U.S. Department of Transportation

Federal Transit Administration

Substance Abuse Management Seminar

The Revised
49 CFR Part 40

49 CFR Part 40 Proponent

- Office of Drug and Alcohol Policy and Compliance (ODAPC)
  - The Secretary of Transportation established the office to provide specialized assistance and consultation on drug and alcohol issues within the transportation industry to the Secretary and to the Operating Administrations

History

- Part 40 - Drug Testing Rules (1989)
- Part 40 - Alcohol Testing Rules (1994)
- Over 100 Interpretations Since 1990
- NPRM Issued ~ December 1999
- Listening Sessions & Electronic Forum
- 3,800 comments ~ 400 interested parties
- Docket Closed ~ April 7, 2000
- Final Rule ~ December 19, 2000

Regulatory Scope

INDUSTRY	DOT MODE	# EMPLOYERS	# EMPLOYEES
Highway	FMCSA	650,000	7,333,000
Railroad	FRA	650	97,000
Aviation	FAA	6,700	364,200
Transit	FTA	2,500	204,000
Pipeline	RSPA	2,450	190,000
Maritime	USCG	12,000	132,000
TOTAL		674,300	8,320,200

Language and Format

- Plain English “No Gobbledygook” Award
- Question and Answer Format
- Organization and Document Flow
- Labor Management Issues
- Changes in the industry
- Looking to the future

Implementation Dates

- January 18, 2001 – Amendments to current rule:
  - Validity testing
  - MRO Review & Split Testing
  - Public Interest Exclusion (PIE)
- August 1, 2001 – Implementation of the full rule

Policy Issues

STAND-DOWN

Definition

- Means temporarily removing an employee from performing safety-sensitive functions <u>after</u> laboratory reports a confirmed positive, adulterated, or substituted test but <u>before</u> MRO completes verification process.

General Rule

- Stand-down is prohibited
- MRO cannot even tell employer about laboratory result until after verification is completed
- Rationale: prevent unfair labeling of employee as violator before MRO review – key safeguard in process – is complete

Waiver to General Rule

- Employer can apply to DOT operating administration for waiver of no stand-down general rule
- Basis for granting a waiver is safety need plus policy that provides protections for employees
- Allows employer to stand employees down while MRO review is pending

Waiver Application

- Safety need with supporting data
- Drug testing statistics
- Information about work situation
  - Size and organization of work units
  - Process to inform employees of stand-down
  - Whether there is an in-house MRO
  - Whether there is a medical disqualification or stand-down policy for matters other than drug testing
- Written policy

Stand-down Policy

- Distributed to each covered employee
- Ensure confidentiality (employee, MRO, and designated employer representative)
- Ensure all covered employees in same job category are treated the same
- No adverse effects on pay and benefits
- Stand-down period cannot exceed 5 days

Process and Action

- Operating administrations began considering waiver requests 8/1/01
- DOT operating administration will provide written response to waiver request
- If employer doesn’t implement safeguards properly, or does stand-down without DOT approval, employer violates DOT rules and is subject to sanctions

Policy Issues

PUBLIC INTEREST EXCLUSION

Purpose

- Protect public interest from serious noncompliance with DOT rules by service agents
- Intended for cases of serious noncompliance

Initiating Official Action

- Informally contacts service agent to get its side of the story
- Sends correction notice to service agent
- If problem can be and is fixed, no further proceedings
- Issues notice of proposed exclusion (NOPE)
- Burden of proof on initiating official (preponderance standard)

Director Involvement

- Would hear Service Agent contest the proposed PIE
- Addresses facts, scope and duration issues
- “Firewall”

Scope of PIE

- Broadens as noncompliance becomes more pervasive
- Not limited to particular location or employer
- Could expand to include employees, affiliates, and contractors of service agent organization

Duration of PIE

- Duration of a PIE is 1 – 5 years
- Depends on seriousness of noncompliance and need to protect other participants
- Duration can be shortened or terminated on application from service agent
- Director can shorten or terminate PIE if noncompliance has been eliminated

Notice of PIE

- Written notice of decision and basis
- Name of service agent listed on DOT web site and in Federal Register
- Service agents must notify all DOT-regulated clients about the PIE
- Employers must stop using service agent's services within 90 days of issuance of PIE
- Issuance of PIE does not result in cancellation of tests conducted by service agent

Policy Issues

VALIDITY TESTING

Validity Testing

- Validity testing currently, is voluntary
- Becomes mandatory when HHS issues final rule effective date
- Split specimen testing and MRO review required
- Laboratory problems discovered last fall
- HHS did review of laboratory procedures as well as past two years' validity tests
- Mistakes had been made; as a result ~ 300 tests cancelled
- HHS is now confident that procedures are being followed properly
- Laboratory problems concerned implementation issues only; HHS criteria and procedures for validity testing remain sound

Policy Issues

TRAINING

and

ROLE OF C/TPAs

Training

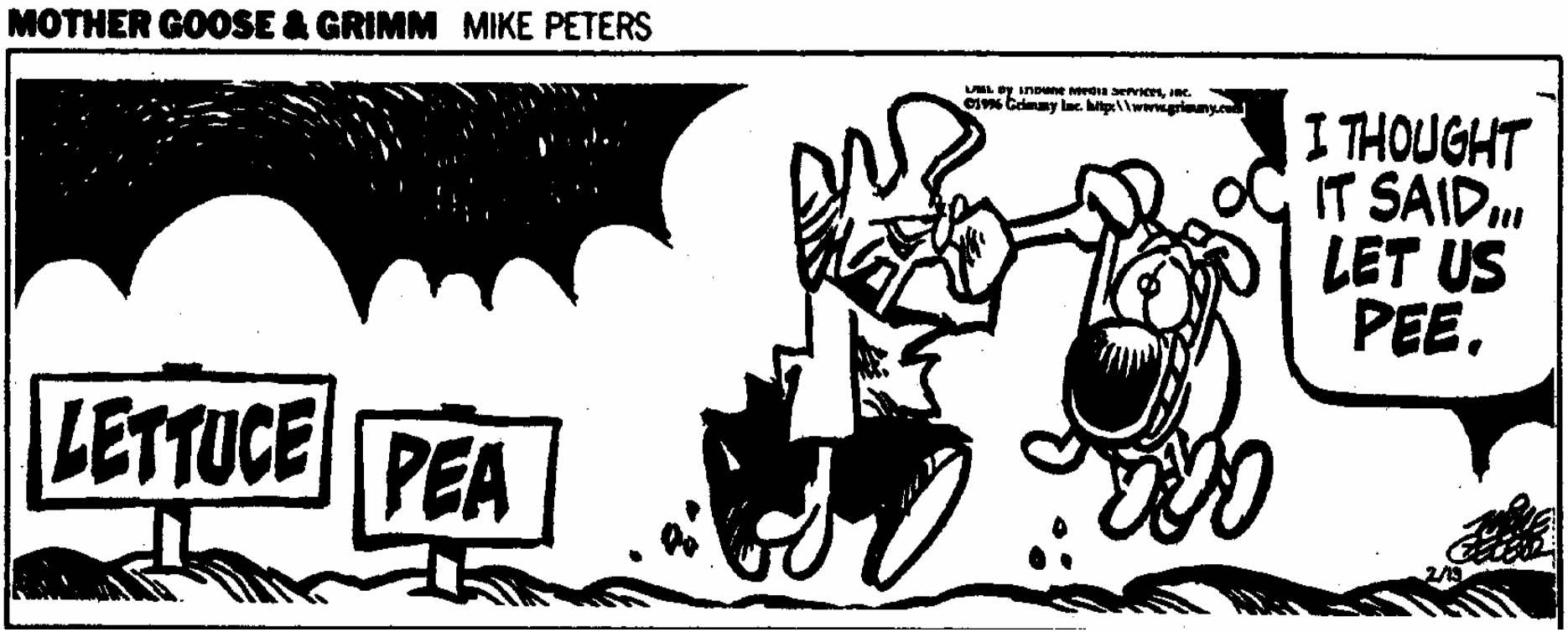
- New rule strengthens training requirements for MROs, SAPs, collectors, BATs, and STTs
- Purpose is to reduce the potential for errors and to make the process work better for everyone
- No certification required by DOT

Role of C/TPAs

- C/TPAs are now able to transmit information to employers (e.g., drug test results from MROs)
- Use of C/TPAs in this capacity is optional with the employer
- Some information cannot be transmitted by C/TPAs (e.g., alcohol “positives,” drug test results from laboratory to MRO)

DRUG TESTING

Drug Testing



Policy Changes in Urine Collection

- Major change in collector training
- Clarified collection site issues
- Changed some procedures

Definition

- Collector: A person who instructs and assists employees at a collection site, who receives and makes an initial inspection of the specimen provided by those employees, and who initiates and completes the CCF

Training of Collectors

- Basic Information: Knowledge of Part 40; current DOT Collection Guidelines; DOT operating administration regulations; & any changes to these
- Methodology: Open-ended – classroom, videos, internet, etc
- NO Certification required by DOT

Qualification Training

- All steps necessary to complete a collection correctly
- Knowledge of problem collections
- Fatal and correctable flaws
- Responsibility for integrity of the process, ensuring privacy, security of the specimen, & professional conduct

Initial Proficiency Demonstration

- After Qualification Training:
- Demonstration by conducting 5 consecutive error-free mock collections
- Must include 2 uneventful; 1 insufficient quantity; 1 temperature out of range; and 1 refusal to sign or initial
- In front of a person who monitors and evaluates proficiency

Who can monitor mock collections?

- Someone who: Is a qualified collector
  - Regularly conducted DOT collections for at least a year, or
  - Conducted training for a year, or
  - Successfully completed a “train the trainer” course
- Must be in-person or real-time observation; and attest in writing that all 5 collections were error-free

Refresher Training

- Every 5 years
- Must meet same requirements as original qualification training and initial proficiency demonstration

Error Correction Training

- When a collector makes mistake causing a test to be cancelled
- Within 30 days of error notification
- Provided and documented by trainer
- Must address area in which error occurred
- Three consecutive error-free mock collections (1 uneventful; 2 related to error area)

Documentation

- Collectors must maintain & provide to DOT agency, employers, or service agents who use collectors' services documentation of their training

Schedule/Dates

- Qualification and Initial Proficiency Training:
- Collector before Aug 1, 2001 and have met requirements, do not have to meet them again
- Collector before Aug 1, 2001 and have NOT met requirements, NLT Jan 31, 2003
- Collector on or after Aug 1, 2001 MUST meet requirement before can be collector

Collection Issues

- Changes in Custody and Control Form (CCF)
- Changes in procedures
- Standardized collection kit
- Split specimens for USCG & RSPA

Collection Site

Collection Site

- Preferred: single-toilet room
  - Full-length privacy door
  - No one else present (unless observed collection)
- Allowed: multi-stall restroom
  - Partial-length door
  - Monitor may be in restroom during collection
  - May secure all water & other substances and blue or secure all toilets <u>or</u>
  - Conduct all collections as monitored – same gender, unless medical personnel

Collection Site Operation

- Site facility may be medical, mobile, or dedicated -- as long as it meets requirements
- Materials, supervision, and security for “integrity of the collection”
- Secure to deter tampering
- Limit access and maintain control
- May remove any person who obstructs process

Use of New CCF

- Must use the new CCF
- Must use the new procedures
- May not use for non-DOT tests
- Correctable flaw to use old CCF
  - Through October 31, 2001
  - November 1, 2001 and thereafter

Standard Collection Kit

- Includes collection container
- Specifies bottle security wrapping
- Requires leak-resistant plastic bag
- Requires absorbent material
- Requires shipping container
- <u>No</u> shipping container seal

Preliminary Steps

- Time of arrival on site –
  - Notify DER (or C/TPA) if “no show”
- If medical attention, do not delay
- Catheterization –
  - Never done by collector
  - Employee normally voiding by self-catheterization is required to do so to provide specimen
- Positive identification required
  - Photo or identification by employer representative
  - Collector may have to contact DER

Inspection of Personal Items

- Pockets: Collectors will require ALL donors to display contents of their pockets
- Boots: Requirement to inspect boots NOT implemented

Collection Process

- Employee –
  - Washes hands
  - Select kit (optional)
  - Provides specimen in a reasonable time
- Collector –
  - Inspects for sufficient specimen, temperature, and signs of tampering
  - Pours urine and seals bottles
  - Completes CCF, obtains employee signature and initials, and packages specimen and CCF

Temperature

- If specimen is out of range, collector will immediately initiate a directly observed collection
- NO requirement to take body temperature
- NO requirement to seek concurrence from supervisor or employer
- Required to notify afterwards

Direct Observation-Mandatory

- Employer: Lab reports invalid test and MRO states no medical reason; Positive, adulterated or substituted cancelled – split not available
- Collector: Observe action indicating attempt to tamper; temperature out of range; specimen appears to have been tampered with

Direct Observation-Optional

- Employer: Option to conduct direct observation for return-to-duty or follow-up test

Direct Observation-Procedure

- Reason for test - same (if 2d test)
- “Observed” check block on new CCF
- Observer <u>ALWAYS</u> same gender
- Observer does not have to be trained collector (note on CCF if not collector)
- Observer -- who is not collector -- does not handle urine specimen

Monitored Collection-Procedure

- Monitor is same gender as employee unless monitor is medical professional
- Monitor may be someone other than collector to ensure same gender (note on CCF if not collector)
- Sounds or observations indicating an attempt to tamper result in observed collection
- Monitor -- who is not collector -- does not handle urine specimen

“Shy Bladder” Procedure

- Urge employee to drink up to 40 ounces
- Refusal to drink is not refusal to test
- Refusal to make an attempt to provide –
  - Discontinue test
  - Contact DER
- 3-hour time limit
- Send CCF copies to MRO & employer

Dilute Specimen

- A negative dilute specimen does <u>not</u> trigger direct observation
- Employer <u>may</u> conduct a 2nd collection – same policy for all
- Employer must <u>not</u> disregard a negative dilute result in pre-employment testing

Refusal to Take Test

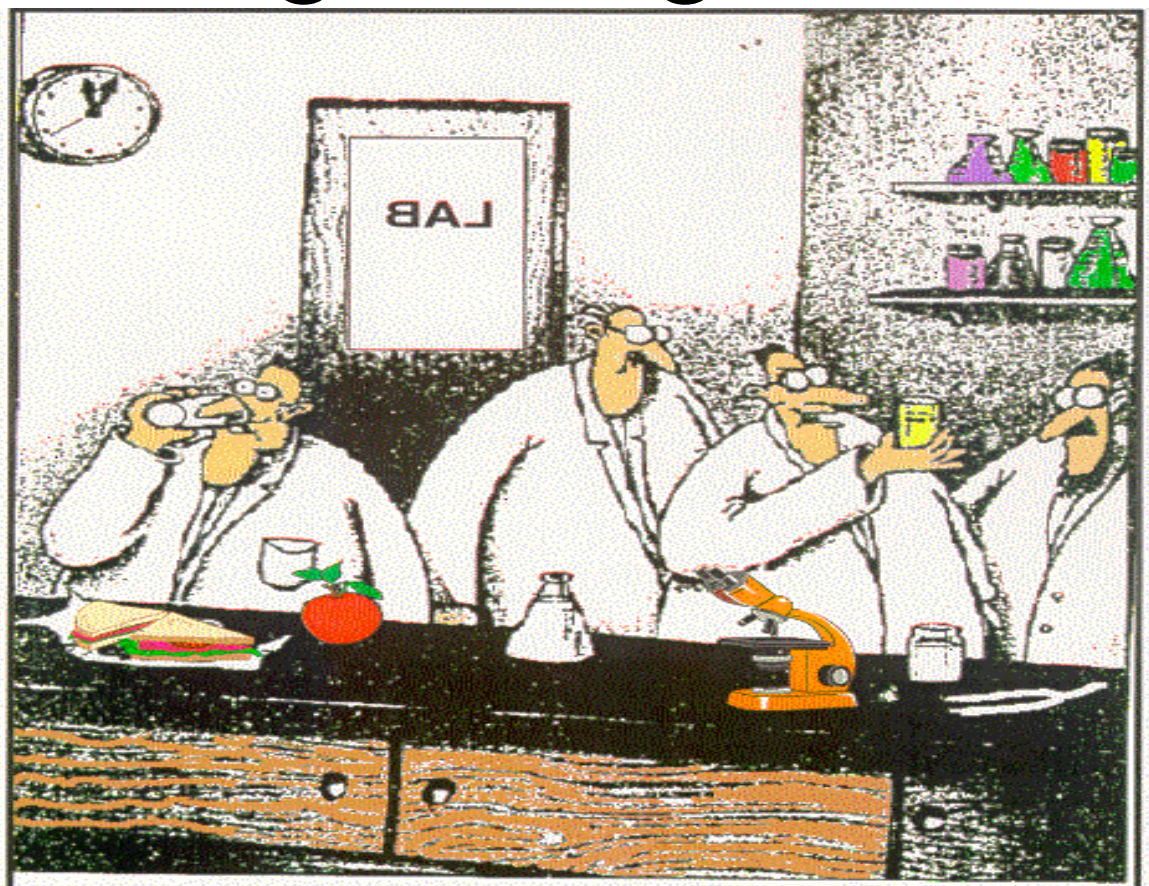
- Fail to:
  - Appear or remain at site
  - Provide urine specimen when required
  - Permit directly observed or monitored collection
  - Take a 2d test as directed
  - Provide sufficient urine (w/no med. explanation)
  - Undergo medical evaluation
  - Cooperate with testing process (e.g., empty pockets)

Correcting Problems

- Collectors have responsibility of trying to successfully compete a collection
- If you discover a problem, you must try to correct, in writing
  - Supply missing information
  - Supply statement for incorrect form
  - Maintain documentation of correction

Laboratory Process

Drug Testing Laboratories



What the? . . .This is lemonade!
Where's my split specimen?

Drug Testing Laboratories

- All DOT specimens are inspected for “fatal flaws” and “correctable flaws”
- All specimens are tested for 5 drugs (THC, COC, PCP, OPI ,AMP) using HHS cutoffs for initial & confirmation tests
- All specimens are subjected to validity testing (permitted now; mandatory after HHS final rule)

“Fatal Flaws”

- Lab inspects each specimen & CCF–
  - Specimen & bottle IDs do not match
  - Bottle seal is broken or tampered with
  - Collector’s name <u>and</u> signature omitted
  - Insufficient urine
- If found – testing process stops
- Report – Rejected for testing (reason)

“Correctable Flaws”

- Lab inspects each specimen & CCF–
  - Collector’s signature omitted
  - Use of old CCF (after Oct 31, 2001)
- If found – document flaw, testing continues, lab attempts to correct
- If not corrected Report – Rejected for testing (reason)
- Temperature out of range – special

Specimen Validity Testing

- Testing to determine if a specimen is adulterated, diluted, or substituted
- Each specimen must be measured for –
  - Creatinine
  - Specific gravity if creatinine is less than 20 mg/dL
  - pH

Specimen Validity Testing

- Each specimen must be tested for substances that may be used to adulterate the specimen
- HHS will define the test requirements
- Specimens suspected of containing an adulterant must be sent to another HHS laboratory for identification

SVT Criteria Defined

- Primary specimen –
  - Dilute
  - Substitute
  - Adulterated
- Split specimen –
  - Substitute (same criteria as primary test)
  - Adulterated (same criteria as primary test for the adulterant detected)

Reporting Results – Negative

- All results only to the MRO
- Fax, courier, mail, electronic image of signed Copy 1 (Lab copy)
- Or electronic laboratory results report
- No image of CCF (e.g., paper, computer copy) required

Reporting Results – Non-Negative

- All results only to the MRO
- Fax, courier, mail, electronic image of signed Copy 1 (Lab copy)
- May provide electronic laboratory results report
- Image of CCF is required (paper, fax or scanned image)

Other Issues on Reporting Results

- Laboratory and MRO have responsibility of ensuring that information is adequately protected from unauthorized access during transmission & storage
- Quantitative results to MRO on request
- Quantitative results to MRO on opiates at or above 15,000 ng/ml

Statistical Reports

- Aggregate statistical summary
- Employer-specific
- Semi-annual (by July 20 & Jan 20)
- Also, at request of employer in response to an audit
- No summary if fewer than 5 results

Conflict of Interest

- Lab may not derive financial benefit by having an employer use a specific MRO
- Examples of conflicts for MRO who reviews lab's specimen results–
  - Lab employs, contracts or retains MRO
  - Lab designates or gives incentive for MRO
  - Lab co-locates with MRO
  - Lab permits MRO to have financial interest in lab

Retention of Specimen & Records

- Positive, adulterated, substituted, invalid, and split specimens for <u>one</u> year
- All records for each specimen, and all employer-specific reports for <u>two</u> years
- MRO, employer, employee, or DOT agency may extend retention time of specimen or records w/written request

Split Specimen Handling

- 1st lab notes presence of split specimen
- 1st lab does not open split
- 1st lab forwards split to 2d lab on request in writing from MRO
- 2d lab tests split to reconfirm the results of primary specimen
- 2d lab reports split results to MRO

MEDICAL REVIEW OFFICER

Medical Review Officers

- Credentials: Licensed MD or DO
- Basic Knowledge: Clinical experience in substance abuse disorders; alternative medical explanations for drug tests; adulterated & substituted specimens; and medical reasons for invalid results
- Knowledge of Part 40; current DOT MRO Guidelines; DOT operating administration regulations; & any changes to these

MRO Qualification Training

- Training
  - Collection procedures
  - CoC, reporting, & record keeping
  - Interpretation of drug & validity results
  - Role & responsibilities of MRO
  - Interaction with others (e.g., DER, SAP)
  - Knowledge of Part 40; DOT agency regulations; & any changes to these
- Examination

MRO Continuing Education

- During each 3 year period following examination, must complete at least 12 hrs of CEUs
- Must include new technologies, interpretations, recent guidance, rule changes
- Must include assessment tools to determine level of knowledge
- MRO trained before August 1, 2001, must have CEUs by August 1, 2004

MRO Training Documentation

- MRO must maintain documentation showing that all requirements were met
- Documentation must be available to DOT agency representatives and to employers or service agents using MRO services

MRO Training Schedule/ Dates

- If MRO before August 1, 2001 <u>and</u> met qualification training, do not have to meet them again
- MRO before August 1, 2001 have <u>not</u> met qualification training, must meet by by Jan 31, 2003
- MRO After August 1, 2001, must meet qualification training before functioning as MRO

Review and Report of Negative Results

- Review lab report and CCF (w/employee signature)
- Staff under supervision of MRO may perform this administrative function
- Prior to reporting, MRO must have --
  - Copy 1 from lab or electronic lab report
  - MRO copy (Copy 2), legible copy, or any copy with employee signature

MRO
Quality Control

- Review of 5% of negative CCFs reviewed by staff, per quarter, including those requiring corrective action
- Reviewed CCFs must be identifiable and retrievable for audit

Review and Report of Non-Negative Results

- Review lab CCF (w/certifying scientist signature) and CCF (w/employee signature)
- Staff under supervision of MRO review CCF, but only MRO may cancel or verify test
- Prior to reporting, MRO must have --
  - Copy 1 from lab (faxed copy or image)
  - MRO copy (Copy 2), legible copy, or any copy with employee signature

Verification Process for Non-Negative Results

- MRO <u>must</u> talk to the employee directly
- Staff may make initial contact
- Limited to scheduling and explaining consequences of declining to talk to MRO
- Staff <u>must not</u> gather medical information
- Staff may advise employee to have medical information available for MRO
- Staff may document “expressly declining”
- Staff may obtain Rx upon request by MRO

Verification Process – Employee Contact

- Reasonable efforts: minimum, 3 attempts in over 24-hours
- Document efforts; dates and times
- Provision for wrong phone numbers
- Contact DER for assistance

Verification Process "Non-contact" Positive

- Employee <u>expressly</u> declines to talk with the MRO
- IF DER contacted employee and more than 72 hours have passed
- If neither MRO nor DER are able to contact employee 10 days of date MRO received lab report
- 60 Day window for employee to present documentation for no contact

Verification Process-Preliminaries

- MRO explains test result, drug(s) involved, basis for adulteration or substitution finding
- MRO must explain verification process, including responsibilities and burdens of proof of MRO and employee w/re different situation
- MRO must give “Miranda warning”
- Generally, face-to-face examination is not required

Verification – Opiates

- 6-AM: MRO must verify test positive
- Morphine or codeine at 15,000 ng/mL or greater: Employee has burden of proof and must demonstrate a legitimate medical explanation
- Lower levels of opiate: MRO has burden of proof that there is clinical evidence of unauthorized use

Verification – Other drugs

- Amphetamines, PCP, marijuana, and cocaine: Employee has burden of proof to demonstrate legitimate medical explanation to MRO
- Employee must present evidence at interview, but MRO can give up to five additional days if appropriate

Foreign Medications

- To be basis for legitimate medical explanation, use of foreign medications must meet the following standards (also true re. opiates):
  - Substance must be obtained legally in foreign country
  - Substance must have a legitimate medical use
  - Substance must be used consistent with proper and intended medical purpose
  - Safety-related medical information must be passed on to employer

MRO Responsibilities – Adulterated/Substituted

- Employee has burden of proof
- Adulteration: Must demonstrate adulterant entered specimen through physiological means
- Substitution: Must demonstrate that he or she can produce urine meeting criteria through physiological means
- If MRO believes there is a reasonable basis for assertion of legitimate medical explanation, MRO may involve “referral physician”

MRO Responsibilities – Invalid Result

- Discuss with certifying scientist
- Contact employee for explanation; if valid medical reason – cancel test (no recollection unless negative needed)
- No valid medical reason – cancel test, immediate direct observation recollection

MRO Responsibilities – Rejected for Testing

- Report to DER cancelled test and the reason
- No further action unless a negative is required

MRO “No-Nos”

- Don’t use “alternative specimens” (e.g., hair, blood) or DNA tests
- Don’t consider allegations of improprieties in collection or improper reasons for test
- Don’t consider assertions that, even if true, would not be legitimate medical explanation (e.g., “medical marijuana,” passive inhalation, hemp)
- Don’t accept medical explanation for PCP, 6-AM, presence of soap, glutaraldehyde, or no creatinine

Changing Results

- MRO can change a verified positive or refusal:
  - **Reopening of "non-contact positive" where employee had legitimate reason for lack of contact**
  - **New evidence of laboratory error**
  - **If MRO made a mistake in reporting results**
  - **If, within 60 days of original verification, MRO gets additional information, not originally available, demonstrating legitimate medical explanation**
  - **MRO who made a verification decision is the only person who can change it later**

Requests for Split Specimen Tests

- On positive or refusal MRO must explain split specimen testing process to employee
- MRO must explain that employer is required to make split specimen test happen if requested in a timely fashion
- Employee has 72 hours after verification to request test of split specimen

MRO Responsibilities – Reporting Results

- Report results to DER or SA
- Phone contact preferred for immediate report
- Negatives:
  - MRO or staff may stamp
  - Copy 2
  - Written report
  - Electronic report
- Non-negatives:
  - MRO must sign Copy 2 or written report with all Copy 2 information

ALCOHOL TESTING

Alcohol Testing

- Few procedural changes
- Revised to be parallel with drugs
- Permit use of variety of training media
- Added requirements for training – refresher training and error correction

STT and BAT Training

- Basic information: Knowledge of alcohol testing procedures & current DOT guidance
- Qualification training: DOT Model STT & BAT Courses or equivalency; proficiency in use of particular devices; responsible for integrity of process
- Instructor: must have been a STT/BAT or conducted training for at least a year; or completed a “train the trainer” course

Initial Proficiency Demonstration

- By completing 3 consecutive error-free mock tests
- Must be monitored & evaluated by instructor
- Same devices that STT/BAT will use
- If use devices involving changes, contrasts, or color readings, must demonstrate ability to see changes

Refresher & Error Correction Training

- Refresher: same training as qualification and initial proficiency every 5 years
- Error correction: if test cancelled because of error, must have error correction training within 30 days
- Provided and documented by instructor; only in area that error was made; 3 consecutive error-free tests –1 uneventful, 2 related to error

Who can monitor mock tests?

- Someone who:
  - Regularly conducted DOT alcohol tests for at least a year, or
  - Conducted STT/BAT training for a year, or
  - Successfully completed a “train-the-trainer” course
- Must be face-to-face; attest in writing that 3 tests were error-free

Schedule/Dates

- <u>Qualification training & initial proficiency demonstration:</u>
- STT/BAT before August 1, 2001, must have met all requirements
- STT/BAT after August 1, 2001, Must meet requirements before conducting tests
- BAT/STT before January 1, 1998, must have refresher training before January 1, 2003

Documentation
STT and BAT Training

- STT/BAT must maintain & provide to DOT agency, employers, or service agents who use their services documentation of their training

Alcohol Testing

- No major changes
- Must secure site and ASDs & EBTs
- Must test only one individual at a time
- Start testing without undue delay
  - Conduct alcohol test before drug test
  - Do not wait for employer or employee reps
- Small changes to the testing form
- BAT must have DER name & phone
- Must notify DER w/in 48 hours of fatal flaw

Alcohol Testing Procedures

- Scheduled tests and arrival time – delay requires notification of DER
- Conduct alcohol test first (if drug test also required)
- Refusal to sign Step 4 – <u>not</u> a refusal
- Employee must be observed between screening and confirmation tests

Alcohol Testing Form

- Minor changes:
- DER name; check boxes for devices; 15 minute wait; attach results to front of form (attaching results to back is still permissible)
- Step 4 (employee signature) is now only to be completed when confirmed alcohol results are 0.02 or higher
- Must not use for non-DOT tests

Problems in Alcohol Testing

- What is a refusal and what are the consequences?
- Insufficient amount of breath
- Fatal & correctable flaws
- Corrective action: may repeat test- not limited to number
- Procedural problems – no adverse effect

Refusal

- Failure to:
  - Appear in timely manner
  - Remain on site until completion
  - Provide sufficient saliva or breath & no medical reason
  - Undergo required medical exam
  - To sign ATF (Step 2)
  - Cooperate with any testing procedures

Alcohol Testing
“Shy Lung” Procedures

- Parallel to drug testing
- Evaluating physician must have expertise
- Employee must obtain evaluation in 5 days (good faith effort)

SUBSTANCE ABUSE PROFESSIONAL

Definition / Function

- A person who evaluates employees who have violated DOT drug and alcohol regulations and makes recommendations concerning education, treatment, follow-up testing, and aftercare
- Protect the public interest in safety

Credentials

- Licensed Physician (MD or DO)
- Licensed or certified
  - Social Worker
  - Psychologist
  - Employee Assistance Professional
  - Drug and alcohol addiction* counselor certified by NAADAC or ICRC

***see next slide**

DOT Adding Other Certified Addiction Counselors

- Certification organizations must:
  - Obtain National Commission for Certifying Agencies (NCCA) accreditation
  - Meet Part 40 Appendix E requirements
  - Petition the Department

Basic Knowledge / Experience

- Diagnosis and treatment of drug- and alcohol-related disorders
- SAP functions as they relate to employer interests in safety-sensitive duties
- 49 CFR Part 40
- DOT agency regulations
- DOT SAP Guidelines
- Changes

Qualification Training

- Background & DOT program
- Part 40 and agency rules
- Key testing issues
- SAP prohibitions
- SAP responsibilities
- Reports & record-keeping

Examination

- Satisfactory completion of an examination by a nationally-recognized professional or training organization
- Exam must cover all basic knowledge and qualification training requirements
- Examination must be validated
- SAP certification is not required nor provided by DOT

Qualification Training Dates

- If SAP before August 1, 2001, meet all requirements by Dec 31, 2003
- If SAP between August 1, 2001 & Dec 31, 2003, meet all requirements by Dec 31, 2003
- If SAP on or after Jan 1, 2004, meet all requirements before functioning as SAP

Continuing Education

- At least 12 CEUs every 3 years
- Must include new technologies, interpretations, recent guidance, rule changes, and developments in SAP practice
- Must include documentable assessment of knowledge

Training Documentation

- SAPs must maintain training and examination documentation & provide it upon request:
  - to DOT agencies
  - to employers or service agents who use or contemplate using their services

Responsibilities

- Face-to-face clinical assessment and evaluation
- Refer to appropriate program
- Face-to-face follow-up evaluation
- Recommendations for continuing education and/or treatment
- Follow-up testing plan
- Report directly to employer

Initial Evaluation

- Recommend assistance in <u>every</u> case
- Recommend the most appropriate course of education and/or treatment
- Must not consider claims of: inappropriate selection; hemp oil or medical MJ; poppy seed use; job stress excuses
- May consult with MRO

Initial Evaluation (Cont.)

- Appropriate education:
  - Self-help groups (e.g., Alcoholics Anonymous)
  - Community lectures
  - Bona fide drug and alcohol education courses
- Appropriate treatment:
  - In-patient hospitalization
  - Partial in-patient treatment
  - Out-patient counseling programs
  - Aftercare

Initial Evaluation (Cont.)

- No seeking additional evaluation(s)
- No one can change a SAP's evaluation
- SAP may modify recommendations

Initial Evaluation Report

- Report must have:
  - Employees' name and SSN
  - Employer's name and address
  - Reason for assessment
  - Date(s) of assessment
  - SAP's education and/or treatment recommendation
  - SAP's telephone number
- Must be on SAP's own letterhead, signed and dated by the SAP

Referral

- Based upon SAP's best recommendation for assistance, serve as source for employee's entry into the appropriate education and/or treatment program

Referral Prohibitions

- In making the referral, SAPs cannot:
  - Refer to own private practice
  - Refer to person or organization paying them
  - Refer to person or organization in which they have a financial interest or association
- 4 exceptions:
  - Public agency
  - Provided by employer or employer contract
  - Health insurance
  - Sole provider reasonably accessible service

Follow-up Evaluation

- Determine successful compliance or not
- One basis for employer decision to return employee to duty
- SAP must:
  - Confer with education and/or treatment professionals
  - Conduct face-to-face clinical interview with employee
  - Make clinical determination regarding successful compliance

Follow-up Evaluation (Cont.)

- One of two determinations is possible:
  - Employee has demonstrated successful compliance
  - Employee has <u>not</u> demonstrated successful compliance
    - No return to safety-sensitive duty
    - SAP can conduct additional follow-up evaluation(s) if employer authorizes
    - Employer may take personnel action

Aftercare Recommendation

- If employee needs on-going services after return to work:
  - Must be in the follow-up evaluation report
  - The employer may use as part of a return-to-work agreement

Follow-up Testing

- SAP determines the number and frequency
- Minimum of 6 tests during the first 12 months
- Can last up to 60 months
- SAP can terminate requirement after the first year of testing
- Requirements follow the employee

Follow-up Report

- Successful-compliance Report
  - **Employee's name and SSN**
  - **Employer's name and address**
  - **Reason for the initial assessment**
  - **Date(s) of the initial assessment and synopsis of the treatment plan**
  - **Name of referral practice(s) or service(s)**
  - **Inclusive dates of employee program participation**
  - **Characterization of program participation**
  - **Clinical determination of compliance**
  - **Follow-up testing plan**
  - **After-care recommendations**
  - **SAP's telephone number**

Follow-up Report (Cont.)

- Unsuccessful-compliance Report
  - **Employee's name and SSN**
  - **Employer's name and address**
  - **Reason for the initial assessment**
  - **Date(s) of the initial assessment and synopsis of the treatment plan**
  - **Name of referral practice(s) or service(s)**
  - **Inclusive dates of employee program participation**
  - **Characterization of program participation**
  - **Date(s) of first follow-up evaluation**
  - **Scheduled date(s) of additional follow-up evaluation**
  - **Clinical determination of noncompliance**
  - **SAP's telephone number**

Final Points

- SAP reports
  - Directly to the employer
  - 40.311 details report information
  - SAP's own letterhead
- Return to duty is an employer's decision
  - Only after SAP's Follow-up evaluation shows successful recommendation compliance
  - Only after a negative return-to-duty test
- SAP must not make "fitness for duty" determination

ROLES AND RESPONSIBILITIES OF SERVICE AGENTS

Role of Service Agents (and C/TPAs)

- “There were a helluva lot of things they didn’t tell me about when I hired on with this outfit.”

Service Agent

- Someone other than the employer or employee
- Someone who provides Part 40 drug and alcohol-services to employers or employees
- Includes: Collectors, BATs & STTs, laboratories, MROs, SAPs, and C/TPAs
- <u>Not</u> employers for purposes of Part 40

Service Agent Role & Responsibility

- SA may perform tasks needed by the employer to comply w/DOT Agency drug & alcohol regulations
- SA is subject to requirements and limitations of Part 40
- Services provided must meet Part 40 and DOT agency reg. requirements

Circumstances for SA as Intermediary

- SA (e.g., C/TPA) may act as intermediary in transmission of certain drug & alcohol information to the employer
- Employer decides whether to receive some or all of the information through C/TPA rather than directly from the source SA

Specific Provisions for Intermediary

- Only situations in which SA may act as intermediary are listed in Appendix F
  - Drug testing information
  - Alcohol testing information
- Confidentiality and timing requirements of intermediary apply as if employer were obtaining information directly from the source SA

Permissible Administration Functions of C/TPA

- May operate random testing programs
- May assisting with other types of testing
  - Pre-employment
  - Post-accident
  - Reasonable suspicion
- May run “random pools”
- May assist in follow-up testing

Records and Maintenance

- SA may receive and maintain – for the employer – all drug & alcohol records
- Includes individual test results (negative, positive, and refusal to test)
- Information needed to operate a program (e.g., CCFs, ATFs, names in random pools, selection lists, and testing notices)

Record Availability and Transfer

- All information must be made available for employer w/in 2 days of request
- Immediate transfer of all records for employer or its employees on request
- If “going out of business” –
  - Immediate notification to all employers
  - Offer to transfer records
  - Transfer records on request

Confidentiality Requirements for SAs

- Must follow same confidentiality requirements as employer w/re use and release of information, and record retention
- Prohibited from providing records to another employer w/o written consent
- Must establish adequate measures to ensure confidentiality and security

Principles for Interacting w/MROs

- C/TPAs may provide MRO services
- MRO performs duties independently and confidentiality
- Physical and operational separation
- Staff under direct supervision of MRO while performing MRO functions
- Only MRO “interviews and verifies”

Limitations on Activities of Service Agents

- Must not require consent, release, or waiver of liability
- Must not receive results from lab
- Must not transmit alcohol results of 0.02 or higher
- Must not transmit SAP reports (except owner-operators)

Limitations on Activities of Service Agents

- No decisions for reasonable suspicion, post-accident, return-to-duty, follow-up tests or refusals (except owner/ operators)
- Must not act as the DER
- No additional conditions (e.g., may advise, provide information, and assist)
- Must not delay transmission of results based on payment or other disputes

CONFIDENTIALITY & RELEASE OF INFORMATION

Confidentiality and Release of Information

- Employer or Service Agent prohibited from releasing to third parties not specifically authorized
- Specific written consent required; <u>no blanket releases</u>
- MRO must not disclose to 2nd employer
- May release in legal proceedings, criminal or civil actions

Release of Information to Employee

- MRO or SA must provide within 10 business days of written request copies of records
- Lab (within 10 days) records related to results
- SAP copies of all SAP reports (no time specified)
- Cost of preparation & reproduction

Release of Information in Legal Proceedings

- Employer may release without consent in certain legal proceedings
- Lawsuit, grievance or administrative brought by an employee
- Include criminal or civil actions if court determines testing results are relevant
- To decisionmaker with binding stipulation
- Must notify employee in writing of release

Information Transmission Through SA (C/TPA)

- Employer stated <u>option</u>
- SA may be intermediary for information (from MRO, BAT, Collection Site, etc.)
- Transmission must meet all requirements (confidentiality, timing)
- Reference – Part 40, Appendix F

Circumstances When Info. Must Be Released

- When written authorization is provided by employee (e.g., for gaining employer)
- When requested by:
  - DOT agency reps (includes facilities & info)
  - NTSB as part of accident investigation
  - Federal, state or local safety agency w/regulatory authority over employee

Record Retention Requirements

- Five years:
  - Alcohol test results of 0.02 or greater
  - Positive drug tests
  - Documentation of refusal to test (incl. adulterated and substituted test results)
  - SAP reports
  - Follow-up test results and schedules

Record Retention Requirements

- Three years:
  - Records obtained from previous employers
- Two years:
  - Records of inspection, maintenance, and calibration of EBTs
- One year:
  - Negative and cancelled drug tests, and alcohol tests less than 0.02

EMPLOYER RESPONSIBILITIES

Employers

"Won't all these new rules impact adversely on the viability of municipalities with fewer than fifty employees?"

General Responsibilities

- Responsible for all rule requirements
- Responsible for ensuring SA meets all qualifications
- For new employees, obtain previous 2 years of testing information*
- As previous employer, provide 2 years of testing information*

  – *with employee written permission

Quality Control (Blind) Specimens

- 2,000 or more covered employees (applies to both employers & C/TPAs)
- One percent of specimens (maximum of 50 per quarter)
- Send to all labs used
- 75% negatives
- 15% positive for one or more drugs
- 10% adulterated and/or substituted

Testing

- Ensure split specimen requests are honored
- Ensure that observed collections take place as required
- Separate DOT and non-DOT testing
- No personnel action for cancelled tests

Return-to-duty Process

- Provide listing of SAPs
  - No charge to employee
- No employer requirement to provide SAP evaluation or treatment
- No safety-sensitive duties until employee completes SAP requirements
- RTD test only after SAP's follow-up report

Final Thoughts!

"Be Brave" **and when all else fails** "Use Common Sense"