Audit Preparation
Are you ready?

Presented By: Lisa Ruehle
The general definition of an audit is an evaluation of a person, organization, system, process, enterprise, project or product.

Audits are performed to ascertain the validity and reliability of information; also to provide an assessment of a system's internal control.

The goal of an audit is to express an opinion of the person/organization/system (etc.) in question, under evaluation based on work done on a test basis.
Why we don’t like audits

- Time Consuming
- Performance Evaluation
- Punitive Consequences
- Different auditors
Why we should appreciate audits
(after you survived one...)

- **Learning Experience**
- **Motivator to look at processes objectively**
- **Identify gaps in the program and our knowledge**
- **The end result is usually a better program**
- **If it was a great audit - you feel really good and there may be be a reward!**
Who gets "audited"?

IRS  
F DA  
ESC  
EE O C  
DOT  

does anybody!

Car  
Inspections  
OSHA  
SOX
Auditing within the Drug-Free Workplace Industry

- Collection Site, C/TPA, MRO, SAP, Lab, Suppliers,
- DER, Lab Collection Site, C/TPA
- Suppliers
The Audit Foundation

- Documents, procedures and knowledge
- Regulations and related publications
- Service agreements and contracts
- Internal company policies

Make sure you know and understand the contents of these documents
How audits take place

- Clandestine
  - Unannounced and Unaware
- Scheduled
  - Full Program reviews
  - Focus Audit
- Audit by association
  - Very short notice
  - Investigation
Sweeping Audit

FMCSA Announces Results of 2012 Drug and Alcohol Inspection Strike Force

Agency's investigations removed 287 unsafe bus and truck drivers from the road

WASHINGTON - The U.S. Department of Transportation's Federal Motor Carrier Safety Administration (FMCSA) today announced that 287 commercial bus and truck drivers were removed from the roads and more than 128 companies face enforcement actions as a result of the agency's annual drug and alcohol strike force sweep that occurred from April 30 through May 11, 2012.
Auditing a Collection Site

*Beyond the basics*

- Mock collection
- Wait time
- Look for regulations, checklists, and information about *your* companies’ protocols
- Security of the specimens and paperwork
- Privacy of the donor
- Training Certificates and on-going education
Auditing a C/TPA

- Verify liability insurance is still in place
- Are they performing the requirements of the negotiated contract?
- Is the consortium in compliance?
- Verify that staff under the supervision of the MRO is not performing MRO functions
- Verify that the MRO is still an MRO
- Documentation on the random selections process
- Procedures for receiving positive test results and contacting the DER
- Review how your files are maintained
Your number has come up!

- Receive a call
- Written notification
- DER notifies service agents
- Respond to Auditor with any preliminary documents they request, such as point of contacts, etc.
- Begin preparing the records for review
Organizing the Records

- Don’t wait for an audit - organize daily, weekly or monthly
- Create a written procedure on how the files are to be maintained
- Prepare files to support the inspection checklist
- Allow the records to tell the story
Hot Buttons

- Pre-employment testing
- 40.25 problems
- SubPart O compliance
- Random pool and testing
- CCF/Collection site issues
Covered Employee Hiring/Transferring List

- Excel Spreadsheet, Alphabetized
- Specific time period (12, 18, 24 months)
- Hire date
- Date began performing safety-sensitive covered functions
- Date entered into the random pool
- Collected Date vs. Hire Date vs. Safety-Sensitive Date formulas
- Position and Location
- Termination Date
Pre-Employment Files

- Verification of Employee Training
- Policy Signature Sheet
- Hiring or Transferring document
- Result
- CCF (optional) with any corrections
- 40.25 (j)
- Release of Records completed or Good Faith Effort
- Application or document listing previous employment, signed by the employee
- Notice of testing required to applicants
40.25 Records Released

- Maintain a file of all the release of records you have answered by year and alphabetically.
- Include any documents you have released with the records, including documents sent to you regarding positives, refusals, etc.
Random Records

- Random selected list (pdf)
- Result and CCF in order of the list
- Documentation for incomplete tests
- Random eligible pool
  - Including dates in/out
  - Be prepared to explain how the random selections are made
- C/TPA - maintains documentation of their methodology
- “Best Practices” strongly advises 24 month record retention for ALL documents related to the random eligibility, selection and testing
Scheduling Random Tests

- Be prepared to explain your process for maintaining the random pool and scheduling random tests
  - Before, During, After
  - Spread evenly over days/times of operation
  - The specific method you follow for scheduling
Reasonable Suspicion

- Result
- CCF (optional)
- Documentation of the observed signs and symptoms
- Documentation that the observing supervisor(s) are trained and current
- Documentation that the employee was removed from duty if required
Post-Accident

- Result
- CCF (optional)
- Accident reports and description
- Documentation of why the alcohol test was not completed within the required time limits, or not at all
- Documentation of why the drug test was not completed within the required time limits, or not at all
- Documentation of the decision not to test
Folder for each employee participating in the SAP process

Documentation the employee was removed from safety-sensitive functions after the violation occurred

SAP Initial evaluation

SAP Follow-up Evaluation

Follow Up schedule

Results and CCFs
Return to Duty and Follow-Up tests

- Evidence that the Return to Duty test was completed and the result was received prior to performing safety-sensitive functions
- Return to Duty and Follow-Up tests were directly observed
  - If not, documentation that the employee was re-tested
  - Measures are put into place to ensure that future tests will be directly observed
- Follow-Up tests are completed in accordance with the SAP letter
Positives

60 month record retention

- Removal from safety-sensitive
- SAP information given
- Result and CCF (2 results if the split was re-tested)
- Documentation that the employee was eligible to be tested
- Termination or date returned to safety-sensitive duty documents
- Notification to agency of positive, if required
- Collector and/or BAT training certificate
- Calibration check log for alcohol
- Keep the records for 5 years, even if you did not hire or transfer the employee into a safety-sensitive position.
Refusals

60 month record retention

- Documentation on why this was considered a refusal
- Removal from safety-sensitive
- Result and CCF
- Documentation that the employee was eligible to be tested
- Termination or date returned to safety-sensitive duty documents
- Notification to agency of positive, if required
- Collector and/or BAT training certificate
- Keep the records for 5 years, even if you did not hire or transfer the employee into a safety-sensitive position.
- Provided SAP information
Cancelled Tests

- Documentation of why the test was cancelled
- Any corrective actions needed
  - Error Correction training (fatal flaw)
  - Procedural changes
- Evidence of re-collection when required by the MRO
Employee Education and Supervisor Training

- Have all the training and education materials available for inspection, including handouts and the policy
- EAP postings with hotline numbers and resources,
- Documentation of training
  - Sign-in sheets
  - Signed training acknowledgements
  - Training Certificates
Contractors performing covered safety-sensitive functions

- Verify they have a program
- Verify the contractor is actively in the program
- Request a copy of any registrations they have with the modality
- Maintain a contractor list to include:
  - Program Number (if applicable)
  - Company Name
  - DER Name and Contact Information
  - Date last verified program compliance
Miscellaneous Documents

- Blind Testing documentation, if required
- MRO certification and continuing education
- Copy of C/TPA contracts
- SAP Information
- MIS reports (previous year)
- Semi-Annual lab reports (2 years)
- Drug and Alcohol Logbooks
- Calibration Logs
- Instructions for collection sites (40.14)
It’s the little stuff....

- Is the time on the alcohol machine correct and/or the clock on the wall?
- Is the gas expired?
- Is the evidence tape truly tamper-proof?
- Do you have the QAP and do you know what it says?
- Can the auditor stand on the toilet and lift the ceiling tiles while items fall down?
- Are you keeping the files locked and specimens secured?
- Is the filing cabinet locked but the key is on top of the cabinet?
- Are the addresses correct on the CCFs?
- Do you have the EAP information displayed?
Help from the Regulations

- BE familiar with ODAPC and Modality web pages
- Carefully read the Inspection Guides and Checklists (FAA)
- Common Compliance Issues (FTA)
- “What Employers Need to Know”
- Record Retention
- How CCFs are corrected
- Previous audits
You have found a problem

- Talk someone through the potential problem
- Re-read the regulations
- Go back and look at the process
- Make sure it is actually a problem that cannot be legally remedied
- If it cannot be remedied, be honest
Audit Etiquette

- Identify a suitable location for the auditor to work
- Ensure access to the files covered by the inspection
- Supplies the auditor may need
- Information on local restaurants, take-out menus, etc.
- Where the facilities and fire escape are located
In-Brief

- Company Representatives
- Auditors provide an overview
- Auditors may ask a series of questions about your records or knowledge
- If there is something you must disclose - now might be the time
During the Audit

- Never give an answer you are unsure of. It is ok to say I will get back with you shortly.
- If there are additional documents that are requested, you can tell them you will bring them shortly.
- Make sure Legal is contacted if the request is possibly outside of the scope of the audit.
Out-Brief

- Company Representatives
- The Auditors give the initial verbal report of their findings and what the next steps are.
- A letter is received in the mail listing the audit concerns.
- The Company has 10 days to respond with additional information or their plan for future compliance.
Keys to Success

- Take the audit seriously
- Have strong policies/procedures that are routinely adhered to
- Periodic self audits
- Have a peer audit your program
- Know the regulations that apply
- Network with industry counterparts to share experiences and ideas
- Thank your service agents for their support
- And the last thing to do is.....
Take a Vacation
Good Luck!

LISA C. RUEHLE
INTERACTIVE MEDICAL CONNECTIONS, INC.
LISA@IMEDICON.COM
(281)486-4434