented to comply with Executive Order 13272 and with the Regulatory Flexibility Act as part of the formal rulemaking process required by law.

The final regulation is amending §§ 219.5 and 219.211 by providing for the routine post-accident testing for non-controlled substances. FRA will treat post-accident test results for non-controlled substances as confidential and will not disclose such results to the relevant railroad or employee.

## I. Description of Regulated Entities and Impacts

The “universe” of the entities under consideration includes only those small entities that can reasonably be expected to be directly affected by the provisions of this final rule. For this final rule there is only one type of small entity that is affected: small railroads.

“Small entity” is defined in 5 U.S.C. § 601. Section 601(3) defines a “small entity” as having the same meaning as “small business concern” under § 3 of the Small Business Act. This includes any small business concern that is independently owned and operated, and is not dominant in its field of operation. Section 601(4) likewise includes within the definition of “small entities” not-for-profit enterprises that are independently owned and operated, and are not dominant in their field of operations. Additionally, 5 U.S.C. 601(5) defines “small entities” as governments of cities, counties, towns, townships, villages, school districts, or special districts with populations less than 50,000.

The U.S. Small Business Administration (SBA) stipulates “size standards” for small entities. It provides that the largest a for-profit railroad business firm may be (and still classify as a “small entity”) is 1,500 employees for “Line-Haul Operating” railroads, and 500 employees for “Short-Line Operating” railroads.<sup>1</sup>

Federal agencies may adopt their own size standards for small entities in consultation with SBA, and in conjunction with public comment. Pursuant to the authority provided to it by SBA, FRA has published a final policy, which formally establishes small entities as railroads that meet the line haulage revenue requirements of a Class III railroad.<sup>2</sup> Currently, the revenue requirements are \$20 million or less in annual operating revenue, adjusted annually for inflation. The \$20 million limit (adjusted

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<sup>1</sup> “Table of Size Standards,” U.S. Small Business Administration, January 31, 1996, 13 CFR Part 121.

<sup>2</sup> See 68 FR 24891 (May 9, 2003).

annually for inflation) is based on the Surface Transportation Board's threshold of a Class III railroad, which is adjusted by applying the railroad revenue deflator adjustment.<sup>3</sup> FRA is using this definition for this final rule.

### Railroads

FRA regulates a total 756 railroads. However, only 644 could be considered to be small for the purposes of this analysis because 7 are large Class I freight railroads, Amtrak and 26 commuter railroads serving communities larger than 50,000 people, and 12 are Class II railroads. All these railroads are not considered to be small. The rest of the railroads not included in this analysis do not operate in the general railroad system and are not subject to the final regulation. Two commuter railroads were included in this analysis, the Hawkeye Express and the Saratoga & North Creek Railway. The Hawkeye Express provides commuter service to Iowa City and is owned by a Class III railroad, a small entity. The Saratoga & North Creek Railway started operations in 2011, serving several stations between North Creek and Saratoga Springs, New York with three trains a day and meets the criteria to be considered a small entity.

Type of Railroad	Total	Railroads that do not Operate in General System	Small
<b>Freight Class I</b>	7	0	0
<b>Freight Class II</b>	12	0	0
<b>Freight Class III</b>	708	66	642
<b>Amtrak</b>	1	0	0

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<sup>3</sup> For further information on the calculation of the specific dollar limit, please see 49 CFR Part 1201.

<b>Commuter</b>	28	0	2
<b>Total</b>	756	66	644

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It is important to note that the small entities being considered in this analysis are knowledgeable about current post-accident testing requirements. Most small railroads have experience on carrying out a post-accident test. Data from the FRA's Drug and Alcohol Program reveals that generally, about 4 or 5 percent of all post-accident testing qualifying events involve a small railroad. For example, in 2011 with a total of 87 post-accident testing events, four implicated Class III railroads. Similarly, in 2010, 85 post-accident testing events involved four Class III railroads.

This final rule does not increase costs for small railroads. The cost for testing additional drugs will be paid by the FRA through existing contracts. Railroads will follow the same collection and shipping process for urine and blood samples that is currently in place. Results originating from this regulatory change will only be used by FRA for research and investigation purposes only and will not be shared with external entities. Therefore, in the eventuality that an employee from a small railroad is found positive on any of these non-controlled substances neither the railroad nor the employee will face additional expenses to respond to that finding.

#### Significant Economic Impact Criteria

Previously, FRA sampled small railroads and found that revenue averaged approximately \$4.7 million (not discounted) in 2006. One percent of that average annual revenue per small railroad is \$47,000. FRA realizes that some railroads will have a lower revenue than \$4.7 million. However, FRA estimates that small railroads will not have any additional expenses over the next ten years to comply with the new requirements in

this final regulation. Based on this, FRA concludes that the expected burden of this final rule will not have a significant impact on the competitive position of small entities, or on the small entity segment of the railroad industry as a whole.

**Substantial Number Criteria**

This final rule will likely burden all small railroads that are not exempt from its scope or application (See 49 CFR § 219.3). Thus, as noted above this final rule will impact a substantial number of small railroads.

**II. Certification**

Pursuant to the Regulatory Flexibility Act (5 U.S.C. 605(b)), FRA certifies that this final rule will not have a significant economic impact on a substantial number of small entities. FRA invited all interested parties to submit data and information regarding the potential economic impact that will result from adoption of the proposals in the NPRM. FRA did not receive any comments concerning this certification in the public comment process.

**Paperwork Reduction Act**

The information collection requirements in this rule are being submitted for approval to the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 19995, 44 U.S.C. 3501 *et seq.* The section that contains the revised information collection requirement and the estimated time to fulfill that requirement is as follows:

CFR Section	Respondent Universe	Total Annual Responses	Average Time per Response	Total Annual Burden Hours
219.211—Analysis and Follow-up -- Reports of Positive Post-Accident Toxicological Test (Controlled Substances) to Medical Review Officer and Employee <b>(Revised Requirement)</b>	698 railroads	16 reports + 16 report copies	15 minutes + 5 minutes	5 hours

All estimates include the time for reviewing instructions; searching existing data sources; gathering or maintaining the needed data; and reviewing the information.

Pursuant to 44 U.S.C. 3506(c)(2)(B), FRA solicits comments concerning: whether these information collection requirements are necessary for the proper performance of the functions of FRA, including whether the information has practical utility; the accuracy of FRA's estimates of the burden of the information collection requirements; the quality, utility, and clarity of the information to be collected; and whether the burden of collection of information on those who are to respond, including through the use of automated collection techniques or other forms of information technology, may be minimized. For information or a copy of the paperwork package submitted to OMB, contact Mr. Robert Brogan, Information Clearance Officer, at 202-493-6292, or Ms. Kimberly Toone at 202-493-6132.

Organizations and individuals desiring to submit comments on the collection of

information requirements should direct them to Mr. Robert Brogan or Ms. Kimberly Toone, Federal Railroad Administration, 1200 New Jersey Avenue, S.E., 3<sup>rd</sup> Floor, Washington, D.C. 20590. Comments may also be submitted via e-mail to Mr. Brogan or Ms. Toone at the following address: [Robert.Brogan@dot.gov](mailto:Robert.Brogan@dot.gov); [Kim.Toone@dot.gov](mailto:Kim.Toone@dot.gov)

OMB is required to make a decision concerning the collection of information requirements contained in this rule between 30 and 60 days after publication of this document in the **Federal Register**. Therefore, a comment to OMB is best assured of having its full effect if OMB receives it within 30 days of publication.

FRA is not authorized to impose a penalty on persons for violating information collection requirements which do not display a current OMB control number, if required. FRA intends to obtain current OMB control numbers for any new information collection requirements resulting from this rulemaking action prior to the effective date of the final rule. The OMB control number, when assigned, will be announced by separate notice in the **Federal Register**.

### **Federalism Implications**

Executive Order 13132, “Federalism” (64 FR 43255, Aug. 4, 1999), requires FRA to develop an accountable process to ensure “meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications.” “Policies that have federalism implications” are defined in the Executive Order to include regulations that have “substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.” Under Executive Order 13132, the agency may not issue a regulation with federalism implications that

imposes substantial direct compliance costs and that is not required by statute, unless the Federal government provides the funds necessary to pay the direct compliance costs incurred by State and local governments, or the agency consults with State and local government officials early in the process of developing the regulation. Where a regulation has federalism implications and preempts State law, the agency seeks to consult with State and local officials in the process of developing the regulation. FRA has analyzed this final rule in accordance with the principles and criteria contained in Executive Order 13132. FRA believes this final rule it is in compliance with Executive Order 13132.

This final rule will not have a substantial effect on the States, on the relationship between the Federal government and the States, or on the distribution of power and responsibilities among the various levels of government. In addition, this final rule will not have any federalism implications that impose substantial direct compliance costs on State and local governments.

This final will have preemptive effect by operation of law under certain provisions of the Federal railroad safety statutes, specifically the former Federal Rail Safety Act (FRSA), repealed and recodified at 49 U.S.C 20106. The former FRSA provides that States may not adopt or continue in effect any law, regulation, or order related to railroad safety or security that covers the subject matter of a regulation prescribed or order issued by the Secretary of Transportation (with respect to railroad safety matters) or the Secretary of Homeland Security (with respect to railroad security matters), except when the State law, regulation, or order qualifies under the “local safety or security hazard” exception to section 20106.

## **Environmental Impact**

FRA has evaluated this final rule in accordance with its “Procedures for Considering Environmental Impacts” (“FRA's Procedures”) (64 FR 28545, May 26, 1999) as required by the National Environmental Policy Act (42 U.S.C. 4321 et seq.), other environmental statutes, Executive Orders, and related regulatory requirements. FRA has determined that this final rule is not a major FRA action (requiring the preparation of an environmental impact statement or environmental assessment) because it is categorically excluded from detailed environmental review pursuant to section 4(c)(20) of FRA's Procedures. In accordance with section 4(c) and (e) of FRA's Procedures, the agency has further concluded that no extraordinary circumstances exist with respect to this regulation that might trigger the need for a more detailed environmental review. As a result, FRA finds that this final rule is not a major Federal action significantly affecting the quality of the human environment.

## **Unfunded Mandates Reform Act of 1995**

The Unfunded Mandates Reform Act of 1995 (Pub. L. 104-4, 2 U.S.C. 1531) requires agencies to prepare a written assessment of the costs, benefits, and other effects of proposed or final rules that include a Federal mandate likely to result in the expenditures by State, local or tribal governments, in the aggregate, or by the private sector, of more than \$100 million annually (adjusted annually for inflation with base year of 1995). The value equivalent of \$100 million in CY 1950, adjusted annually for inflation to CY 2008 levels by the Consumer Price Index for All Urban Consumers (CPI-U) is \$141.3 million. This assessment may be included in conjunction with other

assessments, as it is here. This final rule will not create an unfunded mandate in excess of the threshold amount.

### **Energy Impact**

Executive Order 13211 requires Federal agencies to prepare a Statement of Energy Effects for any “significant energy action.” 66 FR 28355 (May 22, 2001). Under the Executive Order, a “significant energy action” is defined as any action by an agency (normally published in the Federal Register) that promulgates or is expected to lead to the promulgation of a final rule or regulation, including notices of inquiry, advance notices of proposed rulemaking, and notices of proposed rulemaking: (1)(i) That is a significant regulatory action under Executive Order 12866 or any successor order, and (ii) is likely to have a significant adverse effect on the supply, distribution, or use of energy; or (2) that is designated by the Administrator of the Office of Information and Regulatory Affairs as a significant energy action. FRA has evaluated this final rule in accordance with Executive Order 13211, and determined that it is not a “significant regulatory action” likely to have a significant adverse effect on the supply, distribution, or use of energy.

### **Privacy Act**

Anyone is able to search the electronic form of any comments or other written communications received into any of FRA’s dockets, by the name of the individual submitting the comment or other written communication (or signing the comment or other written communication, if submitted on behalf of an association, business, labor union, etc.). See <http://www.regulations.gov/#!privacyNotice> for the privacy notice of

regulations.gov, or you may review DOT's complete Privacy Act Statement in the Federal Register published on April 11, 2000 (65 FR 19477).

### **List of Subjects in 49 CFR Part 219**

Alcohol abuse, Drug abuse, Drug testing, Penalties, Railroad safety, Reporting and recordkeeping requirements, Safety, Transportation

### **The Rule**

For the reasons stated above, FRA amends part 219 of chapter II, subtitle B of title 49, Code of Federal Regulations, as follows:

#### **Part 219—[Amended]**

1. The authority citation for part 219 is revised to read as follows:

Authority: 49 U.S.C. 20102-20103, 20107, 20140, 21301, 21304, 21311; 28 U.S.C. 2461, note; and 49 CFR 1.89.

2. Amend § 219.5 by adding a definition of Non-controlled substance to read as follows:

#### **§ 219.5 Definitions.**

\* \* \* \* \*

Non-controlled substance means any substance (including prescription medications, over-the-counter products, dietary supplements, and herbal preparations) which is not currently regulated under 21 U.S.C. 801-971 or 21 CFR part 1308.

\* \* \* \* \*

#### **§ 219.13 [Removed and Reserved]**

3. Remove and reserve § 219.13.
4. Revise § 219.17 to read as follows:

## **§ 219.17 Construction.**

Nothing in this part—

- (a) Restricts the power of FRA to conduct investigations under sections 20107, 20108, 20111, and 20112 of title 49, United States Code;
- (b) Creates a private right of action on the part of any person for enforcement of the provisions of this part or for damages resulting from noncompliance with this part; or
- (c) Impacts provisions of State criminal law that impose sanctions for reckless conduct that leads to actual loss of life, injury or damage to property, whether such provisions apply specifically to railroad employees or generally to the public at large.

5. Amend § 219.211 by revising paragraph (a), the first sentence of paragraph (b), and paragraph (f)(2) to read as follows:

## **§ 219.211 Analysis and follow-up.**

(a) The laboratory designated in appendix B to this part undertakes prompt analysis of 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.

(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. \* \* \*

\* \* \* \* \*

(f) \* \* \*

(2) With the exception of post-accident test results for non-controlled substances, the toxicology report is a part of the report of the accident/incident and therefore subject to the limitation of 49 U.S.C. 20903 (prohibiting use of the report for any purpose in a civil action for damages resulting from a matter mentioned in the report).

\* \* \* \*

6. Revise Appendix B to part 219 to read as follows:

**Appendix B to Part 219—Designation of Laboratory for Post-Accident Toxicological Testing**

The following laboratory is currently designated to conduct post-accident toxicological analysis under subpart C of this part: Quest Diagnostics, 1777 Montreal Circle, Tucker, GA 30084, Telephone: (800) 729-6432.

Issued in Washington, DC on February 26, 2013.

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Joseph C. Szabo,  
Administrator.

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