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Selected Comments on

MRO
Medical Review Officer

&

DER
Designated Employer Representative
United States Federally MANDATED:

US DOT
- urine only,
- oral fluid & more opiates in the pipeline –
  **15 May 2015: [July 14, 2014]**

- proposed OFMG establish standards and technical requirements for oral fluid collection devices, initial oral fluid drug test analytes and methods, confirmatory oral fluid drug test analytes and methods, processes for review by a Medical Review Officer (MRO), and requirements for federal agency actions.
- urine and oral testing procedures for four Schedule II prescription medications: hydrocodone, hydromorphone, oxycodone, and oxymorphone not currently included in the Mandatory Guidelines.

NON-MANDATED Nationally, Internationally:
- urine
- hair
- oral fluid/saliva

https://www.federalregister.gov/articles/2015/05/15/2015-11523/mandatory-guidelines-for-federal-workplace-drug-testing-programs
Objectives of US DOT Program

Ensure the **Fairness & Integrity** of the testing process

Maintain employee privacy & confidentiality
4th Amendment Protections & Omnibus Act

Have “Gatekeepers” in place to ensure “due process.”

- HHS Certified Drug Testing Laboratories / NLCP
- Evidential Breath Testing Devices
- **Medical Review Officers**
- Substance Abuse Professionals

Systems must be auditable & reviewable by DOT Agencies

Develop “plain-language” regulations, policies, & guidance documents.
What is an MRO?

MRO = Medical Review Officer

A Medical Review Officer is a licensed physician who is responsible for receiving and reviewing laboratory results generated by an employer's drug testing program and evaluating medical explanations for certain drug test results.
Laboratories & MROs
Employers are required to have a

**DER = Designated Employer Representative**

An employee *authorized by the employer to take immediate action(s) to remove employees from safety-sensitive duties, or cause employees to be removed from these covered duties, and to make required decisions in the testing and evaluation processes.*

The DER also *receives test results and other communications* for the employer, consistent with the requirements of Part 40.

*May Not Be Delegated: Service agents cannot act as DERs.*

In the past, this person may have been referred to as the Program Administrator.
The Drug Testing Process

Split Sample is collected

DHHS certified lab tests the specimen and reports the results directly to the Medical Review Officer (MRO).
The Drug Testing Process

CCF: Copy 1 to the lab; Copy 2 to the MRO; Copy 4 to the DER; Copy 5 to the donor

Note that all results go to MRO
The Drug Testing Process

CCF: Copy 1 to the lab; Copy 2 to the MRO; Copy 4 to the DER; Copy 5 to the donor.
Time is of the Essence
Verification Process: Non-Negative

MRO must talk to the employee directly

Staff must not gather medical information
Medical Review Officer

The Basics:

Is there a medical explanation for the result?
Even on the Best of Days....
MRO: Someone Has To Do It

What should be the qualifications of the Medical Review Officer?
In the United States:

Credentials: MD or DO [a physician]
Knowledge of Relevant Regulations
Qualification Training
Qualification Examination
Qualification Training—Exam

Following completion of qualification training must complete an examination administered by nationally-recognized MRO certification organization.

The Government does not provide certification.

Requalification every 5-years.
MRO COMPETENCY AREAS

Substance Abuse
Toxicology, Pharmacology, Pharmacokinetics, Laboratory Issues
MRO Responsibilities and Regulatory Issues
Clinical Aspects
Collections Procedures
The Drug Testing Process

Split Sample is collected

Note that all results go to MRO

DHHS certified lab tests the specimen and reports the results directly to the Medical Review Officer (MRO).

This is the DER
DER

Has Many Responsibilities
Title 49, CFR Part 40 requires employers to have a Designated Employer Representative (DER), Defined [in 40.3] as:

An employee authorized by the employer to:
  take immediate action(s) to remove employees from safety-sensitive duties, or cause employees to be removed from these covered duties, and to make required decisions in the testing and evaluation processes.

The DER also receives test results and other communications for the employer, consistent with the requirements of Part 40.

Service agents cannot act as DERs.”

In the past, this person may have been referred to as the Program Administrator.
The MRO will verify the results and report (using procedures in 49 CFR Part 40) to the DER whether the test was positive or negative and the drugs for which there was a positive result.
Problems Contacting Donor

Positive, Invalid or Adulterated result received from Laboratory

MRO unable to contact donor after at least 3 attempts evenly spaced over 24 hours

MRO notifies The DER

DER tries to contact donor. Documents time and date of first attempt to start 24-hour clock

DER contacts donor

DER notifies donor that he or she has 72 hours to contact MRO

Donor fails to contact MRO within 72 hours

MRO reports laboratory result without donor contact

Der can place donor on temporary medically unqualified status.

Donor cannot be reached by MRO or DER within 10 days after receipt of result from the Laboratory

Must be at minimum 96 hours after result received from Laboratory

Must be at minimum 48 hours after result received from Laboratory

Must be at minimum 10 days after result received from Laboratory
MRO must transmit to the DER on the same day or next business day:

- All verified positive test results
- Results requiring an immediate collection under direct observation
- Adulterated or substituted specimens and other refusals to test

40.167(b)
As an employer who receives a verified positive drug test result, you must IMMEDIATELY remove the employee involved from performing safety-sensitive functions.

You must take this action upon receiving the initial report of the verified positive result.
The Expectation

Laboratory Reports Today:
Negatives Are Reported Within The Hour:  *EVERY DAY*
Non-negatives Assigned To MRO:  *Throughout The Day, Every Day*
Outgoing Calls: 6am/06.00-11pm/23.00 In DONOR'S TIME ZONE:
  At Least 3 Spaced Attempts
    Today, Tonight, Tomorrow:  *Every Day*
Accept Return Call 24 Hours/Day:  *Every Day*

*REPORT 24 HOURS/DAY, EVERY DAY*
Adequate telecommunications capabilities essential.

Quality and availability are important.

24 hour a day – 7 day a week availability to be considered.

Country specific time zone considerations must be evaluated.
MRO Role in International Testing:

Language Impacts

Language capability must be planned.

Native speaker helpful.

Interpreters next best solution.

Commercial service / simultaneous translation capability an option.

Web based language translation programs also worth considering.
## Validity Testing

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<th>IF</th>
<th>Creatinine</th>
<th>AND</th>
<th>S.G.</th>
<th>THEN</th>
<th>Lab Reports</th>
<th>AND</th>
<th>MRO Reports</th>
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<td>≥ 2 mg/dl but &lt; 20 mg/dl</td>
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<td>Cancelled Invalid (SCUDO)*</td>
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<td>&gt; 1.0010 but &lt;1.0200</td>
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*SCUDO = Second Collection Under Direct Observation OK*
40.167 - How are MRO reports of drug results transmitted to the employer

As the MRO or C/TPA who transmits drug test results to the employer, you must comply with the following requirements:

(a) You must report the results in a confidential manner.

(b) You must transmit to the DER on the same day the MRO verifies the result or the next business day all verified positive test results, results requiring an immediate collection under direct observation, adulterated or substituted specimen results, and other refusals to test.

1. **Direct telephone contact with the DER is the preferred method of immediate reporting.** Follow up your phone call with appropriate documentation (see 40.163).

2. You are responsible for identifying yourself to the DER, and the DER must have a means to confirm your identification.

3. The MRO's report that you transmit to the employer must contain all of the information required by 40.163.

(c) You must transmit the MRO's report(s) of verified tests to the DER so that the DER receives it within two days of verification by the MRO.

1. You must fax, courier, mail, or electronically transmit a legible image or copy of either the signed or stamped and dated Copy 2 or the written report (see 40.163(b) and (c)).

2. Negative results reported electronically (i.e., computer data file) do not require an image of Copy 2 or the written report.

(d) In transmitting test results, you or the C/TPA and the employer must ensure the security of the transmission and limit access to any transmission, storage, or retrieval systems.

(e) MRO reports are not subject to modification or change by anyone other than the MRO, as provided in 40.149(c).