U.S. DEPARTMENT OF TRANSPORTATION
FEDERAL AVIATION ADMINISTRATION

ORDER 9120.1D

Effective Date:
08/09/2018

SUBJ : Drug and Alcohol Compliance and Enforcement Inspector Handbook

The Federal Aviation Administration (FAA), Office of Aerospace Medicine (AAM) has prepared this order for Drug Abatement Division (AAM-800) personnel to follow when inspecting and investigating the drug and alcohol testing program of aviation industry employers, contractors, and individuals for compliance with the provisions of 49 CFR part 40, "Procedures for Transportation Workplace Drug Testing Programs;" and 14 CFR part 120, "Drug and Alcohol Testing Program."

Unless otherwise directed by the Drug Abatement Division Manager, inspectors and investigators must adhere to the procedures in this order. The FAA invites comments and suggestions from those who use the order. Input should be submitted to:

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Office of Aerospace Medicine
Drug Abatement Division (AAM-800)
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Chapter 1. General Information

1. Purpose of this Order. This order documents the procedures used by Federal Aviation Administration (FAA) drug and alcohol compliance and enforcement inspectors and investigators to assess the compliance of aviation industry employers, contractors and service agents with the requirements in the Code of Federal Regulations (CFR). Specifically, the regulatory requirements including the Department of Transportation's (DOT) 49 CFR part 40, "Procedures for Transportation Workplace Drug and Alcohol Testing Programs;" the FAA's 14 CFR part 120, "Drug and Alcohol Testing Program;" and other relevant Federal Aviation Regulations. This order is used in conjunction with FAA's "Compliance and Enforcement Program" (Order 2150.3, as amended) and "Safety Risk Management Policy" (Order 8040.4, as amended) to ensure that inspections and investigations are conducted accurately, fairly, and consistently throughout the Drug Abatement Division.

2. Audience. All Drug Abatement Division personnel.

3. Where Can I Find this Order? You can find this order on the MyFAA Employee Web site: https://employees.faa.gov/tools_resources/orders_notices/. This order is available to the public at http://rgl.faa.gov.

4. What this Order Cancels. This order cancels Order 9120.1C, FAA Drug and Alcohol Compliance and Enforcement Inspector Order, dated October 22, 2015.

5. Inspection Authority. The Omnibus Transportation Employee Testing Act of 1991 (49 USC §§ 45101-45107) and the FAA's general statutory safety authority outlined in 49 USC §§ 106(g) and 44701 provide the authority to conduct the inspections and investigations described in this order.

6. Objectives of the Inspection and Investigation Process. Ensuring compliance with the drug and alcohol testing regulations is the primary objective of the inspection and investigation process. The safety of the traveling public and integrity of the inspection and investigation process form the foundation of every inspection. The regulations and the inspection and investigation processes balance the privacy interests of aviation employees with the safety mandate to detect and deter illegal drug use and alcohol misuse. Inspections and investigations must be conducted in a constructive, ethical, unbiased, and professional manner. Implementation of the procedural safeguards within Federal regulations and this order will ensure these objectives.

7. Who Do We Inspect? We inspect the following entities in accordance with the drug and alcohol testing regulations, 14 CFR part 120, and 49 CFR part 40:

a. Employers. Part 40 defines an employer as "A person or entity employing one or more employees (including an individual who is self-employed) subject to DOT agency regulations requiring compliance with this part. The term includes an employer's officers, representatives, and management personnel. Service agents are not employers for the purposes of this part." Part 120 defines an employer as a part 119 certificate holder with authority to operate under parts 121 and/or 135; an operator as defined in 14 CFR § 91.147; or an air traffic control facility not operated by the FAA, or by or under contract for the U.S. Military.

(1) An employer must ensure that individuals hired to perform safety-sensitive functions, directly or by contract (including subcontract at any tier), are subject to drug and alcohol testing.

(2) Employers are responsible for all actions of their officials, representatives, and service agents in carrying out the requirements of the testing regulations.

b. Contractors. Part 120 defines a contractor as, "an individual or company that performs a safety-sensitive function by contract for an employer or another contractor." There are two options for drug and alcohol testing contractors:

(1) The contractor obtains and implements its own drug and alcohol testing program. If the contractor chooses this option, it must implement the program as if it were the employer.

(2) The employer includes the contractor under its own drug and alcohol testing program.

c. Service Agents. Part 40 defines a service agent as, "Any person or entity, other than an employee of the employer, who provides services to employers and/or employees in connection with DOT drug and alcohol testing requirements."

(1) A Consortium/Third-Party Administrator (C/TPA) is a service agent that may implement all or portions of the testing program for an employer or contractor.

(2) Service agents may provide the following services:

(a) Urine drug collections, as specimen collectors

(b) Breath alcohol testing, as breath alcohol technicians (BAT)

(c) Alcohol saliva testing, as screening test technicians (STT)

(d) Laboratory[1]

(e) Medical review officer (MRO) functions

(f) Substance abuse professional (SAP) functions

(3) As part 40 prescribes, service agents are required to comply with all aspects of the regulations. The roles and responsibilities of a service agent are addressed under subpart Q and Appendix F of part 40. Inspections or investigations of any employer or contractor may include a review of its service agent's practices and procedures. The employer or contractor is responsible for compliance with the regulations even when using a service agent. Therefore, a service agent's failure to comply with the regulations may result in violations against the employer or contractor.

(4) A service agent may be subject to a public interest exclusion (PIE), as described under subpart R of part 40, for egregious violations of the regulations. If an inspection or investigation results in allegations of egregious violations of the regulations by a service agent, the inspector must immediately report this information to his/her Compliance and Enforcement (C&E) Center Manager.

[1] The Department of Health and Human Services is responsible for monitoring certified laboratories.

A determination of whether to initiate an inspection, investigation or PIE is determined by the C&E Center Manager in coordination with the Program Administration Branch Manager and the Division Manager. If an inspection is initiated against the service agent, refer to Appendix B of this order for further instructions.

For purposes of this Order, we use the term company to include employer, contractor or service agent, unless it is specifically described.

Chapter 2. Inspection

1. General. A successful inspection entails accomplishing a sequence of five interrelated activities. This sequence begins with inspection scheduling; proceeds through detailed planning, completion of on-site inspection activities, and reporting of inspection results; and concludes with post-inspection follow-up activities. Inspections are executed according to the procedures established in this chapter. The Drug Abatement Division has established an Inspection Guide, which is found under Appendix A of this order. The Guide must be followed by all inspectors and investigators during each inspection. Deviations from the Inspection Guide are strictly prohibited and failure to follow the procedures in the Guide and this chapter may result in a nonconformity and corrective action (NCA). The Compliance and Enforcement Tracking Subsystem (CETS) Reference List should be used to enter out of compliance issues or concerns into CETS. The CETS Reference List is available on the Drug Abatement Division (AAM-800) QMS Web Site.

2. Inspection Scheduling.

a. The FAA employs a variety of inspection activities to ensure companies comply with the drug and alcohol testing regulations. Prior to the beginning of the fiscal year, the inspection weeks are published in CETS. Before every quarter, the Drug Abatement Division composes a quarterly inspection schedule based on this chapter, Drug Abatement's Strategic Compliance Monitoring Plan[2] (SCMP), and the Memorandum of Understanding (MOU) between the FAA and NATCA. Once the priorities are set, a scheduler from the Program Administration Branch assembles the teams of companies and pre-inspection materials for the national inspection schedule. These procedures are found in Appendix E of this order.

b. The inspection team assignments are made in conjunction with the existing MOU. The Program Administration Branch Manager or designated program analyst is responsible for appointing the inspection lead and identifying whether the inspection will be comprehensive or focused. Additionally, inspectors and investigators will be assigned to participate in high impact, special emphasis, and service agent inspections. Inspectors and investigators are required to access their schedules in CETS.

(1) *Comprehensive Inspections*. Comprehensive inspections are thorough reviews of all aspects of a company's drug and alcohol testing program. Although we may sometimes focus emphasis on specific areas based on information concerning potential problems, the overall format of such inspections is standardized in accordance with this order. In some cases, the comprehensive inspection may be conducted without advance notice to the company. The Drug Abatement Division's Program Administration Branch Manager or C&E Center Manager makes the determination as to whether a comprehensive inspection will be announced or unannounced.

[2] The Strategic Compliance Monitoring Plan (SCMP) is the Drug Abatement Division's policy for scheduling inspections.

(2) *Focused Inspections*. Under certain circumstances, focused inspections, which are narrow or limited in scope, may be conducted in response to a specific problem. Problems may be identified from any of a variety of information sources, including analyses of prior inspection results, annual testing reports, individual or union complaints, or other alternative means. For example, FAA headquarters may receive complaints concerning improper collection procedures. In that case, an inspection focusing on the company's collection procedures may be conducted. Focused inspections may involve a single company or entity, as in the example above, or a representative group of companies if information indicates that a problem is widespread. A focused inspection must include the company's administrative and quality assurance activities and mandatory testing (i.e., Medical Review Officer (MRO) verification, pre-employment, random, post-accident, reasonable cause/suspicion, return to duty, and follow-up). The determination as to whether a focused inspection will be announced or unannounced is made by the Drug Abatement Division's Program Administration Branch Manager or C&E Center Manager.

(3) *Announced Inspections*. An announced inspection requires advance notification to the company. This is accomplished by a person assigned to notify the company in accordance with the procedures in Appendix E of this order. The company is contacted and informed of the scheduled inspection and asked to provide information regarding their size, service agents, new hires, etc. Upon receiving the necessary information, the notifier updates the CETS profile and inspection activity and the communication is added to the inspection profile. Once the notifier finalizes the planned schedule, he or she sends an email to the Center Manager and Program Administration Branch Manager indicating the schedule is set. The program analyst/assistant in the Program Administration Branch retrieves the information in CETS and sends the company a letter of notification (LON) to confirm the pending inspection. The LON template is contained in CETS. The program analyst/assistant, following their procedures, must prepare the LON and attachment generated using the CETS template, and must also document the notification in CETS. In cases where a company is added to the schedule after the work plan is sent to the inspector, the inspector should notify the company of the inspection and send the company an LON as soon as possible.

(a) The LON package, sent by the program analyst/assistant, includes a list of records and documents necessary for inspection and a request for the company's points of contact. Upon completing the notification task, AAM-810 will provide an initial work plan to the inspectors, C&E Center Manager, Team Coordinators, Administrative Officer, and AAM-810 Manager. The union representative may request and receive a copy of the work plan(s) upon request.

(b) Prior to the inspection, the inspection lead ensures that the point of contact information has been received from the company and updated in CETS. For larger entities that require a multi- day inspection, the lead inspector prepares the Inspection Schedule (found in Figure 2-1) and distributes it accordingly. During any pre-inspection contact with a company, inspectors should refrain from initiating an inspection prior to on-site arrival. All inspectors and investigators are strictly prohibited from coaching companies or distributing unauthorized documents to them at any time.

(c) There may be instances in which an employer, after receiving an LON, will question the need for an inspection because it has ceased operations under 14 CFR § 119.63, but continues to hold a part 119 certificate with authority to conduct part 121 or 135 operations.

Regardless of whether an employer that holds a certificate is exercising the privileges of its certificate, it must be available for inspection. If the employer advises the FAA that it has ceased its operations, the inspector/investigator must contact the employer's Principal Operations Inspector (POI) or Principal Maintenance Inspector (PMI) to determine whether the employer has surrendered its certificate. That information must then be given to the C&E Center Manager for a determination as to whether the employer will be inspected. The C&E Center Manager will notify and consult with the AAM-810 Branch manager. If an employer which has ceased operations under 14 CFR § 119.63, but has retained its certificate, is unwilling to be inspected, the employer must contact its POI/PMI to surrender its certificate. The inspector/investigator must follow-up with the POI/PMI to ensure that this has been accomplished.

(4) *Unannounced Inspections*. Unannounced inspections are essential to an effective compliance program. Each inspector may be responsible for conducting unannounced inspections during the fiscal year.

(a) C&E Center Managers may schedule an unannounced inspection for any inspector during any inspection week.

(b) Inspection teams may conduct an unscheduled, unannounced inspection, as time allows, which requires the inspectors to locate companies in their assigned geographical areas.

(c) Preparations for unannounced inspections might include contact with the local Flight Standards District Office (FSDO) to ascertain that the company is still operating and has an active certificate.

(d) Inspection leads inform the C&E Center Manager(s) and other teams in the geographical area, if possible, before conducting unscheduled inspections, to preclude multiple inspection attempts at the same company. The C&E Center Manager will notify and consult with the AAM-810 Branch Manager accordingly.

(e) For all unannounced inspections, the inspection lead or team must not contact the company in advance of the inspection.

(5) *High Impact Inspections***.** High impact inspections are conducted by multiple teams of inspectors and investigators from two or more Drug Abatement offices during a one or two-week period. This approach permits the concentration of inspector and investigator resources in a planned geographic area and maximizes visibility for the Drug Abatement Program. By involving inspectors and investigators from two or more offices, high impact inspections promote consistency within the inspection process and the application of the regulations, provide cross-training, and permit managers to directly observe and assess an inspector's/investigator's performance. During high impact inspection weeks, a meeting is scheduled for inspectors, investigators, and managers to meet and discuss program issues. These discussions provide management with topics to be covered in future inspector and investigator training or identify a need for guidance and/or policy development.

(6) *Special Emphasis Inspections.* Special emphasis inspections are defined as inspections that are scheduled to focus on one part of the regulations (e.g., MRO, SAP, or collection site review) at a national level.

(7) *Service Agent Inspections*. Service agent inspections specifically focus on MROs, SAPs,

C/TPAs, collectors, and BATs. Service agent inspections are independent inspections and are not related to a specific company inspection. The standard operating procedures (SOP) for service agent inspections are in Appendix B of this order.

(8) *Inspection Schedule Changes and Cancellations.* While all efforts are made to maintain the inspection schedule as is, at times it is essential to the program to make necessary changes. All requests to change the final inspection schedule must be submitted through the C&E Center Manager to the Program Administration Branch Manager in Washington, DC. Once an inspector's schedule is established, the inspection planning must begin. Prior to canceling an inspection, the inspector must contact the C&E Center Manager. The C&E Center Manager will notify the AAM-810 Branch Manager accordingly. When a scheduled inspection is cancelled, the cancellation must be documented in CETS.

3. Preparation for the Inspection. The inspection lead is responsible for all planning of the assigned inspections. He/she has a critical role in accomplishing the goals of the inspection, ensuring that all critical aspects of an inspection, including planning and reporting, are accomplished according to established procedures (see inspection process guide in Figure 2-2).

a. The inspection lead examines CETS and the drug and alcohol enforcement history of each company to find past noncompliance issues and current potential noncompliance issues (NCTs). This includes previous inspections, open or closed voluntary disclosures, NCTs, and other special issues. This information will help the inspection team identify repeated noncompliance.

b. At a minimum, each inspection will include a review of mandatory testing records (e.g., pre- employment and random testing, positive drug tests, alcohol violations, and refusals), MRO verification, and the records specified in 49 CFR § 40.25. The inspection lead determines if additional areas require evaluation, based on the company's compliance history, such as previous inspections, investigations, voluntary disclosures, compliance actions, administrative actions, legal enforcement actions, etc.

c. Each team member must bring the following inspection tools:

(1) Copy of the regulations

(2) Inspection guide (included in Appendix A of this Order)

(3) Forms (inbriefing/outbriefing sheet, witness form, Small Business Information)

(4) Laptop

(5) Evidence certification stamp

(6) Office supplies (note pads, paper clips, stapler, etc.)

d. The inspection lead notifies the C&E Center Manager if additional personnel are needed or if a change in scope (e.g., comprehensive or expanded focus) is necessary.

e. Inspectors must ensure voluntary disclosure issues are addressed, as described in Chapter 4 of this order.

4. Travel Requirements. Each inspector and investigator is responsible for adhering to the following travel requirements:

a. Inspectors and investigators must adhere to the FAA Travel Policy (FAATP), which is available on the FAA's Employee Web site and the Bargaining Unit Contract.

b. Whenever possible, inspectors and investigators will arrive in the inspection city at approximately the same time. All travel and lodging preparations must be confirmed at least one week prior to the inspection, unless precluded by schedule changes.

c. Inspectors and investigators will conserve time and fiscal resources. For instance, inspectors and investigators will lodge near inspection sites, when possible. The FAATP states, "You must exercise the same care in incurring expenses that a prudent person would exercise if traveling on personal business." The Policy further states, "You are responsible for excess costs and any additional expenses that you incur for personal preference or convenience. FAA will not pay for excess costs resulting from circuitous routes, delays, or luxury accommodations or services unnecessary or unjustified in the performance of official business."

d. Travel must be arranged according to the inspection team's work plan. When exceptions occur, the inspector or investigator must notify his/her Manager or Team Coordinator. This notification may occur prior to or during travel.

5. Final Inspection Work Plan. Each inspector must submit a final inspection work plan to the C&E Center Manager, Team Coordinator(s), and secretary/program assistant of his/her Center no later than Wednesday of the week prior to inspections. The work plan will contain businesses to be inspected, along with their POCs and telephone numbers and hotel information. Service agent information will include the name of the employer or contractor associated with them. The current work plan tool is available electronically on the Drug Abatement Division's QMS website.

6. Pre-Inspection Team Meetings. The inspection lead will hold a meeting before the inspection to help ensure a smooth, professional inspection. These meetings must occur prior to arriving at the inspection site. During the pre-inspection team meeting, the inspection lead will:

a. Provide the company's compliance history to all members of the inspection team;

b. Assign one or more of the following inspection areas to each inspection team member: Administrative and Quality Assurance; Collection Site Review; MRO Review; SAP Review; and specific areas for Record Review.

c. Establish his/her responsibility for the inbriefing, outbriefing, and CETS entry; and

d. Confirm each inspection team member's responsibility to inform the inspection lead immediately of any findings of noncompliance and supporting evidence or areas of concern.

7. On-Site Inspection Activities. It is critical, and mandatory under ISO procedures, to ensure that each inspection is conducted according to the Drug Abatement Division's inspection

protocol. During each inspection, the following requirements must be adhered to:

a. Conduct. All division personnel will conduct themselves professionally and must:

(1) Maintain decorum in speech, dress, and behavior;

(2) Treat their team members and company representatives with respect;

(3) Avoid socializing with any individual associated with a company's inspection, including service agents, in accordance with the Ethics Regulations (5 CFR part 2635);

(4) Avoid discussing internal FAA activities (e.g., anticipated changes in policy, procedures, or rulemaking) with companies;

(5) Avoid discussing pending enforcement matters pertaining to current or previous inspections and investigations;

(6) Avoid conversations regarding other operators; and

(7) Bring inspection issues to the attention of the inspection lead.

b. Inbriefing. The inspection lead will conduct the inbriefing with the company and the inspection team members (see inbriefing/outbriefing guide in Figure 2-3).

(1) The inspection lead makes introductions, circulates a sign-in sheet (see meeting attendance list in Figure 2-4), explains the inspection process and distributes the Small Business information (if applicable).

(2) At the conclusion of the inbriefing, the inspection lead should announce that the next step in the process (the Administrative and Quality Assurance Interview) specifically includes the program manager or designated employer representative (DER). The inspection lead may invite others in attendance to leave, if their presence is not necessary.

c. Administrative and Quality Assurance Interview. At the conclusion of the inbriefing, the inspection lead announces the beginning of the interview phase with the company's representative (program manager or DER) regarding the drug and alcohol testing program. To conduct the interview, each inspector must use the inspection guide found in Appendix A, Part 1. All information provided during the interview must be verified during the record review and evidence collection phase of the inspection.

d. Drug and Alcohol Testing Records Review. Records are the most common form of evidence used to verify the statements of the company's representative. As an example, a company may provide the inspection team with a spreadsheet that includes dates of hire, transfer, and pre-employment testing. The inspection team must verify the spreadsheet information by assembling the source documents (personnel action forms, custody and control forms (CCF), etc.) that pertain to each item on the spreadsheet. The inspection team must not request the company to generate a spreadsheet for the purpose of the inspection. The inspection lead should take all documents provided by the company to support the inspection. These records must be maintained as part of the inspection record and in accordance with Appendix F of this Order.

(1) Inspection leads and team members will take part in record review activities and enter their findings in the inspection results section of CETS. Worksheets are available (see New Hire/Transfer Guide in Figure 2-5, Inspection Compliance Issue Guide in Figure 2-6, and Employee Interview Guide in Figure 2-8) to assist inspectors during record review and/or interview phases of the inspection.

(2) Inspectors/investigators are responsible for reviewing, copying, and certifying documents, as assigned by the inspection lead. The inspection lead must ensure each assigned portion of the review process is completed. Each inspector must initial the records review guide in the area of their assignments (see Part 2 of the Inspection Guide in Appendix A) to demonstrate completion. The inspection lead will enter this information into the official inspection record in CETS, and add the copies to the inspection record (in accordance with Appendix F of this Order).

(3) The inspector/investigator certifies a document by noting on the back of each page when, where, and from whom the document was obtained. This can be accomplished with the Certification of Authenticity (see Figure 2-7). Documents should be certified at the inspection site whenever possible.

(4) To the greatest extent possible, all testing records must be reviewed for the time period established by the C&E Center Manager and inspection lead prior to the inspection. Depending on the circumstances, the time periods may include the past two years, since the last inspection, or the last six months.

(5) Records to review and document, if applicable, include the following categories:

(a) *Positive Drug Test and Alcohol Violation Records*. Inspectors/investigators must review all verified positive drug test results and alcohol violation results, except those that have already been investigated by the Special Investigations Branch (AAM-830) or should have been reported to AAM-830. Inspectors/investigators must also review the records that document the employee's removal from a safety-sensitive function. The company has the authority to terminate or rehabilitate the employee prior to his/her return to safety-sensitive functions. If the employee is returned to safety-sensitive functions, the inspection team must review all return-to-duty records. These records may include the SAP reports, SAP credentials, return-to-duty test result, and follow-up test results. If inspectors discover an individual has returned to work without completing the return- to-duty process, the inspector should address the company violation for not ensuring that the individual completed the return-to-duty process prior to allowing the individual to perform safety sensitive functions. Due to Privacy Act implications for all individuals, and even more stringent restrictions for certificate holders subject to the Pilot's Bill of Rights (PBR), inspectors must refrain from discussing an individual's violation. Inspectors should forward a written statement regarding the individual's violation and copies of any documents found to the Special Investigations Branch manager's email address or AAM830@faa.gov.

(b) *Part 67 Medical Certificate Holders*. If the company fails to report a violation involving the misuse of alcohol, or a verified positive test result by a part 67 medical certificate holder to the Federal Air Surgeon (through the Drug Abatement Division), the inspection lead should forward a written statement regarding the violation and copies of any documents found to the Special Investigations Branch manager's email address or AAM830@faa.gov. Inspectors

must not investigate, comment, or discuss the alleged violation with the company or individual.

(c) *Refusal Records*. Inspectors must review all records concerning refusals to submit to testing, including walk-a-ways, adulterations, substitutions, etc., as defined in 49 CFR part 40. However, if the refusal was by an individual who holds a part 61, 63, 65, or 67 certificate, the matter must be referred to the Special Investigations Branch for investigation. Inspectors should forward a written statement regarding the individual's violation and copies of any documents found to the Special Investigations Branch manager's email address or AAM830@faa.gov. The company has the authority to terminate or rehabilitate the employee prior to his/her return to safety-sensitive functions. If the employee is returned to safety-sensitive functions, the inspection team must also review all return-to-duty records. It is important that the Special Investigations Branch Manager be immediately notified about a suspected failure on the part of the company to report a refusal by an airman who holds a part 61, 63, 65 or 67 FAA certificate.

(d) *Return-to-Duty Testing Records*. Return-to-duty tests are conducted prior to returning an employee to a safety-sensitive function after a verified positive drug test, an alcohol misuse violation, or a refusal. The objective of these tests is to ensure that those who have committed such violations are alcohol or drug-free prior to returning to the performance of safety-sensitive functions. All return-to-duty drug tests must be conducted under direct observation. Verify that the DER advises the collection site that a return-to-duty drug test is required and it must be done under direct observation. These tests occur after the SAP reports that the individual has successfully complied with the prescribed education and/or treatment. Inspectors/investigators must conduct a thorough review of these records, including: (1) documentation of the triggering event (drug positive, alcohol misuse violation, or refusal to submit to testing), (2) SAP reports (initial and follow-up evaluations, including the follow-up testing schedule) and qualifications, (3) return-to-duty CCFs/breath alcohol testing forms and verified drug test results/confirmed alcohol test results, (4) evidence that a new airman medical certificate has been issued , when applicable, and (5) documentation that the employee was returned to safety-sensitive functions and placed into the random drug and alcohol testing pool.

(e) *Follow-up Testing Records*. The SAP establishes a written follow-up testing plan after the individual successfully complies with his/her education and/or treatment. The required follow-up tests are conducted after an employee passes the return-to-duty test and has been returned to the performance of safety-sensitive functions. Similar to the return-to-duty testing, the objective of these tests is to ensure that individuals, who have committed violations involving the misuse of alcohol, a verified positive drug test result, or the refusal to submit to a drug or alcohol test, are compliant with the regulations governing the use of alcohol or prohibited drugs. All follow-up drug tests must be conducted under direct observation. Verify that the DER advises the collection site that a follow-up drug test is required and it must be done under direct observation. Inspectors/investigators must conduct a thorough review of these records to ensure the CCFs/breath alcohol testing forms and verified drug test results/confirmed alcohol test results match the prescribed number of tests recommended by the SAP. Keep in mind that if the employee's employment lapses during the follow-up testing plan (e.g., they are transferred to a non safety-sensitive position or furloughed), the "plan" picks back up upon their return to duty. If you are unsure, please contact your C&E Center Manager or the Program Policy Branch Manager for further clarification.

(f) *Pre-employment Testing Records*. Pre-employment testing is directly tied to aviation safety, in that it is the gateway to safety-sensitive positions. Historically, pre-

employment testing has resulted in the highest rate of verified positive results, demonstrating that such tests are effective in detecting illegal drug use. Pre-employment alcohol testing is optional, but if a company orders an alcohol pre-employment test for one potential hire, all other new hires/transfers to safety-sensitive functions must also be pre-employment alcohol tested. Pre-employment testing records could include personnel position descriptions, personnel action forms, payroll records, internal company hiring and transfer reports, CCFs, and MRO reports. In addition to reviewing the records, the inspector/investigator should interview any individual whose records, if questionable, need to clarified or confirmed. Interviews may be the only evidence available to prove a hire/transfer date, or identify other evidence to be gathered, such as maintenance logs, flight logs, or other performance documentation showing the date safety-sensitive functions were performed. Documentation of performance (whether actual or available to perform) would be used to show aggravating circumstances in an impending legal enforcement action.

(g) *Random Testing Records*. Random testing has three purposes: (1) to detect illegal drug use and alcohol misuse; (2) to deter employees from using illegal drugs and misusing alcohol; and (3) to remove employees engaged in such use from the performance of safety-sensitive functions. It is essential for inspectors and investigators to have thorough knowledge of what comprises a random testing program. Appendix C of this order further explores random testing regulations, including minimum annual rate, selection methodology, excusal policies and over- selection, notification and testing procedures, and testing frequency. Records that could be of use when inspecting a company's random testing program include: (1) random drug and alcohol selection lists, (2) a listing of who was, or is, in the random pool during the covered period, (3) documentation that employees in the pool perform safety-sensitive functions (such as maintenance logs, flight logs, or other performance documentation), (4) dates employees were added or deleted, (5) notification procedures, including notifications to out-lying locations, (6) documentation of whether employees proceeded immediately to the collection site after notification of selection, (7) CCFs, (8) verified drug test results, (9) breath alcohol testing forms with the alcohol test results, and (10) verification that the company is satisfying the minimum testing rate that is published in the Federal Register.

(h) *Reasonable Cause/Reasonable Suspicion Testing Records*. Reasonable cause/suspicion testing is critical in the detection of employees reporting for or performing duties while having drugs and/or alcohol in their system. Companies must ensure that supervisors are trained to make a testing determination. Inspectors/investigators must review all reasonable cause/suspicion testing records, including: (1) documentation of the event that led to testing (if available), (2) documentation that the tested employee reported for or performed safety-sensitive duties (such as maintenance logs, flight logs, or other performance documentation), (3) documentation of supervisory training and the material covered, (4) CCFs, (5) verified drug test results, and (6) breath alcohol testing forms with the alcohol test results.

(i) *Post-Accident Testing Records*. A post-accident test occurs when an employee's performance may have contributed to an aviation accident or cannot be completely discounted as a contributing factor to the accident. Inspectors/investigators must review all post-accident testing records including: (1) documentation of the accident, (2) information regarding the circumstances that led to the determination whether or not to test the employee, (3) CCFs, (4) verified drug test results, (5) breath alcohol testing forms with the alcohol test results, (6) documentation on why alcohol testing was not conducted within 2 hours and/or 8 hours of the accident, and (7) documentation that drug testing was conducted within 32 hours of the accident.

(j) *Drug and Alcohol Records Check.* Inspectors/investigators must examine all drug and alcohol records check forms during inspections, e.g., records relating to 49 CFR § 40.25, regarding whether applicants for safety-sensitive functions had a previous positive test result or refusal at another DOT employer during the past two years. This includes reviewing individual resumes and/or job applications of personnel working in safety-sensitive functions to see if the company conducted the required records checks to previous DOT employers. When reviewing a company's requests for drug and alcohol records, inspectors/investigators must ensure that the company has made a good faith effort to obtain the records. Sending the request to a previous employer and not making a good faith effort (which includes an additional attempt) to obtain the information is unacceptable. Furthermore, unless the company has made such a good faith effort to obtain the information, the employee is not permitted to perform a safety-sensitive function after 30 days from the date on which he or she first performed a safety-sensitive function, as described in § 40.25(d).

(k) *Safety Management Systems (SMS) Records.* The Flight Standards Service is responsible for regulatory oversight of part 121 carriers' safety management systems (SMS). The part 121 SMS rule (14 CFR part 5) made no changes to the drug and alcohol testing regulations, so SMS records should have no bearing on a part 121 carrier's drug and alcohol testing program. However, if the company cites its SMS as a reason or factor in an out of compliance item, or if the inspector/investigator believes SMS records may be relevant to a particular out of compliance item, they may be reviewed. In this situation, the inspector/investigator should notify his or her manager and obtain further guidance before taking further action or providing guidance to the carrier.

Inspectors/investigators should make all attempts to interview any individual whose records need to be clarified.

e. Other Elements of an Inspection. In addition to the previous elements, the inspection is divided into the following remaining sections:

(1) *Collection site and personnel*. Before inspecting a collection site as part of a company inspection, the inspection team should first check CETS to see if the site has already had a comprehensive inspection within the previous 90 days. If so, the inspection team need only confirm that the collection site does conduct collections and do breath alcohol tests for that company. If not, or if an issue is discovered during record review at the company, the team should proceed to do a collection site inspection according to Appendix A, Part 3.

(2) *MRO*. Before inspecting an MRO as part of a company inspection, the inspection team should first check CETS to see if the company's MRO has already had a comprehensive inspection within the previous 2 years. If so, the inspection team need only confirm that the MRO does work for that company. If not, or if an issue is discovered during record review at the company, the team should proceed to do an MRO inspection according to Appendix A, Part 4.

(3) *SAP*. If the company has records of return-to-duty and follow-up testing, the inspection team must contact the SAP to conduct an inspection according to Appendix A, Part 5.

f. Service Agent Issues Discovered. If any collector, laboratory, MRO, or SAP issues/discrepancies are discovered, regardless of the company, the inspector/investigator should collect all the evidence and report to the C&E Center Manager. Any egregious

noncompliance discoveries should be reported to the C&E Center Manager, who must enter a Non-compliance Transmittal for the Service Agent. The C&E Center Manager and Program Administration Branch Manager must coordinate to schedule an inspection of the Service Agent. Refer to Appendix B for service agent inspections.

8. Evidence Collection. Evidence collection is the most critical element of the inspection. To prove or disprove compliance by the company, sufficient documentation must be reviewed and gathered. Inspectors/investigators must review all evidence relevant to an alleged finding of noncompliance whether it proves or disproves the suspected noncompliance by the company. Inspectors/investigators should gather all available evidence to support the finding of noncompliance, not just a single instance. This evidence must answer the questions about what happened, who was involved, and where, when, and why it occurred. The Best Evidence Checklist tool (available on the Drug Abatement Division's (AAM-800) QMS Web site) provides guidance to inspectors/investigators when collecting evidence. When using this tool, inspectors/investigators must consider the type of company and gather the evidence necessary to establish the finding of noncompliance for that type of company.

The following describes different types of evidence and how each type should be handled according to Order 2150.3, as amended:

a. Physical evidence. Physical evidence consists of tangible objects, such as specimen collection materials or computer software programs relating to random testing. Inspectors/investigators must exercise care in handling physical evidence so that damage, loss, or alteration does not occur.

b. Witness interviews. Witness interviews may be used to prove noncompliance and may be helpful in leading the inspector/investigator to other people who have direct knowledge or documentation of the issue.

(1) When possible, interview all witnesses who may be aware of a noncompliance issue.

(2) Witness accounts should be written and signed by the author, who may be the witness or the inspector/investigator. Witnesses should be informed that they are not under oath.

(3) The interview must be conducted in a professional manner with consideration for the following (see Employee Interview Guide in Figure 2-8 and Witness Statement Form in Figure 2-10):

(a) Plan the interview and questions in advance.

(b) Be attentive and take notes.

(c) Maintain control of the interview.

(d) Ask direct, relevant, and open-ended questions.

(e) Request a signed and dated statement.

(4) Inspectors and investigators will prepare a record of interview when outlining the interview/conversation conducted with witnesses or alleged violators. (Note: The record of interview job aid is located in Appendix A (Figure A-3) of FAA Order 2150.3, as amended.) It should only state what the witness provided and it must not include the inspector/investigator's personal views and/or opinions. A record of interview is necessary if a witness declines to provide a statement. Inspectors/investigators are encouraged to try to obtain witness statements that are written, signed, and dated by the interviewee. If the interviewee is unwilling to write his or her own statement, the inspector/investigator should write the interviewee's statement and then ask the interviewee to review it for accuracy and sign and date it. If the interviewee is unwilling to do any of the above, the inspector/investigator should write the interviewee's statement as an inspector/investigator statement and ask the interviewee to review the statement to ensure its accuracy. In the last circumstance, the inspector/investigator should document that the interviewee either affirmed the accuracy of the statement or declined to do so and that the interviewee refused to sign the statement. (For more information concerning witness interviews and statements, see FAA Order 2150.3, as amended, chap. 4, para. 10.c. (2) - (9).)

(5) Inspector/investigator statements (see Record of Interview in Figure 2-10) are used to document findings that are not available in witness statements, technical publications, logbooks, and manuals, etc. They are also used to document a finding of noncompliance that is observed by the inspector/investigator or to capture an interview when a witness is unwilling to sign a record of interview. Inspector/investigator statements must include the date, time, location, and contact information of those present. They must be personally signed and dated by the inspector/investigator and must not include his/her personal views and/or opinions.

9. Documentation of Inspection Results. In preparation for the outbriefing, each inspection lead will, as soon as possible, enter his/her documentation of the inspection results into CETS. The following documentation must be entered into CETS in full detail and according to current guidance in the System Rules for CETS Data Entry:

a. Update of Company Profile. Any new information concerning the company, such as additional locations, company representatives, email address, service agents, etc., must be added to its profile.

b. Outcome of Areas Reviewed and Discovered Issues. The results of an inspection should be noted with the following:

(1) Findings of noncompliance are noted when it is established that an apparent noncompliance of the regulations occurred. It is not sufficient to document only a few findings of noncompliance to show a pattern. All discovered issues must be documented, including issues that are stale. For example, if one regulatory item was out of compliance on multiple occasions, then each occasion must be listed. Documentation of each finding of noncompliance must include a full description of what happened, who was involved, where and when it occurred, and the root cause of the event (e.g., why it occurred).

(2) Concerns are noted when there are issues discovered that are not findings of noncompliance, but may lead to noncompliance if the company and/or service agent fails to resolve the issue. For example, if a collector has never dealt with a shy bladder situation, he/she may be asked to explain the shy bladder procedures as described in 49 CFR § 40.193. If the collector is unfamiliar with these procedures, this will be noted as an area of concern. It is important that the inspection lead educate the collector to the proper shy bladder procedures.

(3) Open items are noted when the issue cannot be resolved without clarification from management, or the team cannot agree on a specific item during the inspection. These items are revisited after a determination is made in coordination with the C&E Center Manager and the inspection lead.

10. Inspection Conclusion. The inspection lead will meet with the inspection team to assure that all applicable items on the inspection guide were covered and appropriate documentation was gathered, in accordance with this chapter**.** Inspectors must gather sufficient documentation to either demonstrate compliance or support the finding of noncompliance.

At this time the team will review and agree on all findings of noncompliance, areas of concern, or open items. If there is disagreement between the team on a particular item(s), the inspection lead must inform the company at the outbriefing that the item(s) will be left open and addressed later. The inspection lead may document the inspection results in CETS prior to the outbriefing, if time permits.

a. Outbriefing. The inspection lead is responsible for the outbriefing (see the Inbriefing/Outbriefing Guide in Figure 2-3).

(1) All members of the inspection team should attend.

(2) The inspection lead circulates the sign-in sheet for those individuals who were not part of the inbriefing (see Meeting Attendance List in Figure 2-4).

(3) If the inspection resulted in no findings of noncompliance, the inspection lead should advise the company representative that no further documentation will be received.

(4) When an inspection results in findings of noncompliance and/or areas of concern, the inspection lead must clearly and briefly identify the items discovered during the inspection. Do not linger on the issues, but explain them and obtain the company's agreement to initiate immediate corrective action. Advise the company representative that he or she will receive a Report of Inspection letter documenting the results of the inspection and requesting written corrective action for each finding of noncompliance. If the company would like to receive the letter via electronic mail in addition to United States Postal Service (USPS) mail, certified return receipt, you should verify the email address for the President/CEO and the DER.

(5) If there are unclear items that need to be resolved with the company that were not clarified during the actual inspection, the inspection lead should do this during the outbriefing. Similarly, the inspection lead should also use this opportunity to clarify any misunderstandings about the regulations and help to educate the company. While we are responsible for training and educating the company representative, that does not remove the finding of noncompliance. Remember not to linger on the topic, but be clear and concise.

(6) Inspectors/investigators must not display any disagreement on the issues or discuss how the findings of noncompliance will be addressed (e.g., with compliance or enforcement action).

(7) The inspection team should not tell the company representative how to respond to the findings of noncompliance. It is up to the company to decide on how to take corrective action; however, it is important to make it clear that correction action is required to address all findings of noncompliance.

b. Post-outbriefing. Following the outbriefing, the inspection team should gather all records and materials and leave the company.

(1) Do not leave anything behind, including papers, folders, extraneous copies of documents. If the company created reports or documents to support your inspection, take them with you to include in the inspection file.

(2) It is not appropriate to socialize with company representatives or service agents, as this might give the appearance of a conflict of interest.

11. Post-Inspection Activities.

a. Post-inspection inspection team meeting. The inspection lead must hold a post-inspection meeting with the inspectors/investigators to discuss lessons learned and to ascertain that all documentation has been gathered and certified. If the outbriefing report has already been entered into CETS, the inspection lead should have each inspector/investigator approve and initial the outbriefing report.

b. CETS. No later than seven (7) in-office working days of returning from the inspection or within the deadline assigned by the Team Coordinator and/or C&E Center Manager, each inspection lead must ensure that the information gathered is entered into CETS thoroughly and accurately, following the guidance described in the System Rules for CETS Data Entry. Specifically:

(1) Activity narrative in inspection profile;

(2) Resources tab (i.e., date and time of inspection);

(3) Updates to company information (i.e., contacts, email address, locations, etc.);

(4) Identifying the findings of noncompliance, areas of concern, and undecided or open items;

(5) Description of each finding of noncompliance item;

(6) Analysis of the root cause of each finding of noncompliance (e.g., why the noncompliance occurred);

(7) Evidence collected;

(8) Programs tab (i.e., drug and alcohol program self-administered or C/TPA and random protocol information);

(9) Interviews (all interviewees identified and a synopsis of their statements); and

(10) When an inspection results in no findings of noncompliance, this is indicated in CETS.

c. Inspection reporting and correspondence. Inspection reports and correspondence are prepared by the inspection lead using CETS (see Inspection Correspondence Flowchart in Figure 2- 11).

(1) *Outbriefing Report.* The inspection lead is responsible for entering the findings of noncompliance in CETS and generating the Outbriefing report. The inspection lead must obtain concurrence with the inspection team on the Outbriefing report.

(2) *Report of Inspection (ROI) Letter*. Using the letter template contained in CETS, the inspection lead is responsible for preparing a Report of Inspection (ROI) letter. The ROI describes all findings of noncompliance discovered during the inspection. The inspection lead must provide the outbriefing report, evidence to support the findings, and a draft ROI letter to the Team Coordinator and/or C&E Center Manager within seven (7) in-office working days of returning from the inspection or within the deadline assigned by the Team Coordinator and/or C&E Center Manager. The ROI letter and outbriefing report are either returned to the inspection lead for changes or approved. If the correspondence is returned to the inspection lead for changes, the review is documented under the Milestones Section in CETS and the process begins again. After the Team Coordinator and/or C&E Center Manager approve the ROI letter, the inspector must document and enter the final sign-off into CETS, in accordance with the Team Coordinator/C&E Center Manager Standards. The ROI letter must be sent to the company through United States Postal Service (USPS) mail, certified return receipt. The inspection lead may send an ADOBE pdf copy of the signed letter via electronic mail to the President/CEO and/or Designated Employer Representative and copy the Team Coordinator and C&E Center Manager.

d. Risk Analysis. Upon receiving the response to the ROI, the inspection lead is responsible for entering company information and inspection data into Drug Abatement's Automated Risk Calculation (ARC) system, and generating a risk analysis for each finding of noncompliance. The ARC system uses a company's compliance history, the inspection finding, evidence of noncompliance gathered during the inspection, the company's response to immediate corrective action, system-wide data, and other relevant information to calculate the risk level, based on FAA's safety risk management (SRM) principles as identified in Order 8040.4, as amended. For matters that are not determined an unacceptable risk to safety, the ARC incorporates guidelines, principles, and factors identified in the Drug Abatement Strategic Compliance Monitoring Plan, FAA's Compliance and Enforcement Order 2150.3, as amended, and the FAA Compliance Philosophy (Order 8000.373). The following are examples of factors used in the risk analysis:

- Corrective action and likelihood of the consequences reoccurring;
- Type of behavior that resulted in noncompliance (e.g., intentional or reckless);
- Compliance history (is it a repeat finding of noncompliance);
- Potential severity of the consequence of noncompliance;

If the company did not respond to the ROI letter, the inspector/investigator should contact the company and encourage a response to provide corrective action. If the company

continues not to respond or provide corrective action, this might, depending on the circumstances, indicate an uncooperative attitude toward compliance or an unwillingness/inability to take appropriate corrective action. A failure to respond to the ROI letter is one factor that should be taken into account as part of the risk analysis.

Taking these and other factors into consideration, the system provides the recommended action (compliance and/or administrative or legal) for each finding of noncompliance. If the inspection evidence will not support compliance, administrative, or legal enforcement action, the inspection lead must recommend that no action be taken.

The inspection lead should discuss the recommended action with the Team Coordinator or C&E Center Manager. If the inspection lead proposes deviating from the action recommended by the final ARC analysis due to mitigating factors, aggravating factors, or other information (e.g., company demographics such as size, type and/or operational experience), he/she should discuss the proposed deviation with his/her Team Coordinator or C&E Center Manager. Deviations are approved by the C&E Center Manager and elevated to the Division Manager when there is a difference of opinion.

e. Types of Recommended Action. According to Order 2150.3, as amended, the inspector or investigator has three options for addressing noncompliance.

(1) Compliance Action. Compliance action may be appropriate when the inspection lead determines that future compliance can reasonably be ensured through compliance action alone, the company displays a constructive attitude that indicates a willingness to comply, and the ARC analysis confirms that the noncompliance does not represent a high safety risk. Compliance action is not appropriate if the conduct that caused the noncompliance disclosed a lack of, or reasonable basis to question, the company's qualifications. Compliance action is not appropriate if the criteria for legal action in Order 2150.3, as amended, are met, or when the company's record shows past or repeated noncompliance, especially when such noncompliance is similar or related to the current noncompliance. Compliance action may not be appropriate if the company has failed to respond to the ROI letter and/or did not provide acceptable corrective action.

The inspection lead determines whether compliance action may be appropriate by reviewing the facts and circumstances of the noncompliance and completing the final ARC analysis. When the final ARC analysis supports compliance action as the appropriate action for one or more findings of noncompliance, the inspection lead determines whether the company's corrective actions during the inspection or provided in response to the ROI letter are acceptable to resolve the issue and ensure the noncompliance does not reoccur. Compliance actions are not assigned an Enforcement Investigative Report (EIR) file number or entered into the Enforcement Information System (EIS). The compliance actions are maintained in CETS.

(2) Administrative Enforcement Action. Administrative enforcement action may be appropriate when the criteria for legal action in Order 2150.3, as amended, are not met, and the inspection lead reasonably and in good faith determines that compliance action will not remediate the noncompliance and ensure future compliance. The inspection lead makes this determination by reviewing the facts and circumstances of the noncompliance and completing the final ARC analysis. When administrative action is decided, CETS will assign an EIR File Number.

(3) Legal Enforcement Action. Legal enforcement action is appropriate when the criteria in Order 2150.3, as amended, are met or in circumstances where noncompliance represents an unacceptable risk to safety, as identified by Drug Abatement in published guidance based on analysis of system-wide enforcement data. Legal enforcement action may also be appropriate when the company shows a reluctance to take compliance action, or there is a pattern of repeated noncompliance that indicates an inability or unwillingness to comply with regulatory requirements. The inspection lead makes this determination by reviewing the facts and circumstances of the noncompliance and completing the final ARC analysis. When the legal action criteria and/or ARC analysis support legal action as the appropriate action for an apparent violation, the inspection lead should consult with the Team Coordinator and/or C&E Center Manager before preparing a legal enforcement report. When legal action is decided, CETS will assign an EIS File Number.

f. Action Letter (AL). The inspection lead prepares an Action Letter, using the letter template contained in CETS, after receiving the company's response to the ROI Letter and completing the final ARC analysis. The Action Letter notifies the company which findings of noncompliance were resolved by the corrective action provided in the company's response to the ROI letter, and which findings of noncompliance will be referred for enforcement action (if applicable). The inspection lead bases these determinations on the inspection results, the company's response to the ROI letter, and the completed ARC analysis. If the response to the ROI indicates there is no finding, the Action Letter should indicate the finding is no longer an issue and may be considered closed. The inspection lead must provide the draft Action Letter to the Team Coordinator and/or C&E Center Manager, which is then either returned to the inspection lead for changes or approved. If the letter is returned to the inspection lead for changes, the review is documented under the Milestones Section in CETS and the process begins again. After the Team Coordinator and/or C&E Center Manager approve the Action Letter, the inspector must document and enter the final sign-off into CETS, in accordance with the Team Coordinator/C&E Center Manager Standards. The approved Action Letter must be sent to the company within 120 calendar days from the date of the inspection or within the deadline assigned by the Team Coordinator or C&E Center Manager. The Action Letter is sent through regular United States Postal Service (USPS) mail. Electronic mail is not authorized. If enforcement action (administrative and/or legal) is included in the Action letter, the inspection lead prepares the 2150-5 form, except for the final action, and enters it into the EIS through CETS.

If the response to the ROI and evidence indicates there is no longer a finding of noncompliance for one or more issues, the inspection lead will note this in the AL and indicate that no further action is necessary pertaining to the issue(s). Separate correspondence is not necessary.

g. Legal Enforcement Action. All follow-up activities are entered into CETS. Using CETS, the inspection lead must generate the legal case and provide it to the Team Coordinator and/or C&E Center Manager within 75 calendar days from the date of inspection or within the deadline assigned by the Team Coordinator or C&E Center Manager. The legal enforcement report is either returned to the inspection lead for changes or approved. If it is returned for changes, the review is documented under the Milestones Section in CETS and the process begins again. After the Team Coordinator and/or C&E Center Manager approve the legal enforcement report, he/she must enter the final sign-off into CETS in accordance with Team Coordinator/C&E Center Manager Standards. Once the legal enforcement report is approved, the Team Coordinator or C&E Center Manager enters into CETS the date that it was sent to the

Program Administration Branch (AAM-810). Through all steps, each person who reviews the file (i.e., Inspection Lead or Investigator, Team Coordinator, or C&E Center Manager) must sign and date the ARC analysis. A complete, tabbed copy of the legal enforcement action must be retained in the field office and separate from the inspection file. The inspection lead prepares the 2150-5 form, including the legal action, and sends it to EIS through CETS.

Office of the Chief Counsel or Regional Counsel will close out an issue with no action when there is insufficient evidence to prove the finding of noncompliance or apparent violation or the issue is untimely under applicable time limitation for legal enforcement actions (see FAA Order 2150.3, as amended, chap. 4, para. 5 and 6). Either situation may result in the issuance of a no action letter. If Counsel returns the case file, the Team Coordinator or C&E Center Manager will provide further instructions.

The FAA's Compliance and Enforcement Program Order 2150.3, as amended, remains the source for inspection and investigation reporting and processing of enforcement activities. Please ensure that you continue to follow the requirements of Order 1600.75 involving "For Official Use Only" (FOUO) designations (see sample FOUO cover sheet in Figure 2-12), and the current Drug and Alcohol Compliance and Enforcement Inspector Handbook, Order 9120.1, as amended. The FOUO cover sheet template is available from the Drug Abatement Division (AAM-800) QMS Web Site and should be placed on top of the Section A tab and behind the last item of proof. All legal enforcement report folders must be prepared using a regular size brown/manila folder. There are two exceptions to this rule: 1) for cases against an individual, the folder must be red, and 2) for cases that are about to go stale, the folder must be bright blue. The top of the folder cover must include a label containing the EIS file number, name of the company (or individual), date of the violation, and the date that the violation becomes stale.

h. Administrative Action. When the final ARC analysis supports administrative action as the appropriate enforcement action for an out of compliance item or items, a letter of correction (LOC) or warning notice (WN) must be prepared for those items using the letter template contained in CETS. An LOC serves the same purpose as a WN, except the LOC is used when there is agreement with the company that corrective action acceptable to the FAA has been taken, or will be taken, within a reasonable time. The inspection lead must provide a draft of the LOC/WN to the Team Coordinator and/or C&E Center Manager within 75 calendar days from the date of inspection or within the deadline assigned by the Team Coordinator or C&E Center Manager. The LOC/WN is either returned to the inspection lead for changes or approved. If it is returned for changes, the review is documented under the Milestones Section in CETS and the process begins again. After the Team Coordinator and/or C&E Center Manager approve the LOC/WN, he/she must enter the final sign-off into CETS, submit the 2150-5 to EIS, and print and sign the 2150-5 in accordance with Team Coordinator/C&E Center Manager Standards. The LOC/WN is sent to the company through USPS mail within 120 calendar days from the date of inspection or within the deadline assigned by the Team Coordinator or C&E Center Manager. Electronic mail is not authorized. The inspection lead prepares the final assembled inspection file for archiving. Through all steps, each person who reviews the file (i.e., Inspection Lead or Investigator, Team Coordinator or Center Manager) must sign and date the final ARC analysis.

i. Inspection Follow-Up Documentation. The inspection lead ensures that all follow-up activities are entered into CETS. He/she must also ensure that any follow-up information, such as documentation of additional corrective action by the company, and incoming and outgoing communication, is obtained and documented in CETS.

j. Inspection File Documentation. The final step in the inspection process is for the inspection lead to compile the inspection file documentation according to Appendix F.

Figure 2-1. Inspection Schedule Sample

This document is available electronically on our Drug Abatement Division (AAM-800) QMS Web Site.

This sample should be used for multiple day inspections.

Inspection Schedule*

Day 1
November 4, 2013

FAA INSPECTION LEAD: John King, Phone Number: (202) 355-6000

Company Name: One Twenty One Airways, Inc.

Company POC: Brian Smith, Phone Number: (703) 111-2222

Time	Activity	FAA Staff	Company Staff
1:00-1:45 PM	Inbrief	Lead: J. King	Brian Smith and other company representatives as determined by the company.
1:50-3:00 PM	Q & A	Lead: J. King	
3:10 –4:45 PM	Review of Records	Lead: J. King	
4:45-5:00PM	Wrap up	Lead: J. King	

Figure 2-1. Inspection Schedule Sample (cont'd)

Inspection Schedule

Day 2
November 5, 2013

FAA INSPECTION LEAD: John King, Phone Number: (202) 355-6000

Company Name: One Twenty One Airways, Inc.

Company POC: Brian Smith, Phone Number: (703) 111-2222

Time	Activity	FAA Staff	Company Staff
8:30-10:45 AM	Inspect Collection Site	Lead: J. King	ABC Collections, Ms. Lee
11:00- 12:30 PM	Inspect MRO	Lead: B. Queen	Dr. Roberts
12:30-1:30 PM	Lunch		
1:30-2:30 PM	Inspect MRO	Lead: B. Queen	
2:45-4:45 PM	Inspect SAP	Lead: R. Knight	Larry Esquire
4:45-5:00 PM	Wrap Up	Lead: J. King	

Figure 2-1. Inspection Schedule Sample (cont'd)

Inspection Schedule

Day 3-4
November 6-7, 2013

FAA INSPECTION LEAD: John King, Phone Number: (202) 355-6000

Company Name: One Twenty One Airways, Inc.

Company POC: Brian Smith, Phone Number: (703) 111-2222

Time	Activity	FAA Staff	Company Staff
8:30-12:30PM	Review of Records	Lead: J. King	Brian Smith and other company representatives as determined by the company.
12:30 –1:30PM	Lunch		
1:30 – 4:45PM	Review of Records	Lead: J. King	
4:45-5:00PM	Wrap up	Lead: J. King	

Figure 2-1. Inspection Schedule Sample (cont'd)

Inspection Schedule

Day 5
November 8, 2013

FAA INSPECTION LEAD: John King, Phone Number: (202) 355-6000

Company Name: One Twenty One Airways, Inc.

Company POC: Brian Smith, Phone Number: (703) 111-2222

Time	Activity	FAA Staff	Company Staff
8:30-11:30PM	Review of Records	Lead: J. King	Brian Smith and other company representatives as determined by the company.
11:30 –12:30PM	Outbriefing	Lead: J. King	

Figure 2-2. Inspection Process Guide

This document is available electronically on our Drug Abatement Division (AAM-800) QMS Web Site.

Pre-Inspection

___ Confirm date of inspection and logistical arrangements with company.

___ Ensure documentation is received from company.

___ Research enforcement history.

___ Provide history to team.

___ Notify C&E Center Manager if additional resources are needed.

___ Provide travel and lodging information to team.

___ Ensure that appropriate management representatives will be available to discuss:

- ___ Company Administrative and Quality Assurance Activities
- ___ Drug Testing and Alcohol Information, Training, and Referral
- ___ Recordkeeping and Reporting
- ___ Specimen Collection
- ___ Breath Alcohol Testing Procedures
- ___ Medical Review Officer Activities
- ___ Substance Abuse Professional Activities

___ Ensure relevant documents will be available.

___ Complete inspection plan and assign areas of responsibility to team members.

___ Submit completed work plan to C&E Center Manager and Team Coordinator(s).

Inspection

___ Conduct initial team meeting.

___ Coordinate inspection team members' activities during the inspection.

___ Conduct inspection using the Inspection Lead Guide.

___ Conduct review meetings with team members during inspection and prior to outbriefing.

___ Contact C&E Center Manager if team is undecided about issues during the review process.

___ Interview safety-sensitive employees, if possible.

___ Ensure that all evidence is gathered, verified, & certified during the on-site inspection.

___ Document findings in CETS (if possible).

___ Conduct final team meeting to discuss good points, problem areas, and lessons learned.

Post-Inspection

___ Enter inspection activity and follow-up actions in CETS (including email address).

___ Team members concur.

___ Complete ARC analysis.

___ Forward documentation to C&E Center Manager/Team Coordinator for final review and approval.

___ Send correspondence to company as appropriate and track corrective actions.

___ Update CETS as activities occur.

___ Prepare and process compliance and/or enforcement (administrative or legal) action.

___Close out or complete CETS record.

___Prepare inspection file.

Figure 2-3. Inbriefing/Outbriefing Guide

This document is available electronically on our Drug Abatement Division (AAM-800) QMS Web Site.

Inbriefing

_____ Introduce team members to company representatives and circulate a sign-in sheet.

_____ Explain the purpose and scope of the inspection.

_____ Review the inspection schedule.

_____ Confirm company POCs, email addresses, C/TPAs and document/record locations.

_____ Inquire about availability of restroom location, copier use and meeting room.

_____ Describe the outbriefing that is to be held at the end of the inspection.

_____ Distribute Small Business Notice, if applicable.

_____ Advise end of inbriefing and allow opportunity for non-participants to leave.

Outbriefing

_____ Thank company for cooperation and assistance, as applicable, and circulate the sign-in sheet.

_____ Inspection lead may request that company hold questions and comments until end of briefing.

_____ If there are no findings of noncompliance, advise company that this concludes the inspection and there will be no further correspondence.

_____ Review scope of inspection and activities conducted and state that there will be a written follow-up to the inspection. Describe review process, but do not discuss possible enforcement.

_____ Describe the findings of noncompliance with the regulations and require immediate corrective action.

_____ Utilize this opportunity to provide training and education on the drug and alcohol testing regulations and the resources available (e.g., web site and email) for additional questions.

_____ Review any open items, if applicable.

_____ State areas of concern, if applicable.

Close inspection and depart facility immediately.
Do not leave any written inspection materials or evidence behind.

Figure 2-4. Meeting Attendance List

This document is available electronically on our Drug Abatement Division (AAM-800) QMS Web Site.

MEETING ATTENDANCE LIST

Company:_____ Date: _____

Name	Title/Organization	Telephone Number	Email Address	Attendance
				☐ In briefing ☐ Out briefing
				☐ In briefing ☐ Out briefing
				☐ In briefing ☐ Out briefing
				☐ In briefing ☐ Out briefing
				☐ In briefing ☐ Out briefing
				☐ In briefing ☐ Out briefing
				☐ In briefing ☐ Out briefing
				☐ In briefing ☐ Out briefing

Figure 2-5. New Hire/Transfer Guide

This document is available electronically on our Drug Abatement Division (AAM-800) QMS Web Site.

The following guide may be used as a tool during the pre-employment record review portion of the inspection/investigation. This document is only to help organize your results of the inspection and is not meant to be evidence to support a violation.

At the conclusion of the inspection, the inspection lead must ensure that all inspection results are captured in CETS. At that time, this document must be destroyed and not maintained as part of the record. The CETS record is the official documentation of the inspection.

Employee Name and Number	Job Category	SS Hire/ Transfer Date	Date of Collection	Date Result Verified	First Performed Date	§40.25 and §40.25j Completed	Employee Training Documented	AMPP Documented Distributed	EAP Distributed

Figure 2-6. Inspection Finding of Noncompliance Issue Guide

This document is available electronically on our Drug Abatement Division (AAM-800) QMS Web Site.

The following guide may be used while onsite at the inspection to help document findings of noncompliance issues discovered during your review of the records or following an interview with a witness.

At the conclusion of the inspection, the inspection lead must ensure that all inspection results are captured in CETS. At that time, these documents must be destroyed and not maintained as part of the record. The CETS record is the official documentation of the inspection.

Regulation Citation(s): _____

CETS Reference Checklist Item Number(s): _____
Brief Statement of Finding of Noncompliance: _____

Root Cause of the Noncompliance: _____

Evidence Collected: _____

Figure 2-7. Sample Certifications of Authenticity

1. Documents copied from originals held by individuals or companies:

I certify that this is a true and accurate copy of the original {insert description of document} held by {insert name of source}.

_____
{Name of FAA Investigative Personnel}

2. Documents secured by FAA Investigative Personnel from sources outside the FAA upon request:

I certify that this copy of {insert description of document} was provided to me upon request by {insert name of source}.

_____
{Name of FAA Investigative Personnel}

3. Photographs either taken or secured by FAA Investigative Personnel:

I certify that this photograph fairly and accurately depicts {describe the image of the photograph} on {insert date and time it was taken}.

_____
{Name of FAA Investigative Personnel}

4. Faxed documents from sources outside the FAA:

I certify that this copy of {insert description of document} was received by fax {insert name of source}.

_____
{Name of FAA Investigative Personnel}

Figure 2-8. Employee Interview Guide

This document is available electronically on our Drug Abatement Division (AAM-800) QMS Web Site.

Company_____ Date/Time_____

Interviewer Name_____

Employee Name_____

Employee Job Title_____

Length of Service with Company_____ Total Experience_____

This interview is voluntary. Its purpose is to help evaluate the drug and alcohol testing program mandated by the FAA.

What type of work do you do and when were you hired? Explain your duties/assignments.

Are you a supervisor?

When did you first perform safety-sensitive duties?

Have you submitted to any drug tests? When?

If a pre-employment test is not mentioned, ask:

Did you have a pre-employment drug test? When?

If the employee cannot recall when he/she received a pre-employment test, ask:

Was this before or after you first performed safety-sensitive functions?

Do you know how your name was selected for a drug test or tests after you were hired?

After you were notified of your selection, when did you have to appear for your test?

Have you submitted to any alcohol tests? When?

After you were notified of your selection, when did you have to appear for your test?

Have you received training regarding the drug and alcohol testing program of your company?

What are some of the effects and consequences of drug use on personal health, safety, and the work environment?

Figure 2-8. Employee Interview Guide (cont'd)

Can you name some of the behavioral indicators that may indicate drug use?

What are some of the effects and consequences of abusing alcohol on personal health, safety, and the work environment?

Can you name some of the behavioral indicators that may indicate alcohol abuse?

Have you received any informational materials on the drug and alcohol testing program? If so, what types of materials have you received?

Have you received a community service hotline telephone number for employee assistance? If so, when and where did you receive the number?

Have you received a copy of your company's policy regarding drug use in the workplace?

(When interviewing Supervisors Only)

Have you received training concerning reasonable cause and reasonable suspicion testing?
Describe the training you received.
When did you receive this training?
How often have you received training?
When was the last time you received this training?
Did the training include specific contemporary physical, behavioral, and performance indicators of drug and alcohol use?
How long was the training?
(*If necessary, ask:*) Was the training at least 60 minutes in length for both the alcohol and drug portions?
Have you ever made a determination to conduct reasonable cause/suspicion testing? If so, explain.

Do you have any general comments, concerns, or complaints regarding the drug and alcohol testing program?

Figure 2-9. Witness Statement Form

This document is available electronically on our Drug Abatement Division (AAM-800) QMS Web Site.

Inspection Witness Statement Form

(PRINT)

Name of Company or C/TPA:_____

Witness Name:_____ Date:_____

Mailing Address:_____ Time:_____

Telephone:(Home)_____(Work)_____Place:_____

Inspector's/Investigator's Name:_____

Others Present:_____

Narrative:

_____

_____

_____

_____

_____

_____

_____

_____

_____

_____

_____

_____

Witness Signature:_____Date:_____

Signature(s) of others present_____,_____,

_____

Inspector/Investigator Signature:_____ Page____of____

Figure 2-9. Witness Statement Form (cont'd)

Witness Statement Form (cont'd)

(PRINT)

Witness Name: _____
Date:_____

Narrative:

_____
_____
_____
_____
_____
_____
_____
_____
_____
_____
_____
_____
_____
_____

Witness Signature:_____Date: _____

Inspector/Investigator Signature:_____ Page_____of_____

Figure 2-10 – Record of Interview

This document is available electronically on our Drug Abatement Division (AAM-800) QMS Web Site.

Record of Interview

Federal Aviation Administration
Office of Aerospace Medicine

EIR#

INTERVIEW SUBJECT

Name:	Telephone:
Position:	Address:
Date/Time of Interview:	

INTERVIEW NARRATIVE

FOR OFFICIAL USE ONLY
Public availability to be determined under 5 USC 552

Inspection Correspondence Flowchart

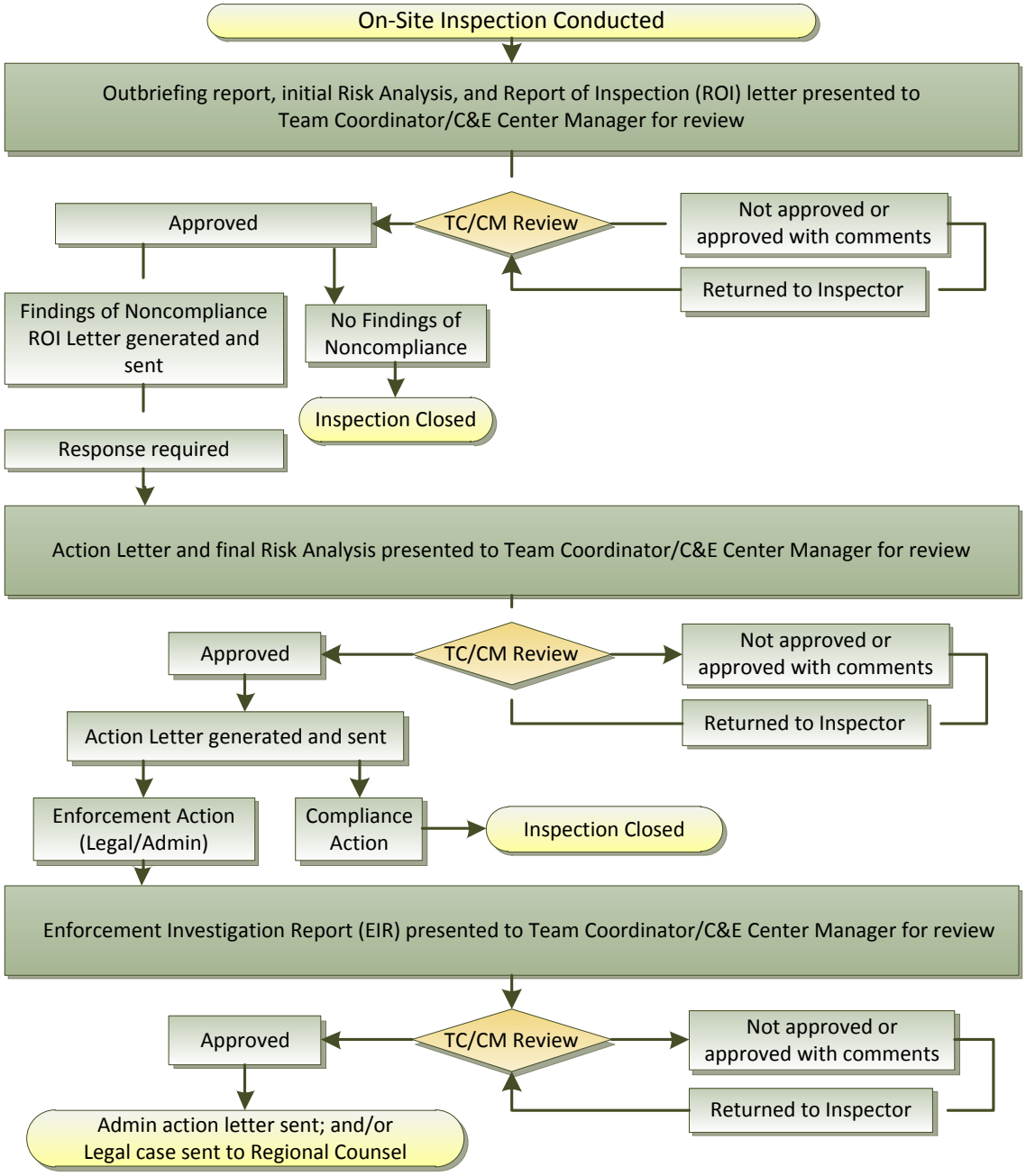


Figure 2-12. Sample FOUO Coversheet

This document is available electronically on our Drug Abatement Division (AAM-800) QMS Web Site.

This document may be duplicated and used with black and white text

Chapter 3. Investigations

1. General. All Drug Abatement Division activities involve elements of an investigation in which the facts of an issue are examined. The majority of these investigations pertain to alleged violations of the drug and alcohol testing regulations by companies or individuals who perform safety-sensitive functions. The purpose of these investigations is to determine whether a finding of noncompliance or apparent violation exists and warrants the need for compliance action, legal action (i.e., civil penalty or certificate action) or administrative action (i.e., WN or LOC) to ensure future compliance with the drug and alcohol testing regulations.

a. Each inspector/investigator is responsible for reporting all alleged violations to his/her manager. Based on the source and subject of the alleged violation, the investigation will be conducted by an inspector in the field or an investigator in the Special Investigations Branch (AAM-830).

b. Investigations are categorized as investigations of a company (i.e., employers, contractors, service agents) or investigations of individuals who perform safety-sensitive functions. This chapter will describe the sources of allegations, categories of investigations, and the Branch or C&E Center responsible for the investigation.

2. Sources of Allegations. An allegation may come from any of the following sources: FAA Aviation Safety Hotline, internal noncompliance transmittals (NCT), Congressional inquiries, refusal reports, part 67 reports, and complaints. Under each company's profile in CETS, there is a tab titled "Special Issues." This tab allows for the documentation of the source and allows for the initiation of an investigation, inspection, or a decision not to conduct a further inquiry. If an investigation is necessary, it will be initiated under the company's activity record.

a. FAA Hotline. These allegations of safety concerns are received through the FAA's Hotline office and directed to the Drug Abatement Division for action and may involve individuals and/or companies. Issues involving individuals are referred to AAM-830 for investigation. However, some issues involving company procedures may be assigned to the C&E Centers for inspection or investigation.

b. NCT. An NCT is an internal process that inspectors, investigators, managers, or anyone within the Drug Abatement Division may use to document issues that emerge during an inspection, an investigation, or through the course of normal duties. These issues typically involve possible noncompliance by another company or an individual. The majority of these will be handled by the C&E Centers, unless circumstances require action by AAM-830.

c. Congressional Inquiries. Congressional inquiries are correspondence requesting information regarding constituents. Congressional inquiries are referred to the Program Policy Branch (AAM-820) for action, but may be coordinated with the other Branches and the C&E Centers where necessary.

d. Refusal Reports. A company is required to report all refusals to submit to drug or alcohol testing by an individual who holds an airman certificate issued in accordance with 14 CFR parts 61, 63, 65 or 67. A company may report refusals to submit by any employee. These cases are investigated by AAM-830.

e. Verified Positive Drug Test Results/Alcohol Misuse Violations. A company is required to report all verified positive drug test results and confirmed alcohol misuse violations by any individual who holds a medical certificate issued in accordance with 14 CFR part 67. A company may report all verified positive drug test results and confirmed alcohol misuse violations by any employee. These cases are investigated by AAM-830.

f. Complaints. Complaints are the result of an individual or company requesting an investigation of an event, or information received from other FAA sources (e.g., Flight Standards Service). These allegations may be against a company or individual. These issues are referred to AAM-830 for review. AAM-830 may conduct the investigation and coordinate with the C&E Centers for assistance where necessary. It is possible that the issue may be referred to the C&E Center for inspection or investigation via a Non-compliance Transmittal Form.

3. Investigations of a Company. Investigations of a company are initiated by a Special Issue in CETS and must be initiated with a Letter of Investigation (LOI) that does not include a File Number. The response to the LOI may result in compliance and/or enforcement action depending on the ARC analysis and require an Action Letter, as described in Chapter 2 of this order. An on-site investigation at the company or one of its locations may or may not be necessary and a Branch or C&E Center Manager makes this determination.

a. Letter of Investigation (LOI). When an investigation results in an LOI, it must be prepared using the letter template contained in CETS. The LOI must describe the alleged finding of noncompliance and the assigned inspector/investigator must provide a draft LOI and background information regarding the alleged noncompliance to the Team Coordinator and/or C&E Center Manager within seven (7) in-office working days of the assigned investigation or within the deadline assigned by the Team Coordinator or C&E Center Manager. The LOI is either returned to the inspector/investigator for changes or approved. If the correspondence is returned to the inspector/investigator for changes, the review is documented under the Milestones Section in CETS and the process begins again. After the Team Coordinator and/or C&E Center Manager approve the LOI, he/she must enter the final sign-off into CETS. The LOI is then sent to the company through United States Postal Service (USPS) mail, certified return receipt. Electronic mail is not authorized. The inspector/investigator will follow the steps in Chapter 2 as it relates to getting the response, documenting the root cause, ARC and preparing the correspondence (e.g., action letter or enforcement action).

4. Investigations of Individuals Who Perform Safety-Sensitive Functions. Investigations involving individuals who perform safety-sensitive functions are critical and require an immediate investigation. All investigations of individuals are the responsibility of AAM-830 and require a LOI with a File Number. Investigations of an individual may result in either legal enforcement action or no action. Compliance and Administrative action are not used when responding to these types of investigations. These investigations most often result from the following:

a. Report of an individual's refusal to submit to a drug or alcohol test;

b. Report of a verified positive drug test or an alcohol misuse violation by an individual who holds a medical certificate issued in accordance with 14 CFR part 67;

c. An individual performing safety-sensitive functions after testing positive or refusing to submit to a drug and/or alcohol test without complying with the return-to-duty process;

The FAA might discover the above issues through an FAA Hotline complaint or a complaint received based on the activities of an employee as they relate to drug and alcohol testing.

5. Individual Violations Discovered During Inspection. If an inspection team finds, during the normal course of an inspection, any issues that relate to violations by an individual who performs safety-sensitive functions, the inspection lead will notify the C&E Center Manager, who will subsequently notify AAM-830. The Manager of AAM-830 will provide further directions/actions and the matter should be left open.

6. Pilot's Bill of Rights. If the individual holds an FAA-issued airman certificate (pilot, mechanic, dispatcher, etc.), the inspection team must apply the Pilot's Bill of Rights (PBR) and follow the guidance in the January 8, 2015 Enforcement Guidance Memorandum: "Requirements for Timely, Written Notification for All Investigations of Airman Certificate Holders". This document is available electronically on our Drug Abatement Division (AAM-800) QMS Web Site. The Pilot's Bill of Rights further restricts what the inspection team can and cannot do and say if it finds evidence of an individual's violations during an inspection:

a. Do not discuss the individual's violation with the individual or his/her company;

b. Do not engage the individual in any discussions about the apparent violations or the company's apparent violations;

c. Address the company's violation only (for example, its failure to ensure that its employee had completed the return to duty process before allowing the individual to perform a safety-sensitive function; or its failure to report a refusal to submit to testing);

d. Make a copy of any evidence showing the violation and refer the individual's violation to AAM-830. Send a written statement to the AAM-830 mailbox (AAM830@faa.gov) as soon as possible, including a copy of any documents you found;

e. Do not advise the company or the individual that this evidence will be reported to AAM-830 or that an investigator will contact them.

Chapter 4. Voluntary Disclosures

1. General. FAA's Compliance Philosophy (Order 8000.373) recognizes that aviation safety depends primarily on voluntary adherence to the regulations. The FAA has developed the Voluntary Disclosure Reporting Program (VDRP) to encourage employers and contractors to examine their own compliance efforts. The Drug Abatement VDRP, described in Advisory Circular (AC) 120-117, allows all employers and contractors (as defined in part 120) to participate by reporting inadvertent violations to the FAA along with a description of their corrective action and comprehensive fix for preventing future violations.

2. Procedures. The Program Administration Branch Manager will assign voluntary disclosure cases to any Drug Abatement employee for processing. When processing voluntary disclosure cases, each assigned Drug Abatement employee must use the information in this chapter, in conjunction with AC 120-117. Failure to follow these procedures may result in a nonconformity and corrective action (NCA). When an employer or contractor has a voluntary disclosure, the inspector/investigator must check the status of the voluntary disclosure during the inspection or investigation. If the disclosure is still pending, the inspector/investigator must gather evidence of the violation, immediate corrective actions, and comprehensive fix. The information should be provided to the Drug Abatement employee who is assigned to the voluntary disclosure. If the disclosure is closed, the inspector/investigator must check to ensure the comprehensive fix has been implemented. All follow-up activities should be entered in CETS.

a. Once an employer or contractor discovers an apparent violation, they may voluntarily disclose it to the FAA, ordinarily within 24 hours. The process for documentation when a disclosure is received is critical to whether it is accepted or rejected. Each Drug Abatement employee is responsible for ensuring that a disclosure is reported immediately to the appropriate Branch or C&E Center Manager.

b. An employer or contractor should submit its initial notification to disclose an apparent violation by written correspondence to the Program Administration Branch Manager. If an employer or contractor notifies an inspection lead of an apparent violation in person during an inspection or investigation, the inspector/investigator should take the information, complete his or her inspection and review of the noncompliance, and inform the employer or contractor to submit the information to the Program Administration Branch Manager as outlined in AC 120-117. As soon as possible, the inspection lead should prepare a detailed statement of the disclosure, including the date, time of the notification, as well as the name and title of the person who provided it, and transmit everything to the C&E Center Manager and Program Administration Branch Manager.

c. After receipt of the disclosure, the Program Administration Branch Manager assigns it to a Drug Abatement employee who determines if the submission meets the conditions outlined in Section 6 of AC 120-117. If the assigned employee determines there is no violation of the regulations, the employer or contractor is advised in writing that its disclosure was not a violation using the letter template contained Drug Abatement Division's (AAM-800) QMS web site.

d. If the disclosure meets the conditions under the VDRP, the assigned employee must prepare a Letter of Acknowledgment (LOA) for the Program Administration Branch Manager's

signature using the letter template contained in Drug Abatement Division's (AAM-800) QMS web site. The LOA is sent through USPS, certified return receipt or electronic mail. The LOA serves two purposes. First, it acknowledges receipt of the initial notification. Second, it identifies, in accordance with AC 120-117, the information that the employer or contractor must submit in writing to the FAA, if not already been provided. This information should be provided to the FAA within 10 working days after the initial notification was made.

e. Upon receipt of the response to the LOA, the assigned employee must analyze the violation and the information, obtain the evidence to show the violation has been corrected, and determine whether the comprehensive fix is acceptable. The determination to reject or accept a voluntary disclosure is based on specific factors of the violation and the employer or contractor's actions. When making this determination, it is important for the assigned employee and Program Administration Branch Manager to follow the procedures established under AC 120-117 and Order 2150.3, as amended. Additionally, it is imperative to coordinate with the Drug Abatement Division Manager and Chief Counsel's Office for disclosures that are complex or require legal guidance.

(1) If the FAA accepts the voluntary disclosure, the assigned employee prepares appropriate written correspondence for the Program Administration Branch Manager's signature using the letter template contained in CETS. The written correspondence is sent through USPS, regular mail. At the conclusion of the disclosure process, the employer or contractor is referred for inspection so we can evaluate the comprehensive fix. The inspection lead annotates the results of his or her evaluation in CETS.

(2) If the voluntary disclosure is rejected, the assigned employee must generate written correspondence for the Program Administration Branch Manager's signature using the letter template contained in Drug Abatement Division's (AAM-800) QMS web site. The written correspondence is sent through USPS, certified return receipt, and the employer or contractor is referred for inspection or investigation in CETS. At the next inspection, the inspection lead should gather evidence of the violation and process inspection paperwork as if the employer or contractor had not disclosed the violation. When closing the inspection, the inspection lead will add notes to the analysis of the voluntary disclosure indicating the findings and action taken with his or her initials and the date information was entered.

f. Once the disclosure is complete, it must be included under the employer or contractor's enforcement record in its C&E Center and CETS profile. In addition to the correspondence and evidence, the C&E Center record must include the following:

(1) *Analysis*. The assigned employee's analysis must include the following (see sample analysis in Figure 4-1):

(a) Summary of the voluntary disclosure. This is a summary of the violation and the circumstances surrounding the violation. This includes a summary of the written and verbal communications to and from the employer or contractor.

(b) Summary of the employer or contractor's comprehensive fix.

(c) List of documentation provided by the employer or contractor.

(d) Analysis and recommendation to reject or accept voluntary disclosure.

(e) Final action.

(2) *Copy of the 2150-5 Form, if applicable*. Refer to the Drug Abatement Division's EIS Manual for entering the 2150-5 form for a voluntary disclosure since the employer or contractor's identification information, such as its name and address, certificate number, etc., is not included on the 2150-5. Records submitted to the FAA under the Voluntary Disclosure Program are protected from release to the public.

Figure 4-1. Sample Voluntary Disclosure Analysis

VOLUNTARY DISCLOSURE ONE TWENTY ONE AIRWAYS, INC.

On January 2, 2018, One Twenty One Airways, Inc.'s Drug and Alcohol Program Manager, Brian Smith, performed an internal audit of its drug and alcohol testing program. During the audit he discovered that on November 15, 2017, One Twenty One Airways, Inc. transferred an employee, Mr. David Baker, from a non safety-sensitive position to a safety-sensitive position, but did not perform a pre-employment drug test on Mr. Smith prior to that transfer. Upon discovering this item of noncompliance, David Baker was immediately sent for a pre-employment drug test. On January 3, 2018, Brian Smith notified the FAA, via written correspondence, and voluntarily disclosed the apparent violation of the drug testing regulations.

On January 5, 2018, an LOA was sent to One Twenty One Airways, Inc., via certified mail, requesting the information prescribed in AC 120-117 and a copy of Mr. Baker's verified negative test result. On January 16, 2018, One Twenty One Airways, Inc. submitted the requested information to the FAA.

RECOMMENDATION:

A review of CETS shows that One Twenty One Airways, Inc. has not had any other violations of this nature. Based upon One Twenty One Airways Inc.'s compliance with the protocol in AC 120-117, I recommend approval of the voluntary disclosure.

FINAL ACTION:

On January 30, 2018, One Twenty One Airways, Inc. was issued written correspondence accepting their disclosure and referred to the inspection planner for a future inspection.

Chapter 5. Administrative Information

1. Authority to Change this Order. Practices, procedures, and documents contained in this order cannot be changed without the consent of the Drug Abatement Division Manager. Supplements to this order are prohibited unless authorized by the Drug Abatement Division Manager.

2. Background. In response to fatal aviation accidents related to substance abuse, the FAA adopted regulations in 1988 (codified as 14 CFR part 121, appendix I), which required aviation employers to implement a drug testing program for those personnel who perform safety-sensitive functions. In 1994, the mandate for alcohol testing was added to 14 CFR part 121, appendix J, as a result of the investigatory findings that the Exxon Valdez oil spill of 1989 was alcohol related and that pilots of a major U.S. air carrier had flown while intoxicated in 1990. In 2009, both appendices I and J were joined to create 14 CFR part 120, Drug and Alcohol Testing Program. Upon the inception of the drug testing regulations, the Drug Abatement Division developed a comprehensive inspection program. This order has been designed to serve as a multipurpose document that will guide the inspectors and investigators in the effective implementation of the inspection program, as well as provide them with supplemental information regarding the FAA-mandated drug and alcohol testing program.

3. References. The following are references that inspectors and investigators must use to perform their jobs.

a. Code of Federal Regulations (CFR). The CFR contains the regulations implemented by each Federal agency to implement statutes passed by the United States Congress. The drug and alcohol testing regulations are located in 14 CFR part 120 and 49 CFR part 40. The CFR can be accessed online through the Government Printing Office Web site at: http://www.fdsys.gov.

b. Federal Register. The Federal Register is the official daily publication for Executive Orders, proposed rulemaking, final rules, and notices of Federal agencies and organizations. The Federal Register is published by the Office of the Federal Register, National Archives and Records Administration (NARA), and can be accessed through the Government Printing Office Web site at: http://www.fdsys.gov.

c. United States Code (USC). The USC consists of Federal statutes passed by the United States Congress. The drug and alcohol testing regulations are promulgated under the statutory authority of the Omnibus Transportation Employee Testing Act of 1991 (49 USC §§ 45101-45107) and the FAA's general safety authority outlined in 49 USC§§106(g) and 44701. The USC can be accessed online through the Government Printing Office Web site at: http://www.fdsys.gov.

d. Drug Abatement Division (AAM-800) QMS Web Site. This site is a part of the FAA's Aviation Safety Quality Management System (AVS QMS) Web site. It contains AAM-800's ISO approved processes and procedures, records, documents, and forms. This Web site can be accessed at: https://my.faa.gov/org/linebusiness/avs/programs/qms/qms_homepages/aam/qms_divisions.html.

e. FAA Drug Abatement Division Web Site. This Web site is a comprehensive source of information as it pertains to the Drug Abatement Division's development,

implementation, administration, evaluation, and compliance monitoring of the aviation industry drug and alcohol testing program described in 14 CFR part 120. This Web site can be accessed at https://www.faa.gov/go/drugabatement.

f. FAA Orders/Notices/Advisory Circulars (AC). FAA orders, such as the Compliance and Enforcement Program Order 2150.3, as amended, Compliance Philosophy Order 8000.373, Safety Risk Management Policy Order 8040.4, as amended, and notices are directives to its own personnel and designees on how to carry out its responsibilities. ACs, such as the Voluntary Disclosure Reporting Program for Apparent Violations of the Drug and Alcohol Testing Regulations AC 120-117, are issued to provide guidance and information in a designated subject area or to show a method acceptable to the Administrator for complying with a Federal Aviation Regulation. FAA orders, notices, and ACs can be accessed online at http://rgl.faa.gov or http://isddc.dot.gov/OLPWeb.ASP.

g. Compliance Enforcement Tracking Subsystem (CETS). CETS provides the Office of Aerospace Medicine's Drug Abatement Division with automated capabilities for tracking, scheduling, and managing enforcement activities (i.e., inspections, investigations, voluntary disclosures, and other enforcement-related activities). It also maintains a database of cases, future schedules, companies and C/TPAs, and correspondence templates. Guidance on using CETS has been published by AAM-800 in the CETS user manual and in accordance with the current guidance in the System Rules for CETS Data Entry. Inspection, investigation and voluntary disclosure correspondence must adhere to the templates included in CETS. Alternations are only permitted at the direction of the Drug Abatement Division Manager.

h. DOT Office of Drug and Alcohol Policy and Compliance (ODAPC) Web Site. The ODAPC Web site is a comprehensive source of information as it pertains to the implementation and interpretation of the drug and alcohol testing regulations in 49 CFR part 40. This Web site can be accessed at: http://www.transportation.gov/odapc.

i. Drug Abatement Division's SharePoint Site. This site catalogues the Drug Abatement Division's policies and guidance documents, office contacts and all program-related information. The site can be accessed at https://avssp.faa.gov/avs/aam/HQ/AAM800/SitePages/Home.aspx.

j. Safety Performance Analysis System (SPAS). SPAS is a Web-based application that tracks the performance of certificate holder—air operators, air personnel, or air agencies such as schools—and equipment such as aircraft. SPAS collects data over time to show trends and to help FAA inspectors spot anomalies. The data in SPAS comes from multiple external FAA and other government databases. SPAS can relate informational data such as Airworthiness Directives and Service Difficulty Reports.

k. Web-Based Operations Safety System (WebOPSS). WebOPSS is used by the Flight Standards Service (AFS) to collect data on operator activities, disseminate FAA policy to the certificate holder and inspector communities, and generate and manage Authorizing Documents on behalf of the operator. The system is also a repository containing some of the most up-to-date data on the airline industry.

This document is available electronically on our Drug Abatement Division (AAM-800) QMS Web Site.

Appendix A. Inspection Guide

The following Inspection Guide is designed to assist inspectors and investigators in conducting an inspection of a company's drug and alcohol testing program. This Guide works in conjunction with the CETS Reference List, the tool used for documenting out-of-compliance items or concerns in CETS. Together, they help to ensure that every inspection is thorough and consistent.

All inspectors and investigators must use the Inspection Guide for conducting all inspections, and deviations from the Guide are strictly prohibited. A failure to follow the procedures in this Guide may result in a nonconformity and corrective action (NCA). Any changes to this guide should be referred to the Program Policy Branch Manager in AAM-820.

A comprehensive inspection consists of the following parts:

Part 1 – Administrative and Quality Assurance Review Guide
Part 2 – Records Review Guide
Part 3 – Collection Site Review Guide
Part 4 – Medical Review Officer (MRO) Review Guide
Part 5 – Substance Abuse Professional (SAP) Review Guide

Not all inspections will include a review of each of the above parts. However, each inspection MUST include a review of parts 1 and 2. Once the inspection lead has entered the information from the inspection guide into the CETS record, the hard copy should be destroyed.

This document is available electronically on our Drug Abatement Division (AAM-800) QMS Web Site.

PART 1: ADMINISTRATIVE AND QUALITY ASSURANCE REVIEW GUIDE

The following guide must be used during each inspection to ensure that areas regarding the company and their testing program are addressed. It is important that the inspector(s) and investigator(s) listen to the answers to verify the information during the records review.

NOTE: It may be necessary to tailor these questions when the company is a single-owner operator. For example, you would not ask the single-owner operator if he/she asked him/herself whether he/she ever tested positive on a pre-employment test for which he/she was not hired. The better way to phrase the question is to ask, "Have you ever tested positive or refused a pre- employment drug test for which you were not hired in the previous two years?" Also, some of these tailored questions may be a good opportunity to educate the operator for when they plan to hire safety-sensitive employees in the future.

Company Name/Certificate or Registration Number: _____

_____

Inspection Date(s): _____
Inspection Team: _____

Company President/CEO Name: _____
Number of Aircraft(s): _____

Please explain the type of business you conduct and whether your company is affiliated with any other operator(s) (e.g., air carrier, repair station or air tour). _____

_____

_____

_____

(If affiliated, obtain copies of A449, LOA and/or registration.)

What kind of work do(es) your employee(s) perform that requires him/her to be subject to the FAA drug and alcohol testing regulations?

_____

_____

_____

_____

Coverage

1. How many total employees do you have? _____

2. How many safety-sensitive employees do you have? _____

3. Where are they located and what are their job categories? _____

4. Do you contract out any or all safety-sensitive work? _____

5. How do you ensure employees hired by contract are subject to an FAA-mandated drug and alcohol testing program? (Alternative Question – If so, are they subject to testing under their own FAA-mandated drug and alcohol testing program?) _____

6. Do you have a company testing program for non safety-sensitive employees?

Service Agent

1. Do you use a consortium/third party administrator to help with your program? If so, provide Name/Location. _____

2. Where do you conduct your collections? _____

3. (If applicable) What collection site do you use for employees at other locations or during non- regular business hours? _____

4. Have you ever received a safety concern letter or report with a negative result from your MRO? If yes, what actions (if any) did you take? _____

Mandatory Testing

Pre-employment Testing

1. Have you hired any new safety-sensitive employees in the last 24 months? What is your process for hiring an employee, identifying the duties from one job category to the other? ___

2. Have you transferred any non safety-sensitive employees into safety-sensitive positions in the last 24 months? What is your process and how is this documented? _____

3. How and when do you advise employees of the requirement for testing and the five drugs?

4. Do you perform alcohol pre-employment testing? If not, move on. If so, are all applicants tested? _____

5. Explain your process for performing the drug and alcohol records check. Have you ever not received a response from a previous employer? When and/or do you make a good faith effort if no response is received? _____

6. Have you ever received a drug and alcohol records check request for a previous employee? If so, how did you respond? _____

7. How do you ask employees about pre-employment positives or refusals that the employee was not hired for? (required under § 40.25(j)) _____

Random Drug and Alcohol Testing

1. Do you manage your own random testing program, or does your C/TPA administer the program for you? _____

2. Are you in your own pool or combined (if managed by a C/TPA)? _____

3. How do you (or your C/TPA) generate the random selection list and how often? _____

4. How do you receive the random selection list? _____

5. Explain your random testing process (at each location) once selections are done, starting from receiving the list, to notification, to ensuring the collection is completed? _____

6. How are employees added or removed from the random testing pool? _____

7. Are you, as the program manager or DER, a safety-sensitive employee? If so, please explain how you are notified. _____

Note: **Additional questions relating to random review are in Appendix C of this Order.**

Post-accident Testing

1. Have you ever had any post-accident testing? If not, move on. _____

2. If so, ask to explain the accident. Verify documentation during the records review. _____

Reasonable Cause/Suspicion Testing

1. Have you ever had a reasonable cause or suspicion test? If not, move on to supervisory training.

2. If so, ask to explain the circumstances including information regarding the trained supervisor who made the determination. Verify information during the records review.

3. How many trained supervisors do you have? If you have multiple worksites/times, do you have a trained supervisor available (if applicable)? _____

4. Who conducts your supervisory training? How often? _____

5. What is covered during this training? _____

Positive Drug Test Results/Alcohol Violations/Refusals

1. Have any of your employees had a verified positive drug test result, alcohol violation, or refused to submit to testing? If not, move on. _____

2. If so, describe your company's response to the outcome of the test. _____

4. Do you provide the SAP information to every employee who tests positive? Verify SAP qualifications during record review and/or SAP interview (if applicable). _____

5. Have any of your employees who hold a part 67 airman medical certificate had a verified positive drug test result or alcohol violation? If so, have you reported the information to the Federal Air Surgeon? _____

6. Have any of your employees refused? If part 61, 63, 65, or 67 airmen, have you reported the information to the Federal Air Surgeon? _____

***Note:* Inspectors/Investigators must verify with the MRO whether he or she is responsible for results for this company.**

Return-to-Duty Testing

1. (If they have a return-to-duty process) Please explain your process for returning individuals or employees to duty after a verified positive drug test, alcohol violation, or refusal. _____

2. How do you receive the SAP recommendation? _____

3. How do you ensure that all return-to-duty tests are conducted under direct observation? _____

Follow-up Testing

1. Explain your follow-up testing process? _____

2. Who performs your follow-up testing notifications? _____

3. When do you perform your follow-up testing? _____

4. How do you ensure that all follow-up tests are conducted under direct observation? _____

Program Responsibilities

How do you or your Consortium/Third Party Administrator (C/TPA) advise your collector of the required information in § 40.14 (e.g., employee name, ID number, type of test, required direct observation, etc.)? _____

Have you received a result indicating insufficient specimen, dilute, cancelled, or invalid? If not, move on. If so, ask to explain what they did with the result.

EAP/Training

1. Where do you display your drug use/abuse materials? _____

2. How do you make your alcohol information available to your employees? _____

3. What information/training do you provide to your employees (including supervisors) about the drug and alcohol testing program? Is this documented? _____

4. Who provides your training and how often? _____

Recordkeeping

1. Where do you maintain your drug and alcohol testing records, which include your drug and alcohol records check? _____

2. Who has access to these records? Are they secured and how? _____

Additional Notes: _____

This is the conclusion of PART 1, Administrative and Quality Assurance Review. The inspection team must move to PART 2, Record Review, to obtain evidence to verify the procedures described. For inspections of service agents (collection site, MRO, or SAP) for this company, use PARTS 3, 4, or 5 of this guide accordingly.

This document is available electronically on our Drug Abatement Division (AAM-800) QMS Web Site.

PART 2: RECORDS REVIEW GUIDE

Each inspection must include a review of one or all of the following program documents/records. For each area inspected, the responsible inspector/investigator must initial in the box on the right.

Documents/Records		Insp/Inv Initials	Time Period of Review (Start to End)	Comments
1. Pre-employment Records, including:				
1a. Federal Drug Testing Custody & Control Forms and Results	☐**Reviewed** ☐**Not Reviewed**			
1b. Job Descriptions	☐**Reviewed** ☐**Not Reviewed**			
2. Drug and Alcohol Records Check Records, including:				
2a. Written Release Forms and Responses	☐**Reviewed** ☐**Not Reviewed**			
2b. Employment Applications	☐**Reviewed** ☐**Not Reviewed**			
2c. Documentation of Good Faith Effort (if applicable)	☐**Reviewed** ☐**Not Reviewed**			
2d. Confirmation of Compliance with § 40.25(j)	☐**Reviewed** ☐**Not Reviewed**			
3. Random Testing Records, including:				
3a. Listing of Random Pool Prior to Selection	☐**Reviewed** ☐**Not Reviewed**			
3b. Random Selections	☐**Reviewed** ☐**Not Reviewed**			
3c. Verified Drug Test Results and/or Custody and Control forms.	☐**Reviewed** ☐**Not Reviewed**			
3d. Alcohol Testing Forms w/ Results	☐**Reviewed** ☐**Not Reviewed**			
4.Work Records, including:				
4a. Maintenance Records/Logs	☐**Reviewed** ☐**Not Reviewed**			

4b. Pilot Flight Records/Logs	☐**Reviewed** ☐**Not Reviewed**			
4c. Other Work Records/logs	☐**Reviewed** ☐**Not Reviewed**			
5. Reportable Accident Records & Post-Accident Test Results	☐**Reviewed** ☐**Not Reviewed**			
6. Reasonable Cause & Reasonable Suspicion Results and Documentation	☐**Reviewed** ☐**Not Reviewed**			
7. Verified Positive Drug Test Records, including:				
7a. Verified positive Drug Test Results	☐**Reviewed** ☐**Not Reviewed**			
7b. Documentation of Removal from Safety-Sensitive Functions, to include Work Records/Logs/Personnel Records	☐**Reviewed** ☐**Not Reviewed**			
7c. Notifications to the Federal Air Surgeon (for part 67 medical certificate holders)	☐**Reviewed** ☐**Not Reviewed**			
7d. If Employee Terminated, Documentation that SAP Contact Information was Provided	☐**Reviewed** ☐**Not Reviewed**			
8. Alcohol Misuse Violation Records, including:				
8a. Records of alcohol misuse test results	☐**Reviewed** ☐**Not Reviewed**			
8b. Documentation of Removal from Safety-Sensitive Functions, to include Work Records/Logs/Personnel Records	☐**Reviewed** ☐**Not Reviewed**			
8c. Notifications to the Federal Air Surgeon (for part 67 medical certificate holders)	☐**Reviewed** ☐**Not Reviewed**			
9. Refusal records (drug and/or alcohol), including:				
9a. Documentation of	☐**Reviewed**			

refusal to submit to testing	☐**Not Reviewed**			
9b. Documentation of Removal from Safety-Sensitive Functions, to include Work Records/ Logs/ Personnel Records	☐**Reviewed** ☐**Not Reviewed**			
9c. Notifications to the Federal Air Surgeon (for parts 61, 63, 65, or 67 certificate holders)	☐**Reviewed** ☐**Not Reviewed**			
9d. If Employee Terminated, Documentation that SAP Contact Information was Provided	☐**Reviewed** ☐**Not Reviewed**			
10. Return-to-duty and follow-up testing records, including:				
10a. Initial and Follow-up Reports from SAP	☐**Reviewed** ☐**Not Reviewed**			
10b. Return-to-duty Testing CCF/ATF and Result	☐**Reviewed** ☐**Not Reviewed**			
10c. Follow-up Testing CCF/ATF and Result	☐**Reviewed** ☐**Not Reviewed**			
10d. If Employee Terminated, Documentation that SAP Contact Information was Provided	☐**Reviewed** ☐**Not Reviewed**			
11. Documents Pertaining to Drug and/or Alcohol Testing Arbitration or Litigation	☐**Reviewed** ☐**Not Reviewed**			
12. Drug and Alcohol Program Training Records, including:				
12a. Employee Records	☐**Reviewed** ☐**Not Reviewed**			
12b.Initial and Recurrent Training Records for Individuals Making Reasonable Cause/Suspicion Determinations.	☐**Reviewed** ☐**Not Reviewed**			
13. EAP and Alcohol Misuse Information, including:				

13a. Company's Policy on Drug and Alcohol Testing	☐**Reviewed** ☐**Not Reviewed**			
13b. Distribution Requirement	☐**Reviewed** ☐**Not Reviewed**			
13c. Display Requirement	☐**Reviewed** ☐**Not Reviewed**			
14. Records to Verify Contractor Compliance	☐**Reviewed** ☐**Not Reviewed**			
15. Collection Site Records, including:				
15a. Collector/Breath Alcohol Technician Training Records	☐**Reviewed** ☐**Not Reviewed**			
15b. Specimen Collection Logs	☐**Reviewed** ☐**Not Reviewed**			
15c. Calibration Logs for EBT devices	☐**Reviewed** ☐**Not Reviewed**			
16. MRO Records, including:				
16a. MRO Qualification/Training Documentation	☐**Reviewed** ☐**Not Reviewed**			
16b. Records of Notification & Determination/Verification	☐**Reviewed** ☐**Not Reviewed**			
16c. Evidence MRO personally reviews at least 5% of all CCFs reviewed by MRO staff quarterly	☐**Reviewed** ☐**Not Reviewed**			
16d. MRO Process for Non-negative Test Results	☐**Reviewed** ☐**Not Reviewed**			
17. SAP Records, including:				
17a. Qualification/Training Records	☐**Reviewed** ☐**Not Reviewed** ☐**Not Applicable**			

17b. Initial and Follow-up Evaluations	☐**Reviewed** ☐**Not Reviewed**			
18. Laboratory Records, including:				
18a.Semi-annual Summaries	☐**Reviewed** ☐**Not Reviewed**			

This document is available electronically on our Drug Abatement Division (AAM-800) QMS Web Site.

PART 3: COLLECTION SITE REVIEW GUIDE

When a company inspection includes a comprehensive review of the company's collection sites, it must include a simulated collection with the specimen collector and/or screening test technician (STT) or breath alcohol technician (BAT) and a review of any areas of non-compliance or concerns noted in previous inspections.

Simulated Collection: A collection site review must include a simulated collection for both drug and alcohol collections. It is important that the inspection lead clearly explain to the collector and/or STT or BAT that the simulated collection should be treated as a real DOT collection. The inspector should not interrupt the process or provide feedback until the conclusion of the simulation.

Each inspector must use the following guide.

Collection Site Facility Name: _____
Interviewee (site manager and/or collector): _____
Lead Inspector/Investigator: _____ **Date:** _____

Evaluation of Facility:

____ Privacy for testing.
____ Security of the testing site, results and specimens.
____ Toilet area for collection is compliant.
____ EBT or ASD are on conforming products listing.
____ If the dry gas method is used to calibrate the EBT, check the expiration date on the "Scotty Bottle".

Documents/areas that must be reviewed:

____ Collector, STT, and BAT qualification and proficiency records and training certificates
____ Quality Assurance Plan for the EBT and ASD
____ Review of custody and control forms and alcohol testing forms used for DOT testing
____ Records of equipment checks and calibrations, including external calibration logs/documentation
____ Facility manuals, to ensure they include the up-to-date regulations.
____ Verify the collection site and personnel do not use any DOT or DOT Agency branding.
____ Verify the collector/BAT/STT is subscribed to the DOT list-serve.

How does the company or Consortium/Third Party Provider advise you of the following information (required under § 40.14)?

(a) Full name of the employee being tested
(b) Employee SSN or ID number
(c) Laboratory name and address (if not pre-printed on the form)
(d) Company name, address, phone number, fax number (if not preprinted on the form)
(e) Designated employer representative (as required by § 40.35)
(f) MRO name, address, phone number and fax number (if not preprinted on the form)

(g) DOT Agency which regulates the employee's safety-sensitive duties (if not pre-checked on the form)
(h) Test reason, as appropriate: Pre-employment, random, reasonable suspicion/reasonable cause, post-accident, return-to-duty, and follow-up
(i) Whether the test is to be observed or not
(j) (Optional) Consortium/Third Party Administrator's name, address and fax number (if not preprinted on the form)

During the simulated urine collection, ensure that the following steps are demonstrated:

Name of Collector: _____
Lead Inspector/Investigator: _____ **Date:** _____

☐ Identify the donor by picture identification.
☐ Explain the collection process, including showing the instructions on the back of the CCF.
☐ Complete step 1 of the custody and control form.
☐ Instruct the donor to remove any unnecessary outer garments, empty pockets, etc. (allow the items to be locked and provide a key?)
☐ Instruct the donor not to list any medications on the CCF.
☐ Instruct the donor to wash and dry their hands. Instruct the donor not to wash their hands again until after delivering the specimen.
☐ Allow the donor to, or in their presence, select a collection cup.
☐ In the donor's presence, open the collection cup from a sealed bag/package.
☐ Prepare the collection area – blue dye in the toilet, tape/shut off faucets and/or soap dispensers.
☐ Inspect the collection area.
☐ Advise the donor to provide 45ml in the cup and not to flush.
☐ Upon receipt of the specimen, and in the presence of the donor, does the collector:
- ☐ Read the temperature and note the CCF?
- ☐ Evaluate specimen for signs of being tampered?
- ☐ Open the two specimen bottles and pour 30ml into the first and 15ml in the second?
- ☐ Firmly cap both bottles, place seal A over the 30ml and seal B over the 15ml bottles. Date both seals.
- ☐ Have the donor initial each seal.

☐ Complete and sign Step 4 of the CCF.
☐ Instruct the donor to read the certification and complete Step 5 of the CCF.
☐ Provide the donor with copy 5; place the sealed bottles and copy 1 of the CCF into the shipping container. Seal the container.
☐ Initial and date the shipping container seal.
☐ Advise the donor that the collection process is complete and that he/she may leave.
☐ Transmit (via fax, mail, etc.) copy 2 to the MRO and copy 3 to the company within 24 hours or the next business day.

Further questions you may ask:

1. Has the collector ever had a shy bladder situation? If so, explain the steps they followed.
_____
_____
_____

2. Has the collector ever had a specimen outside of temperature or that showed signs of tampering for the inspection entity? If so, explain the steps they followed. _____
_____
_____

3. Has the collector ever had a refusal, where an individual refused to cooperate or provide? If so, explain the steps they followed. _____
_____
_____

4. Has the collector ever conducted a direct observation collection? If so, explain the steps they followed. _____
_____
_____

****

During the simulated alcohol test, ensure that the following steps are demonstrated:

Name of STT or BAT (if different from collector): _____
Lead Inspector/Investigator:_____Date: _____

- ☐ Identify the donor by picture identification.
- ☐ Explain the testing process, including showing the instructions on the back of the ATF.
- ☐ Complete Step 1 of the ATF.
- ☐ Instruct the donor to complete Step 2 of the ATF and sign the certification.
- ☐ Open a sealed mouthpiece in view of the donor and attach it to the device.
- ☐ Instruct the donor to blow forcefully into the mouthpiece until adequate breath is provided.
- ☐ Show the donor the result displayed on the EBT.
- ☐ Record the displayed result, test number, device, the serial number of the device, time and result in Step 3 of the ATF or;
- ☐ Attach the printed result to the ATF in the proper place with tamper-evident tape.
- ☐ Advise the donor that the alcohol testing process is complete and that he/she may leave.
- ☐ Transmit (via fax, mail, etc.) the result to the designated employer representative (DER) in a confidential manner.

Further questions you may ask:

1. Has the BAT ever had a result that was above 0.02? If so, do they perform the following steps:
   ☐ Explain the confirmation procedure as follows:

- ☐ Instruct the donor not to eat, drink or put any object or substance in their mouth, and to the extent possible, not belch during the waiting period before the confirmation test.
- ☐ Wait 15 to 30 minutes after the completion of the initial test.

☐ At the completion of the waiting period, conduct the confirmation test.
☐ In the presence of the donor, conduct an air blank and show the reading to the donor.
☐ Open a sealed mouthpiece in view of the donor and attach it to the device.
☐ Instruct the donor to blow forcefully into the mouth piece until adequate breath is provided.
☐ Show the donor the result displayed on the EBT.
☐ Record the displayed result, test number, device, the serial number of the device, time and result in Step 3 of the ATF or; attach the printed result to the ATF in the proper place with tamper-evident tape.
☐ Date and sign the ATF certification in step 3.
☐ Instruct the donor to sign the ATF certification in Step 4.
☐ Immediately transmit (via person, telephone or electronic means) the results using Copy 1 to the designated employer representative in a confidential manner, ensuring it was received.

2. At what point does the BAT perform the EBT calibrations? _____
_____
_____

3. Has the BAT ever had a situation with a shy lung? If so, explain the steps they followed.
_____
_____
_____

4. Has the BAT ever had a refusal, where an individual refused to cooperate or provide? If so, explain the steps they followed. _____
_____
_____

This document is available electronically on our Drug Abatement Division (AAM-800) QMS Web Site.

PART 4: MEDICAL REVIEW OFFICER (MRO) REVIEW GUIDE

If the company's MRO has had a comprehensive inspection within the last 2 years, the inspection team just needs to confirm that the MRO does work for that company. If not, each inspector must include the MRO in the inspection, using the following interview and document review guide.

NOTE: This is not an exhaustive listing of questions for the MRO. If you have information regarding a specific incident, you may require more specific questions.

MRO's Name: _____
Address: _____
Phone Number: _____
Lead Inspector/Investigator: _____ **Date:** _____

Interview Questions:

1. How long have you been a Medical Review Officer? _____

2. What type of initial and qualification training have you completed? _____

3. Are you the MRO for _____ (an employer or contractor) or their Service Agent (_____)? _____

4. Explain your verification process for negatives and non-negatives. _____

5. Are your assistants involved in your verifications? If so, please explain. _____

6. How do you receive the laboratory confirmed results? _____

7. Have you ever downgraded a confirmed positive? If so, please explain your process, including how and when you send a safety concern letter to the company. _____

_____

_____

8. How do you handle the following?
   Invalid Results _____

   _____

   Dilute Positives or Dilute Negatives _____

   _____

   Shy bladder situations _____

   _____

9. Where do you maintain your MRO records and who has access? _____

_____

_____

10. How do you report verified results (negative and non) to the company? _____

_____

_____

11. What is your procedure for fatal flaws or correctible flaws? _____

_____

_____

Documents/areas that must be reviewed:

1. Qualification Training and Certification Records
2. Requalification Training
3. Verify that the MRO is conducting the required five percent quality check of negative drug test results
4. Downgrades and safety concern letters (if applicable)
5. Non-negative tests and verification notes
   ---Efforts to contact employee documented?
   ---Split offered?
   ---Part 67 holder?
6. If the MRO is co-located with the C/TPA, ensure physical and operational separation.
7. Check one or more of the following organizations to ensure the MRO is licensed, trained or certified:
   ---American Association of Medical Review Officer (AAMRO) at www.aamro.com,
   ---Medical Review Officer Certification Council (MROCC) at www.mrocc.org,
   ---American College of Occupational and Environmental Medicine (ACOEM) at www.acoem.org,
   ---American Society of Addiction Medicine (ASAM) at www.asam.org,
   ---American Medical Association (AMA) at www.ama-assn.org, or
   ---American Board of Medical Specialties (ABMS) at www.abms.org.
8. Verify the MRO does not use any DOT or DOT Agency branding.
9. Verify the MRO is subscribed to the DOT list-serve.

Additional Notes:

This document is available electronically on our Drug Abatement Division (AAM-800) QMS Web Site.

PART 5: SUBSTANCE ABUSE PROFESSIONAL (SAP) REVIEW GUIDE

When a company has return-to-duty and follow-up testing records, its inspection must include a review of the SAP. Each inspector must use the following interview and document review guides.

NOTE: This is not an exhaustive listing of questions for the SAP. If you have information regarding a specific incident, you may require more specific questions.

SAP's Name: _____
Address: _____
Phone Number: _____
Lead Inspector/Investigator: _____ **Date:** _____

Interview Questions:

1. How long have you been a Substance Abuse Professional? _____

2. What license(s) or certification(s) do you hold to perform as a SAP? _____

3. Have you received qualification training? _____

4. Explain your role in the evaluation, referral and treatment process of employees who have violated DOT drug and alcohol testing regulations. _____

5. What type of follow-up testing do you recommend? _____

6. How do you determine the number and frequency of follow-up tests? _____

7. How do you report your initial and follow-up evaluation assessment to the company? _____

8. Where do you keep the SAP reports and for how long? _____

Documents/areas that must be reviewed:

1. Qualification Training and Certification Records
2. Continuing Education
3. A check of one or more of the organizations referenced on the ODAPC Web site link for Substance Abuse Professionals (http://www.dot.gov/odapc/sap).
4. Initial and final return-to-duty evaluations, including follow-up testing recommendations
5. Verify the SAP does not use any DOT or DOT Agency branding.
6. Verify the SAP is subscribed to the DOT list-serve.

Additional Notes: _____

Appendix B. Service Agent Inspection Guide

PURPOSE: This guidance establishes procedures for the inspection or investigation of service agents. A service agent is defined in 49 CFR part 40 as any person or entity, other than an employee of the employer, who provides services to employers and/or employees in connection with DOT drug and alcohol testing requirements. This includes, but is not limited to, a consortium/third- party administrator (C/TPA); collection site, collector, or breath alcohol technician; medical review officer (MRO); or a substance abuse professional (SAP). Although service agents are not employers, they must meet the qualifications and requirements set forth in the regulations. Any service agent can be inspected independently or as part of a company inspection.

Note: The guidance established in this appendix applies to independent inspections of service agents. This guide is divided into the following four sections:

- Section I describes the pre-planning aspects of the inspection.
- Section II discusses relationships and why it's important to ask questions to ensure the C/TPA and laboratory, SAP, and/or MRO are separate and confidentiality is maintained.
- Section III outlines the on-site inspection activities, addressing the inspector/investigator's responsibilities once the inspection team arrives at the service agent location.
- Section IV describes the follow-up activities associated with a service agent inspection.

The guidance in this appendix outlines the basic concepts of a service agent inspection and is not intended to be an exhaustive listing and inspectors/investigators should always ask follow-up questions.

All Drug Abatement offices must follow this guidance.

Section I: Pre-Inspection Activity

After AAM-810 assigns a team to inspect/investigate a service agent, the inspector/investigator must accomplish the following tasks prior to arriving at the location:

- Review any relevant documents, including past inspections and noncompliance transmittals (NCTs). Coordinate with other inspectors/investigators that have had issues with the service agent. Some of this information may be helpful in planning your inspection.

- Access the company's Web site to see what services it "advertises." During your review, ensure the company does not use any DOT or DOT Agency branding on its Web site and the material it provides is accurate and up-to-date. If you find use of the DOT or DOT agency title or emblem on the company's Web site, this should be documented as a finding of noncompliance in your inspection and require corrective action. If you find it outside the scope of a service agent's inspection, report it to your Manager.

- Determine priorities/objectives you hope to achieve through the inspection.

- Determine whether information for your assigned service agent is in CETS. If it is not, please see your Team Coordinator (TC) or C&E Center Manager or Branch Manager.

- If the inspection is announced, generate and send a letter of notification announcing your team's review using the same template and process described in Chapter 2 of this Order. The attachments to the LON do NOT go to a service agent. If the inspection is unannounced, a letter is not necessary.

- Discuss the planned inspection with your team, ensuring that you set the priorities, objectives, and what is expected of each of them. The team lead should follow the same steps described in Chapter 2, Paragraph 6 of this Order (Pre-Inspection Team Meetings).

Section II: Relationships

It is important that the inspector/investigator understand the established relationships between the different service agents, employers and contractors. Relationships between the service agents, specifically the laboratories, MROs, and SAPs, must foster independence and confidentiality. If the C/TPA, collection site, MRO, and SAP are all from the same entity, how do they separate their respective functions? How do they maintain confidentiality?

Inspectors/investigators must ask the following questions to ensure all associations between services agents are objective and impartial:

A. C/TPA and the Laboratory

- What is the relationship between the C/TPA and the laboratory?

- Does the C/TPA set up the company's information with the laboratory/ies?
  - How are the CCFs set up for the company?
  - Does the C/TPA or company send the company's information to the laboratory?

- Does the C/TPA have a financial interest in the laboratory?

- Does the relationship foster independence and confidentiality?

- How are testing records secured?

B. C/TPA and the Medical Review Officer (MRO)

- Where is the MRO's place of business?

- Does the MRO have several offices?
  - If yes, which office is his/her primary place of business?
  - Does he/she physically visit the office where the results are received and/or verified?
  - If no, how does he/she oversee the verification process, and who conducts the reviews and verifications?

- Does the MRO have an office or work at another location other than the C/TPA's?

- If the test results are received from the laboratory at the same address as the C/TPA, does the MRO have a confidential fax? How does the MRO maintain confidentiality?

- Does the MRO work out of the C/TPA's place of business?
  - If the C/TPA and MRO are co-located, is there a firewall between the two?
  - Are the files kept separately?
  - Does the C/TPA receive the results from the laboratory on a shared fax, or does the MRO have its own secure fax to maintain confidentiality?
    - Who has access to the results?
    - Where are the MRO records maintained?
    - How are they maintained?
  - If the same employees work for the C/TPA and the MRO, when do they work for the MRO versus the C/TPA? (Duties should remain separate and distinct.)
    - Are the employees' schedules consistent or do the times vary (example of consistent schedule: works for MRO from 8:00 a.m. until noon and the C/TPA from noon until 4:00 p.m.)?
    - Who has direct supervision over the employees (who hires, fires, pays, disciplines)?
  - Is the owner and operator of the C/TPA also the MRO's assistant?
    - If so, how does that relationship work? If the C/TPA hired the MRO and the C/TPA is the MRO's assistant, how do they keep the functions separate and distinct?

C. C/TPA and the Substance Abuse Professional (SAP)

- What is the relationship between the C/TPA and SAP?

- Are there any financial ties?

D. MRO and the Laboratory

- Review and discuss the MRO's relationship with the laboratory.

- Are there any financial ties between the MRO and the laboratory?

Section III: On-site Inspection Activity

This section outlines the inspector/investigator's responsibilities once the inspection team arrives at the service agent location. The inspection team should:

- Conduct an inbriefing, similar to an employer/contractor inspection, with the service agent regarding the scope of your inspection.

- Discuss the types of services the service agent provides to its clients and the procedures/guidance it follows when carrying out each type of service.

- Verify they are providing services to aviation entities by reviewing the service agent's client list or accounts list.

- Conduct interviews with various service agent employees.
  - Does each employee follow the same process for each service provided?

- Review the service agent's material and/or documentation to ensure they do not use DOT or DOT agency emblems or titles.

Specific Areas to Review

A. C/TPA.

- What other modes of transportation does the C/TPA service (i.e., motor carrier, railroads, Coast Guard, etc.)?

- If the C/TPA sets up new collection sites, laboratories, or MROs, review the process used.
  - Is a checklist used? If yes, obtain a copy of it.

- Review and discuss the procedure used when setting up a new client.
  - Is a checklist used?
  - What information is received from the client?
  - What information is provided to the client?

- Are company policies and other informational materials or examples of such provided to clients?
  - Who is responsible for updating the information and how is this communicated with the client?

- Does the service agent provide written documentation on its operational set-up to its clients?

- Does the service agent provide up-to-date information to assist the client in implementing its drug and alcohol program?

- Does it provide information on how and when to test?

- Does it provide information to each of its clients on changes to FAA/DOT regulations?

- How does each client receive information on changes to the regulations? How is each client notified of changes?

- What type of services does the service agent provide regarding the different types of testing?

- Review procedures the service agent uses for (aviation) companies for the various types of testing (random testing, for example; see section below).

- Does the service agent maintain records for its clients?
  - If yes, what records does it maintain? How are the records maintained?
  - If it maintains records for companies, how are those records provided to the client and how long does it take for the client to receive copies, if requested?

- Review documents provided to (aviation) companies.

- Review education and training, if provided to (aviation) companies.

B. *Random Testing*. To ensure a thorough review of a service agent's random testing procedures and records, inspectors/investigators must determine the following:

- Does the C/TPA's selection process meet the regulatory requirements?
  - Does the selection process ensure that each covered employee has an equal chance of being tested each time selections are made?
  - Are various types of safety-sensitive employees being random tested at roughly the same rates? (For example, do pilots and mechanics have an equal chance of being tested each time selections are made for a random test?)

- Did the C/TPA meet the random testing rate each year (25% for drugs and 10% for alcohol) if utilizing a combined pool?

- Does the C/TPA combine the random testing pool of an FAA-regulated company with that of other FAA-regulated companies?

- How and when are the random testing pools updated?

- How and when are random selections made (i.e., computer number generators)?

- How are random selections conducted for each FAA random pool?

- How are companies notified of random selections (secure notifications)?

- Are random notifications documented?
  - Does the C/TPA document when and to whom they provide the random selection lists?

  - Does the C/TPA have its client annotate and report back to the C/TPA who was tested on the random selection list?
  - Does the C/TPA provide information to its client regarding random notifications?

- How are the random notifications conducted for companies that have one individual/employee?

- How does the C/TPA notify individuals, who are also the DERs, of their random selection?

- How does the C/TPA ensure that the individuals selected are tested?

- How many times were individuals selected, but not tested?
  - Is there any follow-up with the companies/clients when tests are not conducted? If so, how is the follow-up conducted?
  - What action does the C/TPA take, if any, against companies who do not random test employees who are selected?

- How do the individual companies or collection sites notify the C/TPA when random alcohol tests are completed?
  - How does the C/TPA ensure that the annual random alcohol rate is met for combined pools?
  - Does the C/TPA provide any follow-up, for companies that have their own pools, regarding whether or not they will meet the annual alcohol testing rate?
  - How does the C/TPA determine if it met its annualized random testing rate for drugs and alcohol?

- How does the C/TPA determine if it met its annualized random testing rate for drugs?

C. *Collection Site*. If the service agent you are reviewing is a drug and/or alcohol collection site, the inspector/investigator must determine the following:

- Is the collection site subscribed to the DOT's list-serve?

- How are collection sites set up for the company?

- Can the collection sites conduct both drug and alcohol collections, or are separate sites used for the different collections?

- Can collection sites conduct collections during the company's operating hours or after hours for emergencies?

- Are there secondary collection sites set up for the times when the primary collection site is closed, no personnel are available, or the evidentiary breath testing device is not working?

- If the C/TPA sets up collection sites, does the C/TPA provide information to the company regarding the collection site? If yes, what type of information?

- Who follows up with collection sites if there are problems? How is the follow-up conducted and documented?

- If the C/TPA does follow up, how does the client know the corrective action has been taken?

- If the C/TPA sets up collection sites, does the C/TPA ensure that the collectors meet the training and qualification requirements and that the collection site meets the regulatory requirements? Review all collectors and BAT's training documentation.

- Is the quality assurance plan (QAP) for each evidentiary testing device (EBT) being met?
  - Review the calibration and external calibration records (reviewing the actual print-out from the EBT, not just a handwritten log book).
  - Review the method used to conduct the external calibration checks.
  - Check the canister for an expiration date. If it is past expiration date, that may not require cancellation of any of the tests. You must elevate this issue to your Branch or Center Manager for resolution.

- Check the value on the dry gas or wet bath solutions and the external calibration results from the EBT to verify results are within allowable limits, as stated in the QAP.

D. *Medical Review Officer (MRO)*. If the service agent you are reviewing is an MRO, the inspector/investigator must determine the following:

- Review the MRO's qualifications, knowledge, and training, specifically their M.D. or D.O. qualification and re-qualification training.

- Verify information you received from the MRO by checking some of the following organizations to confirm the MRO is licensed and trained:
  - American Association of Medical Review Officer (AAMRO) at www.aamro.com,
  - Medical Review Officer Certification Council (MROCC) at www.mrocc.org,
  - American College of Occupational and Environmental Medicine (ACOEM) at www.acoem.org,
  - American Society of Addiction Medicine (ASAM) at www.asam.org,
  - American Medical Association (AMA) at www.ama-assn.org, or
  - American Board of Medical Specialties (ABMS) at www.abms.org.

- Is the MRO subscribed to the DOT's list-serve?

- How does the MRO receive lab test results?

- How does the MRO receive Copy 2 of the CCF?

- What are the procedures used by the MRO or his/her staff in processing negative test results, including downgrades? If the MRO's assistant (staff) is processing the negative test results, how is this being documented on the CCF?
  - How and when does the MRO send a safety concern letter to the company, if applicable?

- What are the procedures used by the MRO or his/her staff in processing positive test results?
  - Is there a checklist/standard protocol and is it consistently used?
  - Who contacts the donor?

        - If it's the MRO, what is initially stated to the donor?
        - If it's the MRO's staff, what is initially stated to the donor?
    - Who conducts the verification interview?
    - What does the MRO tell and ask the donor during the interview?

- What is the MRO's procedure when he/she or designee is unable to contact the donor?

- If there is a stand-down waiver, how does the MRO comply with the waiver?

- Who follows up with the collection sites and/or company and/or C/TPA when Copy 2 of the CCF is not received?
    - Is this follow-up documented? If yes, how?
    - What occurs if, after the first follow-up is conducted, the CCF is not received by the MRO?

- Who reviews the CCFs for quality control (to make sure the items that need correcting are identified and corrective action or appropriate action is taken)?

- Who completes and signs Copy 2 of the CCF?

- How are the CCFs annotated when completed by the MRO assistant?

- How soon after the test is verified does the MRO complete the verification process (sign and date Copy 2 and send a copy of Copy 2 or a written report, if used, to the company)?

- Who signs the written report (if one is prepared and sent)?

- Does the same MRO who conducted the verification also sign the written report?

- Does the MRO provide the company with a copy of Copy 2 and/or a written report?
    - How is this provided to the company?
        - Does the company confer with the MRO to ensure that the referral physician is acceptable to the MRO?
        - Is the company referred to a physician with expertise in the issues(s) of what could cause a shy bladder or the issue(s) the individual stated he/she was experiencing?
        - Does the MRO provide the referring physician with information in part 40?
        - Does the MRO ensure that the referring physician agrees to follow the requirements in 49 CFR 40.193?
        - Does the MRO conduct appropriate follow-up with the referring physician if the information received does not comply with part 40?

- Who sends the test results to the company, the MRO or C/TPA?

- How are invalid results handled?

- Does the MRO confer with the laboratory director or certifying scientist if there is a question about the test result?

- How does the MRO handle shy bladder situations?
  - Does the MRO refer the individual to a physician with expertise in the issue(s) of what could cause a shy bladder or the issue(s) the individual stated he/she was experiencing?
  - Does the MRO provide the referring physician with information in part 40?

- Does the MRO conduct the required quality control checks on negative test results?
  - If the MRO is part of an MRO service, how does the service comply, and how is it monitored?
  - How are the CCFs selected for the 5% review?
  - Does the MRO personally review at least 5 percent of all CCFs reviewed by his/her assistant?

E. *MRO Assistant*. When reviewing the MRO assistant, the inspector/investigator must determine the following:

- Who supervises the assistant (hires, fires, monitors performance)?

- What are the MRO assistant's responsibilities?
  - Does he/she review Copy 2 of the CCF to determine if there are any fatal or correctable errors that may require corrective action or cancellation?
  - Does he/she review the negative laboratory documents to ensure they are consistent with the information on the CCF?
  - Does he/she request a copy of documentation from the laboratory or the collection site if the copy on hand appears unclear?
  - Does he/she prepare reports sent to the company? Prior to sending the report to the company, does he/she ensure the office has the following:
    - A legible copy of Copy 2 of the CCF or another CCF copy containing the employee's signature?
    - A legible copy of Copy 1 of the CCF that conveys the negative test result?
  - When handling a confirmed positive, adulterated, substituted, or invalid test result, does he/she schedule a discussion between the MRO and employee?
  - What information does the assistant provide to the donor?
    - Does he/she explain the consequences to the employee of declining to speak with the MRO?
    - If the employee declines to speak with/schedule a discussion with the MRO, does he/she document this decision, including date and time?
  - Does he/she advise an employee to have medical information ready to present at the discussion with the MRO?
  - Does the MRO/MRO assistant make and document reasonable efforts, including dates and times, to contact the employee at the day and evening phone numbers listed on the CCF?
    - Does he/she make at least three attempts reasonably spaced over a 24- hour period?
  - If the MRO/MRO assistant can't reach the employee, does he/she:

        - Contact the DER, documenting dates and times of attempts to reach him/her, and instruct the DER to contact the employee to tell him/her to contact the MRO?
            - How does the MRO know which time period to use when he/she contacted the donor for assistance?
            - Is the DER advised to contact the MRO after contacting the donor or after making the required reasonable attempts?
    - Who informs the DER that the employee has a confirmed positive, adulterated, substituted, or invalid test?

- Are quality reviews conducted? If yes, by whom and when?

- During your review ensure:
    - The assistant is not canceling tests. This can only be done by the MRO. The assistant does not gather medical information or information containing possible explanations of the test results.
    - The assistant does not participate by sitting or listening in on the MRO's interview with the donor.

F. *Substance Abuse Professional (SAP).* If the service agent you are reviewing is a SAP, the inspector/investigator must determine the following:

- Does the C/TPA provide SAP service or contract out for SAP services for its clients?

- Is the SAP part of a referral agency?

- Is the individual referred to a SAP who is qualified under DOT regulations? This may require a check of one or more of the organizations referenced on the ODAPC Web site link for Substance Abuse Professionals to ensure the SAP is trained or certified (http://www.dot.gov/odapc/sap).

- Is the individual referred to a qualified SAP who is located close to where the individual resides?

- Does the SAP perform his/her duties in accordance with the regulations?

- How does an individual contact the SAP service?

- Does the SAP prepare and send the evaluation reports to the company (or does the referral agency perform this function)?

- Are the reports on the SAP's letterhead, not the referring agency or other organization?

- Is the SAP subscribed to the DOT's list-serve?

G. *Reporting Requirements*. Inspectors/investigators must ask the following questions when reviewing a service agent:

- Is the C/TPA knowledgeable of the types of tests that must be reported to the FAA? NOTE – all tests may be reported; however, some are required.

- How is the FAA notified of positives or refusals that are reportable?

- Are companies advised that a test is reportable to the FAA?

Section IV: Post-Inspection Activity

The post-inspection activities for a service agent include documenting the inspection in CETS and entering the compliance issues into the regulation tab creating an outbriefing report. The letters to a service agent are different than the employer's/contractor's letter. A flowchart of the correspondence process for a service agent review is found in Figure B-1 of this appendix.

The following will briefly discuss the procedures used for reporting a service agent inspection:

- The inspection lead prepares the outbriefing report and briefs the service agent on the findings.

- If the service agent is found to be out-of-compliance, the first correspondence is a Notice of Corrective Action (NOCA). The template for a NOCA is available on the Drug Abatement Division (AAM-800) QMS Web Site. Once the NOCA is generated by the inspector/investigator, it should be provided to the TC and/or Manager for review, and sent to the Drug Abatement Division Manager. Prior to sending the NOCA to the service agent, the Drug Abatement Division Manager or his/her designee will contact the service agent to determine whether there is any further information that will have a bearing on the decision to send a NOCA. The NOCA is then sent, if the service agent does not provide additional information. The letter must be sent through USPS mail, certified return receipt. The inspection lead may send as an ADOBE pdf copy via electronic mail to the service agent and copy the Team Coordinator and C&E Center Manager.

- The service agent has 60 days to respond to the NOCA and provide satisfactory corrective action.

- If the Drug Abatement Division Manager or his/her designee is satisfied that the service agent satisfactorily corrected the issue(s) and is in compliance, the inspector/investigator will prepare a NOCA Closeout letter outlining the issues and the corrective action taken. The NOCA Closeout letter template is available on the Drug Abatement Division (AAM-800) QMS Web Site. The letter is sent to the TC and/or Manager for review before it is referred to the Drug Abatement Division Manager for review and signature. The Drug Abatement Division Manager or his/her designee sends the letter through USPS and our inspection is closed without issuing a public interest exclusion (PIE).

- If the service agent is unable or unwilling to correct the compliance concerns, the inspection lead initiates a PIE proceeding and prepares a report, similar to the legal enforcement format, and a Notice of Proposed Exclusion (NOPE). The NOPE letter template is available on the Drug Abatement Division (AAM-800) QMS Web Site. This

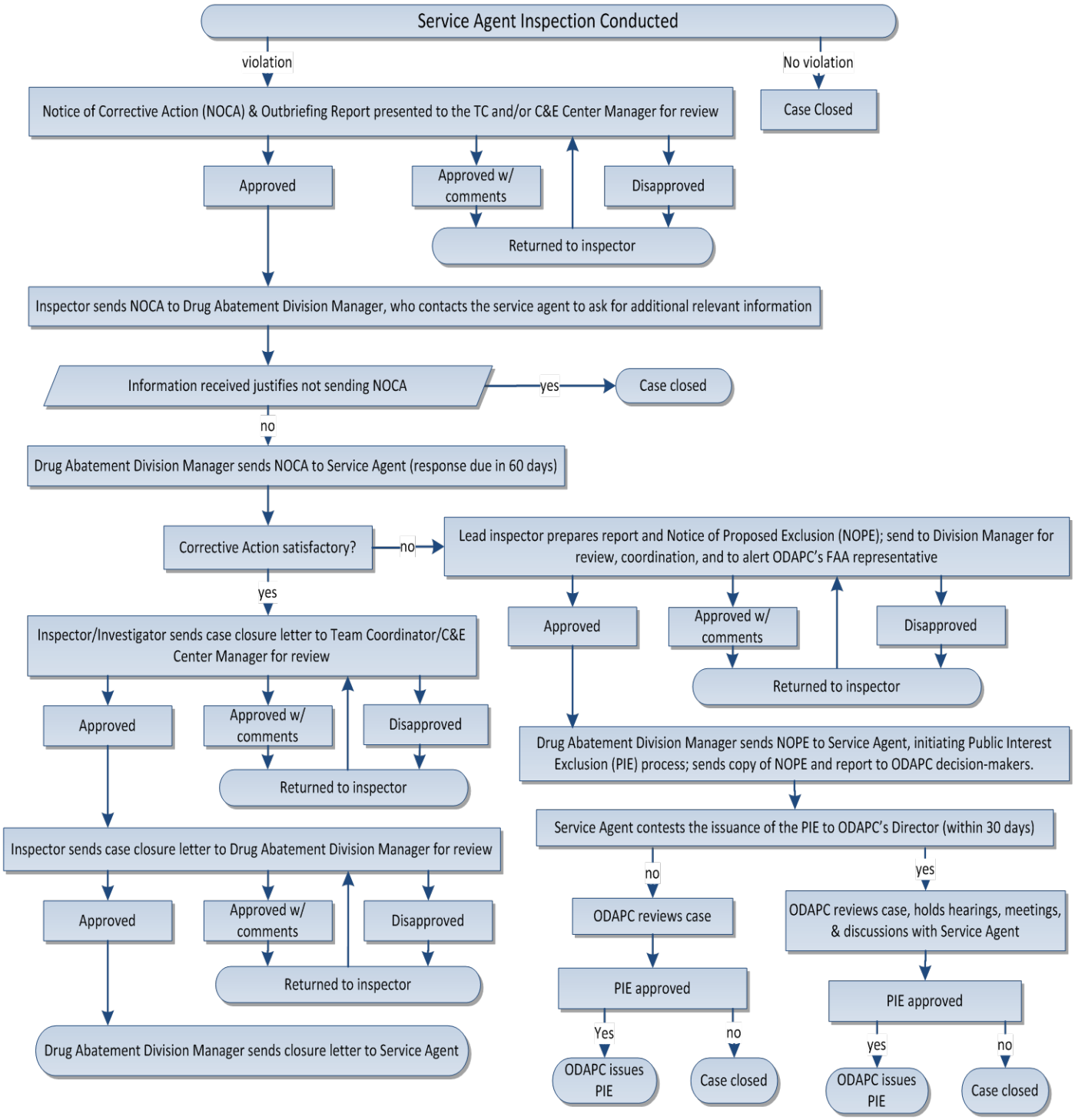
entire process must be coordinated with your Team Coordinator and C&E Center Manager. The report and NOPE must be sent to the Division Manager or his/her designee for review and signature.

- The Division Manager or his/her designee will coordinate with a representative of the Department of Transportation's Office of Drug and Alcohol Policy and Compliance (ODAPC) and provide him/her with a copy of the NOPE and the report supporting the PIE before the NOPE is sent to the service agent. The NOPE must be sent through USPS mail, certified return receipt. Electronic mail is not authorized. The inspection lead prepares the inspection file documentation according to Appendix F.

- The service agent has 30 days to contest the NOPE and proposed PIE by contacting the ODAPC Director and providing information in writing or in person.
  - If the service agent does not contest the NOPE in 30 days, the ODAPC Director or designee will make the final decision based on the information in our report.
  - If the service agent contests the NOPE, the ODAPC Director or designee will consider all information presented in person (informal meeting which will be transcribed) or in writing before making a final decision. The burden of proof is on the FAA.

- The inspection lead updates the inspection file documentation according to Appendix F, if necessary.

Figure B-1 Service Agent Correspondence Flowchart



Appendix C. Random Drug and Alcohol Testing Job Aid

Random testing has two purposes: (1) To detect illegal drug use and alcohol misuse; (2) to deter employees from using drugs and misusing alcohol; and (3) to remove employees engaged in such use from the performance of safety-sensitive functions. The FAA's regulatory authority to mandate random drug and alcohol testing for the aviation industry is found in 14 CFR part 120. The Supreme Court of the United States has upheld this authority, because the FAA has balanced the DOT's need to conduct testing for safety with the individual's expectation of privacy.

In order for an inspector/investigator to determine whether a company's random testing program is in compliance, it is critical for him or her to understand random testing. The following job aid must be used by every inspector/investigator when inspecting a company's random program.

Applicability of Random Testing

Random testing is applicable to all persons who perform, are ready to perform, or are immediately available to perform, a safety-sensitive function either directly or by contract (at any tier) for a part 119 certificate holder with authority to operate under parts 121 and/or 135, an operator as defined in 14 CFR § 91.147, or an air traffic control facility not operated by the FAA or by or under contact to the U.S. military. A repair station or contractor that performs safety-sensitive duties for an employer may be covered under the employer's DOT drug and alcohol testing program. The FAA also permits repair stations and contractors to obtain and implement their own DOT drug and alcohol testing program.

Employees who **do not** perform safety-sensitive duties are not permitted to be included in the DOT drug and alcohol testing program.

Minimum Annual Random Testing Rate

The regulations require random drug and alcohol testing of safety-sensitive employees at a minimum annual percentage rate. The annual rates for random drug and alcohol testing for the coming year are published in the Federal Register each December. Since 1997, the rates have consistently remained at 25% for drugs and 10% for alcohol. However, the FAA Administrator may change these rates based on the reported positive rate for the entire industry.

Formula for Calculating a Company's Annual Testing Rate

Use the following formula to calculate the *average number of safety-sensitive employees*:

$$\frac{\text{Total \# safety-sensitive employees during each testing period}}{\text{\# of testing periods}}$$

Use the following formula to calculate the *Company's Annual Testing Rate*:

$$\frac{\text{\# random testing results}}{\text{Average \# safety-sensitive employees}}$$

Example:

Quarter	SS Employees	Number of Random Tests
1	**50**	**2**
2	**60**	**3**
3	**70**	**4**
4	**90**	**4**

Average Number of Employees = $\frac{50+60+70+90}{4 \text{ quarters}}$ = 68 (Always round up)

Company's Annual Testing Rate = $\frac{2+3+4+4}{68}$ = 19.1%

Selection Methodology

Companies must use a scientifically valid method such as a random-number table or a computer-based random-number generator to select covered employees for testing. Each covered employee in the pool must have a unique identifier such as Social Security Number, payroll number, or other comparable identifying number.

The company must ensure that all employees have an equal chance of being tested each time the selections are made. Specific individuals or groups must not be targeted, including certain occupational groups or locations.

Updating the Random Pool

Before making random selections, the company must ensure that the random pool is complete and up- to-date.

- *Only* those persons performing safety-sensitive functions can be placed in the pool.
- Once an individual is hired or transferred into a safety-sensitive position, he/she should be added to the random pool. He/she must be added to the random pool prior to the next random selection.
- The company must remove any employee from the pool who has been terminated.
- The company may remove an employee from the pool if the employee is unavailable to perform safety-sensitive duties for the length of the selection period.

- Employees who have previously been removed from the pool for any reason should be placed back into the random pool before they start performing safety-sensitive duties again. He/she must be added to the random pool prior to the next random selection.

Notification Procedures

The company, collector/BAT, and employee have responsibilities for ensuring that random drug and alcohol test notifications and collections are conducted in accordance with the regulations. These responsibilities include the following:

- Companies are responsible for notifying the collection site as to when employees are expected to report to the collection site for testing. This will ensure that the collection site will be open and ready for testing (i.e., required equipment/supplies are available and working) when the employee arrives.

- Companies are responsible for notifying the selected employee as close to the test time as possible. This will minimize or eliminate the employee's attempt to avoid a positive drug test or alcohol violation.

- Companies are responsible for requiring the selected employee to immediately report for testing after he/she has been notified. (Reference: 14 CFR § 120.109 (b)(8) and 14 CFR § 120.217 (c)(8))

- The company is responsible for ensuring that random alcohol tests take place just before, during, or immediately after the employee has performed a safety-sensitive function. (Reference: 14 CFR § 120.217 (c)(9))

- Collectors/BATs are responsible for being prepared to conduct drug and/or alcohol tests. This will minimize the number of cancelled tests.

- Collectors/BATs are responsible for notifying the company if an employee fails to appear at the collection site for a test.

- To the greatest extent possible, collectors/BATs must first test an employee for alcohol if the employee is to be tested for both drugs and alcohol. (Reference: 49 CFR § 40.61(b)(1)). Since alcohol dissipates quickly in the body, this ensures that the test result represents the employee's current alcohol concentration.

- Once notified, the employee must proceed immediately to the collection site for testing. Failure to do so may constitute a refusal to test as described in 49 CFR § 40.191.

- The employee is responsible for complying with the collector's/BAT's instructions for providing a specimen. Failure to do so may constitute a refusal to test as described in 49 CFR §§ 40.191 and 40.261.

If an employee is notified and not tested for a reason beyond his/her control, another attempt to test cannot be made during that testing period. One example of "reasons beyond his/her control" is the collection site was closed when the donor arrived for testing. Another example is the facility only collected for drug testing when alcohol testing was also supposed to be conducted.

Policies for Excusing an Individual from Testing

Liberal excusal policies increase the opportunity for testing bias. Companies should not excuse employees from testing during a random selection unless a legitimate reason exists. Legitimate excuses must be implemented in the same way for all safety-sensitive employees. If an employee is excused, the random list should be annotated with the reason for the excusal.

One legitimate basis for excusing an employee occurs when an employee has been terminated from the company, but has not yet been removed from the pool. Likewise, an employee in the hospital who is not expected to return to the workplace before the next testing period could reasonably be excused. However, if an employee is on sick leave, vacation, or travel and will return to the workplace before the next random selection, the employee's name must be held in confidence and the employee tested upon his/her return. In these situations, the employee must not be notified of his/her selection until immediately before the collection is to occur.

Over Selection and the Use of Alternates

Some companies will select more employees than necessary to prevent under-testing when employees are excused. While this practice is not against the regulations, it does create a potential problem. It can lead to a liberal excusal policy. For example, a company finds it difficult to locate employee A, so he decides to skip employee A and move down the list. This practice can also lead to testing bias. Generally, maintenance workers tend to be easy to find, while flight crew and flight attendants can be difficult to track down. *Best Practice:* A company should recalculate the number of selections needed following each selection period to ensure the minimum rate is met.

Frequency of Selecting and Testing

Selections *should* be spaced reasonably throughout the year. This practice ensures a "clean pool". *Best Practice:* Selections should be made a minimum of four times per year. Once a random selection has been made, the names and testing date(s) must remain unannounced until the employees are notified to report for testing.

The testing *must* be spaced reasonably throughout the year. Companies *must* conduct testing throughout the selection period so employees cannot predict when they might be tested. Collecting only at the beginning or end of a month, or collecting on the same date within test periods removes the element of surprise for testing. Companies can test all selected employees at one time or may choose to spread testing throughout a testing period.

Inspecting a Random Program

As previously stated in this Order, an inspector/investigator must adhere to the Inspection Guide for all inspection activities, including those that apply to a random program. In addition to using the Inspection Guide, each inspection of a random program should include the additional questions listed below.

- Is the company meeting its minimum annual testing rates?
- Is the random pool being updated in a timely fashion?
  - Are new employees being added in time for the first selection following their date of hire?
  - Are employees who no longer perform safety-sensitive duties being removed from the selection pool before the next selection period?
- Are all occupation groups being treated equally?
  - Are excusal criteria consistent across occupational groups?
  - Do all employees have an equal chance of being tested regardless of occupation?
  - Does one occupational group have a much higher (or lower) rate of testing than other groups?
- Are all locations being treated equally?
  - Do all employees have an equal chance of being tested regardless of location (or home base)?
  - Does one location have a much higher (or lower) rate of testing than other locations?
- Are employees being tested immediately following notification?
- If an employee is excused in a testing period, is he/she still being tested in that testing year?
- Are the excusal policies too lax?
  - Is the company excusing employees for reasons other than leave that extends through the entire testing period?

Appendix D. Acronyms

Below is a list of acronyms that are used in this order and by inspectors and investigators in the performance of their duties.

ADPM	Alcohol and Drug Program Manager
AAM	Office of Aerospace Medicine
ARC	Automated Risk Calculation
ATF	Alcohol Testing Form
BAT	Breath Alcohol Technician
C&E	Compliance and Enforcement
CCF	Custody and Control Form
CETS	Compliance and Enforcement Tracking Subsystem
CFR	Code of Federal Regulations
C/TPA	Consortium/Third-Party Administrator
DER	Designated Employer Representative
DHHS	Department of Health and Human Services
DOT	Department of Transportation
EBT	Evidential Breath Testing
EAP	Employee Assistance Program
EIR	Enforcement Investigative Report
EIS	Enforcement Information Subsystem
FAA	Federal Aviation Administration
FOIA	Freedom of Information Act
FOUO	For Official Use Only
FSDO	Flight Standards District Office
ISO QMS	ISO Quality Management System

LOA	Letter of Acknowledgement
LOC	Letter of Correction
LOI	Letter of Investigation
LON	Letter of Notification
MRO	Medical Review Officer
NCA	Nonconformity and Corrective Action
NCT	Non-Compliance Transmittal
NIDA	National Institute on Drug Abuse
NOCA	Notice of Corrective Action
NOPE	Notice of Proposed Exclusion
NTSB	National Transportation Safety Board
ODAPC	DOT's Office of Drug and Alcohol Policy and Compliance
OPSPEC	Operations Specifications
OPSS	Operations Safety System
OST	Office of the Secretary of Transportation
PBR	Pilot's Bill of Rights
PIE	Public Interest Exclusion
PMI	Principal Maintenance Inspector
POC	Point of Contact
POI	Principal Operations Inspector
ROI	Report of Inspection
SAMHSA	Substance Abuse and Mental Health Services Administration
SAP	Substance Abuse Professional
SCMP	Strategic Compliance Monitoring Plan
SPAS	Safety Performance Analysis System

STT	Screening Test Technician
USPS	United States Postal Service
WebOPSS	Web-Based Operations Safety System
WN	Warning Notice

Appendix E. Inspection Scheduling Procedures

PURPOSE: This guidance establishes the procedures for developing the national inspection schedule. This appendix applies to the scheduling staff assigned to the Program Administration Branch, AAM- 810. The schedulers are tasked with supporting each C&E Center to establish the inspection schedule. The national inspection schedule is developed in accordance with the Strategic Compliance Monitoring Plan[3] (SCMP) and the Memorandum of Understanding[4] (MOU) between the FAA and NATCA.

All Drug Abatement personnel must follow this guidance, unless specifically advised otherwise by the Drug Abatement Division Manager or Program Administration Branch Manager (AAM-810 Manager).

The inspection process is divided into four stages:

(1) Development of a preliminary schedule in the CETS Planner,
(2) Bidding the schedule,
(3) Notifying companies of planned inspections, and
(4) Completing and distributing the Inspection Week Work Plan.

This following demonstrates the steps for each stage:

Stage 1: Development of the Preliminary Schedule

The scheduler starts to develop the preliminary schedule using the CETS planner. Once the preliminary schedule is developed, it is provided to the AAM-810 Manager and AAM-810 designated program analyst for review. Once the preliminary schedule is approved, it is sent to the Union representatives for bidding.

Each center has an average of 7 to 8 inspection teams completed for each inspection week for the upcoming quarter, depending on how many inspectors currently reside within each center and whether any large companies are on the region's schedule for the inspection week. If a large company that requires additional team members is scheduled for the inspection week, fewer teams will be required for the affected region for the affected week.

Prior to drafting the preliminary schedules in CETS, the schedulers should estimate the length of time needed for each inspection by accessing information listed in the company's CETS profile. The estimate is based on company size, company type, previous inspection out-of-compliance issues and any outstanding issues (i.e., voluntary disclosures, non-compliance transmittal forms, type of company).

When drafting the preliminary schedule in CETS, the scheduler should make selections based on which companies are highest in priority according to the current SCMP.

[3] The SCMP sets the goals to prioritize investigations and the selection of companies and service agencies to inspect; maximizes the number of inspections; and ensures the effectiveness of individual inspections. The SCMP is available on the Drug Abatement Division (AAM-800) QMS Web Site and updated annually.

[4] The MOU, signed on May 9, 2017, explains the procedure for the bidding process between the FAA and the NATCA Bargaining Unit.

After determining which companies are highest in priority and estimating the length of time needed for each inspection, the scheduler must use the mapping feature in the CETS planner, along with any other Internet mapping tools (e.g., Yahoo or Google), to determine which additional companies nearest the location of the highest priority companies may be added to each team. For the preliminary schedule, highest priority companies should normally be scheduled for Tuesday, Wednesday, and Thursday mornings (depending on travel for the team).

Note: The scheduler takes into consideration the time to travel between each location when placing companies on the schedule.

Stage 2: Bidding the Schedule

Once the preliminary schedule is prepared, the AAM-810 designated program analyst will review leave and availability information for each inspector to determine how many teams to use on the final schedule. This will become the bidding schedule. The AAM-810 designated program analyst will submit the bidding schedule for each center to the Center Manager, Union Representative, and the AAM-810 Manager by the deadline in the MOU. The AAM-810 designated program analyst will set a date and time to meet for each center to conduct the bidding process and oversee bidding for each region in accordance with the existing MOU.

Once the bidding is complete, the AAM-810 Manager or AAM-810 designated program analyst finalizes the quarterly schedule and assigns inspection leads.

Stage 3: Company Notification

Once the quarterly schedule is finalized, a person is assigned to notify the company of their upcoming inspections. When contacting the company, the notifier should do the following:

- Confirm the name and phone number of the current Alcohol and Drug Program Manager (ADPM)/Designated Employer Representative (DER). Update CETS accordingly.
- Notify the ADPM/DER of the upcoming inspection. In the communication tab of the inspection profile, the notifier should add the notification, identifying whom they spoke to, the date and time of the notification.
- Verify the correct records location, phone number, fax number and email address. Update CETS accordingly.
- Gather the following information to update the company's CETS profile or work plan:
  - current number of total employees,
  - current number of safety-sensitive employees
  - number of safety-sensitive new hires/transfers in the last two years,
  - number of positive drug and alcohol tests in the last five years,
  - number of refusals to test in the last five years,
  - does the company have a rehabilitation program,
  - who the company uses as their consortium, and
  - who is their MRO

The "Company Schedule Form" (available on Drug Abatement Division (AAM-800) QMS Web Site) will be helpful in gathering and annotating the information discovered during the notification discussion.

Note: If the company claims it is not available for the inspection, the notifier must contact the AAM-810 Manager or AAM-810 designated program analyst to verify removal of the company from the schedule.

Stage 4: Sending the LON and Completion and Distribution of the Inspection Week Work Plan

The final stage of the inspection schedule process is for the scheduler to send the LONs (in accordance with Chapter 2 of this order) and complete the Inspection Week Work Plan (available on the Drug Abatement Division (AAM-800) QMS Web Site) and send it to the AAM-810 designated program analyst via email one week prior to the inspection week. The AAM-810 designated program analyst will annotate whether the inspector should conduct a comprehensive, or remain a focused inspection. He/she will determine team leads and review the workplan. If the team needs a company added or removed, the designated program analyst will make the change and notify the inspectors of the changes. Once the designated program analyst has reviewed the workplan, he/she will send it to the inspector, Center Manager, Team Coordinators, Administrative Officer, Union Representative, and AAM-810 Manager.

If there are any changes to a completed work plan (e.g. adding a company or cancelling an inspection), the inspector is responsible for making the change and informing his or her Team Coordinator and C&E Center Manager. The inspector is responsible for notifying the company and completing any necessary data entry in CETS.

Appendix F. Inspection File Documentation

PURPOSE: This guidance establishes procedures and guidelines for the standardization of Drug Abatement Inspection files. It is the responsibility of every employee within the AAM-800 Drug Abatement Division to understand and comply with these requirements. This will ensure that our approach to inspection files is consistent, including what goes behind each of the file tabs.

In addition to what goes behind each tab, it is important to understand that for cases that proceed to legal enforcement action, you should maintain those records in a separate file. Some of those items include:

- A telephone log capturing discussions or contact with the Office of the Chief Counsel, Regional Counsel, or other parts of AAM-800;
- Any e-mail messages received or sent that are relevant to the questions or routing of the legal case;
- An exact duplicate of the legal case, including copies of all items of proof with tabs and dividers.

Your inspection file documents should be presented in chronological order, with the most current item first. All working copies, handwritten notes, post-its, etc. must be removed from the final inspection record and destroyed.

The following is the inspection file outline that all inspection and voluntary disclosure program files should be maintained:

INSPECTION FILE OUTLINE

1. **Inside Front Cover**:

    a. Point of Contact from company.
    b. Letter of Notification (LON), if applicable.

2. **Front of First Divider**:

    a. Completed Inbriefing/Outbriefing sign in sheet
    b. Inspection schedule, if applicable for a large or multi-day inspection
    c. When an inspector prints the following documents to plan for the inspection, the documents should be maintained in this portion of the file. If an inspector does an on-line review, no documents are necessary:
        - Copies of SPAS/OPSS SPECS/WEB OPSS Information.
        - Previous inspection summary or documents (Legal or Administrative Actions, Compliance Actions, Voluntary Disclosures, Investigations, Service Agent correspondence, etc.).

3. **Back of First Divider**:

a. Outbriefing Report w/team member(s) approval (direct initials or email approvals). Inspections that result in no findings should include a copy of the outbriefing report, regardless of whether it contains no "concerns".
b. Documents (Items of Proof (IOP)) obtained during the inspection, which may include:
    - Statements from witnesses, company official, and/or inspector statements.
    - Testing or program documentation.
c. Ensure that the documents are tabbed to reference the Report of Inspection (ROI) letter macro item and certified, dated, and signed in accordance with 2150.3, as amended.

4. **Front of Second Divider**:

a. Response to ROI letter or NOCA (for a Service Agent), including supporting documentation.
b. ROI letter or NOCA (For a Service Agent), including certified mail receipts (if applicable), review documents and guidance (if applicable).

5. **Back of Second Divider**:

a. Action Letter and/or Administrative Action Letter with 2150-5 form (if applicable). Include the review documents and guidance (if applicable).
b. For a service agent inspection, include a copy of the closeout letter or NOPE, along with a printed copy of the out-briefing report (which may include concerns) and documents provided to support the PIE.

6. **Inside Back Cover**:

Miscellaneous material not related to previous sections, e.g., maps of inspection site area, hotel or other logistical information.

Appendix G. Definitions

Act includes failure to act.

Administrative action means enforcement action other than legal action. Administrative action (Letter of Correction or Warning Notice) does not constitute a finding of violation and, therefore, the opportunity for notice and hearing is not required.

Careless conduct means a slip, lapse, or mistake that was not intentional or reckless.

Compliance action means action taken in response to noncompliance that does not constitute administrative or legal enforcement action, but still effectuates compliance.

Constructive attitude means the alleged violator acts in a positive manner toward regulatory requirements, cooperates willingly with Drug Abatement inspectors/investigators to achieve compliance, and willingly takes actions necessary to correct noncompliance and ensure future compliance.

Hazard means a condition that could foreseeably cause or contribute to an accident and lead to injury or property damage.

Inadvertent means that the noncompliance (act or failure to act) was not the result of purposeful conduct.

Intentional conduct means a deliberate act where the individual or employer knowingly acted contrary to a regulation.

Lack of qualification means a certificate holder lacks the skills and competency or care, judgment, and responsibility necessary to hold that certificate.

Legal action means enforcement action other than administrative action.

Likelihood means the estimated probability (frequent, probable, remote, extremely remote or extremely improbable) that the worst credible outcome (severity) will result from a hazard.

Not systemic conduct means acts that are not pervasive, repeated, or repeatable (indicating a system deficiency).

Reckless conduct means a gross disregard for safety standards or norms for reasonably prudent conduct, considering the certification level of the individual and the type of operation involved.

Safety risk means the level (high, moderate, or low) of potential injury or property damage from a hazard created by an act; a composite of predicted severity and likelihood of the potential effect of a hazard.

Severity means the *worst* credible consequence or impact of a hazard's effect or outcome (catastrophic, hazardous, major, minor, or minimal) in terms of the extent of injury or property

damage potentially caused by a hazard.

Substantial disregard (for safety or security) means that the act or failure to act by a certificate holder was a substantial deviation from the degree of care, judgment, and responsibility normally expected of a person or company holding that certificate with that type, quality, and level of experience, knowledge, and proficiency. For non-certificate holders, *substantial disregard* means that act or failure to act was a substantial deviation from the degree of care and diligence expected of a reasonable person in those circumstances.

Systemic conduct means pervasive, repeated, or repeatable acts indicating a system deficiency.