STATEMENT OF WORK: POST-ACCIDENT TOXICOLOGICAL TESTING (PATT) OVERSIGHT

C.1 BACKGROUND

The Federal Railroad Administration (FRA) was created by the Department of Transportation (DOT) Act of 1966. It is one of ten agencies within the DOT concerned with intermodal transportation. FRA's mission is to enable the safe, reliable, and efficient movement of people and goods for a strong America, now and in the future. FRA's Office of Safety promotes and regulates safety throughout the Nation's railroad industry. The office executes its regulatory and inspection responsibilities through a diverse staff of railroad safety experts. Other functionalities that FRA's Office of Safety provides are railroad safety and customer training (including State safety inspectors), accident and employee fatality investigations and reporting, partnerships between labor, management, and the agency that address systemic initiatives, and development and implementation of safety rules and standards.

Details on FRA of Safety's mission, role, and responsibilities are available at https://www.fra.dot.gov/Page/P0010.

C.2 SCOPE

a. The objective of the effort is to provide FRA support in all technical and scientific areas which relate to the detection and deterrence of drug and alcohol use in the railroad industry.

b. One principal focus of this requirement is to provide the FRA with ongoing technical evaluation and scientific review of laboratory Post-Accident Toxicological Testing (PATT) procedures and protocols. The collection and analysis of whole blood and urine samples, including tissue samples in post-mortem cases, is performed by a laboratory under a separate contract with FRA.
Effective November 1985, the FRA Post Accident Toxicological Testing Program (PATT) was implemented pursuant to Title 49, Code of Federal Regulations, Subpart C of Part 219 (49 CFR Part 219 Subpart C), which constitutes the final rule and is titled "Control of Alcohol and Drug Use." Accuracy and credibility in mandatory PATT has been identified as a critical element in the nationwide FRA railroad safety alcohol and drug control program.

For this element, the Technical Oversight Contractor (Contractor) shall provide technical and scientific oversight specializing in forensic toxicology, laboratory testing procedures and protocols, and inspections of the designated FRA post-accident laboratory. In addition, the Contractor shall perform and administer comprehensive proficiency testing of laboratory procedures and quality assurance methods which promote continuing public confidence in the forensic integrity and scientific credibility of the FRA PATT Program. These tests shall be legally defensible with an unblemished or at a minimum corrected chain of custody. The Contractor shall further provide FRA, upon request, with advice and comment on issues related either directly or corollary to FRA's PATT Program, including the interpretation and meaning of post-accident analytical findings in human urine, blood, and tissue.

c. As an additional principal focus of this contract, the Contractor shall provide technical assistance to FRA, upon request, in matters relating to all compliance aspects (technical, scientific, and policy) of drug and alcohol testing programs conducted by rail carriers striving to be in compliance with 49 CFR Part 219, and the Department's testing procedural regulation, 49 CFR Part 40 titled, "Procedures for Transportation Workplace Drug Testing Programs," as amended. The contractor shall also assist the FRA Alcohol and Drug Program Manager in appropriate subject matter expertise and training program support for the internal FRA workforce and railroad management including "service providers" such as urine and breath collection sites, medical review officers (MRO), and third-party administrators (TPA). These service providers assist the railroads in complying with the requirements and are reviewed by FRA HQ-led Class I compliance audits and FRA Region-led compliance audits of Class II and passenger

railroads. The contractor will assist with rail labor issues as well and provide subject matter consultation and advice to the FRA for the enhancement of the total FRA effort to reduce the adverse effects of substance abuse in the railroad industry.

For Information purposes:
49 CFR Part 40 may be accessed electronically at the Department of Transportation, Drug and Alcohol Regulations web page - Internet address: https://www.transportation.gov/odapc
49 CFR Part 219 may be accessed electronically at the FRA, Office of Safety, Drug and Alcohol home page -
http://www.fra.dot.gov/Page/P0345

C.2 TASK 1- TECHNICAL AND SCIENTIFIC MONITORING OF DESIGNATED FRA POST ACCIDENT LABORATORY

C.2.1 Subtask-Inspection

a. FRA designates one laboratory to conduct FRA post-accident toxicology, currently located in Tucker, GA. This location may be subject to change during the life of this requirement.
The designated, FRA contracted Post-Accident Testing Laboratory (LAB) will be subject to comprehensive monitoring by the Oversight Contractor on behalf of FRA. The Contractor shall inspect the laboratory tri-annually, and/or as directed by FRA, for compliance with:

1. Requirements imposed by FRA (through regulation, contractual terms, established approved protocols and any amendments) and any requirements applicable to the FRA Post Accident Toxicology Program (PATP) that may be incorporated in Mandatory Guidelines issued by the Department of Health and Human Services (DHHS), as amended, or other applicable Federal standards and regulations; and
2. Established (published) forensic toxicology guidelines and principles and national standards of practice promulgated by reputable forensic toxicology boards, related scientific organizations, or laboratory certifying bodies (e.g., the College of American Pathologists (CAP), the Society of Forensic Toxicologists (SOFT), the American Board of Forensic Toxicology (ABFT), or the American Academy of Forensic Sciences (AAFS)).

b. As part of their tri-annual inspections of the laboratory, the Contract Lead shall coordinate the review of designated laboratory protocols, operating procedures, qualification of personnel, equipment, physical security, and facilities to determine if the laboratory operations meet or exceed all applicable scientific and forensic standards. The Contractor shall identify any concerns/deficiencies during the triannual review(s) so that the FRA-contracted laboratory can discuss resolution during the review. Each area of laboratory operations should be rated by the Contractor, coordinated, and reported out by the Contract Lead in the report provided to the FRA SME and COR as in compliance, as requiring a recommendation, as a deficiency, or as a discrepancy. Each reviewed area shall be rated by the Inspection Team and the ratings are defined as follows:

- "In Compliance" - The evaluation area was considered to be in direct compliance with both the contract with the FRA (either meeting or exceeding FRA requirements) and with accepted scientific and forensic laboratory practices. Unless otherwise stated in this Report, areas of consideration were considered to be in compliance.
- "Recommendations Offered" - The evaluation area was considered to be in general compliance with accepted forensic laboratory practices, but some level of action by the Laboratory would be required to either remediate an administrative, technical, or scientific concern by the Inspection Team or to enhance an existing procedure or protocol. The Laboratory has full discretion to incorporate an alternative system, method, or procedure of its choice in order to resolve the issue.

- "Deficiencies Noted" - The evaluation area was not considered to be in general compliance with accepted forensic laboratory practices or FRA requirements and should be reconciled to the satisfaction of the FRA Subject Matter Expert (SME) and Contracting Officer's Representative (COR) by the next Inspection. A problem in this area should be considered serious, but does not indicate a discrepancy, which necessarily impacts on the integrity or credibility of FRA testing. Nonetheless, it dictates resolution. For the purposes of this Inspection Report, the Inspection Team considers "not in compliance with accepted forensic laboratory practices" to describe an evaluation area vulnerable to question or challenge by outside forensic experts or inspecting toxicologists using Department of Health and Human Services-Substance Abuse Mental Health Services Administration (DHHS/SAMHSA), College of American Pathologists (CAP), Center for Disease Control (CDC), or other relevant guidelines.
- "Discrepancies Identified" - The evaluation area was not considered to be in compliance with accepted forensic laboratory practices (as defined above) or FRA requirements to the extent that the integrity and credibility of FRA testing was considered to be in jeopardy. A problem in this area should be considered extremely serious and may demonstrate default or material breach of the contract. These definitions are subject to change by FRA SME and COR throughout the course of this contract. If the inspection concern/deficiency is such that it cannot be resolved immediately, it will be debriefed as a concern/deficiency which will also be part of the review report compiled by the Contract Lead which will require resolution before the next tri-annual review. The Contract Lead shall provide the FRA laboratory with a draft of the tri-annual review report, not later than 30 working days after the review.

  The draft report shall include a detailed narrative addressing concerns/deficiencies identified; discussion of isolated or systemic causes contributing to the concerns/deficiencies (to include recommended remedial actions); action taken by the laboratory to rectify situations or conditions identified in previous inspections; and reports or specific cases relevant to the review. FRA will provide past samples of laboratory tri-annual review reports for format at the program orientation. The tri-annual reports should include analysis and results of any proficiency testing (Subtask C.2.2) that occurred in the previous four-month period. After the laboratory has provided its own internal review of the Contractor's draft report to ensure there are no errors of fact, the Contract Lead shall finalize the report and provide the final report to both the FRA SME and COR, and the laboratory not later than 10 working days after submission of the draft report. The Contract Lead shall continue to confer with the laboratory and discuss and resolve any ongoing issues developed during the inspection and subsequently noted in the final report. Supplemental reports from the Contract Lead to the FRA may be required to address specific concerns raised during discussions between the Oversight Contractor and the laboratory.

c. The Contractor shall maintain laboratory inspection procedures approved by the FRA SME and COR that incorporate applicable standards and procedures as they apply to the primary laboratory. The Contractor shall independently verify the ability of the laboratory to provide consistently reliable, forensically sound, and scientifically defensible methods for the detection and confirmation of alcohol and drugs as specified in the laboratory's contract with FRA, to include required internal quality assurance for proper chain of custody of samples and complete documentation of all assays performed on FRA samples.

The Contractor's inspection shall include every aspect of laboratory operations which impacts the testing of FRA post-accident specimens. Areas to be covered include, but are not necessarily limited to, analytical and laboratory protocols, laboratory administration and staffing, facilities, training, case turnaround time, specimens receiving/aliquoting/ sample preservation, screening, extractions, confirmations, specimen custody and control, data and record review protocols, laboratory security, laboratory safety, specimen and record storage, reports, and quality assurance/quality control. The Contractor will also be asked to judge the laboratory's response and provide a recommendation to the

Contractor's previous report.

d. In performing these reviews, the Contract Lead shall advise FRA SME and COR on the acceptability of standing laboratory procedures and analytical protocols or revisions thereto. The Contractor shall review all post-accident cases (and findings) of samples reported positive, and review all or a representative number of cases (and findings) reported negative (a minimum of 50 percent) which were received and analyzed by the laboratory during the time frame under review. In reviewing these cases, the Contractor shall determine the extent to which reported results are forensically sound and scientifically defensible, the Contractor should also ascertain if testing and analyses were conducted in a manner fully consistent with the procedures and protocols approved under the designated laboratory's contract with FRA. The Contract Lead shall include these abovementioned details in the report to the FRA SME and COR.

e. Inspection of the designated FRA laboratory will require a team of two or three members. The Contract Lead shall confer with the FRA COR and SME at least 30 days in advance to allow for travel scheduling and coordination of the laboratory reviews. When conducting an inspection of the FRA designated toxicology laboratory, each Contractor team member shall be fully qualified to perform these inspections as experts in the forensic toxicology field. Qualification will be defined as holding a credential as a Fellow of the American Board of Forensic Toxicology (F-ABFT), a Diplomate of the American Board of Forensic Toxicology (D-ABFT-FT, DABFT- FA, or D-ABFT-FD), or another equivalent credential acceptable to the FRA SME and COR. At least the lead laboratory inspector for every FRA post-accident laboratory inspection shall hold the F-ABFT credential or another equivalent credential acceptable to the FRA SME and COR. All personnel proposed by the Contract Lead to provide forensic toxicology laboratory inspection services shall be approved by the FRA SME and COR. Team members shall have a strong working knowledge and/or experience in all ranges of blood and urine screening and confirmation methodologies (including EIA, ELISA, GC/MS, and LC/MS/MS). At At least one team member shall have demonstrated experience in post-mortem toxicology.

Historically, these sub tasks (C.2.1 & C.2.2) have been staffed by 3 personnel. Two (2) primaries and one (1) alternate.

C.2.2 Subtask- FRA Post Accident Laboratory Proficiency Testing

a. The Contractor (can be Contract Lead or another technical expert) shall collaborate with the FRA SME and COR regarding the design of, or modification to an open proficiency testing program for the designated FRA post-accident laboratory. The Contractor shall design, implement, and operate a program that has been submitted by the Contract Lead and has been approved by the FRA SME and COR.

The proficiency testing program requires that the Contractor arrange for preparation of human whole blood and urine samples and retain services of one or more referee laboratories to provide analyses of the samples to be used in determining the capabilities and credibility of the designated FRA toxicology laboratory.

b. The Contractor shall arrange for the presentation of these samples to the designated FRA laboratory so that the open sampling methodologies employed are acceptable to the FRA SME and COR.

The Contractor shall prepare and furnish the FRA SME and COR reports within 40 working days detailing the steps and findings and subsequent actions taken for all proficiency tests conducted.

c. The Contractor shall arrange for a minimum of one (1) and preferably two (2) reference laboratories to analyze blank and spiked samples as needed.

d. Proficiency testing for the designated FRA laboratory will include full identification and quantification of FRA-required analytes based on the then current FRA testing protocols for drugs and for alcohol. Generally, drugs are first screened for in urine and presumptive positives or dilute specimens are confirmed in blood or urine. In some circumstances, the blood is screened instead and presumptive positives are confirmed in both blood and urine. Alcohol is first screened in blood and presumptive positives are confirmed in blood and urine. This also means that the Contractor's proficiency testing challenges shall be prepared to cover the full range of analytes and cutoffs the laboratory is testing for under FRA requirements at the time of the challenge.
FRA estimates the 12-month total volume for the proficiency testing program to include 23 sample sets. (Note: a set includes both blood and urine representing the specimens from one railroad employee.)
The samples should comprise approximately 20 sample sets for open testing (which should be coordinated/scheduled with the FRA laboratory during the quarterly review). Generally, open sample sets should contain no more than 10% negatives. The remainder should contain between one and three drug groups.

C.3 TASK 2- RAILROAD PART 219 COMPLIANCE REVIEW SERVICES

a. As directed by the FRA, the Contractor shall provide expert advice and/or program support services related to the detection and deterrence of drug and alcohol use in the railroad industry. This may include, but not be limited to, technical assistance visits and participation in FRA 49 CFR Part 219 compliance audits of rail carriers. The Contractor shall be responsible for providing FRA with one (1) or more acceptable technical experts for Part 219 compliance audits of both rail carriers and their service providers (MRO, SAP, BAT, etc.) at various designated locations throughout the country. These locations vary from CSX – Jacksonville, FL; Norfolk Southern – Atlanta, GA; UP – Omaha, NE; BNSF – Fort Worth, TX; CN – Hammond, IL; AMTRAK – Philadelphia, PA; CPKC – Kansas City, MO. The contractor may also be called upon to provide assistance with large
Class II and passenger railroads to assist FRA Region-led compliance audits. The technical experts shall have demonstrated experience and expertise in 49 CFR Part 40 and/or Part 219 regulations, guidance, and regulatory interpretations. The Contractor should also have working knowledge and experience working with all of the other DOT agency regulations (including FMCSA' 49 CFR Part 382). The Contract Lead shall provide resumes of proposed auditors for FRA approval no later than 30 days prior to the task start date and to also be included in the proposal.

b. Contractor technical experts shall be prepared to act as senior adjunct members of a team of FRA inspectors auditing all drug and alcohol requirements of the applicable federal rules (both Part 219 and Part 40). Special expertise is required in urine, blood, tissue, and breath specimen collection, collection chain-of-custody and documentation; laboratory procedures, analysis, and test result documentation. Medical Review Officer (MRO) procedures and documentation; Substance Abuse Professional (SAP) procedures and documentation; Breath Alcohol Technician (BAT) procedures and documentation; and all types of federal testing with particular emphasis in random testing requirements and allowances, and other requirements of the rules.

c. Contractor technical experts shall be prepared, qualified, and to the extent needed, credentialed to conduct interviews and assess documents and records with railroad officials and vendor representatives (MRO, SAP, BAT etc.); make written recommendations and identify noncompliance or deficiencies with respect to Parts 40 Part 219; provide appropriate, relevant operational guidance; and write reports of findings for use by FRA. The Contract Lead shall coordinate and provide these reports to FRA. FRA will provide past samples of railroad compliance review reports for format at the program orientation. Typically, the FRA SME and COR will request five such compliance audits each year, extending from 3-5 days each for carriers or 1-3 days each for carrier service providers. The FRA SME/program

manager will determine and schedule industry program reviews depending on need. Whenever possible, the Contract Lead will be notified up to a year in advance, however FRA may have a shorten lead time up to two (2) months prior for Contractor technical assistance and audit support services.

C.5 TASK 3- EXPERT CONSULTATION SERVICES

a. Contractor (may be Contract Lead, technical expert, or forensic toxicologist as needed) shall be prepared to provide FRA expert consultation services to support the entire Part 219 and Part 40 program. The Contractor shall be available on a seven-day per week/extended hour basis by at least telephone to respond to FRA requests for expert scientific, technical, and program. The FRA SME will expect immediate verbal advice to inquiries from an individual designated as a key person by the Contractor, to be followed by appropriate, timely (no more than 24 hours), written advice, as required and these shall be documented on all of the below requirements by the Contract Lead for the FRA COR.

The Contractor should additionally expect regular, routine telephone and face-to-face interface with the FRA SME and COR during contract performance relative to administrative case management. These discussions can be initiated by either party, and may occur daily or more often during the processing of high visibility accidents or with a heavy onboard FRA caseload. This interface is most often with the Contractor official (subject matter expert/program manager) responsible for the day-to-day operations of the FRA technical oversight program, and it may be more extensive than in the normal private client contract for technical oversight services. There may also be a need to provide consultation to the FRA SME and COR on support service during competitive procurement for a post-accident laboratory or replacement if the laboratory should lose certification.

In addition, as required by the FRA SME and COR, the Contractor shall be prepared to consult in providing appropriate Part 219 and Part 40 subject matter training to the FRA inspector workforce and the railroad industry (including carrier personnel, rail labor, and program service providers) in areas requiring technical, scientific, and policy expertise including regulatory changes.
Furthermore, the FRA SME and COR will require the Contractor to interpret the post-accident testing results and render an opinion on the influence of an identified drug or alcohol on the cause of a train accident.

b. The Contractor shall keep the FRA SME and COR informed on drugs of abuse/patterns of usage that may have an impact on FRA post-accident toxicological testing results and/or carrier alcohol and drug programs. In addition, the Contractor shall also keep the FRA SME and COR informed on developments in drug and alcohol testing/laboratory methodologies which might impact FRA post-accident toxicological testing. All information conveyed to the FRA SME and COR pertaining to new developments, updates and the like, shall be documented and retained by the Contractor with subject matter date and time and shall be shared with the FRA SME and COR on an on-going basis.

c. The Contractor shall be prepared to provide technical and scientific expertise to FRA SME and COR in assessing and reviewing substance abatement programs in Canada and Mexico for employers who have operations which could adversely affect safety in the United States. As part of a joint FRA and Transport Canada (TC) working group, the Contractor will act as a consultant in analyzing compatibility of programs and suggesting alternative strategies to ensure safety in cross-border operations subject to any limitations imposed or conditions exacted by the host Government. The Contractor will be expected to travel as needed with the joint team to subject foreign countries and to support the team for up to five days on two or three occasions over the life of the contract, inclusive of options.

d. In conjunction with FRA, the contractor will work on the development of program management tools, including an automated Plan-Policy builder and Part 219 audit report-generating, archiving, and data analysis products. The tools will greatly enhance the ability of FRA to process the required plans.

C.6 TASK 4 – DELIVERABLES

a. Laboratory Inspection Reports: (as per Section C.2.1 a – b) including QC/QA results if they occurred in the review period (Three Inspection Reports per year)

b. Class 1 Railroad Part 219 Compliance Reviews: (as per Section C.3 a – c) Medical Review Officer (MRO) and Substance Abuse Professional (SAP) Services Sections for inclusion in Overall Audit Summary (Five MRO Compliance Reviews per year)

The contractor, as coordinated by the Contract Lead, shall include an electronic copy to the FRA SME and to the COR as the tri-annual Laboratory Inspection Report and the Railroad Compliance Reviews are part of the deliverables and the services that the COR will verify on the invoices.
The Contractor, as coordinated by the Contract Lead, shall include the COR on all deliverables or services provided. These include communication through emails, reports, travel notification and any other if applicable.