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Part 219 Alcohol/Drug Program Compliance Manual

FEDERAL RAILROAD ADMINISTRATION

Office of Safety

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1.0

INTRODUCTION

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MANUAL

1.0 INTRODUCTION AND PURPOSE OF THE MANUAL

1.1 INTRODUCTION

Drug and alcohol abuse among Federally regulated transportation workers has continued to trigger significant concern about public safety, environmental protection, and economic impact at the local, state, and national levels. The Department of Transportation (DOT) has made a strong commitment to assist regulated employers with this problem, believing it essential to commercial transportation safety and protection of the American public. Starting in late 1988, the DOT and its various operating administrations enacted aggressive regulations to help employers eliminate the impact of drugs and the abuse of alcohol in regulated transportation industries and to facilitate a safe, drug and alcohol-free workplace.

Federal Railroad Administration (FRA) regulations in 49 CFR Part 219 (as amended) establish minimum Federal safety requirements for the control of alcohol and drug use in railroad operations. The regulations are designed to assist carriers in preventing accidents and casualties by implementing comprehensive drug and alcohol detection and deterrence programs.

Ultimately, Part 219 is intended to be a human factors regulation which reduces both the economic cost to railroad operations and the loss of personnel because of the use of drugs and the misuse of alcohol. To properly comply with its intricacies, carriers must be prepared to devote quality personnel and apply sufficient operational resources to make this essential safety program successful. FRA holds carriers fully accountable and responsible for the proper performance of its program, its program personnel, and its program's service providers.

1.2 PURPOSE OF THE PART 219 COMPLIANCE MANUAL

First implemented in the mid-1980s and amended periodically since, Part 219 is a comprehensive and far-reaching safety regulation. Even with its numerous successes and achievements, however, Part 219 has sometimes proven difficult to properly implement. Its elements, like the problem it hopes to eliminate, are complex and do not always lend themselves to simple compliance strategies. As a consequence, both rail carriers and FRA working in a partnership have sometimes struggled to establish a common ground on the proper implementation of some of the regulation's subparts.

INTRODUCTION AND PURPOSE

Formal audits of carrier compliance with Part 219 provisions can be extremely difficult for both the railroad and FRA. Carrier record systems are often inadequate and documentation of program performance can fall well short of FRA standards. Inadequate carrier record systems are considered non-compliant by FRA.

The purpose of this Compliance Manual is to eliminate some of the complexity and confusion of proper program compliance by providing carriers and FRA Safety Inspectors with an indepth description of exactly what FRA expects in a successful Part 219 drug and alcohol program. For each required program element, FRA has outlined its program goals and offered a summary of what it expects to see when it evaluates a carrier's Part 219 performance. With FRA's expectations more clearly defined, carriers can also better audit themselves and develop Federal drug and alcohol programs which fully meets FRA standards.

1.3 MANUAL REVISIONS

This is the second edition of the Compliance Manual. It incorporates both a number of Part 219 regulation interpretations established since the first edition and the significant regulatory changes required by the new 49 CFR Part 40 which were made effective in August 2001.

The first edition of the Manual was published in separate versions for the railroad industry and for FRA Safety Inspectors. They differed only in that the Inspector version contained additional content directed at the enforcement decisionmaking process for each program element. Starting with the second edition, FRA has decided to incorporate the enforcement content in one or more separate Inspector resource documents and issue an identical Manual for industry and FRA Safety Inspectors.

FRA intends that this Manual will be periodically updated as significant program changes occur, usually no more often than once per year. The latest updated version of the Manual or any of its various sections may be determined by checking the FRA website (www.fra.dot.gov). The version number can be found on the bottom of the inside title page of this Manual.

This edition of the Manual supercedes the previous edition and all Part 219 guidance documents and rule interpretations published to date which cover information reviewed in this Manual.

2.0

APPLICATION,

DEFINITIONS,

REGULATORY AUTHORITY,

AND

ENFORCEMENT PHILOSOPHY

2.0 Application, Definitions, Regulatory Authority, and Enforcement Philosophy

2.1 APPLICATION

All railroads affected by FRA's regulation on the control of alcohol and drug use in regulated operations (49 CFR Part 219) must adhere to the requirements described below.

All railroads which have sixteen (16) or more covered service employees, or who have joint operations with another railroad, must abide by the requirements found in the general section (Subpart A); the prohibitions (Subpart B); mandatory post-accident testing (Subpart C); testing for cause (Subpart D); the identification of troubled employees (Subpart E); pre-employment testing (Subpart F); random testing (Subpart G); drug and alcohol testing procedures (Subpart H); and recordkeeping requirements (Subpart J).

All railroads which have fifteen (15) or less covered service employees need only observe the general section (Subpart A); the prohibitions (Subpart B); mandatory post-accident testing (Subpart C); drug and alcohol testing procedures (Subpart H) when applicable; and recordkeeping requirements (Subpart J) when applicable. They are exempt from Federal testing for cause, programs for the identification of troubled employees, pre-employment testing, and random testing.

Railroads which do not meet the threshold criteria described above may not incorporate other Subparts in their Federal testing program and are not authorized to expand their use of Federal authority to testing categories for which they do not qualify.

Regardless of size, carriers are not limited by FRA regulations from conducting any type or kind of drug or alcohol testing, or implementing drug and alcohol programs for their employees, under their own authority. FRA has no interest in company authority programs except as the lines of distinction appear to be blurred with Federal requirements (i.e. use of a Federal collection form).

Carriers must submit an annual report covering their alcohol and drug use programs (Subpart I), if they have 400,000 or more total manhours in the last calendar year.

When operating in U.S. territory with covered service employees whose primary place of service ("home terminal") is outside the U.S., foreign carriers must

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conform with FRA requirements for the general section (Subpart A), the prohibitions (Subpart B), mandatory post-accident testing (Subpart C), and testing for cause (Subpart D). These operations are exempt from the FRA requirements for programs for troubled employees, pre-employment testing, and random testing.

2.2 DEFINITIONS

For purposes of 49 CFR Part 219 and this Compliance Manual, the following operational definitions apply:

Covered Employee. A covered employee is defined as a person who either performs service during a duty tour or is assigned to perform service subject to the Hours of Service laws. That person may be an employee, contractor, or volunteer. An applicant for a position which has covered service responsibilities is considered a covered employee for all applicable purposes in Part 219. In general, train and engine service employees (including some hostlers), dispatching service employees, signal employees, and select other personnel (such as utility employees) are likely subject to Part 219 regulations.

Railroad. A railroad affected by Part 219 must be operating on a standard gage track which is part of the general railroad system of transportation. This affects both freight and passenger operations, and certain commuter and other short-haul passenger service. Part 219 does not affect a railroad which only operates on tracks inside an installation and/or is not part of the general transportation system (i.e. plant railroads and rapid transit operations within an urban area).

2.3 EFFECT OF HOURS OF SERVICE LAWS

The Hours of Service laws apply to Part 219 employee testing programs as follows:

For random testing, specimen collection must be completed within the employee's Hours of Service duty period. If Hours of Service expires (including during a shy bladder situation), the employee must be released immediately from his or her testing obligation without sanction and the employer may not later recall the employee to complete the collection or place them in a special selection testing pool. However, if the employee is in the middle of a direct observation collection

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because of something that occurred during the collection (problem with the specimen temperature, the donor being caught with a chemical or false specimen, etc.), FRA would require exceeding Hours of Service in order to finish collecting the sample.

Because they are unpredictable tests, a carrier must require an employee to exceed their Hours of Service if the testing is for unpredictable events (mandatory post-accident, reasonable suspicion, or Federal reasonable cause).

FRA also permits exceeding Hours of Service if reasonable cause testing is being conducted under the company's own authority but the thresholds which could trigger a Federal reasonable cause test have been met.

Finally, FRA requires Hours of Service to be exceeded whenever a sample recollection is mandated under Part 40.

In all of the above cases, the railroad must report any excess Hours of Service for the employee. However, FRA will use its prosecutorial discretion and not file a violation if the carrier used reasonable due diligence in completing the collection.

For Federal follow-up testing, Hours of Service laws apply to the normal collection process and the carrier is permitted to reschedule if the collection must be terminated. However, the carrier can require the employee to exceed Hours of Service if the collection turns into a shy bladder situation before the employee's Hours of Service expires. Like in the paragraph above, the carrier must report the employee's excess service but the FRA will not apply a sanction if the carrier demonstrates due diligence in completing the collection.

In certain circumstances, an employee may be called on duty for purposes of having a specimen collected (i.e., a follow-up test when the employer is having difficulty obtaining a specimen because of the employee's unpredictable schedule, or a random test for those employees that are on an emergency call list or are first out on an extraboard, etc.) In such circumstances, normal Hours of Service laws apply for purposes of obtaining specimens.

2.4 REGULATORY AUTHORITY

Regulations which establish Federal requirements for rail carriers conducting drug and alcohol testing under FRA authority can be found at 49 CFR Part 219.

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Department of Transportation Office of the Secretary (DOT) regulations which support FRA testing can be found at 49 CFR Part 40.

FRA regulations establish when testing is required and can be conducted, who is to be tested, and the actions which must be taken when an applicant or employee passes or fails a required test.

DOT regulations provide the technical/scientific/medical detail on how FRA drug and alcohol specimens are to be collected, analyzed, reviewed, and reported. The DOT regulations also encompass the process by which an applicant or covered employee becomes eligible again for covered service after having failed or refused a required drug or alcohol test or has otherwise been disqualified from covered service for violating FRA prohibitions.

Carriers are reminded that in their consideration of any FRA drug and alcohol issue, they must first rely on the plain language text of applicable Federal regulations. In the case of an apparent conflict between regulations (that is, between Part 219 and Part 40), Part 219 is the prevailing regulation. Including the Federal regulations, carriers should rely on the following sources of information (in priority order):

- 49 CFR Part 219, as amended
- 49 CFR Part 40, as amended
- Published FRA guidance documents including this Compliance Manual, and written FRA rule interpretations
- Published DOT guidance documents and written DOT rule interpretations (only on Part 40 issues)
- Verbal guidance from the FRA Alcohol and Drug Program Manager
- Verbal guidance from DOT's Drug and Alcohol Policy and Compliance Office (only on Part 40 issues)
- Verbal guidance from FRA Regional Drug and Alcohol Specialists

Carriers should not rely solely on verbal guidance when taking a significant Part 219 program action, and should instead obtain written affirmation from FRA or DOT as a followup.

Information, rule interpretations, and program guidance provided by third parties including railroad organizations, trade or vendor associations, and unions do not

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hold any weight with FRA in determining carrier compliance with Part 219 or Part 40. Whenever possible, the carrier should not undertake a significant course of action under Part 219 without written Federal authority or reference.

2.5 49 CFR PART 219

49 CFR Part 219, "Control of Alcohol and Drug Use", has been FRA's cornerstone drug and alcohol regulation since 1985. It establishes the purpose and scope of FRA's drug and alcohol program requirements, and provides Federal standards for control of drug and alcohol use on regulated railroads. The regulation is broken down into ten subparts. They are:

- **Subpart A — General [219.1 - 219.23]**. Subpart A establishes the general application, purpose and scope of Part 219. It provides program definitions; identifies the conditions for waivers; establishes responsibility for compliance; and describes general conditions for chemical tests. It also contains important information required of railroads in their drug and alcohol policies and procedures.
- **Subpart B — Prohibitions [219.101 - 219.107]**. Subpart B contains the basic prohibitions regarding on and off-duty drug and alcohol use; describes the use of prescribed and over-the-counter drugs; establishes the carrier's responsibility for action if an applicant or employee violates the prohibitions; establishes the carrier's responsibility for due diligence in preventing violations of Part 219; and describes the consequences for applicants and employees if they refuse a required test.
- **Subpart C — Post-Accident Toxicological Testing [219.201 - 219.213]**. Subpart C establishes the rule-triggering events for which mandatory post-accident testing is required and the thresholds which initiate testing; identifies the covered employees and others who are to be tested after each event; establishes the responsibilities of both the carrier and its employees; describes sample collection and specimen handling for both surviving employees and fatalities; describes the reporting required; and identifies the consequences of refusing this required Federal test.
- **Subpart D — Testing for Cause [219.300 - 219.302]**. Subpart D establishes the requirements for mandatory reasonable suspicion testing and the authorization

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for Federal reasonable cause testing. It also establishes the importance of prompt sample collections for alcohol and drugs and the required timelines for each.

- Subpart E – Identification of Troubled Employees [219.401 - 219.407]. Subpart E contains the carrier's requirements for establishing policies which facilitate the identification, and if applicable, the mechanism for return to duty for covered employees who abuse drugs and alcohol in violation of FRA prohibitions. Included are FRA's standards for a Federal voluntary referral policy and a Federal co-worker report policy, and the requirement to establish mandatory Federal programs to support each policy.
- Subpart F – Pre-Employment Tests [219.501 - 219.505]. Subpart F establishes the requirements for pre-employment testing of personnel who are being hired into or being transferred for the first time into covered service. Also included are the consequences of refusing a Federal pre-employment test.
- Subpart G – Random Alcohol and Drug Testing Programs [219.601 - 219.611]. Subpart G contains the requirements for random testing including the submission requisites and FRA approvals necessary for the carrier's Random Plan; describes the yearly establishment by FRA of the drug and alcohol testing rates; and details random program implementation procedures.
- Subpart H – Procedures for Urine Drug Testing and Alcohol Testing [219.701]. Subpart H establishes the Federal standards for drug and alcohol testing required by Part 219, which are found in DOT's 49 CFR Part 40.
- Subpart I – Annual Report [219.801 - 219.803]. Subpart I contains guidelines on the information required from each carrier in its annual Management Information System (MIS) report submission to FRA.
- Subpart J – Recordkeeping Requirements [219.901 - 219.905]. Subpart J establishes the carrier's recordkeeping and access requirements for drug and alcohol testing records.

The rule also contains several appendices. Appendix A to Part 219 contains a listing of the civil penalties for carriers and employees who fail to comply with

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these regulations. Appendix B contains the name and address of FRA's designated mandatory post-accident laboratory. Appendix C establishes mandatory post-accident sample collection procedures.

2.6 49 CFR PART 40

49 CFR Part 40, "Procedures for Transportation Workplace Drug Testing Programs", establishes standards and procedures in the collection, laboratory analysis, medical review, and reporting of urine drug tests; and the collection, analysis, and reporting of saliva and breath alcohol tests being conducted under Department of Transportation (DOT) operating administration regulations. Part 40 also identifies employer and service agent responsibilities, and the mechanism by which individuals who fail or refuse a Federal test can be made eligible to perform regulated service. These standards and procedures are mandated for all FRA-required testing ordered under Part 219. The regulations are broken down into 18 subparts. They are:

- Subpart A – Administrative Provisions [40.1 - 40.7].
- Subpart B – Employer Responsibilities [40.11 - 40.2].
- Subpart C – Urine Collection Personnel [40.31 - 40.37].
- Subpart D – Collection Sites, Forms, Equipment and Supplies Used in DOT Urine Collections [40.41 - 40.51].
- Subpart E – Urine Specimen Collections [40.61 - 40.73].
- Subpart F – Drug Testing Laboratories [40.81 - 40.113].
- Subpart G – Medical Review Officer and the Verification Process [40.121 - 40.169].
- Subpart H – Split Specimen Tests [40.171 - 40.189].
- Subpart I – Problems in Drug Tests [40.191 - 40.209].

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- Subpart J – Alcohol Testing Personnel [40.211 - 40.217].
- Subpart K – Testing Sites, Forms, Equipment and Supplies Used in Alcohol Testing [40.221 - 40.235].
- Subpart L – Alcohol Screening Tests [40.241 - 40.247].
- Subpart M – Alcohol Confirmation Tests [40.251 - 40.255].
- Subpart N – Problems in Alcohol Testing [40.261 - 40.277].
- Subpart O – Substance Abuse Professionals and the Return-to-Duty Process [40.281 - 40.313].
- Subpart P – Confidentiality and Release of Information [40.321 - 40.333].
- Subpart Q – Role and Responsibilities of Service Agents [40.341 - 40.355].
- Subpart R – Public Interest Exclusion [40.361 - 40.413].

The rule currently contains seven appendices. Appendix A to Part 40 contains the DOT standards for urine collection kits. Appendix B contains the content categories of the DOT drug testing semi-annual laboratory report. Appendix C is reserved by DOT. Appendix D contains the format for reporting to the DOT a split specimen that failed to reconfirm. Appendix E provides the SAP equivalency requirements for certification organizations that wish to petition DOT to be a SAP certifying body. Appendix F identifies the types of drug and alcohol testing information that consortiums and third party administrators may transmit to their employers. Appendix G contains the Federal Alcohol Testing Form. The current Federal drug test form was made effective on 8/1/00 by the Department of Health and Human Services and may be found on that Department's website (<http://workplace.samhsa.gov>).

2.7 OTHER IMPORTANT DOCUMENTS

The carrier and their service agents may wish to obtain copies of other important reference documents, including the DOT's Urine Specimen Collection Guidelines

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(August 2001 version), and the Substance Abuse Professional Guidelines (August 2001 version). A third set of guidelines on the Medical Review Officer are being revised at the time of the publication of this edition of the Manual. It is expected that periodically these sets of guidelines may undergo revision as regulations are updated.

The DOT also periodically issues Part 40 interpretations and publishes them at their website (<http://www.dot.gov/ost/dapc>).

2.8 RESPONSIBILITY OF EMPLOYERS

Both regulations which directly affect Federal (DOT) drug and alcohol testing (49 CFR Parts 219 and 40) make it clear that employers are responsible for both their own compliance with the regulations and the compliance of their service agents (e.g. collectors, laboratories, Medical Review Officers, Substance Abuse Professionals, Consortiums, and Third-Party Administrators).

As the employer, the carrier is responsible for meeting all applicable requirements and procedures found in these regulations. Even if a carrier outsources all of its covered service functions to other carriers or other employers, the carrier of record is the responsible entity as far as compliance with Part 219 is concerned.

The carrier is also responsible for the action of all its officials, representatives, and agents (including service agents) in carrying out its responsibilities in these regulations. Joining a consortium or employing a third-party administrator does not waive the carrier's responsibilities when it comes to compliance. Put directly, failure of a service agent to perform properly under these regulations will likely result in sanctions against the carrier. When any employee performing covered service has been willfully negligent in properly complying with these rules, FRA may also additionally choose to pursue an individual liability action against that individual.

All carrier agreements and arrangements, written or unwritten, between the carrier and its service agents concerning the implementation of these regulations are deemed, as a matter of law, to require compliance with Part 219 and Part 40. When a service agent demonstrates willful and serious negligence in its responsibilities or acts irresponsibly to the point that safety is jeopardized, the FRA

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may choose to take a specific civil penalty action against the service agent (see 219.9).

When FRA feels their actions warrant, FRA can even seek a Public Interest Exclusion (PIE) against the service agent who repeatedly fails or refuses to comply with Federal drug and alcohol testing regulations, or fails to cooperate with FRA or its representatives concerning the investigation of complaints, a compliance audit or enforcement action, or legitimate requests for documents or other information which demonstrates their client's compliance with the regulations. A description of the procedures involved in a PIE action against a service agent can be found in Subpart R of 49 CFR Part 40 (40.361 - 40.413).

2.9 RESPONSIBILITY OF EMPLOYEES

While subject to Part 219, covered employees are responsible for not being in violation of FRA prohibitions. While on duty or subject to duty, covered employees (employees, contractors, and volunteers) may not:

- Possess, be impaired by, or work under the influence of an unauthorized controlled substance.
- Possess, be impaired by, or work under the influence of ethyl alcohol (alcohol).
- Have the verified presence of an unauthorized controlled substance in their urine in a Federal test.
- Have the confirmed presence of alcohol in their breath at 0.04 % or greater in a Federal test. [FRA also requires that the employee must be removed from covered service until at least the next duty period or eight hours (whichever is more) if their confirmed alcohol level is 0.02 % to 0.04 %. This, however, is not a violation of the FRA prohibitions.]
- May not use alcohol within four hours of reporting for covered service, or after receiving notice for reporting for covered service, whichever is later.
- Use any prescription medication or combination of medications (including controlled substances) unless the medication(s) were:

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- taken in accordance with a physician's orders and/or the manufacturer's directions, and
 - were approved as safe to use by at least one physician who knew all of the medications the employee was taking considered in light of their job responsibilities.
- Refuse any Federal test.

2.10 RESPONSIBILITY OF SERVICE AGENTS

Service agents are persons and entities who perform regulated duties and responsibilities on behalf of carriers, and whose functions fall under 49 CFR Part 40. Service agents include, but are not necessarily limited to, urine specimen collectors, Breath Alcohol Technicians (BATs), Screening Test Technicians (STTs), laboratories, Medical Review Officers (MROs), Substance Abuse Professionals (SAP)s, and Consortiums/Third Party Administrators (C/TPAs). Although they may act as agents for a carrier, they cannot be employers for purposes of Part 219 nor do they exempt an employer from responsibility for the duties they perform.

While subject to Part 219, a carrier's service agents performing duties under Part 219 and Part 40 are responsible for complying with both the letter and the intent of these regulations. Failure to comply will likely result in at least sanctions applied against the carrier. If the violations are sufficiently egregious, willful, and unremedied, several types of actions and sanctions may be applied by FRA and by DOT directly against the service agent (a further discussion is at Section 2.8 of this Manual).

FRA will look harshly at any carrier whose service agents attempt to short-cut, obstruct, ignore, or otherwise willfully fail to comply with basic regulatory requirements. Examples include, but are not limited to, MROs who fail to wait for required documentation before reporting test results, C/TPAs who improperly assume responsibilities of other service agents (especially MROs), SAPs who improperly refer employees for assistance, service agents who are not qualified to perform their duties under Part 40, and service agents who fail to maintain proper records, etc.

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Service agents are required to comply in a timely manner with FRA requests to produce records required to be maintained under Parts 219 and 40 (see also Section 14.0 of this Manual). Records are expected to be maintained as originals (scanned copies may not necessarily be accepted), must be readable, and must be auditable. As with carrier records, FRA will be the sole determiner on whether a service agent's records are acceptable.

2.11 ENFORCEMENT PHILOSOPHY

In the past, Part 219 and Part 40 rule requirements were sometimes vague and contradictory, difficult to properly implement, and often required interpretations to ensure a coherent enforcement philosophy. Some of these drug and alcohol testing regulations were as foreign to the railroads as they were to the regulators who were responsible for enforcing them. FRA recognizes that only by fully understanding these complex rules can a carrier become fully compliant with both the letter and the intent of the regulations.

FRA recognizes that most carriers and their employees fully share FRA's commitment to safety and desire to maintain a drug and alcohol free workplace. FRA also acknowledges that most carriers want to establish programs which fully comply with FRA drug and alcohol regulations and guidelines. Most carriers often correct deficiencies and even more serious non-compliance problems on their own without any Federal enforcement action necessary. In many cases, once a carrier understands FRA's intent, non-compliance issues are immediately and permanently resolved.

For FRA, safety must always be the first consideration. Sometimes the application of sanctions are felt to be necessary in order to encourage and facilitate change by a non-compliant carrier. In an effort to correct non-compliance with Part 219 and Part 40, FRA may choose a level of remediation based on history, attitude, and egregiousness of the offense.

However, because of the nature of the program, not all of the elements of the Part 219 and Part 40 regulations equally affect safety. Therefore, not all compliance issues are significant enough to warrant the use of sanctions to facilitate compliance. FRA's goal is to apply the appropriate degree of remedy based on the relative importance of the issue to safety, the carrier's history with that issue, and whether the carrier created the problem through its willful negligence or purposeful action. The final decision regarding utilization of the level of remedy remains the responsibility of the FRA Office of the Chief Counsel.

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Among the questions whose answers are expected to weigh into FRA's assessment of Part 219 and Part 40 issues include:

- Was it a willful action by the carrier or its service agent?
- Although ignorance of the regulation is not an excuse, how knowledgeable was the carrier of the action?
- Was the action part of a systemic problem or an isolated instance?
- Did the action demonstrate willful disregard for the regulation or for safety?
- Was the employee's right to confidentiality or due process purposefully ignored or subverted?
- Did the carrier or its agent lie, falsify records, hide information, or mislead the Inspector's investigation?

The regulations must be interpreted fairly and evenly under all enforcement circumstances, always with an eye to balancing public safety with the rights of the employee and the rights of the employer.

3.0

PROHIBITIONS

3.0 PROHIBITIONS

3.1 OVERVIEW

FRA regulations found in 49 CFR 219.101 – 219.107 (Subpart B) describe FRA drug and alcohol use prohibitions governing railroad employees and their employees, contractors, and volunteers who perform covered service. FRA's intent is that all covered service personnel are aware of FRA prohibitions and the consequences of violating FRA's drug and alcohol rules. FRA's goal is that the carrier exercises due diligence in preventing violations of these prohibitions to the degree possible. FRA prohibitions must be clearly disseminated to all covered service personnel, and the carrier must ensure that all applicable railroad policies, procedures, and practices are consistent with these Federal prohibitions.

3.2 REGULATORY REFERENCES (49 CFR PART 219)

- 219.5 – Definitions: Controlled Substance; Covered Employee; Drug; Possess
- 219.23 – Railroad Policies
- 219.101 – Alcohol and Drug Use Prohibited
- 219.102 – Prohibition on Abuse of Controlled Substances
- 219.103 – Prescribed and Over-the-Counter Drugs
- 219.104 – Responsive Action
- 219.105 – Railroad's Duty to Prevent Violations
- 219.106 – [Reserved]
- 219.107 – Consequences of Unlawful Refusal

3.3 INSPECTION GOAL

The goal for inspecting this element is to determine whether the carrier fully supports and is properly disseminating information on FRA drug and alcohol prohibitions to all covered service personnel. It is essential that the carrier ensure that all of its applicable practices and procedures to train, implement, and enforce these prohibitions are consistent with FRA regulations, and that covered personnel found to be in violation of 219.101 or 219.102 are removed from service expeditiously and handled in strict accordance with FRA requirements.

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3.4 RECORDS REQUIRED

The FRA Inspector should review all applicable carrier drug and alcohol policies, procedures, and distributed materials to ensure that FRA prohibitions are clearly described and distinguished from company policies and Rule G. The Inspector should assess carrier records to determine whether the required dissemination of information to employees on the drug and alcohol prohibitions has been accomplished, and audit the content of the materials provided. The Inspector should also evaluate individual verified positive cases to determine if positive personnel are being relieved without unnecessary delay from covered service and that they are not being returned before they meet the full requirements of the Rule. Interviews with employees and supervisors throughout the carrier's system should be conducted.

3.5 PROHIBITIONS

3.5.1 Determine that all applicable carrier drug and alcohol policies, procedures, training, and other written or posted materials for covered service employees are adequately disseminated and clearly describe FRA prohibitions identified in 219.101 and 219.102.

3.5.2 Determine that all applicable carrier practices for covered service employees, whether formal or informal, clearly support FRA prohibitions described in 219.101 and 219.102, and are clearly distinguishable from the carrier's company policy and/or Rule G if they are different.

All carrier policies, procedures, other related documents and practices must clearly distinguish between Federal drug and alcohol prohibitions and carrier policy if they are different. The carrier's Rule G should at the least support and enhance FRA prohibitions, but if it goes beyond FRA requirements it must also be clearly distinguished from the Federal regulations.

All covered service personnel must be generally knowledgeable of FRA prohibitions, which they should have received from carrier training, from formal or informal interaction with supervisors, from carrier practices, and/or from published materials made available to them to fulfill the requirements of 219.23. The carrier should be prepared to provide documentation on any formal efforts to educate covered employees on FRA prohibitions and testing requirements.

In 219.101, covered service personnel (employees, contractors, volunteers) are prohibited from possessing, being impaired by, or working under the influence of a

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controlled substance while on duty or subject to duty. In addition, covered personnel are also in violation of 219.101 if they are under the influence or impaired by alcohol; have a blood or breath alcohol concentration equivalent to 0.04% or greater; or have ingested alcohol within four hours of reporting for duty or after receiving notice to report for covered service (whichever is the lesser period).

If the alcohol confirmation test result is 0.02 % - 0.039 %, covered personnel must be removed from covered service until their next regularly scheduled duty tour, but for not less than eight hours. They need not be evaluated by a SAP, nor are they required to comply with any other FRA requirements before returning to duty. This is considered a credible positive result, but not a violation of 219.101. The carrier may choose to take additional administrative action against the employee if it wishes under its own authority.

Alcohol concentrations of less than 0.02 % from a Federal collection are negative tests. The carrier is not permitted to take any administrative action on a Federal result of greater than 0.00 % and less than 0.02 %, nor may they use this finding as the nexus for conducting their own alcohol test under company authority.

Additional company policy testing after a negative Federal alcohol test (below 0.02 %) would only be permitted in the extraordinarily rare circumstance where following a reasonable suspicion, Federal reasonable cause, or Federal follow-up test, the carrier's trained supervisor was present and made an independent post-test reasonable suspicion determination based on the covered employee's body odors, speech, behavior, or appearance. However, this same allowance would not be permitted following a Federal random test. Carriers are not permitted to use this special circumstance as an opportunity to achieve a different test result, and any such case should be thoroughly investigated by FRA. Unless the carrier has compelling evidence to support the need for additional testing, FRA will likely consider strong administrative action against the railroad.

In 219.102, covered service personnel are prohibited from using a controlled substance at any time, on or off duty, unless it is authorized or prescribed by a medical practitioner and has been determined not to affect the safe performance of the person's covered duties. This FRA prohibition may differ from the traditional carrier Rule G, which sometimes does not prohibit non-medical use of a controlled substance while off-duty.

In most circumstances, absent other credible evidence which specifically supports a finding of impairment or being under the influence, a urine test positive for drugs will usually only be chargeable under 219.102. By the nature of the sample type

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itself, a urine positive will not ordinarily reveal the amount or recency of the drug used.

In both 219.101 and 219.102, covered personnel in violation of these prohibitions may not be returned to covered service until they meet the requirements of the Substance Abuse Professional (SAP) and are fully qualified for duty under FRA regulations.

In both 219.101 and 219.102, FRA does not address the issue of employment. Carriers may choose to retain or not retain an individual with a verified positive drug test or a confirmed alcohol concentration at or above 0.02%, but the decision must be made in accordance with their own company policy and/or collective bargaining agreement.

FRA expects that the carrier should also be interested in the use of other potentially impairing medications, whether prescribed or over-the-counter, even if they are not controlled substances (this issue will be discussed in more detail in Section 3.5.3 of this Manual).

3.5.3 Determine that the carrier fully supports and enforces a policy that ensures compliance with 219.103.

Even while performing covered service, personnel may use one or more controlled substances when prescribed or authorized by a physician if a medical determination is made that use of the medication(s) will not adversely impact the safe performance of their duties. The medications must be used at the dose prescribed or authorized by the physician. If more than one controlled substance is being used, a single physician with a complete knowledge of all the medications being taken and the employee's duties must make this medical judgment. The determining physician may be either the employee's doctor or a doctor selected by the employer. FRA's intent is that the responsibility for this requirement rests with the employee, but it is the employer's responsibility to ensure that their employee is made aware of the regulation.

The railroad is also not restricted from establishing its own separate notification requirement for any therapeutic drug use, including compelling covered personnel to obtain prior approval from the carrier for such use (usually through the carrier's medical department).

Although not required by the regulations, FRA encourages carriers to remain vigilant about the use of other potentially impairing prescribed and over-the-

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counter medications by employees even if they are not Federally-controlled substances (that is, do not have dependence potential). Carrier attention to this important issue would likely enhance rail safety, demonstrate the carrier's support of FRA's safety interest in this area, and be protective of the health and welfare of its employees. Anecdotal data from DOT agency accident investigations and reports from the NTSB reveal increasing concerns about commonly used over-the-counter and prescription medications which cause such symptoms as drowsiness and light-headedness, and/or impact the ability of the employee to properly focus on and safely perform his or her covered duties.

3.5.4 Determine whether the carrier takes immediate action in relieving covered personnel in violation of 219.101 or 219.102 from duty, whether the employee receives the proper notice and opportunity for a hearing in a timely manner, whether the employee is not returned to covered service until all requirements of the rule are met, and whether the employee receives sufficient follow-up tests once back on covered duty.

3.5.5 Determine whether the carrier takes the same immediate action with covered service personnel who are detected adulterating or substituting their urine sample, or have refused a required drug or alcohol test.

Under 219.104, once a covered employee is determined to be in violation of 219.101 or 219.102 (or having refused a required drug or alcohol test), the carrier is responsible for immediately removing that individual from covered service as soon as it is practical. Personnel so identified must be notified of the reason for their removal from covered service and must be given the opportunity for a hearing within the timeframe specified in the collective bargaining agreement, or absent an agreement, within 10 days of receiving notification from the MRO or the BAT. At the hearing, the employee is given the opportunity to contest the positive result or the refusal. A refusal requires a minimum nine month suspension from covered service.

In a 219.104 hearing, the burden is on the carrier to demonstrate that a violation of the FRA drug or alcohol prohibitions has occurred. In order to help ensure that the employee can properly prepare, the carrier must provide to the employee all relevant documents which establish the violation at least three calendar days before the hearing. At the hearing, the carrier need not ordinarily provide service agent witnesses in person (i.e. specimen collector, laboratory analyst, MRO, etc.) on a positive test or adulterated/substituted specimen unless:

- so requested by the hearing officer,

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- the employee has raised a specific and credible challenge to one or more procedures or actions taken by the service agent, or
- specifically required in a collective bargaining agreement.

Regardless of the findings of the 219.104 hearing, or the later findings of an arbitrator or other neutral, no consideration may be given to returning an employee to covered duties once they had been removed until a SAP has recommended consideration of that individual for return to covered service.¹ The carrier must also ensure that a Federal return-to-work test is on file before the employee is allowed to return (drug, alcohol, or both as determined by the SAP), and that SAP-recommended Federal follow-up tests are all being conducted in the required timeframe. Federal return-to-work and follow-up tests must also be performed for covered personnel who were found to be in possession of a controlled substance in violation of 219.101.

In addition, only the Medical Review Officer (MRO) can change a verified drug test result, such as a positive or refusal to test where the reason was an adulterated or substituted specimen. A hearing arbitrator, or other neutral is not permitted under Federal regulation to overturn the medical judgement of the MRO.

3.5.6 Determine that the carrier has exercised due diligence in ensuring its employees comply with 219.101 and 219.102, and does not permit an employee to either go on covered duty or remain on duty when it has actual knowledge that the employee has violated 219.101 or 219.102.

Under 219.105, a carrier may not allow personnel to perform covered service if a railroad management employee has knowledge that the individual is in violation of 219.101 or 219.102. This knowledge must be based on direct information (not just claims from a third party), and be of sufficient credibility that the management employee may reasonably believe that 219.101 or 219.102 has been violated.

The carrier must make every effort to ensure that its covered personnel are complying with 219.101 and 219.102 and may not overlook potential violations through its own negligent actions (or failure to act). The carrier has a responsibility

¹ However, the carrier may return an employee to covered service without a SAP evaluation in the limited circumstance where the carrier had subsequently uncovered credible evidence that the test result reported on the employee could no longer be judged scientifically sound or legally defensible due to a catastrophic collection, laboratory, or MRO error.

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to continually improve its ability to detect and deter covered service personnel from misusing drugs or alcohol in violation of FRA regulations. The railroad's practices may not offer an opportunity for covered personnel to avoid detection because of carrier carelessness, indifference, or inattentive performance. This includes, but is not limited to, the carrier ensuring that they have in place an effective and proper Part 217 efficiency/operational check program for Rule G (see also Section 11.3.3.2).

In deciding whether they must take action based on an allegation, employers must make a good faith determination based on the available relevant evidence at hand. The decision should be made by a knowledgeable and authorized management official after reasonable inquiry into the facts of the case that are available at that time. No adverse action should ever be taken without specific evidence of a violation. Guesses, suppositions, or conjectures do not constitute evidence. Signed affidavits from credible, reputable witnesses may.

Prohibitions Summary Checklist

I. Prohibitions [3.5]

- A. *Determine that all applicable carrier drug and alcohol policies, procedures, training, and other written or posted materials for covered service employees are adequately disseminated and clearly describe FRA prohibitions identified in 219.101 and 219.102. [3.5.1]*
- B. *Determine that all applicable carrier practices for covered service employees clearly support FRA prohibitions described in 219.101 and 219.102, and are clearly distinguishable from the carrier's company policy and/or Rule G if they are different. [3.5.2]*
- C. *Determine that the carrier fully supports and enforces a policy that ensures compliance with 219.103. [3.5.3]*
- D. *Determine whether the carrier takes immediate action in relieving covered personnel in violation of 219.101 or 219.102 from duty, whether the employee receives the proper notice and opportunity for a hearing in a timely manner, whether the employee is not returned to covered service until all requirements of the rule are met, and whether the employee receives sufficient follow-up tests once back on duty. [3.5.4]*
- E. *Determine whether the carrier takes the same immediate action with covered service personnel who are detected adulterating or substituting their urine sample, or have refused a required drug or alcohol test. [3.5.5]*
- F. *Determine that the carrier has exercised due diligence in ensuring its employees comply with 219.101 and 219.102, and does not permit an employee to either go on covered duty or remain on duty when it has actual knowledge that the employee has violated 219.101 or 219.102. [3.5.6]*

4.0

SPECIMEN COLLECTION

URINE

4.0 SPECIMEN COLLECTION - URINE

4.1 OVERVIEW

Department of Transportation regulations found in 49 CFR 40.31 through 40.73 (Subparts C, D, and E) and FRA regulations found in 49 CFR 219.11 and 219.701 describe requirements for the collection of urine specimens under Part 219 to be analyzed for drugs for all but mandatory post-accident testing (Subpart C). Part 219.205 and Appendix C to Part 219 (with exhibits) contain urine collection instructions for Subpart C rule-triggering events. In this section of the Manual, the principal focus will be on urine collections for all but mandatory post-accident testing, although many of the elements will apply equally.

FRA considers the carrier responsible for the performance of its urine specimen collectors, including for mandatory post-accident testing. This is true even if collection services, collection sites, or individual collectors have been contracted for by an outside third party administrator or consortium.

The role of the urine specimen collector is to ensure that the samples obtained from the carrier's applicants or covered employees have been collected in a manner consistent with DOT and FRA regulations and guidelines. For each FRA collection, the collection site must have been properly prepared; the specimen obtained with Federal standards maintained and proper procedures followed; and the collection properly documented on a Federal collection form.

The specimen arriving at the carrier's laboratory must give ample evidence that it was collected, labeled, and sealed in accordance with the Federal requirements and that there was no evidence that the sample itself had been compromised. There must be no evidence that the sample had been mixed up with another donor's or that the specimen arriving at the laboratory could have been contaminated or adulterated by someone other than the donor.

Collectors must be properly trained in and knowledgeable of all Federal collection requirements; be properly vigilant to detect attempts at diluting, substituting, or adulterating the sample by the donor; and be capable of properly handling refusals, shy bladder situations, or other unusual collection events in accordance with DOT and FRA regulations and guidance.

FRA Inspectors are not permitted to witness or be part of an actual carrier urine specimen collection process. They are authorized and encouraged to use a "mock" collection to evaluate compliance.

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4.2 REGULATORY REFERENCES (49 CFR PART 219 AND 49 CFR PART 40)

- 219.11 – General Conditions for Chemical Tests
- 219.701 – Standards for Drug and Alcohol Testing

- 40.3 – Definitions: Cancelled test; Chain of custody; Collection container; Collection site; Collector; Designated Employer Representative (DER); Error correction training; Service agent; Shipping container; Specimen bottle; Split specimen

- 40.31 – Who may collect urine specimens for DOT drug testing?
- 40.33 – What training requirements must a collector meet?
- 40.35 – What information about the DER must employees provide to collectors?
- 40.37 – Where is other information on the role of the collectors found in this regulation?

- 40.41 – Where does a urine collection for a DOT drug test take place?
- 40.43 – What steps must operators of collection sites take to protect the security and integrity of urine collections?
- 40.45 – What form is used to document a DOT urine collection?
- 40.47 – May employers use the CCF for non-DOT collections or non-Federal forms for DOT collections?
- 40.49 – What materials are used to collect urine specimens?
- 40.51 – What materials are used to send urine specimens to the laboratory?

- 40.61 – What are the preliminary steps in the collection process?
- 40.63 – What steps does the collector take in the collection process before the employee provides a urine specimen?
- 40.65 – What does the collector check for when the employee presents a specimen
- 40.67 – When and how is a directly observed collection conducted?
- 40.69 – How is a monitored collection conducted?
- 40.71 – How does the collector prepare the specimens?
- 40.73 – How is the collection process completed?

4.3 INSPECTION GOAL

The goal for inspecting this element is to ensure that the carrier employs urine collectors for Part 219 testing that are properly trained and fully knowledgeable of

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the regulations; can properly manage Federal specimen collections, including site preparation, sample collection, and transfer of the specimen to the laboratory in accordance with applicable standards of practice; can capably perform difficult or complicated collections (shy bladder, refusals, adulteration attempts, etc.); and can collect samples in a professional manner, seeking a product which can achieve a scientifically sound and legally defensible laboratory test result.

4.4 RECORDS REQUIRED

The FRA Inspector should examine MRO test records (negatives, positives, and MRO downgrades) to ensure the completeness and accuracy of the documentation of collections. The Inspector should interview one or more collectors performing this service for the carrier, and wherever possible, conduct a full mock collection with one or more selected collectors in the carrier's system.

4.5 PREPARATION FOR COLLECTIONS

4.5.1 Determine that the collection location is suitable for a properly secure and confidential urine collection for drugs.

FRA permits Part 219 urine collections at any reasonable location, including carrier property, as long as Part 40 requirements can be met. The location may be in a public restroom, in a van or RV, in a dedicated urine collection site, or a medical clinic where a medical practice is conducted. The collection location must be able to provide (at a minimum) an enclosure where privacy for urination is possible, a toilet or urinal to complete the void, a source of water for washing hands, and a suitable writing surface for annotating the specimen seals and the drug test Custody and Control Form (CCF). A single-toilet room with a full-length swing door is preferred, but the use of a stall in a multi-stall bathroom with a partial-length door could be acceptable if a single-toilet room is not available.

The specimen (the void) must be provided in an area which is secured from the public, other employees, or other unauthorized individuals who may innocently or purposely interfere with the collection process.

The collection area (where the void will be provided) must not allow the donor access to used or unused collection materials (bottles, containers, forms, etc.); cleaning products, soaps, or disinfectants; standing water or liquid of any kind that has not been specially marked with bluing; trash cans, etc. Faucets and other water sources in the collection area must be secured. If this cannot be adequately done, the collection must be accomplished as a "monitored" collection (see Section 4.6.1 of this Manual).

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4.5.2 Determine that the collector has proper urine collection supplies, including Federal CCFs with tamper-evident seals, urine collection containers with temperature strips, split specimen transport bottles, and specimen shipment container(s).

The collector should be fully prepared to collect specimens from the carrier's applicant or covered service employee. They should have sufficient supplies on hand to manage any reasonable eventuality if multiple collection kits or drug testing CCFs become required.

The CCF utilized should be for the laboratory contracted with by the carrier. Although any approved Federal CCF may be used, even one for a different employer or for a different laboratory, modifying the CCF to fit the carrier is neither preferred nor recommended. The unique Urine Identification Number (UIN) on the Form and the UIN on the seals must match exactly. Neither the collector nor the laboratory is permitted to modify the UIN pre-printed on the Form.

4.5.3 Determine that the collector is properly qualified to conduct a Federal urine collection.

The collector may be an employee of the carrier, a contractor, or be completely independent of the railroad. A supervisor in the donor's chain of command cannot be the collector.

The collector must be knowledgeable in Federal requirements for a proper urine collection and should be experienced in conducting Federal collections (either alone or under supervision). Under regulations effective 8/1/01, urine collectors must undergo special qualification training and, within the timeline identified in the regulation, should be able to provide a FRA Inspector with appropriate documentation. It is also expected that collectors will demonstrate their expertise by answering Inspector questions and/or participating in a mock collection conducted by the Inspector. The collector does not need to demonstrate or document their abilities, or provide copies of qualifications or training, directly to the donor or the donor's employee representative at the time of the collection.

The formal qualification training and an initial proficiency demonstration must be completed before a new collector can collect any specimen under FRA or any DOT regulations. Collectors performing duties under these regulations before 8/1/01 are required to complete their formal training program by 1/31/03.

All qualified urine collectors must undergo a formal refresher training program which duplicates their initial training and proficiency requirement within five years

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of their previous qualification. In addition, if a collector makes a mistake on a Federal collection which causes a cancellation of a test by either a laboratory or a MRO, the collector must complete an additional error correction training program within 30 days of the date the error was discovered. The error correction training is to target the subject matter area(s) which caused the test cancellation, and must also include passing a certain number of error-free mock collections in a row with an emphasis on the collection problem they experienced.

As a reference tool, it is recommended that the collector have direct access to written instructions which describe Federal collection requirements. In addition, it would be recommended that the collector also have direct and/or immediate access to a supervisor or someone else who would be knowledgeable of Federal collection procedures.

4.6 FEDERAL DRUG COLLECTIONS

4.6.1 Determine that the collector properly conducts a urine collection, correctly incorporating Federal procedures and standards.

Whenever possible, if both an alcohol and a urine collection are scheduled for a donor, the alcohol collection should proceed first.

All of the urine collection procedures described below are important and should be performed in accordance with the regulation. The failure to follow these elements exactly, however, is not ordinarily fatal to the integrity and credibility of the collection unless otherwise noted. In other words, only a few specific procedural errors could result in the cancellation of the collection.

The collector is responsible for limiting access to the collection site and maintaining control of the collection process at all times. The collector should remove anyone who is attempting to obstruct or in any way interfere.

If the employee has been injured, medical attention must not be withheld or delayed in order to collect Federal specimens.

The employee may not be catheterized for the purposes of obtaining Federal specimens. If the donor normally urinates by a catheter, they may do so to provide the Federal specimen.

If an appointment has been scheduled for an applicant or employee, the collector must notify the employer's DER if the donor does not show within a reasonable time.

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The donor must first be properly identified through a picture ID, through direct identification by a supervisor, or other similar means. Verification of the donor's identity may not be by another worker, another donor, or through non-photo identification. Supervisor verifications may be by telephone as long as the identity of the donor is affirmed in sufficient detail.

The collector may only perform a collection with one donor at a time.

A blank copy of a Federal CCF is found at Tab 1. The preliminary block on the CCF (Step 1) should be filled out before the donor provides the urine. All the other steps (Steps 2, 3, 4, and 5) are to be filled out contemporarily to the individual collection actions themselves. Steps 2 – 5 are not to be filled out in advance of being performed.

The donor should be asked to remove any outer garments as long as they don't intrude upon the donor's modesty. Purses, briefcases, backpacks, or other similar bags may not be taken into the collection area. Only a wallet can be retained by the donor.

The donor must be asked to empty all of his/her pockets. If the employee refuses, the collection is cancelled and it is to be reported to the carrier as a refusal to test.

When the pockets are emptied, any material found which may be used to adulterate or contaminate a sample is to be retained outside the collection area. If it is the collector's reasonable belief that the donor could have attempted to alter their specimen with that material, the procedures necessary to conduct a direct observation collection should be initiated.

Any discovered material which could only have been used to adulterate or contaminate a specimen (i.e., another urine specimen, chemical product, etc.) should be confiscated if possible and given to the employer. Any material which may be either innocent or not (i.e. Visine[®]) can be returned to the donor at the end of the collection process. Failure of a donor to surrender suspicious material before or during the collection may be just cause to terminate the collection for failure to cooperate.

Donors should be asked to wash their hands before the collection, with the intent of removing any adulterants which may be present.

For urination, the collector should provide the donor with a wrapped/sealed collection container (with temperature strip). The wrapped container should be opened in the donor's presence. The donor must provide the specimen directly into the collection container. The specimen's temperature strip must be read

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within four minutes of the void to determine if it falls within the 90 to 100 degree Fahrenheit acceptable range. No temperature device may be placed directly into the urine to be sent to the laboratory.

All DOT testing requires a split specimen.

The donor must be afforded privacy for urination, unless a direct observation collection has been previously authorized. Donors may not be asked to disrobe, either wholly or partially, unless the urine collection is part of a legitimate scheduled medical examination required by a DOT agency's regulations. Currently, no medical examinations are required or authorized by FRA.

The donor is provided a private area for urination, and the collector either is present just outside the door in a single toilet restroom (considered a "private" collection) or stands close by the stall in a secured public restroom (considered a "monitored" collection). A private collection is the preferred method of obtaining a specimen.

A private collection can be conducted by a collector of either gender. A monitored collection must either be conducted by a person of the same gender or a medical professional (such as a doctor, nurse, medical technician, etc.) who may be of the same gender.

When the void is provided, it is brought out to the collector. At least 45 mL is required (30 mL is minimum for the primary bottle and 15 mL is the minimum for the split).

The donor and the collector should proceed together to the area where the CCF is to be completed. The donor should be told not to wash their hands until the paperwork is complete and the specimen is sealed.

The specimen may not leave the presence of the donor until the sealing is completed. Line-of-sight contact between the donor and the specimen is not required. If the urine leaves the donor's presence without the donor's real or implied permission, the collection is seriously and perhaps fatally jeopardized. However, if it is the donor's choice not to be present, then the integrity of the collection is not impacted.

The temperature of any specimen received from the donor is to be recorded in Step 2 of the CCF. If the temperature of the specimen is between 90 to 100 degrees Fahrenheit, it should be accepted unless there is other evidence suggesting temperature tampering. If the temperature is either above or below the range, or does not register, another specimen must be collected immediately

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under direct observation. No special additional procedures (such as taking a body temperature), notifications, or approvals are required before moving to a direct observation collection.

The employer also has the option to conduct a direct observation collection on employees being returned to work after a violation of FRA prohibitions, and for the subsequent follow-up tests.

When a second specimen is separately collected because of a direct observation requirement, both samples should be submitted to the laboratory with an explanatory annotation in the remarks section of the two CCFs. Refusal to cooperate in the second collection is considered a refusal to test. A further discussion of direct observation collections can be found at Section 4.7.4 of this Manual.

The specimen is poured from the collection container into the two transport bottles and the bottles are sealed with the tamper-evident labels from the CCF. The label also contains the same specimen Urine Identification Number (UIN) found on the CCF. Without a label sealing the bottle, or the UIN on the bottle label and the CCF are different, the laboratory will not test the specimen and the problem is not recoverable. The label is to be initialed and dated by the donor after it is on the bottle.

The rest of the CCF (Steps 4 and 5) is then to be filled out. The absence of the donor's signature or the collector's signature could cause the test to be cancelled by either the laboratory or the Medical Review Officer (MRO), as appropriate, unless the problem can be remediated by a signed statement from the collector and/or donor. Other problems (i.e., too little specimen, no seal or UIN on the bottle, discrepant UINs between the bottle and CCF, etc.) may not be recoverable and the test cancelled.

The collector must identify the specific type of courier used in Step 4 (i.e., FedEx, Airborne, UPS, laboratory courier, etc.), but the person actually performing the courier service does not need to sign the CCF.

The sealed specimen and appropriate copies of the CCF (Copies 1 and 2) are to be placed in the plastic bag and sealed. The shipping container itself should also be sealed, as appropriate. Copy 2 of the CCF (the MRO copy) is to be sent directly to the MRO. The other copies (copies 3, 4, and 5) are to be distributed as noted on the Form.

The donor may depart the collection area anytime after the specimen bottles are

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sealed. If the specimen is not to be shipped immediately, it should be held securely until the arrival of the courier service.

4.6.2 Determine if the collector is able to distinguish between Federal and non-Federal collections.

The collector may not employ a Federal form (the CCF) for a non-Federal test, and vice-versa. The collector may not use a portion of the Federal specimen for non-Federal testing (for a company policy test or for medical testing).

4.7 DIFFICULT COLLECTION PROBLEMS

4.7.1 Determine that the collector is capable of handling a shy bladder collection.

Current regulations allow a donor three hours to provide a specimen. DOT regulations (40.193) require the clock to start only after the donor's first attempt. The donor's verbal statement that they can't provide is insufficient to initiate shy bladder procedures. The collector must ensure that the donor is physically in the collection area with collection materials readily available before it is permissible to be notified by the donor that they can't yet produce a specimen. The collector must document the time at which the three hour period begins and ends on the "Remarks" line of the CCF.

Every effort must be made to get the donor to provide an acceptable specimen. The collector must make fluid available, and permit the donor to drink up to 40 ounces of liquid. A collector may not terminate a shy bladder collection because a donor refuses to drink. Regular reminders that the donor should drink, however, are strongly recommended.

The donor may not leave the collection area unescorted or be sent back to work during the waiting period. In all cases, the donor should be monitored during this time by either the collector or some other designated person. The donor's behavior while waiting (how much they drink, etc.) would be valuable information for the collector to record. During the monitoring period, the collector is permitted to conduct other collections as long as someone else is monitoring the shy bladder donor. The monitor does not have to be a qualified or trained collector.

At least once during the three hours, it would be beneficial for the collector to encourage the donor to make another attempt. The collector may extend the collection deadline briefly beyond the three hours only if it appears that the donor may be able to shortly provide an acceptable sample. When possible, the collector should obtain the carrier's concurrence for a time extension.

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Once three hours have passed, the collector is to terminate the collection and report the situation to the carrier. After consultation with the MRO, the carrier must have the donor evaluated by a physician acceptable to the employer. The role of the referral physician is to examine the donor and determine whether there is a legitimate medical or pre-existing psychological reason not to have provided an acceptable specimen volume.

The physician's final report must specifically answer the question at issue without equivocation. There must be a direct link between a medical condition or disease, a medication, or an anatomical problem and the inability to provide a sufficient sample. Dehydration is not an acceptable medical explanation. Situational anxiety is not an acceptable psychological explanation. The physician's report is to be submitted to the employer via the MRO, who may comment but not over-ride the referral physician's report. The employer is responsible for making the final decision on whether the incident was a refusal.

4.7.2 Determine that the collector is capable of handling a refusal to test.

Every effort should be made to encourage a recalcitrant donor to provide an acceptable specimen, including asking for assistance from the carrier whenever possible. If the donor will not provide an acceptable urine specimen, it is to be considered a refusal, and must be reported to the railroad.

If the donor will not sign the CCF but has provided what appears to be a bona fide specimen, the collector is to proceed normally and note the donor's unwillingness to sign in the Step 2 "Remarks". The same procedure should be followed if the donor will not initial the specimen label. In both circumstances, the specimen is acceptable and is to be sent to the carrier's laboratory for testing.

The collector cannot require that the employee sign a release of liability form. The donor's refusal to sign would not constitute a Federal refusal, nor may the collector terminate the collection on that basis.

It is extremely important that an incident not be called a refusal when it does not meet the full requirements of the FRA Rule for that determination. FRA will take very seriously any carrier or service agent misapplication of the refusal regulations.

Once a refusal determination has been made, the regulations do not provide an opportunity for the carrier to ignore a refusal. Instead, the carrier must seek a waiver of compliance from FRA if they feel that extenuating circumstances do not warrant an automatic nine-month removal from covered service.

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4.7.3 Determine that the collector is capable of handling an apparent attempt at substituting or adulterating the urine sample.

Once the specimen is produced, the collector should inspect the freshly voided urine for signs of tampering. If it is apparent that the donor may have made an attempt to adulterate or substitute the specimen (the color is not consistent with normal urine, the urine foams too little or too much, there is a chemical smell, etc.), the collector must complete the collection if possible and initiate the procedures for a second, direct observation collection. Other observed behavior (i.e., a false specimen in plain view, the presence of an adulterating substance in the donor's hand, etc.) may also lead to a directly observed second void.

The collector need not obtain the concurrence of the collector's supervisor or a designated employer's representative before proceeding with the direct observation of a new void. The second collection should be conducted immediately, if practical, but certainly as soon as possible if there is to be a delay in initiating the new collection.

If the donor fails to cooperate or leaves the collection area without the collector's permission, it is now considered a refusal to test and the employer is to be notified. The collector should discard any portion of sample already collected.

4.7.4 Determine that the collection site or collection service is capable of handling a direct observation collection.

Collection sites and mobile collection services must always be prepared to conduct an immediate direct observation collection when it is required by the regulation. There should be no unnecessary delay in waiting for the collection site or collection service to produce a same sex observer.

Direct observation collections must be performed if required by the employer (due to a previous positive, adulterated, substituted, or invalid specimen); when an attempt to adulterate or substitute the specimen was discovered during the collection; or when the specimen temperature is out of range.

Direct observation collections must always be by a person of the same gender as the donor, and may never be by either someone in the donor's direct chain of command or by a collector of the opposite gender even if they are a medical professional. The direct observer must place themselves in a position where they can see the actual urine exit the body and go into the collection cup.

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The observer does not need to be a trained collector themselves, but must operate under the supervision of a trained collector. Only a trained collector is permitted to physically handle a specimen.

If the collector inadvertently dismisses the donor before the direct observation collection can be initiated, the donor must be recalled for all test types (pre-employment, random, mandatory post-accident, return-to-work, and follow-up) to provide a direct observation specimen. Although there is no deadline for recall, the donor should be brought back as soon as possible.

If there have been multiple completed voids during the collection procedure (i.e., after an adulteration or substitution attempt), both the first obtained void (if there is sufficient specimen) and the directly observed void are to be submitted to the laboratory with appropriate remarks entered by the collector on the CCF and notification of the DER.

Specimen Collection – Urine Summary Checklist

I. Preparation for Collections [4.5]

- A. *Determine that the collection location is suitable for a properly secure and confidential urine collection for drugs. [4.5.1]*
- B. *Determine that the collector has proper urine collection supplies, including Federal CCFs with tamper-evident seals, urine collection containers with temperature strips, split specimen transport bottles, and specimen shipment containers. [4.5.2]*
- C. *Determine that the collector is properly qualified to conduct a Federal urine collection. [4.5.3]*

II. Federal Urine Collections [4.6]

- A. *Determine that the collector properly conducts a urine collection, correctly incorporating Federal procedures and standards. [4.6.1]*
- B. *Determine if the collector is able to distinguish between Federal and non-Federal collections. [4.6.2]*

III. Difficult Collection Problems [4.7]

- A. *Determine that the collector is capable of handling a shy bladder collection. [4.7.1]*
- B. *Determine that the collector is capable of handling a refusal to test. [4.7.2]*
- C. *Determine that the collector is capable of handling an apparent attempt at substituting or adulterating the urine sample. [4.7.3]*
- D. *Determine that the collection site or the collection service is capable of handling a direct observation collection. [4.7.4]*

5.0

SPECIMEN COLLECTION

BREATH

5.0 SPECIMEN COLLECTION – BREATH

5.1 OVERVIEW

Department of Transportation regulations found in 49 CFR 40.211 – 40.277 and FRA regulations found in 219.11 and 219.701 describe requirements for the collection of breath and saliva specimens under Part 219 to be analyzed for alcohol for all but mandatory post-accident testing (Subpart C). Subpart C testing for surviving employees requires collection of two different types of specimens (blood and urine). Federal alcohol testing was authorized for FRA pre-employment effective 8/1/01 (see Section 8.0 of this Manual).

FRA considers the carrier wholly responsible for the performance of its alcohol specimen collectors. This is true even if collection services, collection sites, or individual collectors have been contracted for by an outside third party administrator or consortium.

Required Federal alcohol tests may be conducted with approved saliva collection devices (screening only), approved non-evidential breath testing devices (screening only), or approved evidential breath testing devices (screening and confirmation). Screening-level devices may only be employed by specially qualified Screening Test Technicians (STTs). Evidential devices may only be employed by specially qualified Breath Alcohol Technicians (BATs).

For purposes of this Manual, only the role and responsibilities of the BATs will be emphasized. For STTs, many of the responsibilities and procedures are the same or similar as for BATs. However, the Part 40 regulatory text for this function (particularly Subparts J-M) would be the best source for comparing similarities and differences.

The role of the BAT is to ensure that the breath samples obtained from the carrier's covered employees have been collected in a manner consistent with DOT and FRA regulations and guidelines. For each FRA alcohol collection, the BAT must have been properly qualified; the collection location must have been properly prepared; the proper certified testing instrument must have been used; the specimen must have been obtained with the proper Federal standards maintained and procedures followed; and the collection documented on the proper Federal form.

BATs must be knowledgeable about all Federal alcohol collection requirements; be properly vigilant to detect attempts at damaging the integrity of the sample or the collection; and be capable of properly handling refusals, "shy lung" situations, or

SPECIMEN COLLECTION – BREATH

other unusual collection events in accordance with DOT and FRA regulations.

FRA Inspectors are not permitted to witness or be a part of an actual carrier breath specimen collection process. As with urine, however, they are authorized and encouraged to use “mock” collections to evaluate compliance.

5.2 REGULATORY REFERENCES (49 CFR PART 219 AND 49 CFR PART 40)

- 219.11 – General conditions for chemical tests
- 219.701 – Standards for drug and alcohol testing

- 40.30 – Definitions: Air blank; Alcohol; Alcohol concentration; Alcohol confirmation test; Alcohol Screening Device (ASD); Alcohol screening test; Alcohol testing site; Alcohol use; Breath Alcohol Technician (BAT); Consortium / Third Party Administrator (C/TPA); Designated Employer Representative (DER); Error correction training; Evidential Breath Testing Device (EBT); Screening Test Technician (STT); Service Agent.

- 40.211 – Who conducts alcohol tests?
- 40.213 – What training requirements must STTs and BATs meet?
- 40.215 – What information about the DER do employers have to provide to BATs and STTs?
- 40.217 – Where is the other information on the role of STTs and BATs found in this regulation?

- 40.221 – Where does an alcohol test take place?
- 40.223 – What steps must be taken to protect the security of alcohol testing sites?
- 40.225 – What form is used for an alcohol test?
- 40.227 – May employers use the ATF for non-DOT tests, or non-DOT forms for DOT tests?
- 40.229 – What devices are used to conduct alcohol screening tests?

- 40.231 – What devices are used to conduct alcohol confirmation tests?
- 40.233 – What are the requirements for proper use and care of EBTs?
- 40.235 – What are the requirements for proper use and care of ASDs?

- 40.241 – What are the first steps in any alcohol screening test?
- 40.243 – What is the procedure for an alcohol screening test using an EBT or non-evidential breath ASD?

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- 40.245 – What is the procedure for an alcohol screening test using a saliva ASD?
- 40.247 – What procedures do the BAT or STT follow after a screening test result?
- 40.251 – What are the first steps in an alcohol confirmation test?
- 40.253 – What are the procedures for conducting an alcohol confirmation test?
- 40.255 – What happens next after the alcohol confirmation test result?
- 40.261 – What is a refusal to take an alcohol test, and what are the consequences?
- 40.263 – What happens when an employee is unable to provide a sufficient amount of saliva for an alcohol screening test?
- 40.265 – What happens when an employee is unable to provide a sufficient amount of breath for an alcohol test?
- 40.267 – What problems always cause an alcohol test to be cancelled?
- 40.269 – What problems cause an alcohol test to be cancelled unless they are corrected?
- 40.271 – How are alcohol testing problems corrected?
- 40.273 – What is the effect of a cancelled alcohol test?
- 40.275 – What is the effect of procedural problems that are not sufficient to cancel an alcohol test?
- 40.277 – Are alcohol tests other than saliva or breath permitted under these regulations?

5.3 INSPECTION GOAL

The goal for inspecting this element is to ensure that the carrier employs SSTs and BATs for Part 219 alcohol testing that are experienced and fully knowledgeable of the regulations; can properly manage Federal alcohol collections, including calibration and maintenance of the instrumentation, in accordance with applicable standards of practice; can capably perform difficult or complicated collections (shy lung, refusals, etc.); and can collect samples in a professional manner, seeking a product which can achieve a scientifically sound and legally defensible test result.

5.4 RECORDS REQUIRED

The FRA Inspector should examine carrier alcohol test records (negatives and positives) to ensure the completeness and accuracy of the collection documentation. The Inspector should interview one or more BATs performing this service for the carrier, and whenever possible, conduct a mock collection with one or more selected BATs in the carrier's system.

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5.5 PREPARATION FOR COLLECTIONS

5.5.1 Determine that the collection location is suitable for a properly secure and confidential alcohol collection.

Alcohol testing can be conducted at any location, including carrier property, that affords visual and aural (hearing) privacy to the donor. The collection location must be secured from the public, other employees, or other unauthorized individuals who may innocently or purposefully interfere with the collection process. If it is an accident scene, the STT or BAT must attempt to provide visual and aural privacy to the greatest extent practicable. The collection area should also have access to an adjacent writing surface for filling out the Department of Transportation (DOT) Alcohol Testing Form (ATF).

5.5.2 Determine that the BAT has the qualified equipment, proper collection supplies, and sufficient DOT ATFs to perform carrier alcohol tests.

Under the Federal alcohol testing protocol, donors provide an initial screening sample and, if positive, a second confirmatory sample. Carriers may only employ qualified devices to test covered service personnel for the presence of alcohol. FRA permits the initial screening test to be conducted with either a qualified alcohol screening device (ASD) or a qualified evidential breath testing device (EBT).

A qualified ASD may be used in lieu of an EBT for screening only, but it may not be employed for confirmation tests. Qualified ASDs are included on a Conforming Products List published by the National Highway Traffic Safety Administration (NHTSA). Qualified ASDs utilize either breath or saliva as a test medium. Collectors eligible to use ASDs (Screening Test Technicians, or STTs) must have a different training qualification than collectors using EBTs. Although permitted, very few railroad programs use ASDs for screening.

Most carriers use EBTs for both screening and confirmation. For that reason, the rest of this Section of the Manual will focus on EBTs and the personnel who are qualified to use them under FRA regulations. Carriers are referred to the DOT regulations in Part 40 for procedures and instrumentation for screening for alcohol in saliva or with non-evidential breath testing devices (see Subparts J-L).

Qualified EBT devices appear on a Conforming Products List also published by NHTSA. EBTs on the list without an asterisk may be employed in DOT testing.

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EBTs are capable of the accurate quantitative detection of ethyl alcohol at 0.02% and above. The devices have the capability of printing test results in triplicate (or three consecutive copies of a test result); assigning a unique number to each completed test (which is recorded in the device); printing out essential information on the test and the device in the result report; distinguishing alcohol from acetone and other volatiles at 0.02%; testing an air blank prior to each collection of breath; and performing an external calibration check. These and other features allow EBTs to produce test results that are scientifically sound and legally defensible.

Each qualified EBT has a comprehensive Quality Assurance Plan (QAP) developed by the manufacturer and approved by NHTSA, which establishes the scientific and operational standards under which the device must perform. The Plan specifies rigorous inspection, maintenance, operational, and calibration requirements for that particular instrument. The carrier is responsible for ensuring that for every EBT it utilizes, the QAP is being meticulously followed and that the external calibration checks are being precisely performed by qualified personnel.

The BAT must maintain additional supplies to properly support the alcohol collection, and must be prepared to conduct multiple tests if necessary. Regardless of type of device(s) used (ASD and EBT, or EBT alone), collections must be fully documented on the DOT ATF. The specimen's unique identification number (UIN) is provided by the EBT itself.

5.5.3 Determine that the BAT is properly qualified to conduct a Federal alcohol collection.

The collector may be an employee of the carrier, a contractor, or be completely independent of the railroad. A supervisor in the donor's chain of command cannot be the collector.

Breath Alcohol Technicians (BATs) hold the only qualification to perform DOT alcohol confirmatory tests. These collections must be done on EBTs with breath as the medium to detect the presence of alcohol at 0.02% or above. To be qualified to perform Federal tests, the BAT must achieve a special training qualification by completing a course of instruction, demonstrating proficiency with the EBT they are being qualified to use, and passing a written practical examination.

The BAT must be knowledgeable in Federal requirements for a proper alcohol specimen collection and fully capable of conducting Federal collections (either alone or under supervision). The BAT should be able to provide an FRA Inspector with documentation of their training qualifications, and demonstrate their expertise

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by answering Inspector questions or participating in a mock collection. The collector does not need to demonstrate or document their abilities to the donor or the donor's agent (such as an employee representative).

BATs must undergo refresher training within five years of obtaining their qualification. The refresher training must be as comprehensive as the training necessary to obtain an original qualification. In addition, if a BAT makes a mistake which causes a cancellation of a test, he/she must undergo error correction training within 30 days of the date the error was discovered. The training generally consists only of the subject matter area(s) which caused the test cancellation, but must also include passing a certain number of error-free mock collections in a row with an emphasis on the collection problem they had experienced.

As a reference tool, during every collection, it is recommended that the BAT have direct access to written procedures which describe Federal alcohol collection requirements. In addition, it would be recommended that the BAT also have direct and/or immediate access to a supervisor or someone else who would also be knowledgeable of Federal alcohol collection requirements.

5.6 FEDERAL BREATH ALCOHOL COLLECTIONS

5.6.1 Determine that the BAT properly conducts an alcohol collection, correctly incorporating Federal procedures and standards.

The BAT is responsible for limiting access to the collection area and maintaining control of the collection process at all times. The collector should remove anyone who is attempting to obstruct or in any way interfere.

If an employee has been injured, medical attention must not be withheld or delayed in order to collect Federal specimens.

The donor must first be properly identified through a picture ID, through direct supervisor identification, or other similar means. Verification of the donor's identity may not be by another worker, another donor, or through a non-photo identification. Supervisor identification may be by telephone as long as the identity of the donor is affirmed in sufficient detail.

The BAT may only collect one specimen at a time.

For pre-employment testing, once a test sequence is started with an applicant or transfer by selecting a mouthpiece, the collection must be completed (including both screening and confirmatory tests, as necessary) or it is considered a refusal to test.

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For all other test categories, the test sequence is started when the employee is notified that they are required to take a Federal alcohol test.

For all other test categories except pre-employment, failure to appear as scheduled or failure to remain at the collection site constitute a refusal to test. The BAT should make a notation on the ATF and call the carrier's DER or other designated representative immediately.

A blank copy of a Federal ATF can be found at Tab 2. The preliminary block on the BATF (Step 1) should be filled out before the donor provides a breath specimen. The donor must also fill out Step 2. If the donor will not sign Step 2 (which simply certifies that they are about to submit to breath alcohol testing), it is a refusal. If that occurs, the BAT terminates the collection, makes a note on the ATF, and informs the employer's representative immediately.

Once Step 1 and 2 are completed, the BAT and the donor affirm the unique number displayed on the EBT. The BAT opens an individually sealed mouthpiece and attaches it to the instrument. The donor blows into the mouthpiece as instructed. This is the screening test. Once the attempt is completed to the satisfaction of the BAT, the displayed result is read.

If negative (less than 0.02 %), the testing is completed. The printed test from the EBT is affixed with tamper-evident tape to the designated location on the Form or is printed directly on the Form. The BAT then signs the certification statement in Step 3. The donor does not complete the certification statement in Step 4. The negative result is reported by the BAT confidentially either directly to the carrier or through the carrier's C/TPA (if applicable). The ATF is sent to the employer or the employer's service agent who retains it as a test record.

If there is a disparity in the test procedure or documentation produced by the EBT, the test may be declared invalid. However, the regulations permit the BAT to try to remedy the problem if practical. This could include immediately repeating the whole testing process as many times as necessary to successfully complete the collection. For several FRA test types (reasonable suspicion, Federal reasonable cause, return to work, and follow-up), the collection must be repeated until it has been properly completed. For random testing, the covered employee may not be made to reprovide if hours of service have been exceeded.

If the screening test is 0.02 % or greater, a confirmation breath sample must be collected. The same EBT can be used, or another qualified EBT device. The same BAT can perform the confirmation test, or another BAT can collect the specimen. If a new BAT performs the second test, the original BAT completes and signs the original ATF. The confirmation test is then conducted on a new ATF.

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Under no circumstance may an employer take administrative action solely on the basis of a Federal positive alcohol screening result.

The BAT must make the presumptively positive donor wait at least 15 minutes² (but should be no longer than 30 minutes) before conducting the confirmation test on an EBT. Only unforeseen delays in completing the confirmation test, such as an unpredictable equipment failure, are acceptable reasons to extend beyond 30 minutes. Other reasons, such as the unavailability of an EBT or BAT, are unacceptable to FRA. Beginning the confirmation test after 30 minutes does not invalidate either the screening or the confirmation test, but might involve a regulatory sanction against the carrier.

The donor is advised to not smoke, eat or drink, drive, perform covered service, or operate heavy equipment during the waiting period. If the donor refuses the BAT's guidance, it is to be noted in the ATF's remarks section. During the wait, the donor should be monitored by the BAT, another collector, or carrier supervisory personnel.

Before performing the confirmation test, the BAT first ensures that the EBT registers 0.00 % on an air blank. If the device registers greater than 0.00 %, a second air blank is performed. If again greater than 0.00 %, the EBT is to be replaced with a new EBT.

A fresh mouthpiece is to be used to collect the confirmation specimen. The donor is instructed to provide another breath sample, blowing forcefully for as long as instructed. The BAT and donor, having already read the new unique identification number displayed on the EBT, read the confirmation result. The confirmation test result is the final result, and the only one for which the carrier may take administrative action.

The EBT confirmation printout is affixed with tamper-evident tape to the ATF or printed directly on the Form. The BAT then signs and dates the collector certificate statement (Step 3), and the donor signs and dates the donor certification (Step 4). If the donor refuses to sign Step 4, it is not a refusal. The BAT simply annotates the donor's failure to sign in the "Remarks" section and reports the EBT finding to the carrier's designated representative.

² The purpose of the minimum 15 minute wait is to ensure that any alcohol still residing in the mouth (regardless of the source) has a chance to dissipate, and thus cannot influence the test result.

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If the confirmation result is less than 0.02 %, it must be reported to the carrier as a negative result. If it is 0.02 % or greater, the carrier's designated representative must be informed immediately by telephone or in person. No positive confirmed alcohol test result may be first reported to an employer's service agent (i.e. a consortium or third party administrator (C/TPA)).

If the confirmation result is 0.02 % or greater, the donor must again be cautioned not to drive or perform covered service. The BAT must make every effort to contact the carrier's DER or designated representative immediately. Under no circumstances is the BAT expected to physically restrain the donor.

If the EBT ever fails an external calibration check, all positive results (0.02% and above) are declared invalid back to the last calibration check the device passed. It is therefore recommended that regardless of the calibration requirement in the QAP, that each EBT be checked as often as practical.

5.6.2 Determine if the BAT is able to distinguish between Federal and non-Federal collections.

The BAT may not employ a Federal ATF for a non-Federal test, and vice-versa.

5.6.3 Determine that the carrier has taken no administrative action against an applicant or employee based on a Federal test result between 0.00 % and 0.02 %.

The carrier is forbidden from taking any administrative action against an applicant or employee based on either a screening or a confirmatory result of between 0.00 % and 0.02 % BrAC on a Federal alcohol test. Tests whose alcohol concentrations fall within this range are negative tests. Federal test results below 0.02 % are not judged to be scientifically sound or legally defensible by FRA. Under no circumstances may these results be used to take Federally-based or Rule G/company policy-based action against an applicant or employee.

5.7 DIFFICULT COLLECTION PROBLEMS

5.7.1 Determine that the BAT is capable of handling a "shy lung" collection.

If the donor makes a valid attempt to complete the breath test, but is unable to perform acceptably and provide an adequate amount of breath, the BAT must require a second attempt. If that too is unacceptable, the collection is concluded, the BAT records the problem in the remarks section of the ATF, and informs the carrier's DER. The carrier then directs the employee to a physician for a medical

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examination similar to that required in the shy bladder situation (see Section 4.7.1 of this Manual).

5.7.2 Determine that the BAT is capable of handling a refusal to test.

Every effort should be made to encourage a recalcitrant donor to provide an acceptable specimen. Whenever possible, the carrier should be asked for assistance. If the donor refuses to sign Step 2 of the ATF, it is considered a refusal. If the donor signs Step 2, provides an adequate sample, but is unwilling to sign Step 4 of the ATF, it is not a refusal. Abandoning the collection process at any time before the required test is complete, is a refusal.

The BAT cannot require the donor to sign a release of liability form. A donor's refusal to sign would not constitute a Federal refusal, and the BAT may not terminate the collection on that basis.

It is extremely important that an incident not be called a refusal when it does not meet the full requirements of the Rule for that determination. FRA will take very seriously any carrier misapplication of the refusal regulations due to lack of knowledge of the intent of the regulation or due diligence by the BAT or the carrier.

Once a refusal determination has been made, the regulations do not provide an opportunity for the carrier to ignore that decision. Instead, the carrier must seek a waiver of compliance from FRA if they feel that extenuating circumstances do not warrant an automatic nine-month removal from covered service.

Specimen Collection – Breath Summary Checklist

I. Preparation for Collections [5.5]

- A. *Determine that the collection location is suitable for a properly secure and confidential alcohol collection. [5.5.1]*
- B. *Determine that the BAT has the qualified equipment, proper collection supplies, and sufficient DOT ATFs to perform carrier alcohol tests. [5.5.2]*
- C. *Determine that the BAT is properly qualified to conduct a Federal alcohol collection. [5.5.3]*

II. Federal Breath Collections [5.6]

- A. *Determine that the BAT properly conducts an alcohol collection, correctly incorporating Federal procedures and standards. [5.6.1]*
- B. *Determine if the BAT is able to distinguish between Federal and non-Federal collections. [5.6.2]*
- C. *Determine that the carrier has taken no administrative action against an applicant or employee based on a Federal test result between 0.00% and 0.02%. [5.6.3]*

III. Difficult Collection Problems [5.7]

- A. *Determine that the BAT is capable of handling a "shy lung" collection. [5.7.1]*
- B. *Determine that the BAT is capable of handling a refusal to test. [5.7.2]*

6.0

THE LABORATORY

6.0 THE LABORATORY

6.1 OVERVIEW

Department of Transportation (DOT) regulations found in 49 CFR 40.81 - 40.113 (Subpart F) and FRA regulations found in 49 CFR 219.701 (Subpart H) describe requirements for laboratories conducting urine drug testing for all but FRA mandatory post-accident (Subpart C) testing.³ FRA considers the carrier wholly responsible for the performance of its contract laboratory in all but FRA's mandatory post-accident program. This is true even if the laboratory has been contracted for by an outside third-party administrator or consortium. The carrier may employ one or more laboratories to conduct its urine testing.

All laboratories conducting Federal testing under FRA Rule must hold a special qualification (DHHS/SAMHSA certification). For Federal pre-employment, reasonable suspicion, Federal reasonable cause, and random carrier testing, the laboratory is normally responsible for providing collection supplies (drug testing Custody and Control Forms and collection kits) to the carrier's collection sites, transporting specimens from the collection sites to its facility, analyzing the specimens in accordance with DHHS and DOT requirements, and reporting scientifically sound and legally defensible test results to the carrier's Medical Review Officer (MRO). The laboratory is also responsible for retaining positive specimens for at least one year and all testing records for any DOT regulated samples for at least two years.

6.2 REGULATORY REFERENCES (49 CFR PART 219 AND 49 CFR PART 40)

- 219.701 – Standards for drug and alcohol testing
- 40.3 – Definitions: Adulterated specimen; Blind specimen or blind performance test specimen; Cancelled test; Confirmation (or confirmatory) drug test; Confirmation (or confirmatory) validity test; Confirmed drug test; Dilute specimen; Drugs; Initial Drug Test; Initial Validity Test; Invalid drug test; Laboratory; Primary specimen; Shipping container; Specimen bottle; Split specimen; Substituted specimen; Verified Test

³ FRA mandatory post-accident testing laboratory regulations are primarily found in 49 CFR 219.211 and in Appendix C to Part 219. The FRA post-accident program is discussed in Section 10.0 of this Manual.

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- 40.81 – What laboratories may be used for DOT drug testing?
- 40.83 – How do laboratories process incoming specimens?
- 40.85 – What drugs do laboratories test for?
- 40.87 – What are the cutoff concentrations for initial and confirmation tests?
- 40.89 – What is validity testing, and are laboratories required to conduct it?
- 40.91 – What validity tests must laboratories conduct on primary specimens?
- 40.93 – What criteria do laboratories use to establish that a specimen is dilute or substituted?
- 40.95 – What criteria do laboratories use to establish that a specimen is adulterate?
- 40.97 – What do laboratories report and how do they report it?
- 40.99 – How long does a laboratory retain specimens after testing?
- 40.101 – What relationship may a laboratory have with a MRO?
- 40.103 – What are the requirements for submitting blind specimens to a laboratory?
- 40.105 – What happens if a laboratory reports a result different from that expected for a blind specimen?
- 40.107 – Who may inspect laboratories?
- 40.109 – What documentation must a laboratory keep and for how long?
- 40.111 – What and how must a laboratory disclose statistical summaries and other information it maintains?
- 40.113 – Where is other information concerning laboratories found in the regulation?
- 40.199 – What problems always cause a drug test to be cancelled?
- 40.201 – What problems always cause a drug test to be cancelled and may result in a requirement for another collection?
- 40.203 – What problems cause a drug test to be cancelled unless they are corrected?
- 40.205 – How are drug test problems corrected?

6.3 INSPECTION GOAL

The goal for inspecting this element is to ensure that the carrier employs a laboratory for Part 219 testing that is fully qualified under the regulations, produces test results that are scientifically sound and legally defensible, and otherwise performs its duties in full accord with applicable DHHS, DOT, and FRA regulations and the highest scientific standards of practice.

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6.4 RECORDS REQUIRED

The FRA Inspector should examine test records provided by the laboratory to the Medical Review Officer (MRO) to ensure their completeness and accuracy. The Inspector should also review the semi-annual statistical summary reports provided the carrier by the laboratory.

6.5 THE LABORATORY

6.5.1 Determine if the laboratory utilized by the carrier holds DHHS/SAMHSA certification.

The FRA rule requires that any laboratory testing specimens under Part 219, including FRA's special post-accident laboratory, must hold certification by the Department of Health and Human Services/Substance Abuse and Mental Health Services Administration (DHHS/SAMHSA). The certification must be in place during the time that any testing is performed by the laboratory for the carrier.

DHHS publishes each month the updated list of qualified laboratories. The latest list can be obtained from the DHHS website (<http://health.org/workplace>) or the SAMHSA website (<http://workplace.samhsa.gov>). If the former website is used, the monthly laboratory list ("Current List of Laboratories Which Meet Minimum Standards to Engage in Urine Drug Testing for Federal Agencies, and Laboratories that Have Withdrawn From the Program") is found through the "Drug Testing" Section.

Although not required by the FRA rule, it is recommended that the carrier require the laboratory to inform it if their certification is ever suspended or revoked.

6.5.2 Determine that the laboratory is properly cancelling tests for unresolved documentation errors on the Drug Testing Custody and Control Form (DTCCF) or problems with the specimen.

The laboratory, in its receiving/accessioning process, is responsible for cancelling testing for specimens where either the Federal Custody and Control Form (CCF) or the sample itself has unresolvable problems. When the problems are resolvable, the laboratory is responsible for making a reasonable effort to obtain signed statements remedying the problem.

The following problem areas can be remedied with a signed statement:

- The collector's signature is absent.

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- The specimen temperature is not checked and there is no remark regarding the temperature range of the sample.

The following problem areas cannot be remedied and will cause automatic cancellation:

- There is no printed collector's name and there is no collector's signature.
- The specimen ID number on the bottle and on the CCF do not match.
- There is no specimen ID number on the specimen bottle.
- The specimen bottle seal is broken or shows evidence of tampering.
- There is not enough specimen to test.

6.5.3 Determine that the laboratory is reporting test results directly to the MRO, and that the reports contain only the information permitted.

The laboratory must report all test results directly to the MRO. This includes negatives, positives, adulterated and substituted specimens, invalid samples, and rejected specimens. The laboratory may not report results to the MRO via an employer or a C/TPA (consortium or third party administrator). The laboratory can only report test results to the MRO in a secure manner.

Report formats should meet all DHHS and DOT formats. Generally, reports should be categorized as follows:

- Negative for all drugs tested
- Negative for all drugs tested and the specimen was also dilute
- Positive for one or more drugs, all other drugs tested negative
- Positive for one or more drugs, and the specimen was also dilute
- Adulterated for a specific identified substance
- Adulterated for a specific identified substance but one or more drugs also tested positive
- Substituted
- Invalid
- Specimen cancelled (and the reason for the rejection)

The laboratory cannot report a specimen as "pending" (or some other preliminary statement), or adulterated with one or more drugs reported as negative.

The laboratory may not report the presence or absence of a split specimen until a request for split specimen testing is made by the MRO.

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Only opiate quantitations (concentrations) above 15,000 ng/mL are to be automatically reported to the MRO. The MRO may also request blanket test quantitations from the laboratory for all opiate positives, but all requests for quantitations of other drugs must be made on a test-by-test basis.

After the MRO conducts his/her verification of the result (see Section 7.0 of this Manual), the MRO has an obligation to ensure that the employer understands the meaning of the final determination.

6.5.4 Determine that the laboratory is submitting semi-annual summary statistical reports to the carrier, and the carrier is reviewing and retaining these reports.

In accordance with 40.111 (and Appendix B of Part 40), the laboratory is responsible for submitting an employer-specific aggregate statistical summary semi-annually directly to the employer or, if applicable, to the employer via the carrier's consortium or third party administrator (C/TPA). The laboratory is not obligated to send statistical data if there are less than five tests in a summary. Laboratories must also produce a summary if requested by an employer for an audit. This report must be in a format prescribed by the Part 40 regulation (Appendix B) and is to be maintained in hard copy by the carrier for at least two years. Outdated laboratory report formats are not permitted, even if they were previously accepted at one time.

6.5.5 Determine that the laboratory has not issued a false positive report on any carrier urine specimen in the audit timeframe.

Based on the MRO's assessment, the carrier should be made aware of any true false positive reports made by the laboratory to the MRO in the audit timeframe. A true false positive is a test result reported by the laboratory that in actuality never did contain the analyte(s) of interest. The error, whether clerical or scientific, is considered catastrophic and must be reported by the carrier to the FRA for further investigation by the DOT and DHHS/SAMHSA.

False positives, however, are going to be extraordinarily rare. If one ever occurred, however, it would more likely be due to a laboratory clerical or administrative mistake which caused an incorrect report to be issued.

It is not a false positive if the laboratory reports the confirmed presence of a drug, but the source of the drug in the urine was accidental or innocent ingestion.

In some cases, an apparent "false positive" occurs during the split specimen testing procedure. A split specimen that failed to reconfirm when sent to a referee

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laboratory is not 'per se' evidence of a false positive as long as the drug was indisputably present at one time in the donor's urine or the presence of an adulterant was discovered by the referee laboratory. Similarly, failure to reconfirm an adulterated or substituted specimen is also not automatic 'per se' evidence of a false positive. In both cases, however, the carrier must notify FRA of the event for further investigation by DOT and DHHS/SAMHSA.

In addition, the carrier should be sensitive to any false negative reports produced by the laboratory. A false negative report occurs when a negative test result is originally issued by the laboratory which must be then withdrawn because the donor actually tested positive. Although there are no specific remedial actions required by either FRA or DOT, the carrier should be concerned about laboratory errors of this significance and their effect on the integrity of the carrier's drug and alcohol program. Any true false negative report should be reported by the carrier to the FRA for further investigation.

As it evaluates possible false positive and false negative reports, the carrier must determine whether the error had as its source the laboratory or was due to a MRO mistake, or in the case of a blind sample submission, was due to a problem with the blind specimen itself.

6.5.6 Determine that the carrier has been submitting blind quality control samples to the laboratory at a rate and in a manner consistent with the regulation.

Part 40 regulations (40.103) require each employer with 2,000 or more covered employees (or a C/TPA, operating on behalf of that employer) to submit blind specimens at a 1% rate to every laboratory to which they submitted over 100 specimens, up to 50 blind specimens per quarter. That is, for every one hundred Federal tests (pre-employment, random, reasonable suspicion, etc.), one must have been a blind. The samples may be submitted singly or in groups and should be distributed reasonably throughout the year. Approximately 75% of the blind submissions must be blank (negative for all drugs), approximately 15% must be positive for one or more of the five drug groups, and 10% must be adulterated or substituted in accordance with DHHS criteria.

If a carrier belongs to a consortium or falls under a third party administrator, the C/TPA must send in blinds if the total number of covered employees it represents equals or exceeds 2,000.

Blind samples may be obtained from a third party supplier or may be provided specially for this purpose by carrier personnel. Completed chain-of-custody forms

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for blind specimens must generally reflect carrier operations, and it should not be obvious to the laboratory that the submitted sample is a blind. If a third-party administrator or other party is responsible for submitting blinds on behalf of the carrier, documentation of the submissions (likely including copies of chain-of-custody forms) and the laboratory's findings should be regularly received and maintained by the railroad. In some circumstances, it may be permissible for a third-party administrator to submit blinds to the laboratory for a group of carriers through a separate fictitious railroad employer, as long as the audited carrier's blind submission obligations can be clearly differentiated from other consortium members.

6.5.7 Determine that the laboratory has no conflict of interest with the carrier's Medical Review Officer (MRO).

In accordance with 49 CFR 40.101, the laboratory may not derive any financial benefit by having an employer use a specific MRO. This means that neither the laboratory nor the MRO may receive a special discounted price, finder's fee, or bonus payment from the other to perform its services. Each must be seen as independent and not financially beholden to the other entity. This Federal conflict of interest requirement does not extend from either MROs or laboratories to collectors, C/TPAs, or any other partner to the testing process.

6.5.8 Determine that the laboratory is retaining positive and non-negative specimens and test records as required by the regulations.

The laboratory is required to retain positive, adulterated, substituted, and invalid specimens in frozen storage for a minimum of one year after reporting the result to the MRO. Specimens can be retained longer if formally requested in writing by the carrier or the MRO. Negative and cancelled specimens need only be retained a few days before destruction.

The laboratory is required to retain all documentation associated with negative, cancelled, positive, adulterated, substituted, and invalid specimens for two years after reporting the determination to the MRO. The records can be retained longer if requested in writing by the carrier or the MRO.

The Laboratory Summary Checklist

I. The Laboratory [6.5]

- A. *Determine if the laboratory utilized by the carrier holds DHHS/SAMHSA certification. [6.5.1]*
- B. *Determine that the laboratory is properly canceling tests for unresolved documentation errors in the Drug Testing Custody and Control Form or problems with the specimen. [6.5.2]*
- C. *Determine that the laboratory is reporting test results directly to the MRO, and that the reports contain only the information permitted. [6.5.3]*
- D. *Determine that the laboratory is submitting semi-annual summary statistical reports to the carrier, and the carrier is reviewing and retaining these reports. [6.5.4]*
- E. *Determine that the laboratory has not issued a false positive report on any carrier urine specimen in the audit timeframe. [6.5.5]*
- F. *Determine that the carrier has been submitting blind quality control samples to the laboratory at a rate and in a manner consistent with the regulation. [6.5.6]*
- G. *Determine that the laboratory has no conflict of interest with the carrier's / Medical Review Officer (MRO). [6.5.7]*
- H. *Determine that the laboratory is retaining positive and non-negative specimens and test records as required by the regulation. [6.5.8]*

7.0

MEDICAL REVIEW OFFICER

(MRO)

7.0 THE MEDICAL REVIEW OFFICER (MRO)

7.1 OVERVIEW

Department of Transportation regulations found in 49 CFR 40.121 - 40.189 (Subparts G and H) and FRA regulations found in 49 CFR 219.701 describe requirements for Medical Review Officers under the urine testing portions of the FRA rule. The MRO should also be familiar with 49 CFR 40.191 - 40.209 (Subpart I) and other portions of the regulations as necessary to ensure proper oversight of the urine collection and laboratory processes. FRA considers the carrier responsible for the performance of its Medical Review Officer (MRO), including for mandatory post-accident testing. This is true even if the MRO has been contracted for by an outside third party administrator or consortium.

The role of the MRO is to receive all urine drug test results from the carrier's laboratory. In the case of negative results, the MRO's role is purely administrative, reporting the finding to the employer. With laboratory positive and other non-negative test results, however, the MRO is responsible for determining if the donor has a verifiable, legitimate medical explanation for the test finding. If not, the result must be reported to the carrier as a verified positive, adulterated, substituted, or invalid result. If the donor has an acceptable medical explanation which can be verified, the MRO must report the finding as a negative test in a manner which is identical to a report made to the carrier on a laboratory negative result. All test findings, negative or non-negative, must be reported to the carrier in a confidential manner.

The MRO is also responsible for coordinating all requests for split specimen testing. The MRO has no role in Federal alcohol tests, and a limited role in FRA mandatory post-accident testing and shy bladder situations.

7.2 REGULATORY REFERENCES (49 CFR PART 219 AND 49 CFR PART 40)

- 219.605 - Positive drug test results
- 219.701 - Standards for drug and alcohol testing
- 40.3 - Definitions: Cancelled test; Chain of custody; Consortium/Third-Party Administrator C/TPA); Continuing education; Designated employer representative (DER); Medical Review Officer (MRO); Qualification training; Service agent; Verified test.
- 40.121 - Who is qualified to act as a MRO?

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- 40.123 - What are the MRO's responsibilities in a DOT drug testing program?
- 40.125 - What relationship may an MRO have with a laboratory?
- 40.127 - What are the MRO's functions in reviewing negative test results?
- 40.129 - What are the MRO's functions in reviewing laboratory confirmed positive, adulterated, substituted, or invalid drug test results?
- 40.131 - How does the MRO or DER notify an employee of the verification process after a confirmed positive, adulterated, substituted, or invalid test result?
- 40.133 - Under what circumstances may the MRO verify a test as positive, or as a refusal to test because of adulteration or substitution, without interviewing the employee?
- 40.135 - What does the MRO tell the employee at the beginning of the verification interview?
- 40.137 - On what basis does the MRO verify test results involving marijuana, cocaine, amphetamines, or PCP?
- 40.139 - On what basis does the MRO verify test results involving opiates?
- 40.141 - How does the MRO obtain information for the verification decision?
- 40.143 - [Reserved]
- 40.145 - On what basis does the MRO verify test results involving adulteration or substitution?
- 40.147 - [Reserved]
- 40.149 - May the MRO change a verified positive drug test result or refusal to test?
- 40.151 - What are MROs prohibited from doing as part of the verification process?
- 40.153 - How does the MRO notify employees of their right to a test of the split specimen?
- 40.155 - What does the MRO do when a negative or positive test result is also dilute?
- 40.157 - [Reserved]
- 40.159 - What does the MRO do when a drug result is invalid?
- 40.161 - What does the MRO do when a drug test specimen is rejected for testing?
- 40.163 - How does the MRO report drug test results?
- 40.165 - To whom does the MRO transmit reports of drug test results?
- 40.167 - How are MRO reports of drug results transmitted to the employer?
- 40.169 - Where is there other information concerning the role of MROs and the verification process found in this regulation?

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7.3 INSPECTION GOAL

The goal for inspecting this element is to ensure that the carrier employs a MRO for Part 219 testing that is fully qualified under the regulations; properly manages test results and chain-of-custody documents; interprets drug test results and, when applicable, interviews positive and other non-negative donors in accordance with applicable regulations, published guidance, and Federal standards of practice; reports findings in an expeditious and confidential manner, and performs all other MRO responsibilities capably.

7.4 RECORDS REQUIRED

The FRA Inspector should examine test records (negative, non-negative (positive, adulterated, substituted, and invalid), and MRO downgrades) to ensure their completeness and compliance with Federal regulations and standards of practice. The Inspector should interview the MRO (or one or more physicians performing that role for the carrier) and members of the MRO staff. An inspection of the MRO's physical facility may be necessary. Copies of MRO reports made to the carrier should be reviewed.

7.5 MRO QUALIFICATIONS AND ORGANIZATION

7.5.1 Determine if the MRO(s) utilized by the carrier hold the proper qualifications.

Department of Transportation regulations require a MRO to be a physician (MD or DO) holding a valid and active medical license (expected to be at least in the State they are residing), have clinical experience in substance abuse disorders, be knowledgeable of medical reasons for invalid test results, and be capable of properly interpreting laboratory positive and other non-negative test findings in conjunction with the donor's medical history and other relevant biomedical information. He/she must also be knowledgeable of all applicable Federal regulations and guidelines which affect MRO duties.

Under current regulations, the MRO must receive formal training and pass an examination in their MRO roles and responsibilities. The training must include instruction on specimen collection, interpretation of test results (negative and non-negative), MRO procedures, interaction with other partners in the testing process (i.e. DERs, collection sites, laboratories, and SAPs), and Federal regulations and issues affecting the MRO. The MRO must then pass an examination administered by a nationally recognized MRO certification or medical subspecialty body.

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New MROs must have received formal training and pass the required examination before they perform duties under DOT and FRA regulations. Physicians who were practicing as MROs before 8/1/01, have until 1/31/03 to receive the formal training and pass the examination.

MROs must take a specified number of continuing education medical units relevant to performing MRO functions in every three year cycle as part of a continuing education requirement.

Training documentation must be maintained by the MRO and made available for Federal audit and to employers and service agents using their services.

7.5.2 Determine if the MRO's staff organization is consistent with the requirements of the regulations and DOT published guidance for MROs.

A carrier can utilize one or more qualified physicians to act as MRO. Each MRO can be an employee of the carrier, a subcontractor to the carrier's Medical Director, or completely independent from the carrier. Regardless of the relationship, the MRO staff should be under the direct full-time supervision of a physician qualified to be a MRO. Without a qualified MRO resident full-time, a third party administrator, consortium, or even the Medical Department of the carrier will not likely be acceptable to FRA to perform MRO duties. This includes, but is not limited to, receiving test results directly from the laboratory, receiving or reviewing chain-of-custody documents from collection sites, and contacting or interviewing positive donors.

Test results must be received from the laboratory in a secure manner. Electronic transmission is permitted (i.e., fax, laboratory printer, computer-to-computer download, etc.). An unsecure internet transmission is not permitted.

Test results and MRO records should not be accessible to the public or staff personnel who are not directly responsible for MRO duties. This includes, but is not limited to, computer databases, file cabinets, fax machines, etc.

7.6 MRO DETERMINATIONS

7.6.1 Determine that the MRO is administratively reviewing and properly reporting negative laboratory test results.

The MRO or a staff member under the MRO's direct supervision should review:

- (a) the original or facsimile of each donor's MRO copy of the drug testing Custody and Control Form (CCF Copy 2 or equivalent) and

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- (b) the matching laboratory report or a matching Copy 1 of the CCF which contains the certifying scientist's annotation of the negative result.

Once this review is completed, the negative result can be released to the employer.

In unusual cases where the MRO copy of the CCF (Copy 2) is not available, a facsimile or original of another copy of the CCF which contains the donor's signature (Copies 3, 4, or 5) is acceptable.

An MRO must personally review up to 5% of the negative test packets coming through his/her office, or up to 500 tests per quarter, whichever is less. This is for all Federal tests, and need not be specific to FRA. This review can be conducted by one or more MROs performing MRO duties for the carrier (i.e. one MRO could perform the review on behalf of all MROs in the office). The reviewed CCFs must be signed or at least initialed by the reviewing MRO. All MRO-reviewed CCFs must be retrievable for easy audit.

The MRO must review but should not ordinarily cancel negative tests if there are minor problems with an individual Copy 2 (or equivalent) or Copy 1 of the CCF, or the laboratory report. Systemic problems should be remedied with the collection site or the laboratory. Cancellation of a negative test could occur only if the true identity of the donor cannot be ascertained, and may only be done by the MRO (and not the MRO's staff).

7.6.2 Determine that the MRO is properly verifying and reporting positive test results.

The principal role of the MRO in Federal urine testing is to determine if there is a legitimate and verifiable medical explanation for a donor's positive test. In the case of a positive laboratory result, the MRO may not conduct an interview with the donor until the original or a facsimile of the Copy 2 of the CCF (or equivalent) and the laboratory report are available. The MRO may not report the final positive determination until the Copy 1 signed by the certifying scientist has been received from the laboratory (a facsimile of Copy 1 is also acceptable).

Once all of the required paperwork is available, the MRO is expected to complete the case without delay. It is expected that most cases will be resolved within one or two work days.

Most serious documentation problems with the CCF may be recoverable by a signed statement from the collector, laboratory certifying scientist, or donor. If not

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resolved, however, the test may have to be cancelled by either the laboratory or the MRO. The absence of the donor's signature on Step 5 (unless the Form is annotated that the donor refused to sign) or the absence of the certifying scientist's signature on Step 5a are potentially fatal flaws for the MRO on positive tests.

The donor may be contacted by either the MRO or a staff member under the MRO's direction. If it is a staff member, they may not collect medical information from the donor. The MRO (or staff under the MRO's direction) must make a reasonable effort to contact the positive donor, at least three attempts over the first 24 hours. All contact attempts must be documented as to date and time.

The MRO must be the only one conducting the interview (not a staff member), and FRA expects the MRO to make every reasonable attempt to complete the interview. Staff members are not permitted to discourage the donor talking with the MRO in any direct or indirect way, or do other than introduce or initiate the MRO interview.

The three rare circumstances where not interviewing a positive donor is acceptable are: (a) even after being encouraged, the donor refuses to talk to the MRO; (b) the donor does not call the MRO within 72 hours after being directly notified by an employer's representative; or (c) the donor cannot be contacted by either the MRO or the carrier and 10 days have passed. The MRO may reopen a case and conduct an interview if within 60 days the donor presents a reasonable explanation of why he/she was unreachable or was otherwise legitimately unable to contact the MRO in a timely manner.

The MRO may have a blanket request to receive urine drug quantitations from the laboratory. The concentration of an opiate positive at or above 15,000 ng/mL morphine or codeine is required to be automatically reported to the MRO. The MRO must not request quantitations for specimens reported as testing below the cutoff, since these are negative test results.

There is no doctor-patient relationship in a MRO interview. Interviews may be face-to-face or by telephone. The MRO should document all attempts to contact the donor and retain acceptable notes from the interview. The MRO should record the donor's reasons for why the test was positive, any medical information offered, and that donor offered no acceptable medical explanation.

In conducting their interview, the MRO may only talk to the specimen donor. The MRO may not conduct the interview with the donor's union representative, attorney, or any other person present. The sole exception would be a translator acceptable to the MRO. A donor's unwillingness to cooperate with this

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requirement constitutes a refusal to be interviewed. Such a refusal will result in the MRO reporting the test result as positive without further delay.

The MRO must begin every positive interview by warning the donor that any information they provide relating to use of prescription or over-the-counter medications must be reported to an employer if it is judged by the MRO to be a safety concern. However, MROs may not automatically or routinely report any medication a donor is taking to the carrier as a safety concern, but must make a careful and considered judgement in each case. In general, MRO reports to the railroad on this issue should only be an occasional occurrence. If requested by FRA, the MRO must be prepared to justify any such reports by being able to link the medication being taken by that donor to a specific safety issue (such as a likely or probable performance decrement).

There are acceptable medical explanations for four of the drugs tested by FRA (marijuana, cocaine, amphetamines, and opiates). One drug (PCP) does not have a medical explanation. With one exception (opiates), the burden of proof is on the donor to provide a verifiable medical explanation for the positive.

Normally, a positive opiate test must have clinical evidence of abuse, in addition to the result, before it may be verified as a positive by the MRO. At or above 15,000 ng/mL of either morphine and/or codeine, the burden of proof switches to the donor to provide a medical explanation for the presence of the drug in their urine. The presence of 6-AM is absolute evidence of heroin use and the MRO must verify the test as positive. The MRO is not required to have a face-to-face clinical medical examination performed on the donor in order to make an acceptable determination on an opiate positive.

Medical explanations offered by a donor must be affirmed directly with the donor's medical or dental practitioner, pharmacist, etc. Donors can be permitted by the MRO up to five days to gather and present medical information.

Passive exposure to a smokable drug (marijuana, cocaine, heroin, amphetamine) will not cause a positive test under any realistic circumstances and is also not an acceptable medical explanation. Claims of accidental or innocent ingestion may not be considered by the MRO. Claims of the use of hemp products or claims of medical use of marijuana under state law are not acceptable medical explanations under Federal testing programs and must be reported as a positive.

Use of someone else's medication, regardless of the circumstance, is clinical evidence of abuse under FRA regulations (219.103) and must be reported to the carrier as a positive determination.

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Problems alleged by the donor with the collection process or the reasons the donor was selected to test are beyond the scope of the MRO interview, and are not to be investigated by the MRO.

The MRO may not consider the results of any other type of drug test (i.e. for hair, blood, saliva), or permit the specimen or split to be analyzed for other purposes (i.e. such as serological typing or DNA testing) than those permitted by the regulations.

MRO downgrades (laboratory positives where the MRO has verified a legitimate medical explanation) must be reported to the carrier identically as if the donor's specimen had tested negative originally. Under no circumstances may a MRO downgrade a laboratory positive based solely on the donor's assurances of taking a particular medication or undergoing a particular medical or dental procedure. Every claim must be carefully verified and medical explanations authenticated before a downgrade can be permitted.

MROs are not permitted to automatically report all MRO downgrades to a carrier as "safety concerns". In the opinion of FRA, only very occasionally are concerns for safety warranted when an employee is taking prescription medication(s) under a physician's care. If requested by FRA, the MRO must be prepared to justify any such reports by linking the medication being taken by that donor to a specific safety issue (such as a likely or probable performance decrement).

It is permissible for the original MRO in a case to reopen and change a previously reported positive test in any of the following circumstances:

- a) Within 60 days of the original report, the donor offers a reasonable explanation for the lack of contact in a "non-contact" MRO positive report;
- b) There was newly discovered evidence of a laboratory error;
- c) The MRO made a mistake when originally reporting the positive result; or
- d) The donor can provide within 60 days of the original positive determination new evidence that he/she has now uncovered a legitimate, verifiable medical explanation for the positive.

Normally, the MRO is responsible for considering only the use of prescription and over-the-counter medication obtained in this country. However, there are circumstances where a positive donor offers as an explanation medications they obtained in a foreign country (usually in Mexico or Canada, but sometimes

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overseas). The MRO may consider the use of foreign medication as legitimate, but must base their decision on the following factors:

- Was the substance obtained legally in the foreign country?
- Could the substance have a legitimate medical use in this country?
- Was there a compelling medical reason or medical risk which caused the medication not to be approved in the United States?
- Was the substance being used in a manner consistent with its proper and intended medical purpose?

7.6.3 Determine that the MRO is properly verifying other non-negative (adulterated, substituted, and invalid) test results.

The content and structure of the MRO interview with a donor having an adulterated, substituted, and invalid specimen test result is generally the same as for a positive test. The principal differences are in the specific questions posed by the MRO to the donor to provide a medical explanation for these extraordinary types of test findings.

Adulterated or Substituted. When the laboratory reports that a specimen is adulterated or substituted, the MRO must permit the donor the opportunity to provide a medical explanation for the test result.

Adulterated means that the laboratory found the presence of :

- a) an identifiable substance which could not be present in normal human urine, or
- b) an identifiable substance which may be found in human urine but could not be present in the concentration found, or
- c) the pH (acid/base balance) of the sample was inconsistent with human life.

Substituted means that the sample was not consistent with human urine because it had a creatinine concentration so low as to not be possible in a person with a functioning kidney, and the specific gravity of the sample contributed to the concern.

With an adulterated specimen, the burden of proof falls to the donor who must **demonstrate** to the MRO that the adulterant found by the laboratory entered the

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urine specimen through the donor's physiology. This burden must initially be met in the MRO's first interview with the donor.

Similarly, with a substituted specimen, the burden of proof again falls to the donor who must demonstrate that he/she can re-produce these results through their own physiology. Merely citing personal characteristics (race, gender, weight, diet, working conditions) is not sufficient evidence to meet the required burden of proof.

The MRO may not accept a medical explanation for the presence of any material which could not be present in human urine (such as soap or gluteraldehyde), or the absence of creatinine.

For both adulterated and substituted specimens, the MRO can allow the donor to obtain an evaluation from an acceptable referral physician if the MRO feels there is a reasonable basis to consider a medical explanation based on the information provided in the donor's initial interview.

If inadequate information is provided by the donor in the initial interview with the MRO, or if the referral physician is unable to demonstrate to the MRO that the test result was achieved by the donor's physiology, the MRO is required to report the result to the carrier as a refusal to test.

Given the nature of the burden of proof required to overturn an adulterated or substituted laboratory finding, it is expected that a MRO downgrade in such a circumstance would be extraordinarily rare, totally unexpected, and inconsistent with the current state of medical and scientific knowledge.

Invalid. When an invalid test result is reported, the laboratory was unable to achieve an acceptable test result due to some unknown interference. Sometimes this interference is caused by a medication the donor is taking (some non-steroidal anti-inflammatories are well known for causing this problem) or it may be due to an adulterant the donor used to try to beat the test which the laboratory was unable to specifically identify.

When a test is reported as invalid, the MRO is first required to contact a scientist at the laboratory to determine the type and kind of interference observed. In some cases, the specimen may be sent to a referee laboratory to try to cut through the interference. After receiving the laboratory's perspective, the MRO interviews the donor to determine if he/she has a medical explanation for the invalid test result.

If there is a medical explanation, the test is cancelled by the MRO and reported to the carrier. No new specimen may be collected from the donor unless a negative

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test is required to comply with the regulations (for pre-employment, return-to-duty, and follow-up tests). If a new test is required, direct observation of the void is not permitted.

If there is no medical explanation, the MRO cancels the test and informs the employer that the donor is required to immediately test again under direct observation. The employer must ensure that this occurs without delay and without advance notice to the donor.

Whatever test finding is received from the subsequent directly observed collection (whether negative or positive), this is the final result and it should be handled normally in accordance with MRO standard procedures.

The employer may not take an adverse administrative action on the basis of an invalid test result, regardless of what the laboratory suspects is present in the urine. What the laboratory believes, but cannot prove, falls well short of a scientifically sound identification and legally defensible determination. Administrative action taken by a carrier solely on the basis of an invalid test result will result in severe sanction by FRA.

7.6.4 Determine that the MRO is reporting test results to the carrier in a timely and confidential manner.

MRO determinations (negative, non-negative, cancelled) must be reported to the carrier as expeditiously as possible. In general, this should be within 24 hours of the final MRO determination. Especially in the case of non-negative determinations (positive, adulterated, substituted), the MRO should have mechanisms in place to contact the carrier without delay in order to minimize the time a covered employee is allowed to remain in covered service.

The MRO may report test results, both negative and non-negative, to the carrier verbally. A hard copy equivalent of the MRO's final determination on each employee must be sent to the carrier. This may be a signed copy of Copy 2 of the CCF or may be the MRO's own report format. However, if it is the latter, the required content of the report is described in 40.163.

Besides identification of the MRO of record (name, address, telephone number), and the name of who is reporting the test results (if not also the MRO), the MRO's own report format must include:

- a) the full name of the donor (from the CCF)
- b) the unique specimen ID number

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- c) the donor's SSN or employee ID number
- d) the reason for the test (from the CCF)
- e) the date of collection
- f) the date the Copy 2 of the CCF was received by the MRO
- g) the specific result (negative, positive, adulterated, substituted, invalid, or cancelled)
- h) the date the result was verified by the MRO
- i) the specific drug or metabolite (for a positive) or identification of the substance (for adulterants)
- j) the reason for cancellation (if applicable)

MRO negative reports may be in hard copy or in an electronic data file if a signed Copy 2 of the CCF is not used. The electronic data file must also have the date the report was electronically released.

MRO positive and other non-negative reports must be in hard copy only if a signed Copy 2 is not used.

The batch transmission of test results (results on multiple donors on the same report) is not permitted.

The MRO must report test results in a confidential manner to a designated railroad official or limited backup(s). If the carrier directs the MRO in writing, the MRO is permitted to report test results to the carrier through a consortium/third party administrator (C/TPA) performing a management role for the railroad. The carrier is also permitted to authorize simultaneous reporting to such entities if they decide not to have test results reported to them through the C/TPA. In FRA's opinion, the MRO may not transmit test results to the carrier through a C/TPA if such a reporting structure increases the length of time necessary for the carrier to receive the report beyond that if the MRO was reporting directly to the carrier.

A MRO does not have the authority to directly relieve an employee from covered service after a verified non-negative test. If the carrier's Medical Director is also fulfilling the MRO role, only when the physician is clearly acting as the Medical Director can he/she be directly involved in an employment issue.

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Test results may only be disseminated to carrier personnel on a strict need-to-know basis.

Employers may not receive the concentration of a drug or metabolites for a particular positive specimen, or concentrations relating to adulterated or substituted specimens, until after the donor has taken an employment action to challenge the test determination. Substance Abuse Professionals (SAPs; see Section 12.0 of this Manual) assigned to a donor by the carrier may obtain concentrations from the MRO without a release from the donor.

FRA does not require the carrier to routinely provide hard copy notification to an applicant or employee of their test results (whether negative or positive). The applicant or employee can obtain copies of their test results by requesting them from the MRO.

7.6.5 Determine that the MRO notifies positive donors of their right to a test of the split specimen, accepts requests for a minimum of 72 hours, and processes their requests with the laboratory.

In the case of a MRO-verified non-negative determination (positive, adulterated, or substituted), the donor has the right to have the split specimen tested at another DHHS/SAMHSA certified laboratory. The donor has 72 hours to decide to test the split, but the MRO can expand the decision window if there are extenuating circumstances. Who pays for the test cannot be a barrier to the donor's right to have a split tested; if the donor cannot pay but still wants the test, the carrier must ensure that split testing is performed.

Adulterated or substituted specimens are similarly eligible for their splits to be tested. No other drugs or substances, or human identity factors (i.e., DNA or serological typing) are permitted to be analyzed in either the split or the original specimen.

The sole purpose of the split test is to reaffirm the presence of the drug(s) or drug metabolite(s), the presence of an adulterant, or the concentration of creatinine in the donor's sample. Therefore, if the original finding is reconfirmed by the referee laboratory, the donor remains in violation of FRA prohibitions regardless of concentration found in the split test. The referee laboratory concentration is considered irrelevant to any administrative process required or authorized by FRA, and need not be provided by the MRO to the donor or his/her representative.

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7.6.6 Determine that the MRO properly handles and reports dilute and cancelled specimens.

If a specimen is reported by the laboratory as dilute, the MRO is to inform the carrier of the test result (either negative or non-negative) and that the specimen was dilute. A verified positive dilute specimen is to be handled by the carrier as an ordinary positive test. A negative dilute specimen cannot on its own trigger a direct observation at the next collection.

Instead, the carrier may choose to institute a policy where all donors with negative dilute specimens for one test category (i.e. pre-employment testing), several test categories, or all test categories are to be automatically brought back to test a second time. This second collection must be private (it cannot be directly observed) and the verified result obtained from the MRO is the one which is the final determination (the first collection is cancelled). The policy must be consistently applied by the carrier and may not be changed to apply to any donor after the original specimen has already been collected.

If a specimen cannot be tested due to a fatal or unrecoverable flaw, the MRO cancels the test and reports the reason to the carrier. Certain tests (pre-employment, return-to-duty, and follow-up, but not random) must be recollected because the regulation requires the employer to obtain a negative test. Cancelled tests may be counted as an acceptable test for statistical purposes (i.e. meeting the random testing rate) if the carrier had made a good faith effort to complete the test.

7.6.7 Determine that the MRO is retaining negative test records for at least one year and positive test records for at least five years.

All records associated with negative and positive tests (CCFs, laboratory reports, MRO interview notes and memoranda, etc.) must be retained in original hard copy for the designated timeframes. Scanned documents are not acceptable to FRA at this time in place of original documents or true copies retained by the carrier or its representatives.

The Medical Review Officer Summary Checklist

I. MRO Qualifications and Organization [7.5]

- A. *Determine if the MRO(s) utilized by the carrier hold the proper qualifications. [7.5.1]*
- B. *Determine if the MRO's staff organization is consistent with the requirements of the regulations and DOT published guidance. [7.5.2]*

II. MRO Determinations [7.6]

- A. *Determine that the MRO is administratively reviewing and properly reporting negative laboratory test results. [7.6.1]*
- B. *Determine that the MRO is properly verifying and reporting positive test results. [7.6.2]*
- C. *Determine that the MRO is properly verifying and reporting other non-negative test results (adulterated, substituted, and invalid). [7.6.3]*
- D. *Determine that the MRO is reporting test results to the carrier in a timely and confidential manner. [7.6.4]*
- E. *Determine that the MRO notifies positive donors of their right to a test of the split specimen, accepts requests for a minimum of 72 hours, and processes their requests with the laboratory. [7.6.5]*
- F. *Determine that the MRO properly handles and reports dilute and cancelled specimens. [7.6.6]*
- G. *Determine that the MRO is retaining negative test records for at least one year and positive test records for at least five years. [7.6.7].*

8.0

PRE-EMPLOYMENT

TESTING

8.0 PRE-EMPLOYMENT TESTING

8.1 OVERVIEW

FRA regulations found in 49 CFR 219.501 – 219.505 (Subpart F) describe requirements for FRA pre-employment testing. FRA's intent is to ensure that no applicant (employee, contractor, or volunteer) can be placed into covered service by hire, by first-time transfer, or by assignment without first successfully passing a FRA-required pre-employment drug test. FRA's requirement for an effective carrier program is that each applicant for covered service has tested negative on a Federal drug test before any covered service is performed and that no applicant for a non-covered service position is asked to take a Federal drug test. Under FRA regulations effective 8/1/02, pre-employment alcohol testing under Federal authority is now authorized (but not required) by FRA.

8.2 REGULATORY REFERENCES (49 CFR PART 219)

- 219.5 – Definitions: Covered Employee; Positive Rate; Refuse to Submit
- 219.501 – Pre-Employment Drug Testing
- 219.502 – Pre-Employment Alcohol Testing
- 219.503 – Notification; Records
- 219.504 – [Reserved]
- 219.505 – Refusals
- 219.701 – Subpart H – Drug and Alcohol Testing Procedures:
Standards for Drug and Alcohol Testing

8.3 INSPECTION GOAL

FRA's goal for inspecting this element is to determine that all personnel performing covered service for the carrier, with the single exception noted below, must have a properly conducted negative Federal drug test on file from the MRO before performing any covered service. This includes new hires, transferring employees, contractors, and volunteers. The single allowed exception is an unpredicted strike where it is essential that the carrier maintain continued operations. In addition, non-covered personnel must not be made to take what appears to be a Federal drug test for a company policy testing program.

PRE-EMPLOYMENT

8.4 RECORDS REQUIRED. The FRA Inspector should obtain a complete list of all system personnel hired or transferred into covered service by the carrier during the audit timeframe. The Inspector should also obtain a complete list of all personnel hired into non-covered service positions during that same audit timeframe. The Inspector should inquire about any emergency hiring that occurred, and obtain a complete list of any personnel assigned by the carrier to perform covered service temporarily. Interviews with headquarters and field staff may be necessary. Copies of test results and/or certifications from the MRO are likely to be required.

8.5 PRE-EMPLOYMENT TESTING

8.5.1 Determine whether the carrier's identification of covered service positions for pre-employment testing is reasonable, complete, and consistent with FRA regulations.

All covered service positions throughout the carrier's system should be clearly identified by the carrier as requiring FRA pre-employment testing. The list should include all geographically diverse job categories and individual covered service job assignments in the carrier's system. For purposes of the rule, all personnel preparing to perform covered service require a Federal pre-employment drug test, including those positions filled by contractors and volunteers.

8.5.2 Determine whether all personnel hired, transferred for the first time, or assigned into covered positions in the audit timeframe had taken a FRA pre-employment drug test. Assess whether the drug test result from the MRO was on file with the carrier on or before the same day the individual began covered service.

The carrier should have a mechanism in place to ensure that Federal pre-employment drug testing is conducted for all covered positions in the carrier's system. All specimens must be collected on a Federal Custody and Control Form (CCF). Attention should be paid to pre-employment tests in all carrier geographic areas, job categories, and covered job assignments. The carrier should be especially vigilant with all covered positions being filled by contractors or volunteers, that have been out-sourced, or that may only occasionally perform covered service (such as utility employees (see 218.22)). The carrier should also have an effective mechanism in place to ensure that employees transferring into covered service from non-regulated assignments are tested.

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Under FRA regulations, a Federal pre-employment drug test is a one-time requirement for each employer. A covered service employee need never take a second pre-employment test for a carrier even if returning to covered service after a lay-off, termination, etc. Personnel performing covered service for a carrier before 3/1/86, are not required to have a Federal pre-employment test for that employer.

The carrier must have a negative Federal test pre-employment result on file from the MRO before allowing an applicant, transfer employee, contractor, or volunteer to perform covered service. The carrier must document the date it received the negative results and this record must match the MRO's record of reporting the result.

If an individual is unable to provide a sufficient amount of urine in a Federal pre-employment drug test because of a permanent or long-term medical or psychological condition, the carrier has options under Part 40 (see 40.195) which permit it to still hire or transfer the individual into covered service. Such medical conditions, however, must be of the nature of a collapse or destruction of kidney functioning, an unrepaired damage to the urinary tract, or a severe long-standing psychiatric condition which is focused on the urination process. Transitory or temporary conditions (such as situational anxiety) do not warrant consideration for this exception.

8.5.3 Determine whether the carrier is performing pre-employment alcohol testing, and if they are, whether the testing is being conducted in accordance with FRA requirements.

Under FRA regulations effective 8/1/01, a carrier is authorized, but is not mandated, to conduct Federal pre-employment alcohol testing. The carrier can test under FRA regulation, or may choose to conduct an alcohol testing program under its own authority, or even test separately under both authorities.

Once the carrier chooses to conduct Federal pre-employment alcohol testing, they must test all new hires and transfers into covered positions. They may not exempt anyone or any job category. Whether or not to institute such a program, since it is Federally-authorized but not a Federal requirement, may be subject to a labor agreement. However, if instituted, all collection and testing procedures must follow Part 219 and Part 40 regulations and guidelines.

If a Federal pre-employment alcohol testing program is instituted, the carrier must have on file both a negative Federal alcohol and a drug test before allowing an

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applicant, job transfer, volunteer, or contractor to perform covered duties. As with all Federal drug tests, the carrier must document the date it received the negative result and the carrier's record must match the collector's record of reporting the test result.

A confirmed positive pre-employment alcohol test of .04 % Breath Alcohol Concentration (BrAC) is a positive result and a violation of FRA prohibitions. The positive applicant or transfer must go through the equivalent of a Federal return-to-work procedure (see Section 12.0 of this Manual) before being allowed into covered service.

An individual who tests positive at .02 - .039 % is eligible to perform covered service without special Federal return-to-work requirements and need not pass a new test (test negative, or below .02 %) in order to be permitted into covered service. However, carriers are neither required nor obligated to hire or transfer individuals who test positive at 0.02 % and above.

If an individual tests below .02 % but above .00 % on a Federal alcohol test, the carrier is forbidden from taking any administrative action such as denying employment or transfer based on the test result. The result is considered a Federal negative test, and as such, is not permitted to be considered as a violation of Rule G [Section 5.6.3 of this Manual provides a further discussion].

8.5.4 Determine whether any verified positive applicants or refusals performed covered service without meeting the FRA's re-eligibility requirement.

Carriers may not immediately test again and place into covered service those applicants who have a verified positive result on a Federal pre-employment test, have refused the collection, or have attempted to either adulterate or substitute their urine specimen (another form of refusal). In order to perform covered service after a verified positive or a refusal, the applicant must have met the requirements of the Substance Abuse Professional (SAP) of record, have been recommended for eligibility to return to covered service by the SAP, and have passed a Federal return-to-work test.

Applicants or transfers into covered service are also ineligible if they have a previous non-negative test or violation of Federal drug or alcohol prohibitions for any other employer regulated by the Department of Transportation, and have not yet successfully completed a SAP process.

An individual is not judged to have refused a test if they fail to commence the drug or alcohol test and/or withdraw their application or letter of transfer request before

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actually starting the collection. However, once the collection has started (that is, once the donor accepts a urine collection kit or breath test mouthpiece), failing to complete the collection is a refusal.

The carrier is under no obligation to consider an individual's application for covered service further after the original positive or refusal determination. Carriers are also under no obligation to complete a shy bladder medical assessment for applicants.

8.5.5 Determine whether any non-covered service pre-employment drug or alcohol tests are being improperly conducted using Federal custody and control collection forms.

The carrier should have a mechanism in place to ensure that non-covered service hires are not tested on a Federal form. Use of the Federal CCF or Alcohol Testing Form (ATF) for a non-regulated carrier pre-employment test transforms it to FRA authority, regardless of the original reason for the collection.

Carriers may not Federally test individuals who only have a possibility or small likelihood of later performing covered service. In some circumstances, a carrier is found to have conducted a Federal pre-employment test on an individual who ultimately never performs covered service. This is permissible only when the carrier can demonstrate they fully intended that this employee would be assigned to covered duties within a reasonable timeframe (i.e. within several months).

8.5.6 Determine whether replacement workers (i.e., for a predicted strike) were allowed to perform covered service without a valid negative pre-employment test(s) on file.

When a predicted shortfall of covered service personnel occurs (i.e., during an expected strike), carriers must exercise due diligence to ensure that before performing covered service, all replacement workers have a Federal pre-employment drug test on file for that carrier. If it is the employer's policy that a Federal pre-employment alcohol test is also required, replacement workers must be given this test as well.

If the strike was unpredicted, the carrier may place personnel in covered positions temporarily without a pre-employment test on file if they can document that the delay to accomplish the test would have severely impacted carrier operations. In such a circumstance, the FRA may permit the carrier no more than a 30 day waiver to conduct pre-employment tests on all replacement personnel.

PRE-EMPLOYMENT

8.5.7 Assess whether the carrier can provide an adequate auditable record on the implementation of its FRA pre-employment testing program.

Records which demonstrate compliance with the audit elements described in this section are essential, and the carrier must be capable of documenting audit elements and providing complete systems which manage supporting records. Inadequate record systems should be considered as noncompliance by the carrier.

Pre-Employment Test Summary Checklist

I. Pre-Employment Testing [8.5]

- A. *Determine whether the carrier's identification of covered service positions for pre-employment testing is reasonable, complete, and consistent with FRA regulations.* [8.5.1]
- B. *Determine whether all personnel hired or transferred into the identified covered positions in the audit timeframe had taken a FRA pre-employment drug test. Assess whether the drug test result from the MRO was on file with the carrier on or before the same day the individual began covered service.* [8.5.2]
- C. *Determine whether the carrier is performing pre-employment alcohol testing, and if they are, whether the testing is being conducted in accordance with FRA requirements.* [8.5.3]
- D. *Determine whether any verified positive applicants or refusals performed covered service without meeting the FRA's re-eligibility requirement.* [8.5.4]
- E. *Determine whether any non-covered service pre-employment tests are being improperly conducted using Federal custody and control collection forms.* [8.5.5]
- F. *Determine whether replacement workers (i.e., for a predicted strike) were allowed to perform covered service without a valid negative pre-employment test(s) on file.* [8.5.6]
- G. *Assess whether the carrier can provide an adequate auditable record of the implementation of their FRA pre-employment testing program.* [8.5.7]

9.0

RANDOM TESTING

9.0 RANDOM TESTING

9.1 OVERVIEW

FRA regulations found in 49 CFR 219.601 – 219.611 (Subpart G) describe requirements for FRA random drug and alcohol testing. FRA believes that random testing is the best deterrence weapon available to combat the use of drugs and abuse of alcohol by all railroad employees performing covered service. FRA's goal for an effective carrier program is that every covered employee believes that they may be called for a random drug and/or alcohol test without advance warning at any time they are on duty.

9.2 REGULATORY REFERENCES (49 CFR PART 219)

- 219.5 – Definitions: Covered Employee; Positive Rate; Violation Rate
- 219.601 – Railroad Random Drug Testing Programs
- 219.602 – Administrator's Determination of Random Drug Testing Rate
- 219.603 – Participation in Drug Testing
- 219.605 – Positive Drug Test Results; Procedures
- 219.607 – Railroad Random Alcohol Testing Programs
- 219.608 – Administrator's Determination of Random Alcohol Testing Rate
- 219.609 – Participation in Alcohol Testing
- 219.611 – Test Result Indicating Prohibited Alcohol Concentration; Procedures
- 219.701 – Subpart H – Drug and Alcohol Testing Procedures: Standards for Drug and Alcohol Testing

9.3 INSPECTION OR AUDIT FOCUS

There are four major elements in a carrier's random testing program which must be assessed:

- The Random Testing Plan
- The Random Testing Pools
- Random Selection Procedures
- Random Program Implementation and Specimen Collection

RANDOM TESTING -- THE RANDOM PLAN

9.4 THE RANDOM TESTING PLAN

9.4.1 Inspection Goal. The goal for inspecting this element is to determine whether the carrier has a FRA-approved Random Plan for Drug and Alcohol Testing as required by 219.601, whether the Plan has been updated to reflect the current program design, whether the Plan matches current carrier practices, and whether the Plan achieves the level of deterrence expected by FRA.

9.4.2 Records Required. The FRA Inspector should obtain a copy of the latest Random Plan maintained by the carrier and a copy of the latest approved Plan on file with FRA headquarters (obtained from the FRA Drug and Alcohol Program Manager (DAPM)). The alcohol program is likely available as an amendment to the master Drug Plan. The Plan on file with the FRA DAPM is considered to be the operational document for purposes of assessment and to measure against current carrier practices.

9.4.3 The Random Plan

9.4.3.1 *Determine that the carrier has a FRA-approved drug and an approved alcohol Random Plan.*

9.4.3.2 *Determine that Plan amendments are being submitted properly for FRA approval.*

Every employer of 16 or more covered service personnel must have a FRA-approved drug and a FRA-approved alcohol Random Plan on file with the DAPM. Program amendments of significance (e.g., changes in service providers, new organization of the pool(s), new selection procedures, etc.) must be approved by FRA at least 30 days before their implementation. Changes in collection sites (if they were part of the original plan submission) do not require amendments. Carriers must not underestimate the importance of keeping their Plan up-to-date so that the FRA-approved version held by the DAPM exactly represents current carrier practices.

9.4.3.3 *Determine that the Plan is complete and up-to-date on its face.*

Each plan should contain descriptive information and sufficient detail for the FRA to determine that:

- a. The carrier has correctly identified which positions or types of positions are to be incorporated into the random testing program and that all employees performing covered service throughout the carrier's system are being included. Contractors, volunteers, or other individuals performing covered service not

RANDOM TESTING – THE RANDOM PLAN

directly employed by the carrier are also required to be randomly tested in a FRA-approved program.

- b. The carrier has identified which positions or types of positions are identified as providing only “de minimus” covered service, and how the carrier intends to handle these personnel within their random program. [“De minimus” service is described in Section 9.5.3.2 of this Manual]
- c. The random pools used for selection have been properly constructed (see Section 9.5 of this Manual) and the Plan describes a specific mechanism so that they are regularly updated by the carrier to ensure that they are always accurate and complete.
- d. The selection method appears to offer an objective means to select employees without apparent bias.
- e. The selection method clearly states how employees are to be selected for drug testing, for alcohol testing, or for both.
- f. The implementation plan is designed to ensure that the carrier can collect specimens from at least 90% of its selections from each pool.
- g. The implementation plan clearly describes any “windows” permitted by the carrier to ensure that selections can be collected.
- h. The implementation plan describes how and when the selectee is to be notified to test, how the collections are to be accomplished, and identifies acceptable circumstances for not testing the individual or pool entry.
- i. The implementation plan offers an objective means to collect specimens from each selectee without discretion by the field supervisors or other management personnel on whom is to be tested.
- j. The carrier is providing a reasonable deterrent to its covered service employees by testing throughout its entire operation on all shifts and on all days it operates.
- k. The carrier has identified specific service providers for the laboratory analysis, MRO duties, and SAP responsibilities. Identification of individual collection sites is not necessary, nor is it a priority to update the list if it is included in the Plan.
- l. The carrier has a procedure for the proper retention of records.

RANDOM TESTING – RANDOM POOLS

Because a Plan has been previously approved by FRA does not mean that it is acceptable under current FRA random program standards or that it provides an acceptable deterrent when it is observed in practice. Inadequate, incomplete, or missing program elements must be remedied. The Plan on file with FRA must reflect current carrier practices, including the detailed characterization of each element described above.

9.5 THE RANDOM TESTING POOLS

9.5.1 Inspection Goal. The goal for inspecting this element is to determine whether the carrier has constructed its random testing pool(s) properly, whether all covered service personnel are included, and whether any personnel who are performing “de minimus” covered service are unnecessarily diluting the pool(s).

9.5.2 Records Required. The FRA Inspector should obtain a copy of each random pool the carrier utilized for selections during the audit period. Based on how the pools are organized, the Inspector may need additional documents from the carrier such as operations schedules, yard employee lists, payroll rosters, etc.

9.5.3 Pools

9.5.3.1 *Determine that each FRA random pool established by the carrier completely and accurately includes or encompasses all covered service personnel who should be in that pool.*

The carrier must have a mechanism in place to ensure that each of its pools is complete and does not include inappropriate entries or non-covered service personnel. The carrier’s specification of covered positions/employees must be uniform across its system. The carrier’s interpretation of who is to be included in each of its pools must be clear and unambiguous.

The carrier must ensure that its pools are inclusive of all personnel assigned to covered job categories and assignments, and have encompassed all carrier geographical locations, work centers (urban and rural), and any of its more unusual operations (seasonal hiring locations, locations where contractors or volunteers perform covered service functions, remote services, newly acquired operations, shop operations, bridge operations, etc.).

The pool(s) for each selection period audited should be checked for compliance. The following guidelines are offered:

- a. Whoever is performing safety-sensitive “covered service,” regardless of title or status, is subject to FRA random testing. This includes contractors and volunteers.

RANDOM TESTING -- RANDOM POOLS

- b. Covered service and non-covered service personnel cannot be mixed in the same pool.
- c. Multiple pools are permitted, with no limit on number as long as each pool meets the other criteria for random pools outlined in this text.
- d. Employees need not be placed in separate pools for drug and alcohol testing selection.
- e. Employees from different DOT operating administrations can be placed in the same pools (i.e., FRA and FMCSA). If the carrier does this, however, it is suggested that they not mix personnel who are to be tested at different drug and alcohol rates (i.e., have some pool entries that are to be tested at a 25% rate and some at a 10% rate). If they do mix these personnel, the carrier must test the entire pool at the highest selection rate for any of the groups with regulated employees in the pool.
- f. Besides individual employees, specific jobs (i.e., third shift train dispatcher at XYZ location) or operational units (i.e., train symbol 123) may also be entries in a specific random pool. Although in general, the best practice is to not mix different types of entries (such as train symbols and individual yard crew personnel) in the same pool, different types of entries may be mixed together as long as all pool entries are of approximately the same size.

Larger entries must be broken into sub-entries if necessary to achieve a balance to the rest of the pool (i.e., the entire third shift of 14 dispatchers as a large single entry could be broken up into four to six entries of two or three dispatchers each to match with a pool filled with two to three person train crews). This must be done in a way, however, which ensures that the makeup of each of the smaller entries remains absolutely stable, so that parts of a pool entry do not "float" between several smaller entries or any discretion is permitted in determining who is part of that entry.

It can be permissible for a carrier to identify individual employees as a pool entry, and when they are selected, test the entire train crew or work group on which that employee serves on the selected day. This, however, must be a pre-approved part of their Random Plan.

- g. Pool entries may not be constructed in a way which could result in a field manager or supervisor eventually having discretion in who would be actually collected. Field personnel may not select testing days or pick jobs when such discretion would be perceived as allowing the targeting of one or more

RANDOM TESTING – RANDOM POOLS

employees and/or the purposeful exemption of others. In addition, a pool entry must be tested in its entirety and arbitrarily selecting only a portion of the entry to test is not permitted even if it is part of the carrier's approved Plan.

9.5.3.2 Determine that carrier pools do not mix personnel regularly performing covered service with personnel who provide "de minimus" service.

As a general rule, no random testing or other Part 219 coverage is required of any employee if they perform covered service less than once a quarter. FRA considers this "de minimus" service. Carriers are permitted to randomly test such personnel, but they must not be placed in a pool with other entries that are performing covered duties more regularly. An exception can be made if the rare periods of covered service performed by an ordinarily "de minimus" employee are excessive or in some other way the carrier determines that the individual's covered service performance may substantially or extraordinarily affect safety.

In addition, true "de minimus" individuals may still be permitted to perform covered service even if they are not subject to random testing, as long as they continue to meet the "de minimus" rule.

Carriers are strongly discouraged from placing high numbers of yard or shop personnel in random pools to keep large groups "qualified" for covered service, when they are unlikely to be called upon. In general, FRA will not accept such a practice. Instead, carriers should plan to "qualify" only a limited number of personnel who are the most likely to be needed to perform covered service.

9.5.3.3 Determine that the carrier is updating its pools routinely.

As a general rule, pools should be updated at least monthly with a changing workforce or operation, or at least quarterly for employers with a generally stable operation. Most carriers (large and small) are expected to update their pools as changes occur (monthly or more often).

9.5.3.4 Determine that the carrier is maintaining copies of its random pools for at least two years after they are used for selection.

Besides a copy of its actual selections, carriers are required to capture a snapshot of each pool from which selections were drawn. These records should ordinarily be in hard copy and must have been produced contemporaneously to when they were in use. Carriers may not "re-create" pools at some later date.

RANDOM TESTING – RANDOM SELECTIONS

9.6 RANDOM SELECTION PROCEDURES

9.6.1 Inspection Goal. The goal for inspecting this element is to determine whether the carrier employs a method of selection which is free from apparent bias and cannot be controlled or manipulated by the carrier or its representatives to either target or exclude any employee or operational unit.

9.6.2 Records Required. The employer should be able to provide a detailed written description of the method of selection. If a computer program is employed, the description should include information on how pool entries are inputted or modified, detail on the computer program being employed (whether proprietary or off-the-shelf), how the computer program operates against the pool, and how the selections are transmitted to the employer. Printouts of each set of selections during the audit timeframe should be obtained by the FRA Inspector. If a computer program is not employed to make the selections, original documents associated with the selection process must be maintained along with any notes or records which support the selections made.

9.6.3 The Selection Data Base. *Determine that every entry in a pool (individual employee, job assignment, or operational unit) has an equal chance of selection in each selection period.*

9.6.3.1 *Assess whether anybody still actively performing covered service was deleted from the selections without just cause.*

Once a random selection has been made, the entry should be tested. After selection, it is generally too late to ignore pool entries or delete a selection. Acceptable reasons for deletion include the individual no longer being employed or the job is no longer operating, documented long-term illness, the individual no longer has any opportunity to perform covered service, or the individual has not performed covered service in previous designated time period and is unlikely to do so in the upcoming period.

9.6.3.2 *Assess whether there were any selections made without replacement.*

An individual or pool entry cannot be dropped from a pool or eliminated as a selection because they were previously tested (regardless of how many times).

RANDOM TESTING – RANDOM SELECTIONS

9.6.3.3 Assess whether there were any selection weightings which would increase or decrease the chance of an employee being selected.

No part of the selection process may increase or decrease the likelihood that any individual pool entry is selected.

9.6.4 The Selection Method. Determine that the carrier employs an acceptable method of selection which meets FRA standards.

9.6.4.1 Assess whether there is any evidence that the carrier attempts several selection runs in a selection procedure in order to ensure the absence or presence of any individual, job, or operating unit.

9.6.4.2 Assess whether the carrier employs an acceptable method of random selection.

The following methods are examples of selection programs that are acceptable to FRA:

- a. Computer programs which randomly select entries from a list without apparent bias. The specific selection criteria used by the computer must be extensively detailed in writing, and each computer draw must be retained as a record for a minimum of two years.
- b. Manual selection from a list of employees using a random number table or equivalent. The specific criteria used to select from the table must be documented in writing, including detail on how the initial starting point in the table was determined. Each draw, as well as a copy of the table portion used, must be retained as a record for a minimum of two years.

Some discretion may be allowed by FRA regarding whether to apply a sanction if the employer has used an alternate procedure, method, or selection strategy not described here as long as it is a clear good faith effort to comply with the intent and the letter of the regulations and the guidance provided in this Manual. Regardless, the method must have been previously approved by FRA in the carrier's Random Plan. Manual selection using a name or social security number drawn out of a hat (or equivalent) is not currently an acceptable selection method to meet FRA requirements.

RANDOM TESTING -- RANDOM SELECTIONS

9.6.4.3 Determine that adequate records are being retained by the carrier to ensure that the carrier is complying with the intent and the letter of the regulation.

This should include, but not be limited to, computer printouts, rough notes, memoranda for the record (MFRs), etc.

9.6.5 Selection Rates. Determine that selections are being made in a manner which supports a reasonable distribution of tests throughout the year, will allow compliance with the published FRA test rate requirements, and be responsive to an employer's changing workforce.

9.6.5.1 Assess whether random selections are being made contemporarily enough to the collection period to ensure an up-to-date pool .

There is an expectation by FRA that collections will be evenly distributed throughout the year. It is preferred that for most carriers, a separate selection process be conducted every month after ensuring that the pools are up to date. Unless a carrier's workforce and/or train operations are extraordinarily stable, quarterly selections from their pools would not be permissible if it allowed a predictable influx of new workers or new jobs to avoid the deterrent effect of random testing for up to three months.

9.6.5.2 If a testing pool is so small that it does not allow testing each selection period, assess whether the carrier has in place a mechanism to randomly determine which selection period will have selections and which will not.

The specific criteria used to make the determination should be detailed in writing in the carrier's Plan, and each selection list must be retained as a record for a minimum of two years.

9.6.5.3 Assess how the carrier is determining whether a selection is to be tested for drugs, for alcohol, or for both.

If required testing rates are different (i.e., 50% for drugs and 25% for alcohol), it is permissible to select a single list of employees from a pool and designate a proportion for both drug and alcohol testing and a proportion for drug testing only. The specific criteria used to make this determination must be standardized and detailed in writing in the carrier's Plan. The master selection list with both sub-groups clearly identified must be retained as a record for a minimum of two years.

RANDOM TESTING -- IMPLEMENTATION AND COLLECTIONS

9.6.5.4 Assess whether the carrier is monitoring significant changes in its workforce in order to ensure that an appropriate number of tests will be conducted each year.

The regulation permits a single annualized assessment of the number of covered service employees for purposes of calculating the number of random tests required. However, if the employer's basic covered service workforce is unstable with either predictable (i.e. seasonal hires) or unpredictable changes (unexpected layoffs), the carrier's Plan should allow a more fluid ability to recalculate the number of tests required to comply with the intent of the regulation.

In general, changes of greater than 10% in a quarter should result in a recalculation of total FRA tests required.

9.7 RANDOM PROGRAM IMPLEMENTATION AND SPECIMEN COLLECTIONS

9.7.1 Inspection Goal. The goal for inspecting this element is to determine whether, within reason, the carrier is testing all of its random selections appropriately, whether collections are distributed throughout the duty day and work year in a manner which contributes to the deterrent effect of the program, and whether collections can be controlled or manipulated by carrier field personnel to target or exclude any employee or operational unit.

9.7.2 Records Required. The carrier should be able to provide specific data on geographic and job-craft distributions of its covered service personnel. Printouts of all selections during the audit timeframe, including information on each selection's craft, job assignment, and job location may be important for the FRA Inspector to review. Printouts of all random collections conducted in the audit timeframe, again including information on each tested individual's craft, job assignment, and job location should be obtained. Records which demonstrate the reason for every time a selection was not collected are an essential part of FRA's review.

9.7.3 Random Collections.

9.7.3.1 *Assess whether the carrier has tested sufficient covered service employees to comply with the random testing rates for drug and alcohol testing required by FRA.*

This assessment is to be made based on FRA's determination of the number of covered service personnel who are to be subject to testing during a one year audit timeframe. Any specimen from a completed collection with an acceptable verified

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result (i.e., negative, positive, adulterated, substituted, or invalid) can be counted towards meeting the FRA's rate requirement. A specimen rejected because of a procedural or documentation error at the collection site, shy bladder or shy lung, or a donor refusal may also be counted towards the rate requirement.

When a selected pool entry cannot be collected in its entirety (i.e., one or more members of a train crew have expired hours of service), the collections already successfully completed are still to be counted as valid tests.

9.7.3.2 Assess whether the carrier uses due diligence to ensure that random selections are tested.

Carriers must make a strong effort to try to ensure that at least 90% of its selections from each pool are tested.

To assist in meeting that goal, carriers are reminded that only pool entries and not testing days have to be randomly selected. A carrier may select a day for testing a pool entry based on availability of the pool entry for testing and the logistics of getting the collection completed (i.e. the availability of a qualified collector).

In order to help ensure that selections are tested, the carrier may incorporate into its Random Plan a "window" to test railroad operations which may not necessarily operate or work on the day selected. Carriers are not permitted to employ a collection window unless and until it has been approved by FRA. Ordinarily, the window should be limited to encompass a reasonable timeframe (e.g. 72 hours, one week). If a window is not specifically designated in the Plan, no window beyond the identified day for collections is permitted.

Under no circumstances can a field supervisor be permitted to pick which day in the window or which crew or crew member is to be tested. The carrier must establish objective and fair criteria on how a train or job assignment is to be selected for collection within the window timeframe.

This window, once approved by FRA, may not be waived or extended by the carrier without FRA permission. The window must be consistent for all collections from a pool, but may be different for each pool as long as it is so designated in the carrier's Random Plan.

Collections which cannot be completed in the plan's designated window are to be cancelled and may not be rescheduled. Random Plans which do not designate a window of more than 24 hours (the day selected) are assumed by FRA to only permit collections on the original day selected by the carrier. FRA will not approve a window that extends more than 30 days.

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9.7.3.3 Assess whether collections appear to be unpredictably distributed throughout the designated testing period, covering all operating days (including Saturdays, Sundays, and holidays) and shifts (up to a 24-hour operations clock).

There is no expectation that weekday/weekend/holiday, off-hours, or shift distributions of collections be equal to their actual percentage in carrier operations, but there has to be sufficient testing in all of these categories to establish deterrence throughout the carrier's system. Comparisons between selections and actual collections should be made, and if either are discrepant by over 20% from the carrier's percentage of operations in any time period, day of the week, or location, it should be investigated to ensure that the carrier is making an acceptable effort to test all of its operations. For example, if 20% of a carrier's operations are equally distributed on Saturdays and Sundays but only 5% of collections occur on these days and no collections occur after Saturday at noon, FRA would have a significant concern.

9.7.3.4 Assess whether collections appear to be unpredictably distributed throughout the carrier's geographic system, covering both urban and rural locations.

Random selections are expected to generally mirror carrier operations. Similarly, collection distributions should also generally mirror carrier operations. Special attention should be placed on locations where there has been an overabundance or underabundance of tests noted in, for example, an operationally intense area, a particular geographic location, an operating unit, or a craft.

9.7.3.5 Assess whether collections are unpredictable within a work shift.

For covered employees not assigned to train operations, it is expected that drug and alcohol collections will occur at generally unpredictable times within the work shift. There is no expectation that the "within-shift" (beginning, middle, or end) collection distributions be equal, but sufficient testing must have been conducted at different intervals to provide a measure of deterrence throughout an employee's work day.

It is understood that the majority of drug and alcohol tests will occur at either the beginning or at the end of the work shift to accommodate carrier operations. For drugs, this practice is generally acceptable. However, because alcohol concentrations decline so rapidly, some proportion (at least 10%) of collections for alcohol must be conducted at the opposite end of the shift. Carriers who can test train operations personnel occasionally in mid-shift, especially for alcohol, are

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seen by FRA as substantially enhancing the deterrent affect of their random programs.

It is essential that all covered disciplines (dispatchers, signal personnel, train and engine personnel, etc.) receive at least beginning-shift and end-shift alcohol collections.

9.7.3.6 Assess whether the carrier allows field supervisory and management personnel discretion with collection dates or collection times which could result in a selective choice by a field supervisor on who was actually collected.

If a test window or some other timeframe allowance is permitted in a carrier's program, a field manager or supervisor with knowledge of personnel assignments may not be permitted any discretion in selecting who is to be collected. For example, if Train Symbol 123 is selected for testing and operates each of the three days in the carrier's collection window established in their Random Plan, a field supervisor may not decide which day to test if each crew is made up of different personnel.

In all cases, the carrier must be able to demonstrate to FRA that the person, job, or operating unit selected was the one actually collected.

It is understood that the carrier's drug and alcohol program manager, in the course of fulfilling his/her responsibilities, will need to make decisions which might affect who will be tested. This might include which day to test such as in the example described in the first paragraph. This is permissible to FRA, since it is reasonable that someone in a position of program authority will have to make such decisions in order for the program to work effectively and efficiently.

9.7.3.7 Assess whether the carrier can provide written reasons for each "no-test" situation, explaining why a particular selection was not collected, with records to be maintained for two years.

In general, every selection should have a specimen collected, unless there is a reason acceptable to FRA. Acceptable explanations to FRA are: a critical safety concern, an unforeseen or unpredictable adverse impact to operations, or employee illness or vacation. Unacceptable reasons include: carrier convenience, collector or supervisor unavailability, and expiration of hours of service. A 10% "no-test" rate or greater is considered unsatisfactory. Special emphasis should be placed on assessing a carrier's "no-test" rate for high priority operations, including premier money-making trains, local freights, etc., and trains or covered service assignments working at unusual times or difficult locations.

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9.7.3.8 Assess whether the carrier's practice of notifying employees of a random test gives too much advance warning of the collection.

Employees must not be given an opportunity to obtain false samples or contaminating products, or to avoid the collection because the carrier's program gives too much notice and allows the employee to go unsupervised. The recommended practice is for carriers to notify an employee of their selection and escort them directly to the collection site.

Carriers must not contact trains in transit and give the crew any more advance notice than necessary. In no circumstance should it be greater than one hour before arrival.

Until employees are specifically notified that they are to be Federally tested, they may not be charged with a refusal to test. Selected employees must not be given an opportunity to "mark off" after being notified but awaiting collection.

9.7.3.9 Assess whether the carrier can provide an adequate auditable record on the implementation of its FRA random program.

Records which demonstrate compliance with the audit elements described in this section are essential. The carrier must be capable of fully documenting each element and provide complete data collection and retrieval systems which manage supporting records. Inadequate record systems should be considered as noncompliance by the carrier.

9.7.4 Removal From Covered Service. Determine whether the carrier removes employees from covered service as soon as practical once notified by the MRO of a verified non-negative drug test result. Determine whether the carrier removes employees from covered service immediately upon notification by the breath alcohol collector (BAT) that the employee is a verified positive for alcohol (.02% BrAC or higher).

The carrier must have a procedure in place that facilitates the timely notification and removal of covered service employees once a verified drug positive or other non-negative (adulterated or substituted) report is made by the MRO. The carrier must relieve a verified non-negative train crewmember or other covered service employee as soon as practical, but the procedure employed may reasonably accommodate carrier operations. Times for relieving a train crewmember can be at the beginning or end of a shift, or at the next routine train stop where suitable relief is available, whichever is sooner. The non-negative employee must be removed from covered service in a way that maintains the employee's right to privacy with other employees within a reasonable need to know basis.

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The carrier must have in place a mechanism that will remove an employee who is a verified positive for alcohol from covered service once the confirmation test is completed by the alcohol collector (BAT). Carriers must ensure that the appropriate supervisory personnel are available and prepared to immediately take action as soon as the test is reported by the BAT.

Carriers who remove an employee from covered service or otherwise sanction an employee for testing negative on a Federal alcohol test (less than .02 % but greater than .00 % BrAC) will be given the severest sanction possible by FRA.

Random Testing Summary Checklist

I. The Random Testing Plan [9.4]

- A. *Determine that the carrier has a FRA-approved drug and an approved alcohol Random Plan.* [9.4.3.1]
- B. *Determine that Plan amendments are being submitted properly for FRA approval.* [9.4.3.2]
- C. *Determine that the Plan is complete and up-to-date on its face.* [9.4.3.3]

II. The Random Testing Pools [9.5]

- A. *Determine that each FRA random pool established by the carrier completely and accurately includes or encompasses all covered service personnel who should be in that pool.* [9.5.3.1]
- B. *Determine that carrier pools do not mix personnel regularly performing covered service with personnel who provide "de minimus" service.* [9.5.3.2]
- C. *Determine that the carrier is updating its pools routinely.* [9.5.3.3]
- D. *Determine that the carrier is maintaining copies of its random pools for at least two years after they are used for selection.* [9.5.3.4]

III. Random Selection Procedures [9.6]

- A. **The Selection Data Base.** *Determine that every entry in a pool (individual, job assignment, or operational unit) has an equal chance of selection in each selection period.* [9.6.3]
 - 1. *Assess whether anybody still actively performing covered service was deleted from the selections without just cause.* [9.6.3.1]
 - 2. *Assess whether there were any selections made without replacement.* [9.6.3.2]
 - 3. *Assess whether there were any selection weightings which would increase or decrease the chance of an employee being selected.* [9.6.3.3]

Random Testing Summary Checklist

B. The Selection Method. *Determine that the carrier employs an acceptable method of selection which meets FRA standards. [9.6.4]*

1. *Assess whether there is any evidence that the carrier attempts several selection runs in a selection procedure in order to ensure the absence or presence of any individual, job, or operating unit. [9.6.4.1]*
2. *Assess whether the carrier employs an acceptable method of random selection. [9.6.4.2]*
3. *Determine that adequate records are being retained by the carrier to ensure that the carrier is complying with the intent and the letter of the regulation. [9.6.4.3]*

C. Selection Rates. *Determine that selections are being made in a manner which supports a reasonable distribution of tests throughout the year, will allow compliance with the published FRA test rate requirement, and be responsive to an employer's changing workforce. [9.6.5]*

1. *Assess whether random selections are being made contemporarily enough to the collection period to ensure an up-to-date pool. [9.6.5.1]*
2. *If a testing pool is so small that it does not allow testing each selection period, assess whether the carrier has in place a mechanism to randomly determine which selection period will have selections and which will not. [9.6.5.2]*
3. *Assess how the carrier is determining whether a selection is to be tested for drugs, for alcohol, or for both. [9.6.5.3]*
4. *Assess whether the carrier is monitoring significant changes in its workforce in order to ensure that an appropriate number of tests will be conducted each year. [9.6.5.4]*

IV. Random Program Implementation and Specimen Collection [9.7]

A. Random Collections. [9.7.3]

1. *Assess whether the carrier has tested sufficient covered service employees to comply with the random testing rates for drug and alcohol testing required by FRA for the audit timeframe. [9.7.3.1]*

Random Testing Summary Checklist

2. *Assess whether the carrier uses due diligence to ensure that random selections are tested. [9.7.3.2]*
3. *Assess whether collections appear to be unpredictably distributed throughout the designated testing period, covering all operating days (including Saturdays, Sundays, and holidays) and shifts (up to a 24-hour operations clock). [9.7.3.3]*
4. *Assess whether collections appear to be unpredictably distributed throughout the carrier's geographic system, covering both urban and rural locations. [9.7.3.4]*
5. *Assess whether collections are unpredictable within a work shift. [9.7.3.5]*
6. *Assess whether the carrier allows field supervisory and management personnel discretion with collection dates or collection times which could result in a selective choice by a field supervisor on who was actually collected. [9.7.3.6]*
7. *Assess whether the carrier can provide written reasons for each "no-test" situation, explaining why a particular selection was not collected, with records to be maintained for two years. [9.7.3.7]*
8. *Assess whether the carrier's practice of notifying employees of a random test gives too much advance warning of the collection. [9.7.3.8]*
9. *Assess whether the carrier can provide an adequate auditable record on the implementation of their FRA random program. [9.7.3.9]*

B. Removal From Covered Service.

1. *Determine whether the carrier removes employees from covered service as soon as practical once notified by the MRO of a verified non-negative drug test result. [9.7.4]*
2. *Determine whether the carrier removes employees from covered service immediately upon notification by the breath alcohol collector (BAT) that the employee is a verified positive for alcohol (.02 % BrAC or higher). [9.7.4]*

10.0

MANDATORY

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TESTING

10.0 MANDATORY POST-ACCIDENT TESTING

10.1 OVERVIEW

FRA regulations found in 49 CFR 219.201 – 219.213 (Subpart C) describe requirements for FRA mandatory post-accident testing. The FRA post-accident testing program has been the cornerstone of FRA's drug and alcohol testing effort, and pre-dates the publication of most of the rest of Part 219. This program helps FRA determine after Rule-triggering train accidents or incidents whether the use of drugs or alcohol by railroad covered service employees may have caused or contributed to the severity of the event.

FRA's goal for an effective carrier program is that each railroad is fully prepared to conduct testing if a Rule-triggering event occurs; that the decision to test is made quickly after reasonable inquiry and a good faith judgment by on-site carrier supervisory personnel; that whenever possible, blood and urine collections from surviving employees are completed within four hours of the accident with the proper supplies and forms; and that blood, urine, and tissue collections from deceased employees or other railroad personnel are completed as soon as practical.

10.2 REGULATORY REFERENCES (49 CFR PART 219)

- 219.5 – Definitions: Covered Employee; Hazardous Material; Impact Accident; Independent; Medical Facility; Medical Practitioner; NTSB; Passenger Train; Railroad; Railroad Property Damage or Damage to Railroad Property; Reportable Injury; Reporting Threshold; Supervisory Employee; Train; Train Accident; Train Incident
- 219.201 – Events for Which Testing is Required
- 219.202 – [Reserved]
- 219.203 – Responsibilities of Railroads and Employees
- 219.204 – [Reserved]
- 219.205 – Specimen Collection and Handling
- 219.206 – FRA Access to Breath Test Results
- 219.207 – Fatality
- 219.208 – [Reserved]
- 219.209 – Reports of Tests and Refusals
- 219.210 – [Reserved]

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- 219.211 – Analysis and Follow-Up
- 219.212 – [Reserved]
- 219.213 – Unlawful Refusal; Consequences
- Appendix C to Part 219 – Post-Accident Testing Specimen Collection

10.3 INSPECTION OR AUDIT FOCUS

There are four major elements in a carrier's mandatory post-accident testing program which must be assessed:

- Carrier Preparation
- The Post-Accident Testing Decision
- Collections From Surviving Employees
- Collections From Fatally Injured Employees

10.4 CARRIER PREPARATION

10.4.1 Inspection Goal. The goal for inspecting this element is to determine whether the carrier is properly prepared to conduct mandatory post-accident collections on any portion of its system at any time during carrier operations. This includes assessing whether the carrier has access to proper collection facilities which fully cover the railroad's catchment area and whether all its supervisors who may be responsible for making that determination are properly trained in FRA post-accident determinations. Supervisors must be capable of making the proper regulatory decisions on whether to test and whom to test when confronted with a possible Rule-triggering event.

10.4.2 Records Required. The carrier should be able to provide specific data on the geographic distribution of post-accident collection sites and FRA post-accident toxicology kits throughout its system. Copies of supervisor and management training records are also important for the FRA Inspector to review. Interviews with field supervisors and headquarters personnel are likely to be required.

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10.4.3 Collections.

10.4.3.1 *Determine that the carrier has an adequate supply of FRA mandatory post-accident toxicology boxes to support its entire system.*

Generally, FRA intends that carriers should be able to get at least two FRA toxicology boxes to any of its designated post-accident collection sites within two hours of an accident. In an emergency, additional boxes can often be obtained from local FRA Inspectors or other railroads, but this should not be considered by the carrier to solve its distribution obligation.

It is strongly recommended that the carrier conduct a periodic inventory of toxicology boxes by location at least once a year.

10.4.3.2 *Determine that the carrier's toxicology box supply has been kept up to date and includes an accurate address for the designated FRA post-accident laboratory and unexpired blood tubes in each kit.*

The carrier should periodically ensure that each FRA post-accident toxicology box it maintains is complete, and has up-to-date and unexpired supplies.

10.4.3.3 *Determine whether the carrier maintains an up-to-date list of collection locations which adequately ensures that post-accident collections can occur during all hours and days of carrier operations throughout the carrier's entire system.*

Carriers are responsible for ensuring that they have active access to sufficient contracted independent collection facilities to support post-accident testing throughout its system. Arrangements with collection sites must be made in advance, so that carrier supervisory personnel are aware of exactly where to go when they have a Rule-triggering event. It is hoped that wherever possible, satisfactory collection services are to be available within two hours of any potential accident site on the carrier's system.

Collectors and collection facilities must be independent of the carrier. That is, no employee of the railroad may collect specimens, nor may specimens be collected on carrier owned or controlled property.

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10.4.3.4 Determine whether the carrier has properly trained all its field supervisory personnel responsible for the test decision in post-accident qualifying events and the post-accident collection procedures.

Carriers must ensure that all field supervisors who may be responsible for the testing determination are properly trained (at least one hour) in all aspects of the FRA post-accident requirements. Successful completion of this training for each individual must be documented in the carrier's records. Sign-in sheets specific to the training and similar records provide acceptable documentation of compliance. Records held by the carrier must be able to verify supervisor attendance, training content, training length, and date and location of the training.

The training content itself must be auditable and should include at least a clear differentiation of the qualifying events; a description of who is to be tested (and who may not be tested) in each of the qualifying events; the exceptions to testing; a discussion on the authority of outsiders (local police officers, NTSB, etc.); a review of what constitutes a good faith determination by the on-site railroad official; the importance and timeliness of sample collection; the circumstances under which an employee could be recalled for testing; and specimen collection and transfer procedures.

When queried, field supervisory personnel should be able to describe FRA post-accident requirements, and/or must be able to immediately access carrier reference documents on post-accident determinations and collections which are intended to be closely available to the supervisor during an accident or incident. In other words, it is acceptable for a supervisor to not remember the specifics of the FRA Rule-triggering events, as long as he/she is generally familiar with the testing requirement and remembers where to obtain the specific information immediately when an accident or incident occurs.

10.5 THE POST-ACCIDENT TESTING DECISION

10.5.1 Inspection Goal. The goal for inspecting this element is to determine whether the carrier is making the correct testing decisions on potential post-accident qualifying events.

10.5.2 Records Required. The carrier should be able to produce copies of its monthly FRA F6180.55, F6180.55a, and F6180.54 reports made to FRA headquarters during the audit timeframe. These reports should cover all carrier reportable accidents and incidents. A summary of these reports can also be obtained from FRA's Accident Reports Section. Copies of Subpart C testing events reported to FRA (qualifiers and cancellations) can be obtained from FRA's

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Drug and Alcohol Program Manager. Interviews with carrier field supervisors and program management staff may also be required to discuss specific cases.

10.5.3 Determinations to Conduct Post-Accident Testing.

10.5.3.1 *Determine whether each Subpart C testing determination was made by on-site supervisory personnel, and in a timely manner.*

10.5.3.2 *Determine whether each Subpart C test actually conducted in the audit timeframe was a proven qualifying event under the regulations.*

10.5.3.3 *Determine that employees actually tested and personnel excluded from testing were properly decided.*

10.5.3.4 *Determine whether any incorrect testing determinations were made under Subpart C requirements and assess the reasons for the inappropriate decision.*

Determinations on Subpart C testing must be made by an on-site carrier supervisor properly trained in FRA post-accident requirements. The supervisor must have had no direct involvement in the accident or incident.

The on-site supervisor is responsible for making a good faith determination with proper due diligence on whether the event was a Rule-triggering event, based on a reasonable inquiry into the relevant facts that could be uncovered at the time of the accident/incident. The on-site supervisor may consult with other carrier personnel, both technical and managerial, but is to be ultimately responsible for the final decision on whether the event is a Subpart C qualifier.

There may be no unnecessary delay in making the determination of whether the accident or incident was a qualifying event, in deciding which employees must be tested (including employees at other locations), or in sending surviving employees to the contracted collection site. Time is of the essence, and both speed in decision-making and an expeditious execution of the decision are among the most essential elements in the post-accident program.

In making a proper determination, the supervisor must consider all FRA requirements, including:

- Whether the event was one of the four qualifying categories (major train accident, impact accident, fatal train incident, and passenger train accident) requiring mandatory testing

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- Whether the event was one of the three categories (major train accident, impact accident, and passenger train accident) requiring a minimum damage threshold
- Whether any damage can be counted towards the minimum Federal damage threshold established by the rule and the damage categories found in either a major train accident (\$1,000,000) or an impact accident (\$150,000)
- Whether the criteria for a major train accident were met (must reach the minimum Federal damage threshold and then have a fatality, employee or not; a release of hazardous material lading accompanied by an evacuation, voluntary or not, or a reportable injury from the release; or railroad damage of \$1,000,000 or more)
- Whether the criteria for an impact accident were met (must reach the minimum Federal damage threshold and then have a reportable injury or damage to railroad property of \$150,000 or more) and that no testing is authorized in certain kinds of impacts
- Whether the criteria for a fatal train incident were met (must involve a fatality to any on-duty railroad employee as a consequence of the movement of on-track equipment)
- Whether the criteria for a passenger train accident were met (must meet the minimum Federal damage threshold and have a reportable injury to any person passenger or employee)
- Whether the event fell within one of the testing exclusions (highway/rail grade crossing, wholly due to natural causes, or vandalism)
- Whether, depending on the type of event, any employees are allowed to be excluded from testing because there was clear non-involvement in the cause and/or severity of the event
- Whether any covered employees not part of the train crew need also be tested
- Whether any covered employees required to be tested were already released from duty, and the circumstances (if any) under which they could be recalled

After investigating the circumstances and consequences of each accident or injury/fatality reported by the carrier, it should be determined whether the carrier made accurate and timely decisions on whether to test and who to test under FRA regulations.

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Employees subject to possible testing should have been retained in a duty status until the testing decision had been made and executed. Once released, an employee cannot be recalled for testing unless:

- a) The employee went off duty normally prior to being contacted by a supervisor and instructed to remain; and
- b) The railroad's investigation indicated a clear probability that the employee played a role in the cause or severity of the accident/incident; and
- c) The accident/incident occurred on the employee's duty tour.

It is essential that specimens be collected from the proper personnel after every Rule-triggering event. Personnel may be required to exceed hours of service limitations while the test determination and specimen collections are being completed. Excess hours of service must be reported, but FRA will likely use its prosecutorial discretion and not cite the carrier as long as the carrier proceeded with reasonable due diligence.

In addition, the carrier should be aware that there could be accidents that are qualifying events but no one may be tested under FRA authority. One example would be the collision of two hi-rail vehicles where the damage exceeded the reporting threshold and several non-hours of service personnel received reportable injuries. If no hours of service personnel were involved either directly or indirectly in that accident, no one is permitted to be Federally tested. However, nothing would keep the carrier from testing under its own authority in such an instance.

There are circumstances where an incorrect Subpart C determination may have been made, but the on-site supervisor demonstrated commendable due diligence, common sense, and good faith given the available facts and the need to make a timely decision required by the FRA rule. Such an error may often not warrant remedial action or administrative sanction by FRA. However, poor or incorrect decisions due to ignorance of the testing events or Subpart C exclusions, personal or professional negligence, or because the supervisor failed to follow standard carrier procedures, is unacceptable and will likely evoke a strong sanction by FRA.

10.6 COLLECTIONS FROM SURVIVING EMPLOYEES

10.6.1 Inspection Goal. The goal for inspecting this element is to determine whether the carrier is able to transport employees to post-accident collection sites in a timely manner, whether the collection sites appear to be performing their duties and responsibilities correctly, and whether specimens are being transported

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to the FRA post-accident laboratory within the timeframe required by FRA regulations.

10.6.2 Records Required. Copies of all FRA Forms F6180.73s and F6180.74s for qualifiers and test cancellations should be reviewed and compared with other laboratory and carrier records which document the collection and specimen transfer. Interviews with carrier personnel and collection site personnel may be required.

10.6.3 Surviving Covered Employee Collections.

10.6.3.1 *Determine whether specimens on surviving covered employees are being obtained within four hours of a qualifying event, and if not, establish whether the reasons for the delay are acceptable.*

Carriers need to ensure that whenever possible specimens are collected within four hours of a qualifying accident or incident. There should be no unnecessary delays in relieving train crewmembers from the accident scene. Crewmembers and other covered employees designated for testing should be transported to the collection site as soon as the accident scene is stabilized and crew and passenger safety has been established.

The carrier is required to maintain documentation when a collection occurs more than four hours after a Rule-triggering event. Any delays beyond four hours in obtaining specimens should be investigated to determine if the explanations were reasonable and not due to factors within the carrier's control (i.e., waiting for a breath alcohol test to be conducted, failure to relieve crewmembers from the accident scene without adequate justification, the designated collection site was too far away when a closer one could have been previously arranged, confusion at the collection site, etc.)

10.6.3.2 *Determine whether collection sites are qualified to collect urine and blood specimens in accordance with FRA post-accident procedures, are performing collections in accordance with the regulations, are properly documenting chain-of-custody, and are facilitating the transportation of specimens to the FRA post-accident laboratory to ensure arrival within 24 hours.*

Collection Sites. Post-accident collections must be conducted at an independent medical facility capable of the proper care and treatment necessary to protect the health and medical safety of carrier employees involved in the accident or incident. The facility may not be on carrier property or property under the direct control of the carrier (i.e., cannot be presently located as part of the carrier's medical department).

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Specimens must also not be collected by medical personnel under the carrier's direct control (i.e., may not be carrier employees), even if they are fully qualified. Collectors must be independent contractors in relation to the carrier, but not necessarily employees of the independent medical facility (although it is strongly recommended).

A carrier-hired contract collection service may perform post-accident collections at another independent medical facility, as long as the contractor is otherwise medically qualified under the regulation and medical emergencies can be immediately handled.

Even though they may not be there to actually collect specimens, a contract collection service may also be retained by the carrier to provide oversight to the independent medical facility's collector personnel, advising them of proper FRA post-accident collection procedures. This is permissible as long as they do not physically interfere with the collectors of record. This does not waive the employer's responsibility to have a railroad official present, who has ultimate authority for control of the collection process.

In certain circumstances, it may be permissible for a physician who is performing duties as the carrier's contract medical director and/or the personnel employed by the carrier's contract medical clinic to qualify to collect post-accident specimens. This would be acceptable to FRA only if it was perceived by the carrier's employees that the doctor or the clinic were not the carrier's "medical department" and/or were not equivalent to railroad employees.

The Collection Procedure. The carrier is responsible for ensuring that the collectors are provided their copies of the instructions found in the post-accident toxicology box. The railroad official accompanying the employees to be tested should be knowledgeable of FRA's collection requirements.

Specimen collections must be properly documented on FRA's post-accident collection forms (FRA F6180.73 and FRA F6180.74, often called Forms 73 and 74).

The F6180.73 is an accident summary form to be filled out by the railroad representative accompanying the employees to the collection site. An example of a properly completed Form 73 can be found at Tab 3.

Each individual chain-of-custody collection form (F6180.74) must be properly completed by the donor and the collector(s). The Form 74 fully documents both blood and urine collections up through the point of specimen shipment, and contains all collector, observer, and donor signatures. An example of a properly

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filled out Form 74 using two collectors working in tandem can also be found at Tab 3.

Potentially fatal flaws in a collection include the absence of one or more collector or donor signatures; a discrepancy between the identification number on the form and numbers on the specimens themselves; specimen seals absent or breached; and the appearance on the chain-of-custody form of names or signatures of individuals who are not the collector, observer, or donor. Errors in documentation can often be recovered through the use of signed statements, with the exception of those where the proper identify of the specimen cannot be absolutely determined.

It is essential that both blood and urine samples are collected from each donor. Blood should be collected first to avoid any potential delay due to a shy bladder situation. A single collector can obtain both blood and urine specimens, or multiple collectors can be employed (i.e., one collecting the blood and a second collecting urine).

Each collector can only collect one sample from one donor at a time until the particular specimen is labeled, sealed, and documented on the Form 74. It is permissible for a single collector to collect blood samples from the entire donor group, one at a time, then return and collect urine specimens one at a time from the same donor group.

Neither a railroad representative nor a FRA Inspector may physically participate in any way in the collection of specimens (including as an observer in a direct observation urine collection). The railroad representative may advise collection personnel on proper FRA procedures, but neither the railroad representative or the Inspector may materially interfere with the collector and his/her performance of duties.

Specimen Shipment. The carrier is responsible for ensuring that the specimens are transported to the FRA's post-accident laboratory to arrive within 24 hours from when the samples were ready for shipment.

The selected courier service agent, arriving to take possession of the sealed post-accident toxicology box for shipment, does not personally sign the chain-of-custody form. Documentation of specimen transfer is only to be made on the Form 74 as to the identity of the specific courier service (i.e., FedEx, Airborne, UPS, etc.).

Documentation of the identity of the specific courier agent is sufficient on the courier service's shipping bill. It is not a fatal flaw if the actual courier service

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transporting the specimen is different than the service identified on the Form 74. The already sealed box is not to be opened to amend the Form 74.

A representative of the carrier may take possession of the sealed toxicology box for purposes of delivering it to an overnight courier, an airport, or an airline. In such circumstance, the handling of the transport box by the railroad representative also need not be documented on the chain-of-custody form. However, the carrier should be knowledgeable of that occurrence, and be prepared to identify any supervisors involved and the specific reasons that the collection site would or could not ship the box.

FRA's shipping requirement assumes door-to-door delivery to its post-accident laboratory. FRA expects the carrier to use whatever type of courier service is necessary to ensure that specimens arrive within the required 24 hour timeframe. This mandate assumes that the carrier is prepared to ensure delivery on weekdays, weekends, or holidays. Shipment problems outside of the carrier's control (weather delays, delayed delivery etc.) will not ordinarily incur a sanction if the carrier used reasonable diligence to meet the FRA requirement.

10.6.3.3 Determine whether the carrier removes employees from covered service as soon as practical once notified by the MRO of a verified non-negative test result.

Carriers may not hold employees out of covered service pending the laboratory results of a post-accident test using Federal authority, but holding employees out of service under their own company or medical department authorization based on the post-accident event is acceptable.

Carrier personnel may contact the FRA's Drug and Alcohol Program Manager or his designee about the progress of the laboratory in the testing of post-accident specimens, but are not to directly contact laboratory personnel before the release of the final reports other than to ensure that the toxicology box arrived.

Test results from Subpart C post-accident events will be sent by the FRA contract post-accident laboratory directly to all surviving employees and to the carrier's MRO for both surviving and deceased employees. The MRO has no role with fatalities, but performs his/her duties in accordance with DOT requirements on results from surviving employees. The MRO is then responsible for reporting all test determinations to the carrier.

The carrier must have a procedure in place that facilitates the timely notification and removal of surviving covered service employees once a verified positive or

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other non-negative (adulterated or substituted) report is made by the MRO. The carrier must relieve a verified non-negative train crewmember or other covered service employee as soon as practical, but the procedure employed may reasonably accommodate carrier operations. Times for relieving a train crewmember can be at the beginning or end of a shift, or at the next routine train stop where suitable relief is available, whichever is sooner. The employee verified as non-negative must be removed from covered service in a way that maintains the employee's right to privacy with other carrier personnel within a reasonable need to know basis.

10.7 COLLECTIONS FROM FATALLY INJURED EMPLOYEES

10.7.1 Inspection Goal. The goal for inspecting this element is to determine whether the carrier has exercised due diligence in ensuring that required specimens from fatally injured employees are harvested by competent authority and transported to the FRA's post-accident laboratory in as expeditious a manner as possible.

10.7.2 Records Required. Copies of relevant FRA Forms F6180.73 and 74s may be necessary to be reviewed. Interviews with carrier personnel and medical examiner/coroner/mortuary personnel may be necessary.

10.7.3 Collections From Fatally Injured Employees. *Determine whether the carrier has exercised due diligence in ensuring that the required specimens (blood, urine, and tissue) are collected from fatally injured employees and that the specimens are transported to the FRA post-accident laboratory as soon as possible.*

Carriers do not need to ensure that specimens from fatally injured employees are harvested within any specific timeframe, only that the requirement is accomplished as soon as practical. The carrier is only responsible for ensuring that the local jurisdiction (medical examiner, coroner, etc.) is made aware of the Federal requirements and may need to directly involve the FRA if it becomes a jurisdictional issue beyond the carrier's control.

Under Federal law, no consent to take samples is required from the deceased's family. Family wishes, religious affiliation, or cultural background do not exempt an employee from the Federal requirement to have specimens harvested.

Chain-of-custody issues are still important but are not considered as critical with a fatally injured carrier employee. Therefore the carrier has no obligation to accompany the body to the medical examiner, coroner, or mortuary. In addition,

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there is no circumstance where any carrier representative must be present at the harvesting of the specimens. It is essential, however, that the set of instructions for the collection of post-mortem specimens be presented to the authority collecting the samples.

Depending on availability, all the following specimens are important to be obtained (in order of significance) at autopsy and before embalming:

- whole blood
- urine
- vitreous
- liver
- brain
- kidney

It is FRA's intent that all of the samples on this list be obtained if they are available. Other specimens (i.e., bile, spleen, lung) may also be of use but are not as critical to obtain unless many of the other sample types are not available.

At least 20 mL of blood should be obtained from an intact femoral vein or artery or from peripheral vessels and an intact heart. If no uncontaminated blood is available, bloody fluid or clots may be acceptable but they should not be labeled as blood. As much urine as possible (up to 100 mL) would be valuable. All vitreous fluid available from any intact eyes and 50-100 grams of the other tissues and fluids should be obtained if possible.

By the end of 2002, FRA will have special fatality toxicology boxes available for use by the carrier. If these special collection supplies are not available, the carrier can continue to use a regular FRA post-accident toxicology box. Although FRA toxicology boxes are not specifically designed to collect post-mortem specimens, they are more than acceptable to transfer samples to the FRA laboratory. If the agency harvesting the specimens has better containers to house the specimens, they may use their own supplies.

The carrier need not be directly involved in the transportation of post-mortem samples, but must ensure that the local jurisdiction transfers the specimens to the FRA post-accident laboratory as soon as possible. It is permissible for the agency harvesting specimens to delay transport to properly prepare the samples for shipment (i.e. freezing tissues, etc.).

Post-Accident Test Summary Checklist

I. Carrier Preparation [10.4]

- A. *Determine that the carrier has an adequate supply of FRA mandatory post-accident toxicology boxes to support its entire system. [10.4.3.1]*
- B. *Determine that the carrier's toxicology box supply has been kept up to date and includes an accurate address for the designated FRA post-accident laboratory and unexpired blood tubes in each kit. [10.4.3.2]*
- C. *Determine whether the carrier maintains an up-to-date list of collection locations which adequately ensures that post-accident collections can occur during all hours and days of carrier operations throughout the carrier's entire system. [10.4.3.3]*
- D. *Determine whether the carrier has properly trained all its field supervisory personnel responsible for the test decision in post-accident qualifying event and the post-accident collection procedures. [10.4.3.4]*

II. The Post Accident Testing Decision [10.5]

- A. *Determine whether each Subpart C testing determination was made by the on-site supervisory personnel, and in a timely manner. [10.5.3.1]*
- B. *Determine whether each Subpart C test actually conducted in the audit timeframe was a proven qualifying event under the regulations. [10.5.3.2]*
- C. *Determine that employees actually tested and personnel excluded from testing were properly decided. [10.5.3.3]*
- D. *Determine whether any incorrect testing determinations were made under Subpart C requirements and the reasons for the inappropriate decision. [10.5.3.4]*

III. Collections From Surviving Employees [10.6]

- A. *Determine whether specimens on surviving crewmembers are being obtained within four hours of a qualifying event, and if not, establish whether the reasons for the delay are acceptable. [10.6.3.1]*

Post-Accident Test Summary Checklist

- B. *Determine whether collection sites are qualified to collect urine and blood specimens in accordance with FRA procedures, are performing collections in accordance with the regulations, are properly documenting chain-of-custody correctly, and are facilitating the transportation of specimens to the FRA post-accident laboratory to ensure arrival within 24 hours. [10.6.3.2]*
- C. *Determine whether the carrier removes employees from covered service as soon as practical once notified by the MRO of a verified non-negative test result. [10.6.3.3]*

IV. Collections From Fatally Injured Employees [10.7]

- A. *Determine whether the carrier has exercised due diligence in ensuring that the required specimens (blood, urine, and tissue) are collected from fatally injured employees and that the specimens are transported to the FRA post-accident laboratory as soon as possible. [10.7.3]*

11.0

REASONABLE

SUSPICION

REASONABLE

CAUSE

11.0 REASONABLE SUSPICION/ REASONABLE CAUSE

11.1 OVERVIEW

FRA regulations found in 49 CFR 219.300 – 219.302 (Subpart D) describe requirements and authorization for FRA reasonable suspicion and reasonable cause testing. As defined by FRA, reasonable suspicion involves a concern about the possible drug and/or alcohol impairment of an individual employee.

Reasonable cause primarily involves a concern about an event, either a specified Rule violation or involvement in a FRA reportable accident/incident, where one or more employees' acts or omissions contributed to the cause or severity.

Reasonable suspicion is a mandatory Federal test, involves the face-to-face assessment of the employee by either one or two trained supervisors (depending on whether alcohol or drugs is suspected), and must be based on the behavior, speech, or body odors seen in that particular employee at that moment.

Federal reasonable cause testing is authorized by FRA regulations but is not required. When conducted under Federal authority, reasonable cause testing may be necessitated when there has been an accident or incident reportable under Part 225 (but does not meet Subpart C thresholds) and the employee may have played a role in its cause or severity, or there has been a violation of one of the operational rules or errors identified in 219.301.

A carrier is permitted to maintain a reasonable cause testing program under its own authority, which may be used instead of, or as a complement to, Federal reasonable cause testing. That is, a carrier may conduct reasonable cause testing under Federal authority, under its own authority (company policy), or not conduct reasonable cause testing at all. It is even permissible to switch back and forth without notice for each new event.

Through implementation of an effective reasonable suspicion and Federal reasonable cause testing program, the carrier will be able to uncover impaired employees, and by doing so, help deter use of alcohol and drugs on or just before duty. FRA's goal for an effective carrier program is that carrier supervisors have at least two hours training in reasonable suspicion and reasonable cause determinations; that carrier supervisors are able to clearly distinguish between reasonable cause testing under Federal authority and under company authority, if applicable; and that the carrier's Rule G efficiency check observations conducted

REASONABLE SUSPICION

under Part 217 are effective in detecting Rule G violations and act as a deterrent to drug and alcohol use by covered employees. FRA's objective is that supervisors are actively working to ensure employee compliance with alcohol and drug use prohibitions. Employees are to be treated fairly and objectively judged based on the available facts, and not on third party information or supposition.

11.2 REGULATORY REFERENCES (49 CFR PART 219)

- 219.5 – Definitions: Covered Employee; Co-Worker; Refuse to Submit; Reportable Injury; Supervisory Employee
- 219.300 – Mandatory Reasonable Suspicion Testing
- 219.301 – Testing for Reasonable Cause
- 219.302 – Prompt Sample Collection; Time Documentation

11.3 REASONABLE SUSPICION

11.3.1 Inspection Goal. The goal for inspecting this element is to determine whether the carrier is properly conducting mandatory reasonable suspicion testing in accordance with FRA regulations. This includes assessing whether supervisors have been properly trained in reasonable suspicion determinations, and whether they are prepared to conduct testing when confronted with an employee who may be impacted by drugs and/or alcohol on the job.

An evaluation should also be conducted to determine whether the carrier's program has sufficient trained collectors (urine and breath) with access to appropriate supplies and qualified equipment to accomplish required testing on very short notice. In addition, it should be assessed whether the railroad's program of Part 217 operational (efficiency) tests and inspections are being conducted in a manner where a competent Rule G or reasonable suspicion determination is possible.

11.3.2 Records Required. Copies of supervisory management training records are important for the FRA Inspector to review. An assessment of records from a number of reasonable suspicion determinations would be essential. Records which document the carrier's compliance with Part 217.9 (Program of Operational Tests and Inspections) will also be necessary to review. Extensive interviews with field supervisors and headquarters personnel should be required.

REASONABLE SUSPICION

11.3.3 Reasonable Suspicion.

11.3.3.1 Determine that all supervisory personnel who may be responsible for making a reasonable suspicion determination have the proper training.

In general, carriers are responsible for ensuring that all of its field supervisors who may be assigned to make a reasonable suspicion determination on covered employees have been properly trained (at least two hours) in all aspects of the Federal requirements. Although not directly required by the Rule, FRA expects that supervisors responsible for this determination should have received their original training or a refresher in the past two years.

Successful completion of this training for each supervisor must be documented in the carrier's records. Sign-in sheets recording supervisor attendance, class content, and date of training would be examples of acceptable documentation. The training content itself should also be auditable and should include both a clear description of the signs and symptoms which suggest employee drug and alcohol use, but also the procedures necessary to confront a covered employee who may be impaired, supervisor do's and don'ts, and proper supervisor documentation elements.

11.3.3.2 Determine that supervisory personnel responsible for the reasonable suspicion determination are fully knowledgeable of their duties and responsibilities when they suspect a covered employee of being impaired by drugs and/or alcohol.

Field supervisory personnel should be able to describe FRA reasonable suspicion requirements, or must be able to immediately access carrier reference documents on reasonable suspicion determinations which should be closely available to the supervisor at all times.

Supervisors should use a variety of means of personal contact and communications to assess employees for drug and/or alcohol impairment. One of the more important mechanisms in the opinion of FRA is the Part 217 efficiency/operational test mechanism for Rule G provided for by the regulations.

FRA expects trained supervisors to use the Part 217 efficiency check in a manner which ensures a face-to-face evaluation of each covered employee during each operational test and inspection contact listed on page 5 of the FRA yearly Management Information System (MIS) report. In order to be counted, the supervisor must have been able to directly assess at least one of the categories which suggest impairment (behavior, speech, employee body odors, etc.). FRA's expectations are that valid Rule G checks as described above are to be conducted

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at a rate equal to the number of covered employees each quarter. That is, if the carrier has 1,000 covered employees, FRA expects the carrier would conduct at least 4,000 valid Rule G checks each year.

Supervisors must not be afraid to confront potentially impaired covered employees, and must always be available to other supervisors who require a second opinion on an employee they are confronting. With reasonable suspicion, supervisors need not always be right, but instead must have made a good faith determination to test based on the available facts (which they must be able to articulate). Carriers must fully support the use of reasonable suspicion as an important tool to help ensure rail safety.

11.3.3.3 Assess reasonable suspicion cases in the audit timeframe to ensure that both supervisor and carrier documentation of the incident indicates compliance with FRA regulations.

In reasonable suspicion, the trained supervisor must base their determination on specific, contemporaneous, articulable observations concerning the appearance, behavior, speech, or body odors of the covered employee. For drugs, a second supervisor's concurrence with the original supervisor's assessment is necessary. The second supervisor need not be trained or even physically present for the determination (a telephone consultation or similar means of communication is permitted).

Under no circumstances can a supervisor use information obtained from another source or a third party to require a reasonable suspicion test. The entire basis of the determination must be what the supervisor observes personally.

Carriers and supervisors are expected to maintain documentation which supports each reasonable suspicion determination, including the date and time of the incident, observed behavior, evidence of the concurrence of a second trained supervisor (drugs only), name of witnesses (and witness statements if available), and final disposition of the case. A breath specimen for alcohol and/or a urine specimen for drugs is required, but the collection of other types of samples (i.e., blood) is not permitted.

Hours of service limitations take a secondary position in a reasonable suspicion collection once the decision to test is made. However, the excess service must be reported and FRA will likely use its prosecutorial discretion not to apply a sanction if the carrier has used due diligence to complete the collection as soon as possible. Shy bladder rules, of course, still apply.

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Once a decision is made that reasonable suspicion exists, the carrier must use due diligence to test the employee immediately and without unnecessary delay. It is expected that the carrier will make a strong effort to ensure that if at all possible, necessary specimens will be collected within several hours of the decision to test. Donors should be monitored in the interim period, and not released from duty until the specimens are collected. Under Federal regulations, no alcohol test may be conducted after eight hours.

The carrier must maintain a written record any time a reasonable suspicion test is not conducted within two hours of the decision (for either drugs or alcohol). The carrier must also maintain a written record any time an alcohol test is not conducted before eight hours had passed since the determination.

11.3.3.4 Determine whether the carrier removes employees from covered service as soon as practical once notified by the MRO of a verified reasonable suspicion non-negative test result.

There is no FRA requirement which mandates whether an employee may be retained in covered service pending the carrier receiving the results of the reasonable suspicion test. It is expected, however, that most carriers will suspend a person from covered service under their own authority in such a circumstance based on the reasonable suspicion of impaired job performance due to a violation of FRA drug or alcohol prohibitions.

If the carrier retains the employee in covered service, the carrier must have a procedure in place that facilitates the timely notification and removal of the employee once a verified positive or other non-negative (adulterated or substituted) report is made by the MRO. A verified non-negative train crewmember or other covered service employee must be relieved as soon as practical, but the method employed should reasonably accommodate carrier operations. Acceptable times for relieving a crewmember can be at the beginning or end of a shift, or at the next routine train stop where suitable relief is available, whichever is sooner. The non-negative employee must be removed from covered service in a way that maintains the employee's right to privacy with other employees, but within a reasonable need to know basis.

REASONABLE CAUSE

11.4 REASONABLE CAUSE

11.4.1 Inspection Goal. The goal for inspecting this element is to determine whether the carrier is conducting any reasonable cause testing; whether the testing is under Federal authority or company policy, or both; whether the testing authority is being properly represented to the employee; and whether any testing performed under Federal authority is being properly conducted in accordance with FRA regulations.

11.4.2 Records Required. Copies of all carrier policies and reports which support Federal authority and company policy reasonable cause testing decisions would be important to review. These include, but are not limited to, copies of custody and control forms, and copies of 54 and 55A reports (FRA 6180.54 Rail Equipment Accident/Incident Report; FRA 6180.55A Rail Injury and Illness Summary). Interviews with field supervisory personnel would be essential.

11.4.3 Reasonable Cause.

11.4.3.1 *Determine whether the carrier is conducting Federal reasonable cause testing, company policy testing, or a blend of both. If both, determine the circumstances which would cause a supervisor to choose between Federal or company authority.*

Carriers testing for reasonable cause under Federal authority must be sure that their test-triggering mechanisms are limited to the elements described in 219.301. If both Federal authority and company policy reasonable cause testing procedures are being employed by the carrier, the carrier must ensure that supervisors are clear on when they are to test under Federal authority.

Carriers relying on their own company authority exclusively are not constrained by Federal guidelines, and may test a broader range of employees with less restrictive thresholds than is permitted under FRA regulations. FRA would be interested in such a company reasonable cause program only to determine that the appearance of Federal authority is not being given in any company program-related documents or policy guidelines and Federal chain-of-custody forms are not being used. FRA should also ensure that the carrier is not applying Federal sanctions based on the results of a positive company test. This especially includes decertification of engineers.

REASONABLE CAUSE

11.4.3.2 If both Federal and company authority is being used, determine if field supervisory personnel are capable of distinguishing between the two programs, and can clearly articulate the threshold requirements for the Federal reasonable cause program.

If the carrier is blending both types of reasonable cause testing, all company policies, procedures, and published guidelines should clearly differentiate on how and when each program is to be applied. In all circumstances, it must always be made known to the employee under whose authority they are being tested. At the least, use of Federal and non-Federal chain-of-custody forms provides a minimum notification to the employee.

Supervisors must be clear on when Federal or company authority is being utilized when conducting a test, and be able to distinguish when an accident or incident automatically reaches the FRA mandatory post-accident testing threshold. Such information should be made part of a formal carrier training program.

The carrier should also ensure that collectors know which collection form (Federal or company policy) to use to properly collect the sample.

11.4.3.3 If Federal authority is being used, assess Federal reasonable cause cases in the audit timeframe to ensure that both supervisor and carrier documentation of the event indicates compliance with FRA regulations.

If Federal authority is being utilized for a reasonable cause determination, all applicable portions of Part 219 and Part 40 apply. A breath specimen for alcohol and/or a urine specimen for drugs is required, but other types of samples (i.e., blood) may not be obtained. Federal chain-of-custody forms must be utilized.

Hours of service limitations on Federal reasonable cause collections must not stop the collection, but the carrier must report the excess service to FRA. FRA will likely use its prosecutorial discretion not to apply a sanction if the carrier used due diligence to complete the collection. Shy bladder rules, of course, still apply.

Testing using Federal authority may be required only if the following Part 219 provisions are met:

- a covered service employee is involved in a rail equipment accident or incident reportable under Part 225 but which does not meet Subpart C thresholds, and the supervisor's investigation suggests that one or more employees' acts or omissions could have caused or contributed to the severity of the event, or

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- a covered service employee is involved in one of the Rule violations or errors identified in 219.301.

For reportable accident/incidents, Federal reasonable cause testing must be separately determined for each individual employee. When the employee could not have had any responsibility for the event, they may not be tested. In each instance where the carrier intends to use an accident/incident event to initiate a Federal test, the supervisor must make a reasonable inquiry and develop facts to support whether each involved covered service employee contributed to the occurrence or severity of the event.

If the Federal criteria for a Rule violation is met, there is no requirement for an acts or omissions determination to be made. The Rule violation provides "per se" reasonable cause for a Federal drug and/or alcohol test.

While not required by the rule, documentation maintained by the supervisor about the circumstances of the event and the reasons for the supervisor's determination may assist in later carrier or FRA investigations.

Only the results of Federal tests are acceptable in Part 240 engineer decertification actions.

If Federal reasonable cause testing is required by the employer, the testing decision should be made as soon as the observation is made or as soon as all personnel are safe and/or the situation stabilized so that public or employee safety is no longer a concern. The decision should not be unnecessarily delayed.

Once the decision is made to test under Federal authority, the carrier must proceed to testing without delay and use due diligence to ensure that specimens are collected as soon as practical. It is expected that all specimens should be collected within several hours of the decision, but testing is not permitted if more than eight hours have expired. For drugs, the eight hour requirement is met if the employee has been delivered to the collection site and the collector is present. Employees may not be brought back on duty to be tested if they already have been normally released by the carrier.

11.4.3.4 Determine whether the carrier removes employees from covered service as soon as practical once notified by the MRO of a verified Federal reasonable cause non-negative test result.

There is no FRA requirement which mandates whether an employee can be retained in covered service pending the results of a Federal reasonable cause test.

REASONABLE CAUSE

It is expected that many carriers will automatically suspend a person from covered service in such a circumstance.

However, if the carrier retains the employee in covered service, the carrier must have a procedure in place that facilitates the timely notification and removal of an employee once a verified positive or other non-negative (adulterated or substituted) report is made by the MRO. The carrier must relieve a verified non-negative train crewmember or other covered service employee as soon as practical, but the procedure employed may reasonably accommodate carrier operations. Acceptable times for relieving a train crewmember can be at the beginning or end of a shift, or at the next routine train stop where suitable relief is available, whichever is sooner. The non-negative employee must be removed from covered service in a way that maintains the employee's right to privacy with other employees, within a reasonable need to know basis.

RS/RC Test Summary Checklist

I. Reasonable Suspicion. [11.3.3]

- A. *Determine that all supervisory personnel who may be responsible for making a reasonable suspicion determination have the proper training.* [11.3.3.1]
- B. *Determine that supervisory personnel responsible for the reasonable suspicion determination are fully knowledgeable of their duties and responsibilities when they suspect a covered employee of being impaired by drugs and/or alcohol.* [11.3.3.2]
- C. *Assess reasonable suspicion cases in the audit timeframe to ensure that both supervisor and carrier documentation of the incident indicates compliance with FRA regulations.* [11.3.3.3]
- D. *Determine whether the carrier removes employees from covered service as soon as practical once notified by the MRO of a verified reasonable suspicion non-negative test result.* [11.3.3.4]

II. Reasonable Cause. [11.4.3]

- A. *Determine whether the carrier is conducting Federal reasonable cause testing, company policy testing, or a blend of both. If both, determine the circumstances which would cause a supervisor to choose between Federal or company authority.* [11.4.3.1]
- B. *If both Federal and company authority is being used, determine if field supervisory personnel are capable of distinguishing between the two programs, and can clearly articulate the threshold requirements for the Federal/ reasonable cause program.* [11.4.3.2]
- C. *If Federal authority is being used, assess Federal reasonable cause cases in the audit timeframe to ensure that both supervisor and carrier documentation of the event indicates compliance with FRA regulations.* [11.4.3.3]
- D. *Determine whether the carrier removes employees from covered service as soon as practical once notified by the MRO of a verified Federal reasonable cause non-negative test result.* [11.4.3.4]

12.0

**RETURN TO COVERED
SERVICE**

**SUBSTANCE ABUSE
PROFESSIONAL**

RETURN-TO-WORK

FOLLOW-UP

12.0 RETURN TO COVERED SERVICE (SAP, Return-to-Work, Follow-Up)

12.1 OVERVIEW

FRA regulations found in 49 CFR 219.104 and 219.405 outline requirements to return an employee to covered service after failing a required FRA drug or alcohol test; after any other violations of 219.101 and 219.102; after refusing a required FRA drug or alcohol test; or after completion of a co-worker report initiated program (as outlined in 219.405). These guidelines also apply in part after completion of a voluntary referral program (as outlined in 219.403) if a SAP is used. Regulations regarding the role and responsibilities of the Substance Abuse Professional (SAP) may be found in 49 CFR 40.281 - 40.313 (Subpart O).

In order to return to covered service, personnel must be assessed by a qualified SAP and successfully complete the treatment plan (counseling, treatment, or education) established for them. Once the employer has received a recommendation for return to work from the SAP and has agreed to accept an employee back into covered duty, the employee must take and pass a Federal drug and/or alcohol return-to-work test. They must also undergo mandated Federal follow-up testing for the length of time and frequency directed by the SAP. No Federal return to work or follow-up testing is required for participants in a FRA voluntary referral program.

It is FRA's intent that carriers not return personnel to covered duty until it can be determined that the employee is now unlikely to violate the drug and alcohol prohibitions of the FRA regulation. Once returned, FRA intends the employee be subject to the deterrence of unannounced follow-up testing to help ensure that they remain in compliance with FRA prohibitions. With the exception of the voluntary referral program, it is FRA's goal that the carrier's Part 219 program does not return personnel to covered service until they are recommended by the SAP, have demonstrated they are currently drug and alcohol free by passing a Federal return-to-work test, and have evidenced their commitment to remain drug and/or alcohol free by passing continued unannounced follow-up tests.

12.2 REGULATORY REFERENCES (49 CFR PART 219 AND 49 CFR PART 40)

- 219.5 – Definitions: Covered employee
- 219.104 – Responsive action (Subpart B)
- 219.403 – Voluntary referral policy (Subpart E)
- 219.405 – Co-worker report policy

THE SUBSTANCE ABUSE PROFESSIONAL

- 40.281 - Who is qualified to act as a SAP?
- 40.283 - How does a certification organization obtain recognition for its members as SAPs?
- 40.285 - When is a SAP evaluation required?
- 40.287 - What information is an employer required to provide concerning SAP services to an employee who has a DOT drug and alcohol violation?
- 40.289 - Are employers required to provide SAP and treatment services to employees?
- 40.291 - What is the role of the SAP in the evaluation, referral, and treatment process of an employee who has violated DOT agency drug and alcohol testing regulations?
- 40.293 - What is the SAP's function in conducting the initial evaluation of an employee?
- 40.395 - May employees or employers seek a second SAP evaluation if they disagree with the first SAP's recommendations?
- 40.297 - Does anyone have the authority to change a SAP's initial evaluation?
- 40.299 - What is the SAP's role and what are the limits on a SAP's discretion in referring employees for education and treatment?
- 40.301 - What is the SAP's function in the follow-up evaluation of an employee?
- 40.303 - What happens if the SAP believes the employee needs additional treatment, aftercare, or support group services even after the employee returns to safety-sensitive duties?
- 40.305 - How does the return-to-duty process conclude?
- 40.307 - What is the SAP's function in prescribing the employee's follow-up test?
- 40.309 - What are the employer's responsibilities with respect to the SAP's directions for follow-up tests?
- 40.311 - What are the requirements concerning SAP reports?
- 40.313 - Where is there other information on SAP functions and the return-to-work process found in this regulation?

12.3 INSPECTION GOAL

The goal for inspecting this element is to determine whether the carrier has returned covered service employees back to duty consistent with requirements established by the FRA Rule, and has made a good faith effort to monitor the employee's continued compliance through the proper application of unannounced follow-up tests.

THE SUBSTANCE ABUSE PROFESSIONAL

12.4 RECORDS REQUESTED

The FRA Inspector should evaluate records for employees returned to covered service in the audit timeframe, including letters for the carrier from the SAP; the results of the Federal return-to-work tests; and the results of all Federal follow-up tests. A review of personnel and payroll records may also be required. Interviews may be necessary with the carrier's SAP. The Inspector will not ordinarily review SAP clinical records or notes.

12.5 THE SUBSTANCE ABUSE PROFESSIONAL (SAP)

12.5.1 Determine that the SAPs performing the service for the carrier are fully qualified under Department of Transportation regulations.

In order to qualify to perform SAP services, the proposed SAP must be a licensed physician (MD or DO); be a licensed or certified psychologist, social worker or employee assistance professional; or be an addiction counselor certified by the National Association of Alcoholism and Drug Abuse Counselors Certification Commission (NAADAC) or the International Certification Reciprocity Consortium/ Alcohol and Other Drug Abuse (ICRC). No other certifications or licenses are currently acceptable. The SAP may be an employee of the carrier, under contract to the carrier, or be completely independent from the carrier.

Under current regulations, the SAP must receive formal training and pass an examination on their SAP roles and responsibilities. The training must include instruction on key testing issues, SAP prohibitions, SAP procedures, interaction with other partners in the testing process (i.e. MROs and DERs), and the Federal regulations and issues affecting the SAP. The SAP must then pass an examination administered by a nationally-recognized SAP professional or training organization.

SAPs beginning to practice on or after 1/1/04 must have received formal training and pass the required examination before they perform duties under DOT and FRA regulations. Individuals who were practicing as SAPs before 12/31/03 have until that date to receive the training and pass the examination.

SAPs must take a specified number of continuing education units relevant to performing SAP functions in three year cycles as part of a continuing education requirement.

THE SUBSTANCE ABUSE PROFESSIONAL

12.5.2 Determine that carrier SAPs are conducting proper initial assessments of covered service employees referred to them and referring employees in accordance with the SAP regulations.

All SAP initial assessments must be conducted face-to-face with the covered employee, and may not be conducted by telephone or through a third party. The assessment may not be conducted by someone supervised by or operating under the direction or authority of the qualified SAP. The person conducting the interview must be the qualified SAP.

The SAP actually interviewing the employee remains the SAP of record throughout the case. The assessment, referral, and return to work decisions may not be deferred to any other individual, even if that person is also a qualified SAP.

The SAP must have knowledge and clinical experience in the diagnosis and treatment of alcohol and other substance abuse disorders. SAP responsibilities include providing an initial clinical assessment and evaluation (determining what level of assistance is needed); developing a treatment plan; referring the employee to an appropriate treatment or to an education program; evaluating the employee for return to duty when they have successfully completed a sufficient proportion (or all) of the treatment plan; and establishing a follow-up testing plan.

The SAP may not refer a covered employee to their own private practice, to a person or agency paying them, or to a person or agency in which they have a financial interest. The intent is that the SAP should make the best therapeutic decision possible, and be unable to derive direct or indirect financial benefit from their choice of referral. An exception may be made if the SAP refers the employee to a public agency; to a person or group under contract to the employer to provide drug or alcohol treatment; to the sole source of a therapeutically appropriate treatment under the employee's health insurance program; or to the sole source of a therapeutically appropriate treatment reasonably accessible to the employee.

The choices generally available to the SAP for referral would include an education program or 12-step meetings; outpatient individual or group counseling; or inpatient treatment or day-treatment. Under no circumstances may the SAP refer a covered employee to a category of care below that required clinically or defer the decision of an employee's referral to a medical service provider or the employer.

In very rare cases, the SAP may recommend that the covered employee requires no treatment or counseling assistance at all. In such circumstances, the employee must successfully complete at least an education program before being considered for return to covered service. The employee is still subject to passing a

THE SUBSTANCE ABUSE PROFESSIONAL

return to work test and follow-up testing which may last up to 60 months at the discretion of the SAP.

The result of the SAP's initial assessment should be placed in a report to the employer. The contents of the report are described in 49 CFR 40.311. The report must be on the SAP's own letterhead and is to be sent directly to the carrier.

12.5.3 Determine that carrier SAPs are conducting proper return to work assessments of eligible covered service employees.

The SAP of record is responsible for monitoring the progress of the covered employee throughout the treatment plan, and is expected to be in regular contact with both the employee and the treatment, counseling, or education professionals handling the employee's case. The SAP is free to utilize other referral resources during the course of the treatment plan, or to escalate or downgrade the category of care if it is in the best interests of the employee's rehabilitation. Under no circumstances can those decisions be delegated beyond the SAP of record, or be influenced by the rules of a medical service provider, a managed care organization, or an employee assistance program.

The SAP's recommendation for return to work is intended to be the primary basis for the carrier's decision whether to return an employee to covered service, but the timing of the employee's return is always at the discretion of the carrier. In some cases, the employee may even be terminated and not offered a return to covered service by that employer. In FRA Subpart E cases (Troubled Employees), however, return to covered service cannot be unreasonably withheld if the employee has cooperated fully with the SAP's requirements

The SAP's return to work assessment must also be conducted face-to-face, and must consider whether the employee has made sufficient clinical progress to warrant return to safety-sensitive functions. Usually, completion of the first phase of treatment or counseling and some measure of aftercare is expected before a return to work assessment is scheduled. Under no circumstances may the SAP recommend an employee for return to covered service until the SAP is confident that the individual is a low risk to violate FRA drug and alcohol prohibitions.

The results of the SAP's return to work determination should be placed in a report to the employer. The contents of the report are described in 40.311, again must be on the SAP's own letterhead, and must be sent directly to the carrier.

THE SUBSTANCE ABUSE PROFESSIONAL

12.6 THE FEDERAL RETURN-TO-WORK TEST AND FOLLOW-UP TESTING

12.6.1. *Determine that covered employees are not being returned to covered service until the SAP has made a formal written recommendation and the results of a Federal return-to-work test have been received by the carrier.*

Employees may not re-enter covered service until the carrier has received the SAP's recommendation, a Federal return-to-work test is performed, and the negative result from that test has been received by the employer. The timing of the employee's return is totally at the discretion of the employer, with the exception of FRA-mandated suspensions (i.e. nine months out on a refusal, etc.) which may establish some minimum requirements for the employee being placed out-of-service.

Employees may only receive a Federal return-to-work test if the original nexus was a violation of FRA regulations. A company reasonable cause test is not a Federal test, and entrance into a FRA voluntary referral program also does not have as its basis a violation of FRA prohibitions.

Although there is no formal limitation on the number of times an employee can be found in violation of FRA drug and alcohol regulations and be returned to covered service, FRA expects that carriers will not permit a revolving door policy. More than one violation of 219.101, 219.102, and/or 219.107 regulations (and consequent removal from covered service) would seem to be a sufficient demonstration that the employee will be an ongoing risk to rail safety. A carrier should expect that FRA will question their decision to retain such an employee in the interests of 219.104 and 219.105.

12.6.2 *Determine that covered employees being returned to covered service are receiving sufficient Federal follow-up tests to comply with the plan provided by the SAP.*

The SAP is responsible for providing the carrier with the number and frequency of follow-up tests to be conducted by the employer. It is the carrier's determination when to test. The carrier or its EAP may not countermand the SAP's decision on follow-up test frequency. At least six tests are required in the first 12 months, but the SAP should individualize the requirement for each employee depending on the SAP's judgment as to the employee's degree of problem and risk of future violations of FRA drug and/or alcohol prohibitions. It is the SAP's determination on whether the employee requires drug, alcohol, or both types of follow-up tests. If the returning employee is an engineer, drug and alcohol tests are mandatory.

THE SUBSTANCE ABUSE PROFESSIONAL

Although follow-up testing may be conducted for up to 60 months, the SAP of record may re-assess the frequency each year and terminate follow-up testing any time after the first year. As a general rule, two years would most often be the appropriate timeframe for employees, with longer follow-up programs necessary for more difficult cases depending on the SAP's assessment of the depth of the problem. However, that final determination is always within the purview of the SAP of record.

Follow-up testing should be unannounced, and every effort must be made by the carrier to ensure that the follow-up program acts as a deterrent for the covered employee. Tests should be administered unpredictably within the working day, working week, month, and year. Employees who do not have predictable hours may be called to duty to be tested, but the employer should use this option sparingly to avoid the appearance of harassing the employee.

Follow-up tests are independent tests, and random tests or other tests may not be used in lieu of the scheduled follow-up tests and vice-versa.

No Federal follow-up tests are required when the employee has graduated from a FRA voluntary referral program, although nothing prohibits the carrier from mandating a company return-to-work test and follow-ups to ensure compliance with 219.105.

The carrier retains the right of conducting Federal follow-up drug tests as observed collections.

13.0

IDENTIFICATION

OF

TROUBLED

EMPLOYEES

13.0 IDENTIFICATION OF TROUBLED EMPLOYEES

13.1 OVERVIEW

FRA regulations found in 49 CFR 219.401 – 219.407 (Subpart E) describe FRA requirements for the identification of covered employees impacted by drugs and/or alcohol who have not yet been found in violation of FRA's drug and alcohol use prohibitions. FRA's intent is that carriers implement voluntary self-referral and co-worker report programs which are viable, active, and accessible to carrier covered employees. FRA's goal is the railroad will provide a realistic opportunity for covered employees with substance abuse problems to seek confidential assistance on their own (voluntary referral) and an opportunity to protect the safety of themselves and their fellow employees without endangering the livelihood of the troubled employee (co-worker report).

13.2 REGULATORY REFERENCES (49 CFR PART 219)

- 219.5 – Definitions: Covered Employee; Co-Worker
- 219.401 – Requirement for Policies
- 219.402 – [Reserved]
- 219.403 – Voluntary Referral Policy
- 219.404 – [Reserved]
- 219.405 – Co-Worker Report Policy
- 219.406 – [Reserved]
- 219.407 – Alternate Policies

13.3 INSPECTION GOAL

The goal for inspecting this element is to determine whether the carrier has made a good faith effort to develop and support Federal voluntary referral and Federal co-worker report programs as they are described in the regulations, and/or has an alternate type of program in place which is acceptable to FRA.

Traditional "Operation Redblock"-type programs which provide all of the elements of the two required Federal programs can fulfill the compliance requirements of this section. If the carrier's program does not meet all of the requirements, the railroad should request either a waiver under 219.7 or have their program considered as an alternate type of program under 219.407.

TROUBLED EMPLOYEES

13.4 RECORDS REQUIRED

The FRA Inspector should evaluate all carrier policies, published documents, and handouts relating to their Federal voluntary referral and co-worker report programs. Interviews should be conducted with carrier Employee Assistance Program (EAP) or equivalent personnel and employees in the field. Data from the carrier's EAP, SAP, and other resources should be examined. Carriers should be able to segregate Federal data from data from other non-covered employees so that the carrier and FRA can easily track the utilization of the Federal programs.

13.5 THE FEDERAL VOLUNTARY REFERRAL PROGRAM

13.5.1 Determine if the carrier maintains an active Federal voluntary referral program, and supports it by encouraging participation through advertisement, handouts or postings, employee meetings, etc.

The carrier must maintain a Federal voluntary referral program policy which is available for FRA inspection. The policy should encompass all elements described in 219.403, including how the employee can access the program in a confidential manner; what is available to the employee in terms of a leave of absence (which must be able to extend 45 days or more); the degree to which confidentiality must be maintained by the program and by the carrier; and the mechanism for becoming eligible to return to work.

Although the Rule mentions only the Substance Abuse Professional (SAP) in the assessment and return to work role, voluntary referral programs have traditionally fallen within the capable responsibility of a carrier's Employee Assistance Program (EAP). Even though an EAP service provider is not necessarily qualified as a SAP, FRA will continue to permit a qualified and experienced EAP professional to perform the responsibilities outlined in 219.403 on behalf of the carrier.

The carrier's Federal voluntary referral program should be sufficiently well advertised that all covered employees are knowledgeable about the program and understand how to access it. The FRA Rule does not require that the carrier compensate the employee while the employee is out of service or is on medical leave to attend treatment. FRA also does not require the carrier to honor a Federal voluntary self-referral claim if the employee was just about to be detected by the railroad for a violation of FRA prohibitions and was attempting to use the program as a safe haven.

In addition, participation in the program does not exempt the employee from disciplinary action or dismissal for Rule violations or criminal offenses determined

TROUBLED EMPLOYEES

independently from the referral. The carrier may choose in its policy to limit access to the program to those who have not previously used it or have never previously been identified under the carrier's co-worker report policy.

13.5.2 Determine that the carrier is implementing the Federal voluntary referral program consistent with the intent of the regulations.

Access to the program should be confidential, and referrals should be acceptable from the employee themselves, a fellow employee, or a union representative. The carrier is also permitted to expand this list to include referrals from other sources (i.e., supervisory employees). If supervisors are going to be allowed as part of the referral program, the carrier's written policy must clearly explain how this will work and yet also fully support other mandatory FRA programs such as reasonable suspicion testing. Mandatory reasonable suspicion must always take precedence over a voluntary referral for a supervisor.

A contact mechanism (toll-free telephone number, etc.) for the Federal program should be well publicized on the property. The confidential contact offered to the employee may only be fulfilling a role equivalent to an EAP, SAP, or other employee assistance effort, and may not be a supervisor or management official unless they are a formal part of such a program.

If necessary based on the extent of the employee's problem, the carrier must grant the employee a leave of absence of at least 45 days to allow completion of primary counseling or treatment and to stabilize the drug and/or alcohol problem. If properly complying with program requirements, the employee's employment relationship with the carrier must remain intact while they are enrolled and making satisfactory progress.

If permitted by the carrier's policy, the employee may have their confidentiality waived if they refuse to cooperate with the treatment plan, or they continue their alcohol and/or drug misconduct.

To return to work in covered service, the employee must successfully complete at least the initial phase of a counseling or treatment program, if applicable, and be recommended for return to work by the EAP or the SAP. The ability of the employee to return to full covered duty may not be unreasonably withheld by the carrier, but the railroad is permitted to require a return-to-service medical exam as a condition of reinstatement. Although this program is a Federal requirement, Federal return-to-work and follow-up tests are not necessary because no violation of FRA regulations has been charged. Nothing limits, however, the company requiring return-to-work or follow-up testing under its own authority.

TROUBLED EMPLOYEES

13.6 THE FEDERAL CO-WORKER REFERRAL PROGRAM

13.6.1 *Determine if the carrier maintains an active Federal co-worker report program, and supports it by encouraging participation through advertisement, handouts or postings, employee meetings, etc.*

The carrier must maintain a Federal co-worker report policy which is available for FRA inspection. The policy should encompass all of the elements described in 219.405, including the criteria which co-workers should use to access the program; the mechanism to confidentially report the violation of 219.101 or 219.102 to a supervising employee; the procedure by which the allegation is to be properly investigated and affirmed as a violation by a railroad representative; the rights of the employee when confronted with the violation; the criteria for program eligibility (including waiver of the Rule charge violation and the requirement to contact the SAP within a designated timeframe); the mechanism for becoming eligible to return to work (including the role of the SAP); and follow-up testing requirements.

The carrier's written Federal co-worker report policy must clearly explain what the role of the supervisor is to be, and how action under this program can be distinguished from other mandatory programs such as reasonable suspicion. Ordinarily, if the supervisor uncovers the 219.101 or 219.102 violation only because of the intercession of the co-worker, the employee should be eligible for the co-worker report program. If the supervisor would have almost instantaneously discovered the employee's violation on their own, a co-worker cannot attempt to use the program as a means of protecting the employee or avoiding disciplinary action for that employee.

The carrier's Federal co-worker report program should be well advertised in a manner which ensures that all covered employees are knowledgeable about the program's existence and understand how to access it.

FRA guidance on employee compensation while out of service applies equally for the Federal co-worker report program as it did for voluntary referral. Enrollment in a treatment program because of a co-worker report is usually a one-time opportunity, and should not generally be allowed for a second offense.

13.6.2 *Determine that the carrier is implementing the Federal co-worker report program consistent with the intent of the regulations.*

Co-workers who wish to come forward to report a fellow employee must be made fully knowledgeable of how to properly contact supervision. They must be made aware before they identify the employee (and the alleged Rule violation) that disciplinary action can only be waived if the identified covered service employee

TRoubLED EMPLOYEES

accepts help in lieu of discipline. If properly complying with the program, however, the identified employee's employment relationship with the carrier must remain intact.

Confidentiality for the troubled employee is not necessarily granted under the Federal co-worker report program. However, if granted by the carrier in its policy, confidentiality can be waived if the employee fails to cooperate with the program or engages in continued drug and/or alcohol use. The criteria for leave of absence and return to work described previously under the Federal voluntary referral program section of this Manual similarly applies here.

To return to work in covered service, the employee must successfully complete at least the initial phase of a counseling or treatment program, if applicable, and be recommended for return to work by the SAP. The ability of the employee to return to full covered duty may not be unreasonably withheld by the carrier, but the railroad is permitted to require a return-to-service medical exam as a condition of reinstatement.

With co-worker report, a Federal return-to-work test is required. In addition, there should be greater emphasis on monitoring the identified employee with a Federal follow-up drug and/or alcohol testing program. The SAP should determine the number and frequency of follow-up tests, with the employer determining the dates. Return to work and follow-up tests are to be Federal tests even though no violation of FRA regulations has been formally charged.

13.7 ALTERNATE PROGRAMS

The regulation permits the carrier to implement an alternative program to the voluntary referral and/or co-worker report programs required by the regulation. The alternate programs may be limited to any group of covered carrier employees, but anyone not participating in the alternate program must be covered by a Federal voluntary referral and co-worker report program identical in scope to that previously described.

Any alternative program must have the written concurrence of the union(s) representing the group of affected employees which must be filed with the FRA. Any changes to the approved alternate program (including cancellation) must be filed with FRA 30 days in advance of implementation. The alternative program, to be acceptable to FRA, must be at least as protective of both the carrier and the troubled employee as are the voluntary referral and co-worker report programs. An alternate program may not be used as a mechanism to avoid or circumvent FRA's intent with regard to this portion of the rule.

Troubled Employees Summary Checklist

I. The Federal Voluntary Referral Program [13.5]

- A. *Determine if the carrier maintains an active Federal voluntary referral program, and supports it by encouraging participation through advertisement, handouts or posting, employee meetings, etc. [13.5.1]*
- B. *Determine that the carrier is implementing the Federal voluntary referral program consistent with the intent of the regulations. [13.5.2]*

II. The Federal Co-Worker Referral Program [13.6]

- A. *Determine if the carrier maintains an active Federal co-worker report program, and supports it by encouraging participation through advertisement, handouts or postings, employee meetings, etc. [13.6.1]*
- B. *Determine that the carrier is implementing the Federal co-worker report program consistent with the intent of the regulations. [13.6.2]*

14.0

RECORDS

AND

CONFIDENTIALITY

14.0 RECORDS AND CONFIDENTIALITY

14.1 OVERVIEW

FRA regulations found in 49 CFR 219.901 – 219.905 (Subpart J) summarize carrier recordkeeping requirements. FRA regulations found in 49 CFR 219.711 and Department of Transportation regulations found in Subpart P (40.321 - 40.333) and throughout other sections of Part 40 summarize confidentiality requirements for test results. Other confidentiality elements are described throughout the Rule text and in guidance documents for the Medical Review Officer (MRO) and the Substance Abuse Professional (SAP).

FRA's intent is to establish the minimum carrier recordkeeping and confidentiality requirements of the Rule. FRA's goal is that the carrier will maintain sufficient records and recordkeeping systems which allow it to properly document full compliance with Part 219 and Part 40 elements. In most cases, acceptable documentation for an audit may need to exceed that described in Subpart J. The carrier must also ensure that all of its records and internal and external communications are fully protective of the right to privacy of its employees.

14.2 REGULATORY REFERENCES (49 CFR PART 219 AND 49 CFR PART 40)

- 219.901 – Retention of alcohol testing records
- 219.902 – [Reserved]
- 219.903 – Retention of drug testing records
- 219.904 – [Reserved]
- 219.905 – Access to facilities and records
- 219.711 – Confidentiality of test results

- 40.321 – What is the general confidentiality rule for drug and alcohol test information?
- 40.323 – May program participants release drug or alcohol test information in connection with legal proceedings?
- 40.325 – [Reserved]
- 40.327 – When must the MRO report medical information gathered in the verification process?
- 40.329 – What information must laboratories, MROs, and other service agents release to employees?
- 40.331 – To what additional parties must employers and service agents release information?
- 40.333 – What records must employers keep?

RECORDS AND CONFIDENTIALITY

14.3 INSPECTION GOAL

The goal for inspecting this element is to ensure that the carrier retains full and comprehensive records necessary to demonstrate compliance with FRA drug and alcohol regulations for as long as required in 219.901 and 219.903 and Subpart P of Part 40. It must also be determined that the carrier maintains appropriate confidentiality on applicable records and test results, limiting internal access to a strict need-to-know basis and external access based on the limitations imposed by the FRA and DOT Rules.

14.4 RECORDS REQUIRED

The FRA Inspector should examine the records outlined in 219.901, 219.903, 40.25, and 40.333 to determine whether they are being retained for the proper duration. The Inspector should also examine how the carrier maintains confidentiality. Employees and supervisors should be interviewed and documents which are associated with the release of information outside the carrier should be reviewed.

14.5 RECORDKEEPING

14.5.1 Determine that the carrier retains drug and alcohol records described in 219.901, 219.903, and 40.333 for the proper duration.

The carrier is required to retain the following drug and alcohol records in a secure location for five years:

- Records detailing verified drug positive tests and confirmed alcohol positives of 0.02% or above (including custody and control forms)
- Records on drug and alcohol test refusals (including adulterated and substituted tests)
- Records on employee SAP referrals, return-to-duty recommendations, return to work tests, and follow-up tests
- A summary of each covered employee's drug and alcohol testing history
- Documentation supporting the annual MIS submission

RECORDS AND CONFIDENTIALITY

The carrier is required to retain the following drug and alcohol records in a secure location for three years:

- Records on information obtained from an applicant's previous employer concerning Federal drug and alcohol test results.

The carrier is required to retain the following drug and alcohol records in a secure location for two years:

- Records detailing negative and cancelled drug tests (including custody and control forms)
- Records detailing negative and cancelled alcohol tests (including custody and control forms)
- Records on Evidential-Level Breath Testing (EBT) instrumentation calibrations (including for devices maintained by contract collectors)
- Records on the random selection process, including but not limited to, computer code, pool entries, pool selections, and reasons for no-tests
- Records on all reasonable suspicion and Federal reasonable cause determinations
- Records on all mandatory post-accident testing decisions
- Records on all shy bladder and shy lung determinations
- Records documenting reasonable suspicion/Federal reasonable cause and mandatory post-accident training for supervisors, including training content

Carriers will note that the above list reconciles an apparent recordkeeping contradiction in the regulations covering FRA drug and alcohol testing. There is a difference between the two regulations (Part 40 and Part 219) on how long a test result or test refusal must be retained (five years for positives and refusals and one year for negatives in Part 40; two years for all test records in Part 219). FRA requires that the carrier retain the records for the longest of the two requirements: five years for positive tests and refusals; two years on negative tests and test cancellations. FRA intends to resolve this contradiction in the next version of Part 219.

RECORDS AND CONFIDENTIALITY

Where permitted, records could also be efficiently maintained by a contract service provider (such as the MRO or the C/TPA). This is an acceptable practice, as long as they are properly secured, but must be retrievable with three days notice.

None of the records sets described above require the carrier to maintain the employer's copy of the CCF sent to them by the collection site.

Scanned documents are not permitted at this time to be offered in lieu of original hard copy or certified true copies of records. Carriers are permitted to have documents scanned, as long as the "original" records are still available for inspection or audit upon request.

14.5.2 Determine that the carrier maintains records in a secure location and appropriately limits access.

Carriers must ensure that records maintained in compliance with this Rule are properly secured and that carrier personnel without a direct need-to-know are not granted access.

14.6 CONFIDENTIALITY

14.6.1 Determine that the carrier maintains proper confidentiality on all drug and alcohol testing information, limiting internal communications to a strict need-to-know basis.

Positive and negative test results may not be communicated by the carrier to its personnel except on a strict need-to-know basis. The carrier must always make a good faith effort to comply with both the letter and the intent of the confidentiality regulations. In the case of relieving a verified positive employee from covered service, the carrier or its representatives may not themselves disclose the reason to any management employee, supervisor, or worker unless it is necessary to perform the required removal.

14.6.2 Determine that the carrier does not release test information on applicants and covered employees to outsiders without a written release of information from the donor, or as provided for by the Rule or other Federal authority.

Requests for specific test information on applicants and covered employees may not ordinarily be released to an outside person or agency without a written release from the donor that specifies the type of information to be released and the time

RECORDS AND CONFIDENTIALITY

period the release applies. Exceptions to this rule include release of information required by law (a bona-fide subpoena or other legal instrument); as necessary for the carrier to defend itself in a legal or administrative employment action taken by the applicant or employee; to the NTSB as part of an accident investigation; to the FRA; or to other Federal agencies as directed by the Rule.

Records and Confidentiality Summary Checklist

I. Recordkeeping [14.5]

- A. *Determine that the carrier retains drug and alcohol records described in 219.901 and 219.903 for the proper duration. [14.5.1]*
- B. *Determine that the carrier maintains records in a secure location and appropriately limits access. [14.5.2]*

II. Confidentiality [14.6]

- A. *Determine that the carrier maintains proper confidentiality on all drug and alcohol testing information, limiting internal communications to a strict need-to-know basis. [14.6.1]*
- B. *Determine that the carrier does not release test information on applicants and covered employees to outsiders without a written release of information from the donor, or as provided for by the Rule or other Federal authority. [14.6.2]*

15.0

**STAND
DOWN**

15.0 STAND DOWN

15.1 OVERVIEW

FRA regulations in 49 CFR 219.7 describe the procedures for obtaining a waiver to permit a carrier to practice "stand down". The regulatory text defining stand down is found in DOT's regulation (49 CFR 40.21). Stand down is the process of suspending an employee from safety duties who is known to have submitted a positive, substituted, or adulterated specimen for their drug test but before the MRO has completed the required verification.

Stand down is not currently permitted under FRA regulations. However, FRA will consider a carrier's petition for waiver to be permitted to stand down its positive employees. FRA will require the carrier to meet at least the threshold standards described in both the DOT regulation (40.21) and FRA regulations for safety waivers (219.7 and 211) in order for a petition to be considered.

15.2 REGULATORY REFERENCES (49 CFR PART 219 AND PART 40).

- 219.7 - Waivers
- 40.21 - May an employer stand down an employee before the MRO has completed the verification process?

15.3 INSPECTION GOAL

The goal for inspecting this element is to ensure that no carrier is standing down employees, directly or indirectly, without having first obtained a written waiver from FRA.

15.4 RECORDS REQUIRED

The FRA Inspector should examine carrier records associated with any employee removed from covered service after a verified positive drug test is reported by the MRO. In addition, records from the MRO evaluating when they notified the carrier of their final positive determination will be used to compare with carrier records.

STAND DOWN

15.5 STAND DOWN

15.5.1 Determine Whether The Carrier Is Directly Standing Down Employees Without Having First Obtained A Written Waiver From FRA.

15.5.2 Determine Whether The Carrier Is Indirectly Standing Down Employees Without A Written Waiver From FRA.

Stand down is a practice where a carrier requires their Medical Review Officer (MRO) to notify them immediately upon receiving a Federal positive, adulterated, or substituted laboratory report but before the MRO has completed his/her verification determination. The employer then suspends or disqualifies the employee from performing covered service pending the MRO determination.

Stand down is not permitted by FRA under any circumstances without receiving a formal written waiver using the petition procedure described in 40.21 and 219.7. FRA's consideration of a waiver request will be based solely on the carrier's ability to describe procedures which enhance (and not just maintain) the current level of safety and at least equally protect the rights of the employee established by Parts 219 and 211, and Part 40. Petitions will be closely scrutinized by FRA, and approved waivers will be closely audited for compliance.

However, it is permitted for MROs to contact the carrier's Designated Employer Representative (DER) to arrange a required interview any time the MRO is unable to get in touch with an employee. MROs must use their best professional judgement on how quickly they may need to communicate with the DER for assistance. This is a safety judgement by the MRO, and is subject to Part 40 requirements.

The key to distinguishing stand down from an acceptable MRO practice is whether, once the employer is contacted, the employee is allowed to remain in covered service (or subject to covered service) awaiting the MRO determination. If the employee is considered by FRA to have been suspended, disqualified, or otherwise removed from covered service pending the MRO interview, the carrier is judged to be standing down that employee. The only exception would be for an employee who is already on vacation or out with a long-term illness or injury, and is not permitted back to work in covered service until he/she talks to the MRO.

It is permissible for a DER, once he/she is notified that the MRO needs to talk to a particular employee, to have the employee's new immediate assignment be to call or to go to a face-to-face appointment with the MRO. However, care should be

STAND DOWN

taken to ensure that any delay in accomplishing the MRO interview in these circumstances does not stray into a stand down policy.

Practicing stand down without a FRA waiver actually in hand should likely result in a significant sanction applied against the carrier. Even if a petition for waiver has been submitted and is eventually granted by FRA, a stand down practice before approval is obtained will result in strong enforcement action.

Stand Down Summary Checklist

I. **Stand Down** (15.4)

- A. *Determine whether the carrier is directly standing down employees without having first obtained a written waiver from FRA. [15.5.1]*
- B. *Determine whether the carrier is indirectly standing down employees without a written waiver from FRA. [15.5.2]*

TAB 1

**URINE SPECIMEN
COLLECTION
FORMS**

FEDERAL DRUG TESTING CUSTODY AND CONTROL FORM



35858164
SPECIMEN ID NO.

CLIENT ACCOUNT NO.
CLIENT NAME
LOCATION CODE



NORTHWEST DRUG TESTING
A DIVISION OF NWT, Inc.
1141 EAST 3900 SOUTH, SUITE A-110
SALT LAKE CITY, UTAH 84124
(801) 293-2300 FAX (801) 263-3605

STEP 1: COMPLETED BY COLLECTOR OR EMPLOYER REPRESENTATIVE

LABORATORY ACCESSION NO.

A. Employer Name, Address, I.D. No. _____ B. MRO Name, Address, Phone and Fax No. _____

C. Donor SSN or Employee I.D. No. _____

D. Reason for Test: Pre-employment Random Reasonable Suspicion/Cause Post Accident
 Return to Duty Follow-up Other (specify) _____

E. Drug Tests to be Performed: THC, COC, PCP, OPI, AMP THC & COC Only Other (specify) _____

F. Collection Site Address: _____

Collector Phone No. _____
Collector Fax No. _____

STEP 2: COMPLETED BY COLLECTOR

Read specimen temperature within 4 minutes. Is temperature between 90° and 100° F? Yes No, Enter Remark _____

Specimen Collection: Split Single None Provided (Enter Remark) _____ Observed (Enter Remark) _____

REMARKS

STEP 3: Collector affixes bottle seal(s) to bottle(s). Collector dates seal(s). Donor initials seal(s). Donor completes STEP 5 on Copy 2 (MRO Copy)

STEP 4: CHAIN OF CUSTODY - INITIATED BY COLLECTOR AND COMPLETED BY LABORATORY

I certify that the specimen given to me by the donor identified in the certification section on Copy 2 of this form was collected, labeled, sealed and released to the Delivery Service noted in accordance with applicable Federal requirements.

Signature of Collector _____ Time of Collection _____ AM/PM
 _____ Date (Mo./Day/Yr.) _____

SPECIMEN BOTTLE(S) RELEASED TO:
 _____ Name of Delivery Service Transferring Specimen to Lab

RECEIVED AT LAB:

Signature of Accessioner _____ Date (Mo./Day/Yr.) _____

Primary Specimen Bottle Seal Intact
 Yes No, Enter Remark Below _____

SPECIMEN BOTTLE(S) RELEASED TO:

STEP 5a: PRIMARY SPECIMEN TEST RESULTS - COMPLETED BY PRIMARY LABORATORY

NEGATIVE POSITIVE for: MARIJUANA METABOLITE CODEINE AMPHETAMINE ADULTERATED
 DILUTE COCAINE METABOLITE MORPHINE METHAMPHETAMINE SUBSTITUTED
 REJECTED FOR TESTING PCP 6-ACETYLMORPHINE INVALID RESULT

REMARKS

TEST LAB (if different from above) _____
 I certify that the specimen identified on this form was examined upon receipt, handled using chain of custody procedures, analyzed, and reported in accordance with applicable Federal requirements.

Signature of Certifying Scientist _____ (PRINT) Certifying Scientist's Name (First, MI, Last) _____ Date (Mo./Day/Yr.) _____

STEP 5b: SPLIT SPECIMEN TEST RESULTS - (IF TESTED) COMPLETED BY SECONDARY LABORATORY

 Laboratory Name

 Laboratory Address

RECONFIRMED FAILED TO RECONFIRM - REASON _____
 I certify that the split specimen identified on this form was examined upon receipt, handled using chain of custody procedures, analyzed, and reported in accordance with applicable Federal requirements.

Signature of Certifying Scientist _____ (PRINT) Certifying Scientist's Name (First, MI, Last) _____ Date (Mo./Day/Yr.) _____

Donor Initials _____
Date / /



35858164 SPECIMEN ID NO.

35858164
KIT SEAL

COLLECTOR INITIAL _____ DATE _____

Donor Initials _____
Date / /



35858164 SPECIMEN ID NO.

35858164
KIT SEAL

COLLECTOR INITIAL _____ DATE _____

FEDERAL DRUG TESTING CUSTODY AND CONTROL FORM



NORTHWEST DRUG TESTING
A DIVISION OF NWT, Inc.
1141 EAST 3900 SOUTH, SUITE A-110
SALT LAKE CITY, UTAH 84124
(801) 293-2300 FAX (801) 263-3605

CLIENT ACCOUNT NO.

CLIENT NAME

LOCATION CODE

35858164
SPECIMEN ID NO.

LABORATORY ACCESSION NO.

STEP 1: COMPLETED BY COLLECTOR OR EMPLOYER REPRESENTATIVE

A. Employer Name, Address, I.D. No.	B. MRO Name, Address, Phone and Fax No.
C. Donor SSN or Employee I.D. No. _____	
D. Reason for Test: <input type="checkbox"/> Pre-employment <input type="checkbox"/> Random <input type="checkbox"/> Reasonable Suspicion/Cause <input type="checkbox"/> Post Accident <input type="checkbox"/> Return to Duty <input type="checkbox"/> Follow-up <input type="checkbox"/> Other (specify) _____	
E. Drug Tests to be Performed: <input type="checkbox"/> THC, COC, PCP, OPI, AMP <input type="checkbox"/> THC & COC Only <input type="checkbox"/> Other (specify) _____	
F. Collection Site Address: _____	
	Collector Phone No. _____
	Collector Fax No. _____

STEP 2: COMPLETED BY COLLECTOR

Read specimen temperature within 4 minutes. Is temperature between 90° and 100° F? <input type="checkbox"/> Yes <input type="checkbox"/> No, Enter Remark _____	Specimen Collection: <input type="checkbox"/> Split <input type="checkbox"/> Single <input type="checkbox"/> None Provided (Enter Remark) _____ <input type="checkbox"/> Observed (Enter Remark) _____
REMARKS _____	

STEP 3: Collector affixes bottle seal(s) to bottle(s). Collector dates seal(s). Donor initials seal(s). Donor completes STEP 5 on Copy 2 (MRO Copy)

STEP 4: CHAIN OF CUSTODY - INITIATED BY COLLECTOR AND COMPLETED BY LABORATORY

I certify that the specimen given to me by the donor identified in the certification section on Copy 2 of this form was collected, labeled, sealed and released to the Delivery Service noted in accordance with applicable Federal requirements.

<input checked="" type="checkbox"/> _____ Signature of Collector _____ (PRINT) Collector's Name (First, MI, Last)	_____ Time of Collection _____ Date (Mo./Day/Yr.)	SPECIMEN BOTTLE(S) RELEASED TO: _____ Name of Delivery Service Transferring Specimen to Lab
--	--	--

RECEIVED AT LAB:

<input checked="" type="checkbox"/> _____ Signature of Accessioner _____ (PRINT) Accessioner's Name (First, MI, Last)	_____ Date (Mo./Day/Yr.)	Primary Specimen Bottle Seal Intact <input type="checkbox"/> Yes <input type="checkbox"/> No, Enter Remark Below _____	SPECIMEN BOTTLE(S) RELEASED TO: _____
--	-----------------------------	---	---

STEP 5: COMPLETED BY DONOR

I certify that I provided my urine specimen to the collector; that I have not adulterated it in any manner; each specimen bottle used was sealed with a tamper-evident seal in my presence; and that the information provided on this form and on the label affixed to each specimen bottle is correct.

<input checked="" type="checkbox"/> _____ Signature of Donor	_____ (PRINT) Donor's Name (First, MI, Last)	_____ Date (Mo./Day/Yr.)
Daytime Phone No. () _____	Evening Phone No. () _____	Date of Birth _____ Mo. Day Yr.

Should the results of the laboratory tests for the specimen identified by this form be confirmed positive, the Medical Review Officer will contact you to ask about prescriptions and over-the-counter medications you may have taken. Therefore, you may want to make a list of those medications for your own records. THIS LIST IS NOT NECESSARY. If you choose to make a list, do so either on a separate piece of paper or on the back of your copy (Copy 5). —DO NOT PROVIDE THIS INFORMATION ON THE BACK OF ANY OTHER COPY OF THE FORM. TAKE COPY 5 WITH YOU.

STEP 6: COMPLETED BY MEDICAL REVIEW OFFICER - PRIMARY SPECIMEN

In accordance with applicable Federal requirements, my determination/verification is:

NEGATIVE POSITIVE TEST CANCELLED REFUSAL TO TEST BECAUSE:
 DILUTE ADULTERATED SUBSTITUTED

REMARKS _____

<input checked="" type="checkbox"/> _____ Signature of Medical Review Officer	_____ (PRINT) Medical Review Officer's Name (First, MI, Last)	_____ Date (Mo./Day/Yr.)
--	--	-----------------------------

STEP 7: COMPLETED BY MEDICAL REVIEW OFFICER - SPLIT SPECIMEN

In accordance with applicable Federal requirements, my determination/verification for the split specimen (if tested) is:

RECONFIRMED FAILED TO RECONFIRM - REASON _____

<input checked="" type="checkbox"/> _____ Signature of Medical Review Officer	_____ (PRINT) Medical Review Officer's Name (First, MI, Last)	_____ Date (Mo./Day/Yr.)
--	--	-----------------------------

FEDERAL DRUG TESTING CUSTODY AND CONTROL FORM



NORTHWEST DRUG TESTING
A DIVISION OF NWT, Inc.
1141 EAST 3900 SOUTH, SUITE A-1
SALT LAKE CITY, UTAH 84124
(801) 293-2300 FAX (801) 263-366

CLIENT ACCOUNT NO.

CLIENT NAME

LOCATION CODE

35858164

SPECIMEN ID NO.

LABORATORY ACCESSION NO.

STEP 1: COMPLETED BY COLLECTOR OR EMPLOYER REPRESENTATIVE

A. Employer Name, Address, I.D. No.

B. MRO Name, Address, Phone and Fax No.

C. Donor SSN or Employee I.D. No. _____

D. Reason for Test: Pre-employment Random Reasonable Suspicion/Cause Post Accident
 Return to Duty Follow-up Other (specify) _____

E. Drug Tests to be Performed: THC, COC, PCP, OPI, AMP THC & COC Only Other (specify) _____

F. Collection Site Address: _____

Collector Phone No. _____

Collector Fax No. _____

STEP 2: COMPLETED BY COLLECTOR

Read specimen temperature within 4 minutes. Is temperature between 90° and 100° F? Yes No, Enter Remark _____

Specimen Collection: Split Single None Provided (Enter Remark) _____ Observed (Enter Remark) _____

REMARKS

STEP 3: Collector affixes bottle seal(s) to bottle(s). Collector dates seal(s). Donor initials seal(s). Donor completes STEP 5 on Copy 2 (MRO Copy)

STEP 4: CHAIN OF CUSTODY - INITIATED BY COLLECTOR AND COMPLETED BY LABORATORY

I certify that the specimen given to me by the donor identified in the certification section on Copy 2 of this form was collected, labeled, sealed and released to the Delivery Service noted in accordance with applicable Federal requirements.

_____ Signature of Collector
Time of Collection _____ AM/PM

(PRINT) Collector's Name (First, MI, Last) Date (Mo./Day/Yr.)

SPECIMEN BOTTLE(S) RELEASED TO:

Name of Delivery Service Transferring Specimen to Lab

RECEIVED AT LAB:

_____ Signature of Accessioner

(PRINT) Accessioner's Name (First, MI, Last) Date (Mo./Day/Yr.)

Primary Specimen Bottle Seal Intact

Yes
 No, Enter Remark Below

SPECIMEN BOTTLE(S) RELEASED TO:

STEP 5: COMPLETED BY DONOR

I certify that I provided my urine specimen to the collector; that I have not adulterated it in any manner; each specimen bottle used was sealed with a tamper-evident seal in my presence; and that the information provided on this form and on the label affixed to each specimen bottle is correct.

_____ Signature of Donor

(PRINT) Donor's Name (First, MI, Last) Date (Mo./Day/Yr.)
Daytime Phone No. () _____ Evening Phone No. () _____ Date of Birth _____
Mo. Day Yr.

Should the results of the laboratory tests for the specimen identified by this form be confirmed positive, the Medical Review Officer will contact you to ask about prescriptions and over-the-counter medications you may have taken. Therefore, you may want to make a list of those medications for your own records. THIS LIST IS NOT NECESSARY. If you choose to make a list, do so either on a separate piece of paper or on the back of your copy (Copy 5). —DO NOT PROVIDE THIS INFORMATION ON THE BACK OF ANY OTHER COPY OF THE FORM. TAKE COPY 5 WITH YOU.

STEP 6: COMPLETED BY MEDICAL REVIEW OFFICER - PRIMARY SPECIMEN

In accordance with applicable Federal requirements, my determination/verification is:

NEGATIVE POSITIVE TEST CANCELLED REFUSAL TO TEST BECAUSE:
 DILUTE ADULTERATED SUBSTITUTED

REMARKS

_____ Signature of Medical Review Officer

(PRINT) Medical Review Officer's Name (First, MI, Last) Date (Mo./Day/Yr.)

STEP 7: COMPLETED BY MEDICAL REVIEW OFFICER - SPLIT SPECIMEN

In accordance with applicable Federal requirements, my determination/verification for the split specimen (if tested) is:

RECONFIRMED FAILED TO RECONFIRM - REASON _____

_____ Signature of Medical Review Officer

(PRINT) Medical Review Officer's Name (First, MI, Last) Date (Mo./Day/Yr.)

FEDERAL DRUG TESTING CUSTODY AND CONTROL FORM



NORTHWEST DRUG TESTING
A DIVISION OF NWT, Inc.
1141 EAST 3900 SOUTH, SUITE A-110
SALT LAKE CITY, UTAH 84124
(801) 293-2300 FAX (801) 263-3605

CLIENT ACCOUNT NO.

CLIENT NAME

LOCATION CODE

35858164
SPECIMEN ID NO.

STEP 1: COMPLETED BY COLLECTOR OR EMPLOYER REPRESENTATIVE

LABORATORY ACCESSION NO.

A. Employer Name, Address, I.D. No.

B. MRO Name, Address, Phone and Fax No.

C. Donor SSN or Employee I.D. No.

D. Reason for Test: Pre-employment Random Reasonable Suspicion/Cause Post Accident
Return to Duty Follow-up Other (specify)

E. Drug Tests to be Performed: THC, COC, PCP, OPI, AMP THC & COC Only Other (specify)

F. Collection Site Address:

Collector Phone No.

Collector Fax No.

STEP 2: COMPLETED BY COLLECTOR

Read specimen temperature within 4 minutes. Is temperature between 90° and 100° F? Yes No, Enter Remark

Specimen Collection: Split Single None Provided (Enter Remark) Observed (Enter Remark)

REMARKS

STEP 3: Collector affixes bottle seal(s) to bottle(s). Collector dates seal(s). Donor initials seal(s). Donor completes STEP 5 on Copy 2 (MRO Copy)

STEP 4: CHAIN OF CUSTODY - INITIATED BY COLLECTOR AND COMPLETED BY LABORATORY

I certify that the specimen given to me by the donor identified in the certification section on Copy 2 of this form was collected, labeled, sealed and released to the Delivery Service noted in accordance with applicable Federal requirements.

X Signature of Collector Time of Collection AM PM
(Print) Collector's Name (First, MI, Last) Date (Mo./Day/Yr.)

SPECIMEN BOTTLE(S) RELEASED TO:
Name of Delivery Service Transferring Specimen to Lab

RECEIVED AT LAB:

X Signature of Accessioner Date (Mo./Day/Yr.)
(Print) Accessioner's Name (First, MI, Last)

Primary Specimen Bottle Seal Intact

Yes No, Enter Remark Below

SPECIMEN BOTTLE(S) RELEASED TO:

STEP 5: COMPLETED BY DONOR

I certify that I provided my urine specimen to the collector; that I have not adulterated it in any manner; each specimen bottle used was sealed with a tamper-evident seal in my presence; and that the information provided on this form and on the label affixed to each specimen bottle is correct.

X Signature of Donor (Print) Donor's Name (First, MI, Last) Date (Mo./Day/Yr.)
Daytime Phone No. Evening Phone No. Date of Birth Mo. Day Yr.

Should the results of the laboratory tests for the specimen identified by this form be confirmed positive, the Medical Review Officer will contact you to ask about prescriptions and over-the-counter medications you may have taken. Therefore, you may want to make a list of those medications for your own records. THIS LIST IS NOT NECESSARY. If you choose to make a list, do so either on a separate piece of paper or on the back of your copy (Copy 5). --DO NOT PROVIDE THIS INFORMATION ON THE BACK OF ANY OTHER COPY OF THE FORM. TAKE COPY 5 WITH YOU.

STEP 6: COMPLETED BY MEDICAL REVIEW OFFICER - PRIMARY SPECIMEN

In accordance with applicable Federal requirements, my determination/verification is:

NEGATIVE POSITIVE TEST CANCELLED REFUSAL TO TEST BECAUSE:
DILUTE ADULTERATED SUBSTITUTED

REMARKS

X Signature of Medical Review Officer (Print) Medical Review Officer's Name (First, MI, Last) Date (Mo./Day/Yr.)

STEP 7: COMPLETED BY MEDICAL REVIEW OFFICER - SPLIT SPECIMEN

In accordance with applicable Federal requirements, my determination/verification for the split specimen (if tested) is:

RECONFIRMED FAILED TO RECONFIRM - REASON

X Signature of Medical Review Officer (Print) Medical Review Officer's Name (First, MI, Last) Date (Mo./Day/Yr.)

FEDERAL DRUG TESTING CUSTODY AND CONTROL FORM



NORTHWEST DRUG TESTING
A DIVISION OF NWT, Inc.
1141 EAST 3900 SOUTH, SUITE A-11.
SALT LAKE CITY, UTAH 84124
(801) 293-2300 FAX (801) 263-3605

CLIENT ACCOUNT NO.

CLIENT NAME

35858164

LOCATION CODE

SPECIMEN ID NO.

LABORATORY ACCESSION NO.

STEP 1: COMPLETED BY COLLECTOR OR EMPLOYER REPRESENTATIVE

A. Employer Name, Address, I.D. No. B. MRO Name, Address, Phone and Fax No. C. Donor SSN or Employee I.D. No. D. Reason for Test: Pre-employment, Random, Reasonable Suspicion/Cause, Post Accident, Return to Duty, Follow-up, Other (specify). E. Drug Tests to be Performed: THC, COC, PCP, OPI, AMP, THC & COC Only, Other (specify). F. Collection Site Address. Collector Phone No. Collector Fax No.

STEP 2: COMPLETED BY COLLECTOR

Read specimen temperature within 4 minutes. Is temperature between 90° and 100° F? Yes No, Enter Remark. Specimen Collection: Split, Single, None Provided (Enter Remark), Observed (Enter Remark).

REMARKS

STEP 3: Collector affixes bottle seal(s) to bottle(s). Collector dates seal(s). Donor initials seal(s). Donor completes STEP 5 on Copy 2 (MRO Copy)

STEP 4: CHAIN OF CUSTODY - INITIATED BY COLLECTOR AND COMPLETED BY LABORATORY

I certify that the specimen given to me by the donor identified in the certification section on Copy 2 of this form was collected, labeled, sealed and released to the Delivery Service noted in accordance with applicable Federal requirements.

Signature of Collector, Time of Collection (AM/PM), Date (Mo./Day/Yr.), SPECIMEN BOTTLE(S) RELEASED TO: Name of Delivery Service Transferring Specimen to Lab.

RECEIVED AT LAB:

Signature of Accessioner, Date (Mo./Day/Yr.), Primary Specimen Bottle Seal Intact (Yes/No, Enter Remark Below), SPECIMEN BOTTLE(S) RELEASED TO:

STEP 5: COMPLETED BY DONOR

I certify that I provided my urine specimen to the collector; that I have not adulterated it in any manner; each specimen bottle used was sealed with a tamper-evident seal in my presence; and that the information provided on this form and on the label affixed to each specimen bottle is correct.

Signature of Donor, (PRINT) Donor's Name (First, MI, Last), Date (Mo./Day/Yr.), Daytime Phone No., Evening Phone No., Date of Birth (Mo./Day/Yr.).

Should the results of the laboratory tests for the specimen identified by this form be confirmed positive, the Medical Review Officer will contact you to ask about prescriptions and over-the-counter medications you may have taken. Therefore, you may want to make a list of those medications for your own records. THIS LIST IS NOT NECESSARY. If you choose to make a list, do so either on a separate piece of paper or on the back of your copy (Copy 5). —DO NOT PROVIDE THIS INFORMATION ON THE BACK OF ANY OTHER COPY OF THE FORM. TAKE COPY 5 WITH YOU.

STEP 6: COMPLETED BY MEDICAL REVIEW OFFICER - PRIMARY SPECIMEN

In accordance with applicable Federal requirements, my determination/verification is:

- NEGATIVE, POSITIVE, TEST CANCELLED, REFUSAL TO TEST BECAUSE: DILUTE, ADULTERATED, SUBSTITUTED

REMARKS

Signature of Medical Review Officer, (PRINT) Medical Review Officer's Name (First, MI, Last), Date (Mo./Day/Yr.).

STEP 7: COMPLETED BY MEDICAL REVIEW OFFICER - SPLIT SPECIMEN

In accordance with applicable Federal requirements, my determination/verification for the split specimen (if tested) is:

- RECONFIRMED, FAILED TO RECONFIRM - REASON

Signature of Medical Review Officer, (PRINT) Medical Review Officer's Name (First, MI, Last), Date (Mo./Day/Yr.).

TAB 2

**BREATH SPECIMEN
COLLECTION
FORMS**

U.S. Department of Transportation (DOT)

Alcohol Testing Form

(The instructions for completing this form are on the back of Copy 3)

STEP 1: TO BE COMPLETED BY ALCOHOL TECHNICIAN

A: Employee Name _____
(Print) (First, M.I., Last)

B: SSN or Employee ID No. _____

C: Employer Name _____

Street _____

City, ST ZIP _____

DER Name and _____

Telephone No. _____

DER Name _____ DER (Area Code & Phone Number) _____

D: Reason for Test: Random Reasonable Susp. Post-Accident Return to Duty Follow-up Pre-employment

STEP 2: TO BE COMPLETED BY EMPLOYEE

I certify that I am about to submit to alcohol testing required by U.S. Department of Transportation regulations and that the identifying information provided on the form is true and correct.

Signature of Employee _____ Date _____ Month / Day / Year

STEP 3: TO BE COMPLETED BY ALCOHOL TECHNICIAN

(If the technician conducting the screening test is not the same technician who will be conducting the confirmation test, each technician must complete their own form.) I certify that I have conducted alcohol testing on the above named individual in accordance with the procedures established in the U.S. Department of Transportation regulation, 49 CFR Part 40, that I am qualified to operate the testing device(s) identified, and that the results are as recorded.

TECHNICIAN: BAT STT DEVICE: SALIVA BREATH* 15-Minute Wait: Yes No

SCREENING TEST: (For BREATH DEVICE* write in the space below only if the testing device is not designed to print.)

Test #	Testing Device Name	Device Serial # <i>QR</i> Lot # & Exp. Date	Activation Time	Reading Time	Result
--------	---------------------	---	-----------------	--------------	--------

CONFIRMATION TEST: Results MUST be affixed to each copy of this form or printed directly onto the form.

REMARKS: _____

Alcohol Technician's Company _____ Company Street Address _____

(PRINT) Alcohol Technician's Name (First, M.I., Last) _____ Company City, State, Zip _____

Phone Number (Area Code & Number) _____

Signature of Alcohol Technician _____ Date _____ Month / Day / Year

STEP 4: TO BE COMPLETED BY EMPLOYEE IF TEST RESULT IS 0.02 OR HIGHER

I certify that I have submitted to the alcohol test, the results of which are accurately recorded on this form. I understand that I must not drive, perform safety-sensitive duties, or operate heavy equipment because the results are 0.02 or greater.

Signature of Employee _____ Date _____ Month / Day / Year

U.S. Department of Transportation (DOT)

Alcohol Testing Form

(The instructions for completing this form are on the back of Copy 3)

STEP 1: TO BE COMPLETED BY ALCOHOL TECHNICIAN

A: Employee Name _____
(Print) (First, M.I., Last)

B: SSN or Employee ID No. _____

C: Employer Name _____

Street _____

City, ST ZIP _____

DER Name and Telephone No. _____
DER Name DER (Area Code & Phone Number)

D: Reason for Test: Random Reasonable Susp. Post-Accident Return to Duty Follow-up Pre-employment

STEP 2: TO BE COMPLETED BY EMPLOYEE

I certify that I am about to submit to alcohol testing required by U.S. Department of Transportation regulations and that the identifying information provided on the form is true and correct.

Signature of Employee _____ Date _____ Month / Day / Year

STEP 3: TO BE COMPLETED BY ALCOHOL TECHNICIAN

(If the technician conducting the screening test is not the same technician who will be conducting the confirmation test, each technician must complete their own form.) I certify that I have conducted alcohol testing on the above named individual in accordance with the procedures established in the U.S. Department of Transportation regulation, 49 CFR Part 40, that I am qualified to operate the testing device(s) identified, and that the results are as recorded.

TECHNICIAN: BAT STT DEVICE: SALIVA BREATH* 15-Minute Wait: Yes No

SCREENING TEST: (For BREATH DEVICE* write in the space below only if the testing device is not designed to print.)

Test #	Testing Device Name	Device Serial # OR Lot # & Exp. Date	Activation Time	Reading Time	Result
--------	---------------------	--------------------------------------	-----------------	--------------	--------

CONFIRMATION TEST: Results MUST be affixed to each copy of this form or printed directly onto the form.

REMARKS: _____

Alcohol Technician's Company _____ Company Street Address _____

(PRINT) Alcohol Technician's Name (First, M.I., Last) _____ Company City, State, Zip _____

Phone Number (Area Code & Number) _____

Signature of Alcohol Technician _____ Date _____ Month / Day / Year

STEP 4: TO BE COMPLETED BY EMPLOYEE IF TEST RESULT IS 0.02 OR HIGHER

I certify that I have submitted to the alcohol test, the results of which are accurately recorded on this form. I understand that I must not drive, perform safety-sensitive duties, or operate heavy equipment because the results are 0.02 or greater.

Signature of Employee _____ Date _____ Month / Day / Year

U.S. Department of Transportation (DOT)

Alcohol Testing Form

(The instructions for completing this form are on the back of Copy 3)

STEP 1: TO BE COMPLETED BY ALCOHOL TECHNICIAN

A: Employee Name _____
(Print) (First, M.L., Last)

B: SSN or Employee ID No. _____

C: Employer Name _____

Street _____

City, ST ZIP _____

DER Name and _____

Telephone No. _____

DER Name

DER (Area Code & Phone Number)

D: Reason for Test: Random Reasonable Susp. Post-Accident Return to Duty Follow-up Pre-employment

STEP 2: TO BE COMPLETED BY EMPLOYEE

I certify that I am about to submit to alcohol testing required by U.S. Department of Transportation regulations and that the identifying information provided on the form is true and correct.

Signature of Employee _____

Date _____ Month / Day / Year

STEP 3: TO BE COMPLETED BY ALCOHOL TECHNICIAN

(If the technician conducting the screening test is not the same technician who will be conducting the confirmation test, each technician must complete their own form.) I certify that I have conducted alcohol testing on the above named individual in accordance with the procedures established in the U.S. Department of Transportation regulation, 49 CFR Part 40, that I am qualified to operate the testing device(s) identified, and that the results are as recorded.

TECHNICIAN: BAT STT DEVICE: SALIVA BREATH* 15-Minute Wait: Yes No

SCREENING TEST: (For BREATH DEVICE* write in the space below only if the testing device is not designed to print.)

Test #	Testing Device Name	Device Serial # OR Lot # & Exp. Date	Activation Time	Reading Time	Result
--------	---------------------	--------------------------------------	-----------------	--------------	--------

CONFIRMATION TEST: Results **MUST** be affixed to each copy of this form or printed directly onto the form.

REMARKS: _____

Alcohol Technician's Company _____ Company Street Address _____

(PRINT) Alcohol Technician's Name (First, M.L., Last) _____ Company City, State, Zip _____

Phone Number (Area Code & Number) _____

Signature of Alcohol Technician _____ Date _____ Month / Day / Year

STEP 4: TO BE COMPLETED BY EMPLOYEE IF TEST RESULT IS 0.02 OR HIGHER

I certify that I have submitted to the alcohol test, the results of which are accurately recorded on this form. I understand that I must not drive, perform safety-sensitive duties, or operate heavy equipment because the results are 0.02 or greater.

Signature of Employee _____ Date _____ Month / Day / Year

INSTRUCTIONS FOR COMPLETING THE U.S. DEPARTMENT OF TRANSPORTATION ALCOHOL TESTING FORM

NOTE: Use a ballpoint pen, press hard, and check all copies for legibility.

STEP 1 The Breath Alcohol Technician (BAT) or Screening Test Technician (STT) completes the information required in this step. Be sure to print the employee's name and check the box identifying the reason for the test.

NOTE: If the employee refuses to provide SSN or I.D. number, be sure to indicate this in the remarks section in STEP 3. Proceed with STEP 2.

STEP 2 Instruct the employee to read, sign, and date the employee certification statement in STEP 2.

NOTE: If the employee refuses to sign the certification statement, do not proceed with the alcohol test. Contact the designated employer representative.

STEP 3 The BAT or STT completes the information required in this step and checks the type of device (saliva or breath) being used. After conducting the alcohol screening test, do the following (as appropriate):

Enter the information for the screening test (test number, testing device name, testing device serial number or lot number and expiration date, time of test with any device-dependent activation times, and the results), on the front of the ATF. For a breath testing device capable of printing, the information may be part of the printed record.

NOTE: Be sure to enter the result of the test exactly as it is indicated on the breath testing device, e.g., 0.00, 0.02, 0.04, etc.

Affix the printed information in the space provided, in a tamper-evident manner (e.g., tape), or the device may print the results directly on the ATF. If the results of the screening test are less than 0.02, print, sign your name, and enter today's date in the space provided. The test process is complete.

If the results of the screening test are 0.02 or greater, a confirmation test must be administered in accordance with DOT regulations. An EVIDENTIAL BREATH TESTING device that is capable of printing confirmation test information must be used in conducting this test.

After conducting the alcohol confirmation test, affix the printed information in the space provided, in a tamper-evident manner (e.g., tape), or the device may print the results directly on the ATF. Print, sign your name, and enter the date in the space provided. Go to STEP 4.

STEP 4 If the employee has a breath alcohol confirmation test result of 0.02 or higher, instruct the employee to read, sign, and date the employee certification statement in STEP 4.

NOTE: If the employee refuses to sign the certification statement in STEP 4, be sure to indicate this in the remarks line in STEP 3.

Immediately notify the DER if the employee has a breath alcohol confirmation test result of 0.02 or higher.

Forward Copy 1 to the employer. Give Copy 2 to the employee. Retain Copy 3 for BAT/STT records.

TAB 3

**MANDATORY
POST-ACCIDENT
COLLECTION
AND
REPORT FORMS**



U.S. Department
of Transportation
Federal Railroad
Administration

ACCIDENT INFORMATION REQUIRED FOR POST-ACCIDENT TOXICOLOGICAL TESTING (49 CFR PART 219)

NOTE: This form must be completed by the Railroad Representative present at the collection facility.

1. Name of Reporting Railroad ABC RAILROAD	2. Name(s) of Other Railroads Involved in Accident N/A
3. Date of Accident (month /day/year) 11/9/99	4. Time of Accident 4 : 15 <input checked="" type="checkbox"/> AM <input type="checkbox"/> PM Hr Min
5. Locations of Accident (City and State) MILEPOST 153	6. Nearest Railroad Station DES PLAINES, IL

7. Event which Qualifies Accident for Mandatory Post-Accident Testing (one must be checked)
NOTE: All accident events (not incidents) must meet the railroad property damage reporting threshold.

MAJOR TRAIN ACCIDENT: Fatality
 \$1,000,000 damage or more (to railroad property)
 Release of hazardous material (and evacuation)
 Release of hazardous material (and reportable injury from product)

IMPACT ACCIDENT: Reportable injury
 Damage of \$150,000 or more (to railroad property)

PASSENGER TRAIN ACCIDENT: Reportable injury to any person in the accident

TRAIN INCIDENT: Fatality to on-duty railroad employee

8. Name and Address of Collection Facility GREAT LAKES OCCUPATIONAL HEALTH 123 BIG LAKE BLVD. DES PLAINES, IL 60027	9. Telephone Number of Collection Facility (847) 567-8910
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10. Employee(s) Whose Samples are Contained in this Shipping Box.
NOTE: A sample set identification number is pre-printed on FRA Form 6180.74 and differs for each person.

NAME OF EMPLOYEE	JOB TITLE (engineer, conductor, etc.)	TRAIN DESIGNATION	SAMPLE SET IDENTIFICATION NUMBER
KEN SWART	ENGINEER	XYZ123	112603
DON EDGELL	CONDUCTOR	XYZ123	112605
MARY SHATINSKY	ENGINEER TRAINEE	XYZ123	112604

11. Name of Medical Review Officer JIM BERNSTEIN, MD 7890 ELVIS PRESLEY ROAD MEMPHIS TN 38182	12. Address of Medical Review Officer Telephone: (901) 234-5678
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13. Name of Railroad Representative WOODIE WOODWARD 4567 SOUTH MAPLE AVENUE DES PLAINES, IL 60018	14. Address of Railroad Representative Telephone: (847) 789-0123
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15. Signature of Railroad Representative Woodie Woodward	16. Date (month/day/year) 11/9/99	17. Was a breath alcohol test conducted pursuant to the above accident under FRA Authority? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No
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FEDERAL RAILROAD ADMINISTRATION

POST-ACCIDENT TESTING BLOOD/URINE CUSTODY AND CONTROL FORM (49 CFR 219)

NOTE: This form must be completed in accordance with instructions provided by the Railroad representative. Separate instructions are available for the employee and the collectors. If more than one collector provides services, each must direct special attention to properly documenting the chain of custody for the blood and urine specimens, as applicable.

Employee Identification Number or Social Security Number 548-68-2183	Sample Set Identification Number (Pre-printed) 112603
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STEP 1. COMPLETED BY EMPLOYEE (DONOR) PROVIDING SPECIMENS

Name Print (last, first, mi) SWART, KENNETH R.	Name of Employing Railroad ABC RAILROAD
Home Address 6543 COLUMBIA AVENUE DES PLAINES IL 60014	Name of Home terminal DES PLAINES

STEP 2. COMPLETED BY COLLECTOR OF BLOOD SPECIMEN

Name of Collector Print (last, first, mi) LEE, SARA J.	Collection Date 11/9/99	Collection Time 0735	Remarks:
I certify the blood specimen was presented to me by the person named in Step 1. The specimen (in two blood tubes) bears the sample set identification number as printed above and was collected, labeled, and sealed according to the Federal Railroad Administration's instructions provided to me.			
I HAVE COMPLETED THE REQUIRED ENTRY IN STEP 5 BELOW, AS EXPLAINED IN THE INSTRUCTIONS GIVEN TO ME.			
			<u>Sara J. Lee MT</u> Signature of Collector

STEP 3. COMPLETED BY COLLECTOR OF URINE SPECIMEN

Name of Collector Print (last, first, mi) CROCKER, BETTY L.	Collection Date 11/9/99	Collection Time 0750	Remarks:
Temperature of Specimen was read within 4 minutes <input checked="" type="checkbox"/> YES <input type="checkbox"/> NO	Temperature was within range of 32°-38°C/90°-100°F <input checked="" type="checkbox"/> YES <input type="checkbox"/> NO		If not, actual temperature was _____ °
I certify the urine specimen was presented to me by the person named in Step 1. The specimen (in two bottles) bears the sample set identification number as printed above and was collected, labeled, and sealed according to the Federal Railroad Administration's instructions provided to me.			
I HAVE COMPLETED THE REQUIRED ENTRY IN STEP 5 BELOW, AS EXPLAINED IN THE INSTRUCTIONS GIVEN TO ME.			
			<u>Betty L. Crocker</u> Signature of Collector

STEP 4. COMPLETED BY EMPLOYEE

I certify the information I have given in Step 1 is correct and that I provided the specimens described in Steps 2 and 3; that each specimen is in a container which have the above sample set identification numbers recorded on the tamper-evident seals; that I have not adulterated the urine specimen in any manner, that each container has a tamper-evident seal that was applied by the collector in my presence, and I have placed my initials on each label (SIGN AFTER ALL SPECIMENS ARE SEALED.)

EXAMPLE OF MY INITIALS KS

Kenneth R. Swart
Signature of Employee

STEP 5. COMPLETED IN SEQUENCE BY COLLECTORS AND OTHERS TAKING POSSESSION OF SPECIMENS (Including Laboratory)

DATE MO. DAY YR.	SPECIMEN RELEASED BY	TYPE OF FLUID(S)		SPECIMEN RECEIVED BY	PURPOSE OF CHANGE
		BLOOD	URINE		
11/9/99	DONOR- NO SIGNATURE	2		Signature <u>Sara J. Lee MT</u> Name <u>SARA J. LEE</u>	PROVIDE SPECIMEN FOR TESTING
11/9/99	Signature <u>Sara J. Lee MT</u> Name <u>SARA J. LEE</u>	2		Signature <u>Betty L. Crocker</u> Name <u>BETTY L. CROCKER</u>	TRANSFER SPECIMENS TO SECOND COLLECTOR
11/9/99	Signature <u>DONOR</u> Name		2	Signature <u>Betty L. Crocker</u> Name <u>BETTY L. CROCKER</u>	PROVIDE SPECIMEN FOR TESTING
11/9/99	Signature <u>Betty L. Crocker</u> Name <u>BETTY L. CROCKER</u>	2	2	Signature <u>JIM'S OVERNIGHT</u> Name <u>COMMON SENSE</u>	TRANSFER SPECIMENS TO LABS

STEP 6. COMPLETED BY MEDICAL FACILITY/PHYSICIAN

Describe any medication, solution, transfusion, anesthetic, or other treatment the employee received after the accident that might affect toxicological analyses. None	Was a breath alcohol test conducted on the donor above, pursuant to this accident, using FRA authority? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No
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Northwest Drug Testing, NWT Inc.
 1141 East 3900 South Salt Lake City, UT 84124 800-322-3361

**FEDERAL RAILROAD ADMINISTRATION POST-ACCIDENT
 FORENSIC TOXICOLOGY RESULT REPORT**

REFERENCE INFORMATION

RAILROAD: ABC RAILROAD
ACCIDENT: Des Plaines, IL 11/09/99 4:15 am
FRA CASE: 987
EMPLOYEE: Kenneth R. Swart
SPECIMEN SET ID NO: 112603

SPECIMEN(S) TESTED

URINE: FR8042
BLOOD: FR8042

LABORATORY TESTING INFORMATION

Drug	Urine	Blood
Cannabinoids	NEG	*
Cocaine	NEG	*
Opiates	NEG	*
Amphetamine	NEG	*
Methamphetamine	NEG	*
Phencyclidine	NEG	*
Barbiturates	NEG	*
Benzodiazepines	NEG	*
Ethyl Alcohol	*	NEG

* Testing not required; see attached summary

TESTING PERFORMANCE EXPLANATION

Testing of specimens was in accordance with the FRA Post-Accident Testing Program. Additional descriptive information of testing procedures are summarized on the attachment "Summary of Analyses Performed on Specimens for Toxicology under FRA Post-Accident Testing Program" (Revised 2/02/99), which is an integral part of this report.

SPECIMEN DISPOSITION

Negative specimens will be retained at NWT Inc, for not less than six months from the report date. Positive specimens will be retained for not less than two years.

RESULTS

NO DRUGS OR ALCOHOL WERE IDENTIFIED

CERTIFICATION

I certify that I am a laboratory certifying official at NWT Inc, and the results identified above were correctly determined in accordance with the FRA Post-Accident Testing Program.

David J. Kuntz, Ph.D., Laboratory Director

11-11-99

Report Date

**SUMMARY OF ANALYSES PERFORMED ON SPECIMENS FOR TOXICOLOGY
UNDER FRA POST-ACCIDENT TESTING PROGRAM**

Revised 2/02/99

The following summarizes the procedures for analysis of blood and urine specimens submitted under the FRA Post-Accident Program.

Urine Integrity Test: Urine is tested for pH, specific gravity, and creatinine. If the pH or temperature is out of range, the specific gravity is less than 1.003, the creatinine is less than 20 mg/dL, or the sample appears adulterated, both the urine and the blood specimens may be tested for drugs.

Analysis of Drugs/Initial Testing: Initial testing is performed on urine by KIMS (kinetic interaction of microparticles in solution), or blood, if urine is unavailable or unsuitable, by RIA (radioimmunoassay) for the drug groups shown. If the tests are negative (that is, the results are below the cut-off), routinely no further analyses are performed.

Drug or Metabolite ^a	Cutoffs (ng/mL) ^b	
	Urine	Blood
Cannabinoids	20	10
Cocaine	300	20
Opiates	300	50
Amphetamine	300	50
Methamphetamine	300	50
Phencyclidine	25	2.5
Barbiturates	200	100
Benzodiazepines	100	50

Analysis of Drugs/Confirmation: If the initial test is presumptively positive, the urine and/or the blood specimens are analyzed using gas chromatography/mass spectrometry (GC/MS). Normally, blood analysis is not required if urine results are negative. Except as noted, only positive confirmed findings at or above the cutoff are reported; they are expressed as quantitative results based on the confirmatory analysis.

Specific Drug or Metabolite	Confirmation Cutoffs (ng/mL) ^b	
	Urine	Blood
Cannabinoids	Delta-9-tetrahydrocannabinol (THC) ^c	N/A
	THCA (a metabolite of THC)	15
Cocaine	Cocaine	50
	Benzoylcegonine (a metabolite of cocaine)	150
Opiates	Morphine (total)	300
	Morphine (unconjugated)	N/A
	Codeine (total)	300
	Codeine (unconjugated)	N/A
	6-Monoacetylmorphine (6-MAM)	LOQ ^d
Phencyclidine		25
	Amphetamines	
	Amphetamine	100 ^e
	Methamphetamine	100 ^e

Specific Drug or Metabolite (cont.)

	Confirmation Cutoffs (ng/mL) ^b	
	Urine	Blood
Barbiturates	Pentobarbital	200
	Secobarbital	200
	Amobarbital	200
	Butalbital	200
	Phenobarbital	1000
Benzodiazepines	*Nordiazepam	LOQ
	*Oxazepam	LOQ
	*Temazepam	LOQ
	*N-Desalkylflurazepam	LOQ
	*alpha-Hydroxyalprazolam	LOQ
	*alpha-Hydroxytriazolam	LOQ
	Diazepam	N/A
	Flurazepam	N/A
	Chlordiazepoxide	N/A
	Alprazolam	N/A
	Triazolam	N/A

**Urine benzodiazepine concentrations are reported if above the LOQ and only if the blood concentrations are above the cutoff. If a blood specimen is not received and the urine benzodiazepine concentration is greater than the LOQ, then the urine specimen may be reported.*

Note: If a drug included in a drug group is detected below the cutoff and another drug in that group is present above the cutoff, then the first drug may be reported.

Analysis for Alcohol: The blood specimen (or urine if blood is unavailable) is analyzed for ethyl alcohol by gas chromatography (GC). If the blood specimen is positive, the analysis is repeated using a separate portion of the specimen and the urine is also analyzed by gas chromatography. In fatalities, vitreous (if available) is also analyzed.

Substance	Initial Test Cutoff (g/100 mL)	Confirmation Cutoff (g/100 mL)
Ethyl Alcohol	0.01	0.01

Analysis in the Case of a Fatality: If urine or blood is not available, or as directed by the FRA, other body fluids and/or tissue specimen(s) may be analyzed.

Special Assays: On direction from the FRA, additional testing for controlled substances and/or their metabolites may be conducted. If such tests are performed, they are specifically described on each individual report.

^aMetabolites and/or analogs of these compounds may also be detected.

^bThese cutoffs are subject to periodic review and update.

^cTHC is the active constituent of marijuana or hashish preparations.

^dLOQ: Limit of quantitation.

^eA confirmed urine positive for amphetamine or methamphetamine will result in a d&l isomer analysis and is reported as the % of each isomer present.