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University Services



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01.215.637.6800

MRO and DER

Selected Comments on

MRO

Medical Review Officer

&

DER

Designated Employer Representative

MRO Experience - What the US MRO Faces

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

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.

Certification required



What is an MRO?

MRO = Medical Review Officer

A Medical Review Officer is a

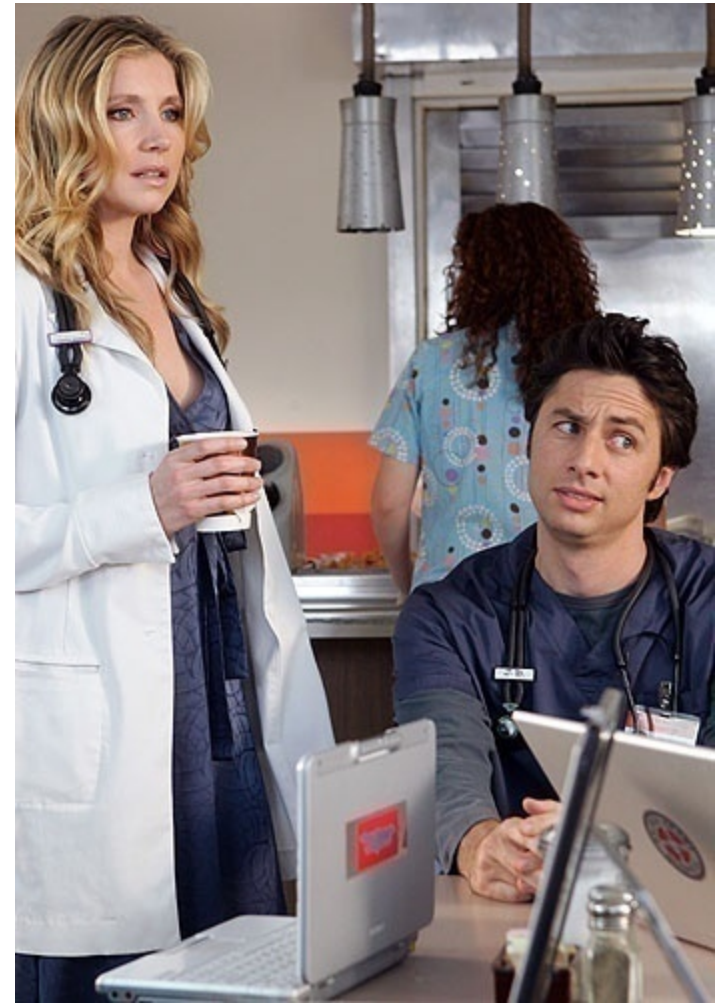
licensed physician who is responsible for

receiving and reviewing laboratory results generated by an employer's drug testing program and

evaluating medical explanations for certain drug test results.



Laboratories & MROs



DER

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."*

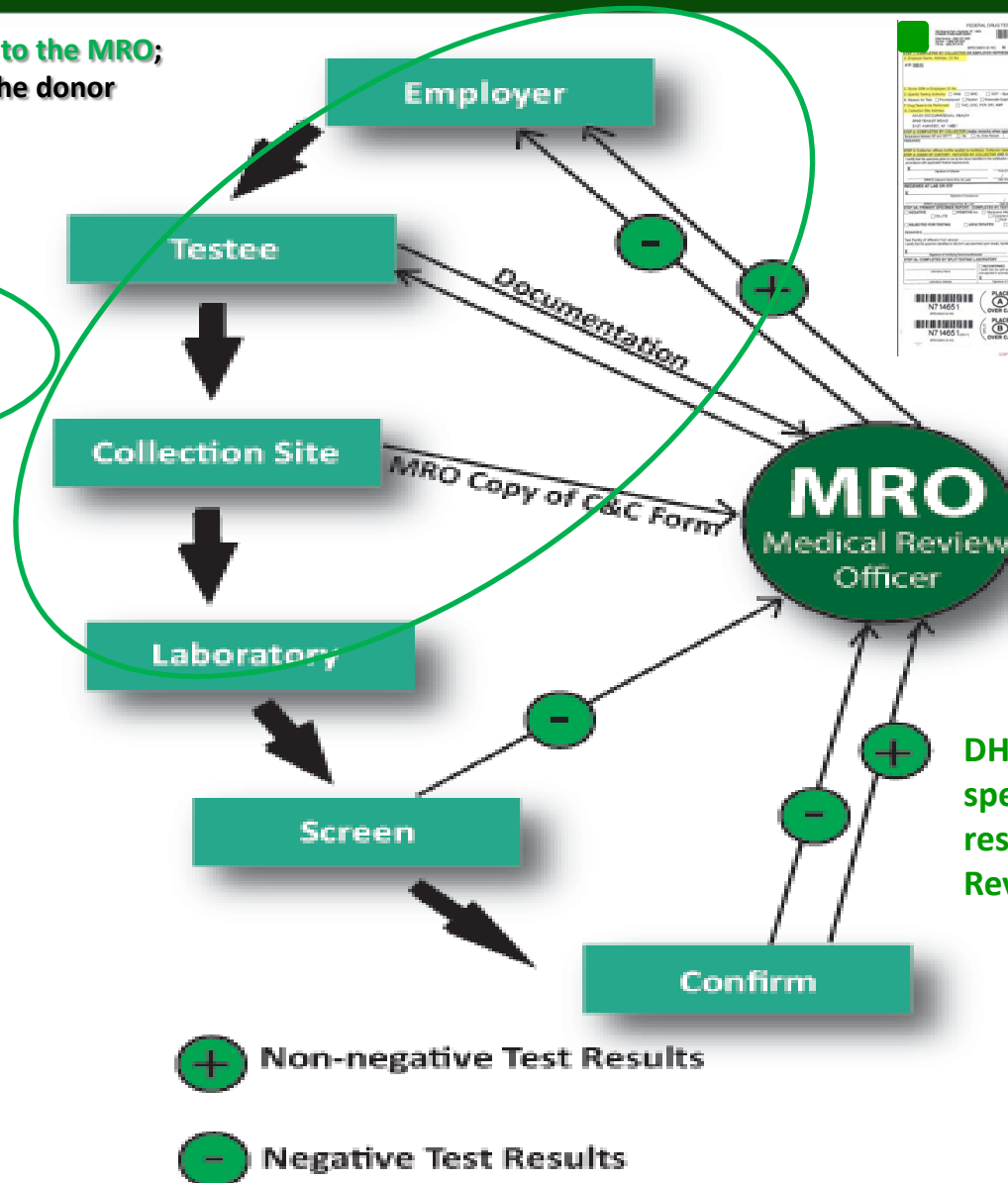
In the past, this person may have been referred to as the Program Administrator.



The Drug Testing Process

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

Split Sample is collected

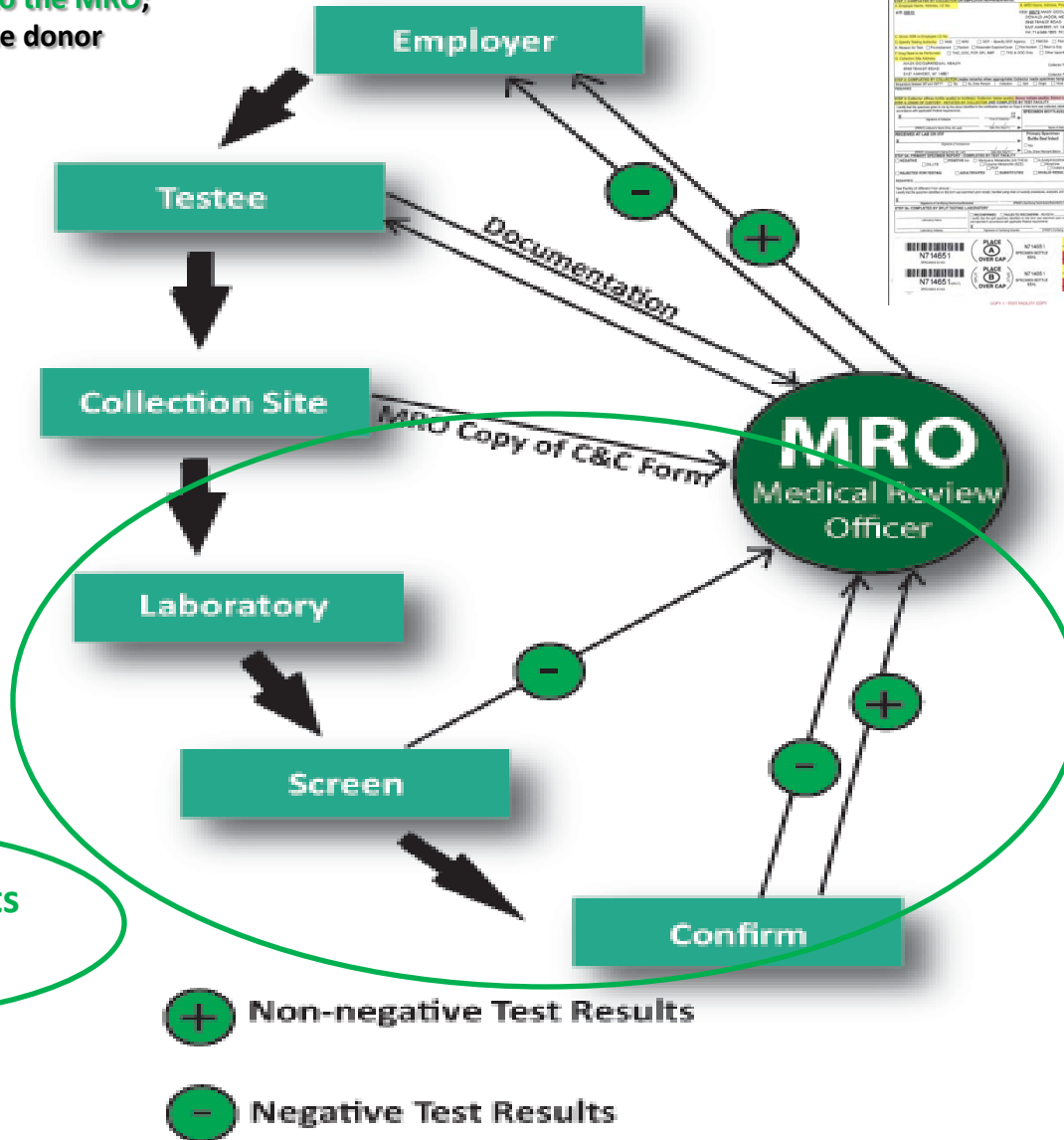


DHHS certified lab tests the specimen and reports the results directly to the Medical Review Officer (MRO).

FEDERAL CRIME TESTAMENT CLERKSHIP AND CONTROL FORM	
<div style="display: flex; justify-content: space-between;"> FD-560 (Rev. 1-7-73) 7-74651 </div>	
1. NAME a. Last Name: _____ b. First Name: _____ c. Middle Name: _____	
2. ADDRESS a. Street Address: _____ b. City: _____ c. State: _____ d. Zip: _____	
3. EMPLOYMENT a. Employer: _____ b. Position: _____ c. Date of Birth: _____ d. Social Security Number: _____	
4. EDUCATION a. School: _____ b. Degree: _____ c. Date of Graduation: _____	
5. MARITAL STATUS a. Single <input type="checkbox"/> Married <input type="checkbox"/> Divorced <input type="checkbox"/> Widowed <input type="checkbox"/>	
6. RELIGIOUS BELIEFS a. Religion: _____ b. Denomination: _____	
7. CRIMINAL RECORD a. Have you ever been convicted of a crime? <input type="checkbox"/> Yes <input type="checkbox"/> No b. If yes, specify: _____	
8. SIGNATURE a. Signature: _____ b. Date: _____	
9. WITNESSES a. Name: _____ b. Address: _____ c. City: _____ d. State: _____ e. Zip: _____	
10. NOTES _____ _____ _____	

FEDERAL BUREAU OF INVESTIGATION AND CONTROL, POLICE		7-17-65	
			
1. Name _____		2. Address _____	
3. Date of Birth _____		4. Sex _____	
5. Race _____		6. Height _____	
7. Weight _____		8. Eyes _____	
9. Hair _____		10. Complexion _____	
11. Occupation _____		12. Education _____	
13. Marital Status _____		14. Social Security Number _____	
15. Place of Birth _____		16. Date of Entry into U.S. _____	
17. Date of Arrival in U.S. _____		18. Date of Departure from U.S. _____	
19. Date of Return to U.S. _____		20. Date of Departure from U.S. _____	
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FEDERAL BUREAU OF INVESTIGATION AND CONTROL SERVICE
U.S. DEPARTMENT OF JUSTICE
7-14631

TO: DIRECTOR, FBI (100-441100)

FROM: SAC, NEW YORK (100-100000)

SUBJECT: [REDACTED]

1. DATE OF REPORT: 10/15/64

2. DATE OF INVESTIGATION: 10/15/64

3. NAME OF PERSON OR FIRM: [REDACTED]

4. ADDRESS: [REDACTED]

5. CITY: [REDACTED] **STATE:** [REDACTED] **ZIP:** [REDACTED]

6. PHONE NUMBER: [REDACTED]

7. TYPE OF VIOLATION: [REDACTED]

8. NATURE OF VIOLATION: [REDACTED]

9. ACTION TAKEN: [REDACTED]

10. COMMENTS: [REDACTED]

11. NAME OF PERSON OR FIRM: [REDACTED]

12. ADDRESS: [REDACTED]

13. CITY: [REDACTED] **STATE:** [REDACTED] **ZIP:** [REDACTED]

14. PHONE NUMBER: [REDACTED]

15. TYPE OF VIOLATION: [REDACTED]

16. NATURE OF VIOLATION: [REDACTED]

17. ACTION TAKEN: [REDACTED]

18. COMMENTS: [REDACTED]

19. NAME OF PERSON OR FIRM: [REDACTED]

20. ADDRESS: [REDACTED]

21. CITY: [REDACTED] **STATE:** [REDACTED] **ZIP:** [REDACTED]

22. PHONE NUMBER: [REDACTED]

23. TYPE OF VIOLATION: [REDACTED]

24. NATURE OF VIOLATION: [REDACTED]

25. ACTION TAKEN: [REDACTED]

26. COMMENTS: [REDACTED]

27. NAME OF PERSON OR FIRM: [REDACTED]

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29. CITY: [REDACTED] **STATE:** [REDACTED] **ZIP:** [REDACTED]

30. PHONE NUMBER: [REDACTED]

31. TYPE OF VIOLATION: [REDACTED]

32. NATURE OF VIOLATION: [REDACTED]

33. ACTION TAKEN: [REDACTED]

34. COMMENTS: [REDACTED]

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40. NATURE OF VIOLATION: [REDACTED]

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48. NATURE OF VIOLATION: [REDACTED]

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50. COMMENTS: [REDACTED]

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57. ACTION TAKEN: [REDACTED]

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65. ACTION TAKEN: [REDACTED]

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73. ACTION TAKEN: [REDACTED]

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81. ACTION TAKEN: [REDACTED]

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102. PHONE NUMBER: [REDACTED]

103. TYPE OF VIOLATION: [REDACTED]

104. NATURE OF VIOLATION: [REDACTED]

105. ACTION TAKEN: [REDACTED]

106. COMMENTS: [REDACTED]

107. NAME OF PERSON OR FIRM: [REDACTED]

108. ADDRESS: [REDACTED]

109. CITY: [REDACTED] **STATE:** [REDACTED] **ZIP:** [REDACTED]

110. PHONE NUMBER: [REDACTED]

111. TYPE OF VIOLATION: [REDACTED]

112. NATURE OF VIOLATION: [REDACTED]

113. ACTION TAKEN: [REDACTED]

114. COMMENTS: [REDACTED]

115. NAME OF PERSON OR FIRM: [REDACTED]

116. ADDRESS: [REDACTED]

117. CITY: [REDACTED] **STATE:** [REDACTED] **ZIP:** [REDACTED]

118. PHONE NUMBER: [REDACTED]

119. TYPE OF VIOLATION: [REDACTED]

120. NATURE OF VIOLATION: [REDACTED]

121. ACTION TAKEN: [REDACTED]

122. COMMENTS: [REDACTED]

123. NAME OF PERSON OR FIRM: [REDACTED]

124. ADDRESS: [REDACTED]

125. CITY: [REDACTED] **STATE:** [REDACTED] **ZIP:** [REDACTED]

126. PHONE NUMBER: [REDACTED]

127. TYPE OF VIOLATION: [REDACTED]

128. NATURE OF VIOLATION: [REDACTED]

129. ACTION TAKEN: [REDACTED]

130. COMMENTS: [REDACTED]

131. NAME OF PERSON OR FIRM: [REDACTED]

132. ADDRESS: [REDACTED]

133. CITY: [REDACTED] **STATE:** [REDACTED] **ZIP:** [REDACTED]

134. PHONE NUMBER: [REDACTED]

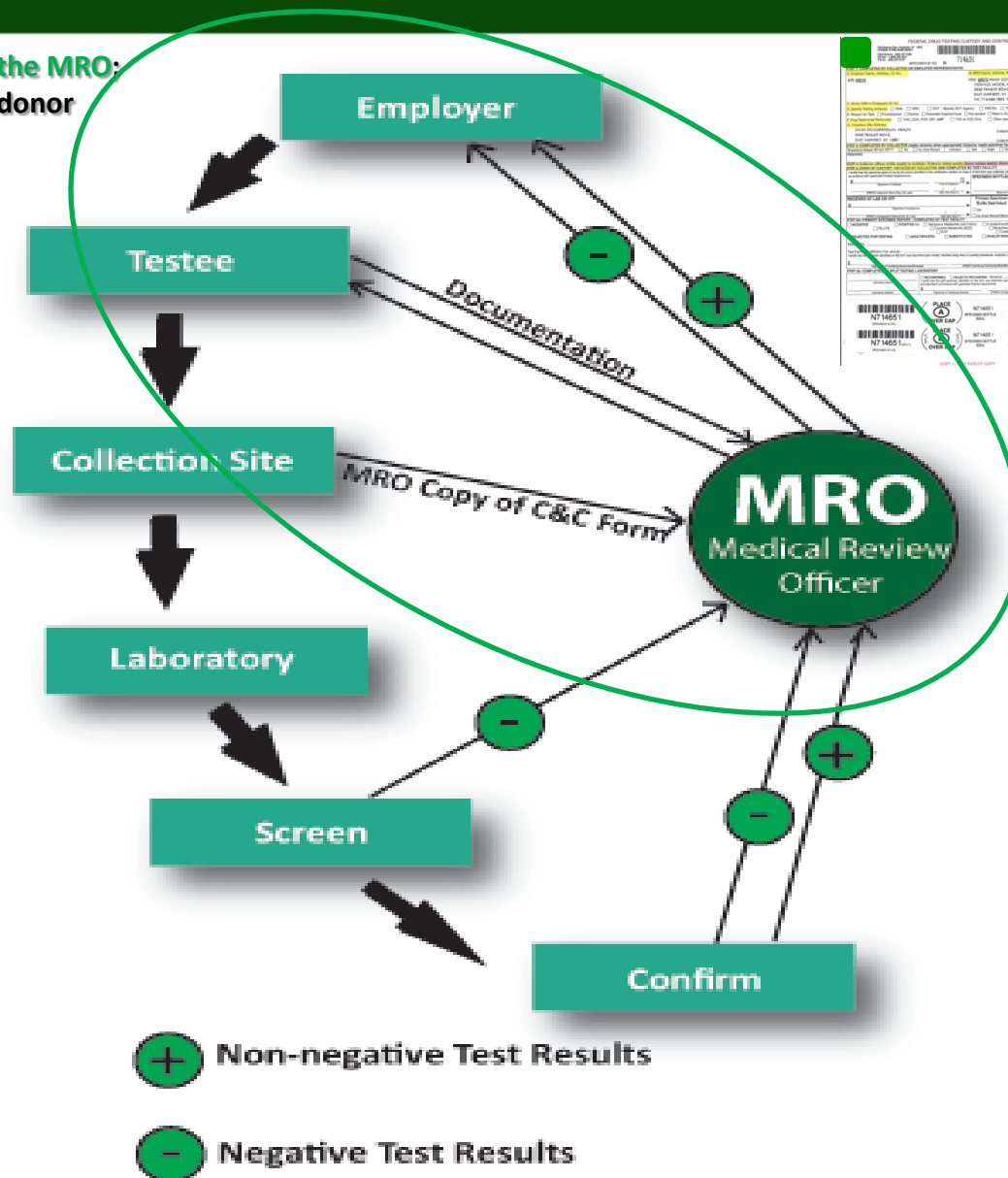
135. TYPE OF VIOLATION: [REDACTED]

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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



FEDERAL BUREAU OF INVESTIGATION AND CONTROL, INQUIRY

714631

U.S. DEPARTMENT OF JUSTICE

1. NAME OF PERSON OR ORGANIZATION AMERICAN OVERSIGHT FOUNDATION

2. ADDRESS 1000 17th Street, N.W.

3. CITY WASHINGTON, D.C. **4. STATE** DC **5. ZIP** 20036

6. TELEPHONE (202) 331-1100 **7. FAX** (202) 331-1100 **8. E-MAIL** info@americanoversight.org

9. SUBJECT AMERICAN OVERSIGHT FOUNDATION

10. DATE OF REQUEST 01/11/2011 **11. DATE OF RECEIPT** 01/11/2011

12. TYPE OF REQUEST FOIA REQUEST

13. REQUESTOR'S INTEREST AMERICAN OVERSIGHT FOUNDATION

14. REQUESTOR'S ADDRESS 1000 17th Street, N.W.

15. REQUESTOR'S CITY WASHINGTON, D.C. **16. REQUESTOR'S STATE** DC **17. REQUESTOR'S ZIP** 20036

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22. REQUESTOR'S TITLE Director

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138. REQUESTOR'S TELEPHONE (202) 331-1100 **139. REQUESTOR'S FAX** (202) 331-1100

FEDERAL BUREAU OF INVESTIGATION AND CONTROL
INVESTIGATION REPORT

7-147575

1. SUBJECT NAME JOHN EDWARD GALT

2. SUBJECT ADDRESS 1000 10th St. S.W.

3. SUBJECT CITY ALBUQUERQUE, N.M.

4. SUBJECT STATE N.M.

5. SUBJECT ZIP 87102

6. SUBJECT PHONE 505-263-1234

7. SUBJECT OCCUPATION SALES

8. SUBJECT EMPLOYER ABC COMPANY

9. SUBJECT DATE OF BIRTH 01/01/1945

10. SUBJECT SEX M

11. SUBJECT RACE W

12. SUBJECT RELIGION C

13. SUBJECT MARITAL STATUS M

14. SUBJECT NUMBER OF CHILDREN 2

15. SUBJECT SOCIAL SECURITY NUMBER 123-45-6789

16. SUBJECT FINGERPRINTS 10-10-10

17. SUBJECT PHOTOGRAPH 10-10-10

18. SUBJECT SIGNATURE 10-10-10

19. SUBJECT DATE OF INTERVIEW 10-10-10

20. SUBJECT INTERVIEWER 10-10-10

21. SUBJECT INTERVIEW LOCATION 10-10-10

22. SUBJECT INTERVIEW METHOD 10-10-10

23. SUBJECT INTERVIEW RESULTS 10-10-10

24. SUBJECT INTERVIEW COMMENTS 10-10-10

25. SUBJECT INTERVIEW SIGNATURE 10-10-10

26. SUBJECT INTERVIEW DATE 10-10-10

27. SUBJECT INTERVIEW TIME 10-10-10

28. SUBJECT INTERVIEW DURATION 10-10-10

29. SUBJECT INTERVIEW NOTES 10-10-10

30. SUBJECT INTERVIEW SUMMARY 10-10-10

31. SUBJECT INTERVIEW CONCLUSION 10-10-10

32. SUBJECT INTERVIEW RECOMMENDATION 10-10-10

33. SUBJECT INTERVIEW FOLLOW-UP 10-10-10

34. SUBJECT INTERVIEW STATUS 10-10-10

35. SUBJECT INTERVIEW REVIEW 10-10-10

36. SUBJECT INTERVIEW APPROVAL 10-10-10

37. SUBJECT INTERVIEW DISAPPROVAL 10-10-10

38. SUBJECT INTERVIEW CANCELLATION 10-10-10

39. SUBJECT INTERVIEW RESCINDMENT 10-10-10

40. SUBJECT INTERVIEW REVOCATION 10-10-10

41. SUBJECT INTERVIEW ANNULLMENT 10-10-10

42. SUBJECT INTERVIEW SET ASIDE 10-10-10

43. SUBJECT INTERVIEW REVERSAL 10-10-10

44. SUBJECT INTERVIEW CORRECTION 10-10-10

45. SUBJECT INTERVIEW AMENDMENT 10-10-10

46. SUBJECT INTERVIEW SUPPLEMENT 10-10-10

47. SUBJECT INTERVIEW ADDENDUM 10-10-10

48. SUBJECT INTERVIEW EXHIBIT 10-10-10

49. SUBJECT INTERVIEW ATTACHMENT 10-10-10

50. SUBJECT INTERVIEW ENCLOSURE 10-10-10

51. SUBJECT INTERVIEW INCLUSION 10-10-10

52. SUBJECT INTERVIEW INCORPORATION 10-10-10

53. SUBJECT INTERVIEW INTEGRATION 10-10-10

54. SUBJECT INTERVIEW IMBUEMENT 10-10-10

55. SUBJECT INTERVIEW INFUSION 10-10-10

56. SUBJECT INTERVIEW INFILTRATION 10-10-10

57. SUBJECT INTERVIEW INFUSEMENT 10-10-10

58. SUBJECT INTERVIEW INFUNDING 10-10-10

59. SUBJECT INTERVIEW INFUSION 10-10-10

60. SUBJECT INTERVIEW INFILTRATION 10-10-10

61. SUBJECT INTERVIEW INFUSEMENT 10-10-10

62. SUBJECT INTERVIEW INFUNDING 10-10-10

63. SUBJECT INTERVIEW INFUSION 10-10-10

64. SUBJECT INTERVIEW INFILTRATION 10-10-10

65. SUBJECT INTERVIEW INFUSEMENT 10-10-10

66. SUBJECT INTERVIEW INFUNDING 10-10-10

67. SUBJECT INTERVIEW INFUSION 10-10-10

68. SUBJECT INTERVIEW INFILTRATION 10-10-10

69. SUBJECT INTERVIEW INFUSEMENT 10-10-10

70. SUBJECT INTERVIEW INFUNDING 10-10-10

71. SUBJECT INTERVIEW INFUSION 10-10-10

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73. SUBJECT INTERVIEW INFUSEMENT 10-10-10

74. SUBJECT INTERVIEW INFUNDING 10-10-10

75. SUBJECT INTERVIEW INFUSION 10-10-10

76. SUBJECT INTERVIEW INFILTRATION 10-10-10

77. SUBJECT INTERVIEW INFUSEMENT 10-10-10

78. SUBJECT INTERVIEW INFUNDING 10-10-10

79. SUBJECT INTERVIEW INFUSION 10-10-10

80. SUBJECT INTERVIEW INFILTRATION 10-10-10

81. SUBJECT INTERVIEW INFUSEMENT 10-10-10

82. SUBJECT INTERVIEW INFUNDING 10-10-10

83. SUBJECT INTERVIEW INFUSION 10-10-10

84. SUBJECT INTERVIEW INFILTRATION 10-10-10

85. SUBJECT INTERVIEW INFUSEMENT 10-10-10

86. SUBJECT INTERVIEW INFUNDING 10-10-10

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88. SUBJECT INTERVIEW INFILTRATION 10-10-10

89. SUBJECT INTERVIEW INFUSEMENT 10-10-10

90. SUBJECT INTERVIEW INFUNDING 10-10-10

91. SUBJECT INTERVIEW INFUSION 10-10-10

92. SUBJECT INTERVIEW INFILTRATION 10-10-10

93. SUBJECT INTERVIEW INFUSEMENT 10-10-10

94. SUBJECT INTERVIEW INFUNDING 10-10-10

95. SUBJECT INTERVIEW INFUSION 10-10-10

96. SUBJECT INTERVIEW INFILTRATION 10-10-10

97. SUBJECT INTERVIEW INFUSEMENT 10-10-10

98. SUBJECT INTERVIEW INFUNDING 10-10-10

99. SUBJECT INTERVIEW INFUSION 10-10-10

100. SUBJECT INTERVIEW INFILTRATION 10-10-10

1. SUBJECT NAME JOHN EDWARD GALT

2. SUBJECT ADDRESS 1000 10th St. S.W.

3. SUBJECT CITY ALBUQUERQUE, N.M.

4. SUBJECT STATE N.M.

5. SUBJECT ZIP 87102

6. SUBJECT PHONE 505-263-1234

7. SUBJECT OCCUPATION SALES

8. SUBJECT EMPLOYER ABC COMPANY

9. SUBJECT DATE OF BIRTH 01/01/1945

10. SUBJECT SEX M

11. SUBJECT RACE W

12. SUBJECT RELIGION C

13. SUBJECT MARITAL STATUS M

14. SUBJECT NUMBER OF CHILDREN 2

15. SUBJECT SOCIAL SECURITY NUMBER 123-45-6789

16. SUBJECT FINGERPRINTS 10-10-10

17. SUBJECT PHOTOGRAPH 10-10-10

18. SUBJECT SIGNATURE 10-10-10

19. SUBJECT DATE OF INTERVIEW 10-10-10

20. SUBJECT INTERVIEWER 10-10-10

21. SUBJECT INTERVIEW LOCATION 10-10-10

22. SUBJECT INTERVIEW METHOD 10-10-10

23. SUBJECT INTERVIEW RESULTS 10-10-10

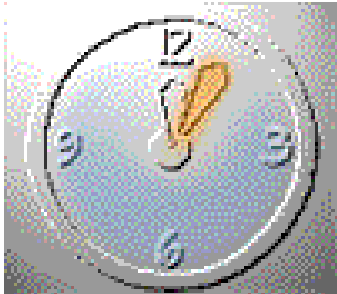
24. SUBJECT INTERVIEW COMMENTS 10-10-10

25. SUBJECT INTERVIEW SIGNATURE 10-10-10

26. SUBJECT INTERVIEW DATE 10-10-10

27. SUBJECT INTERVIEW TIME 10-10-10</

Time is of the Essence



Verification Process: Non-Negative

MRO must talk to the employee directly

Staff must not gather medical information



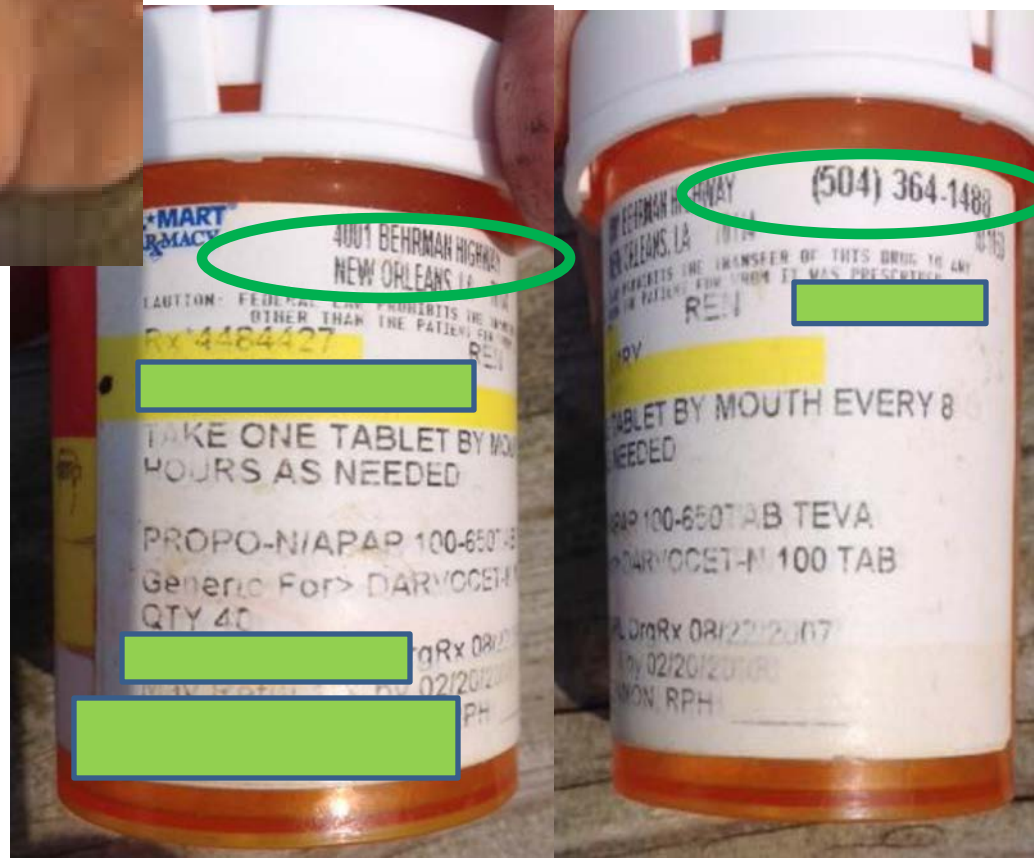
Medical Review Officer

The Basics:

Is there a medical explanation for the result?



Documentation



Even on the Best of Days....



MRO: Someone Has To Do It

What should be the qualifications of the Medical Review Officer?



MRO

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

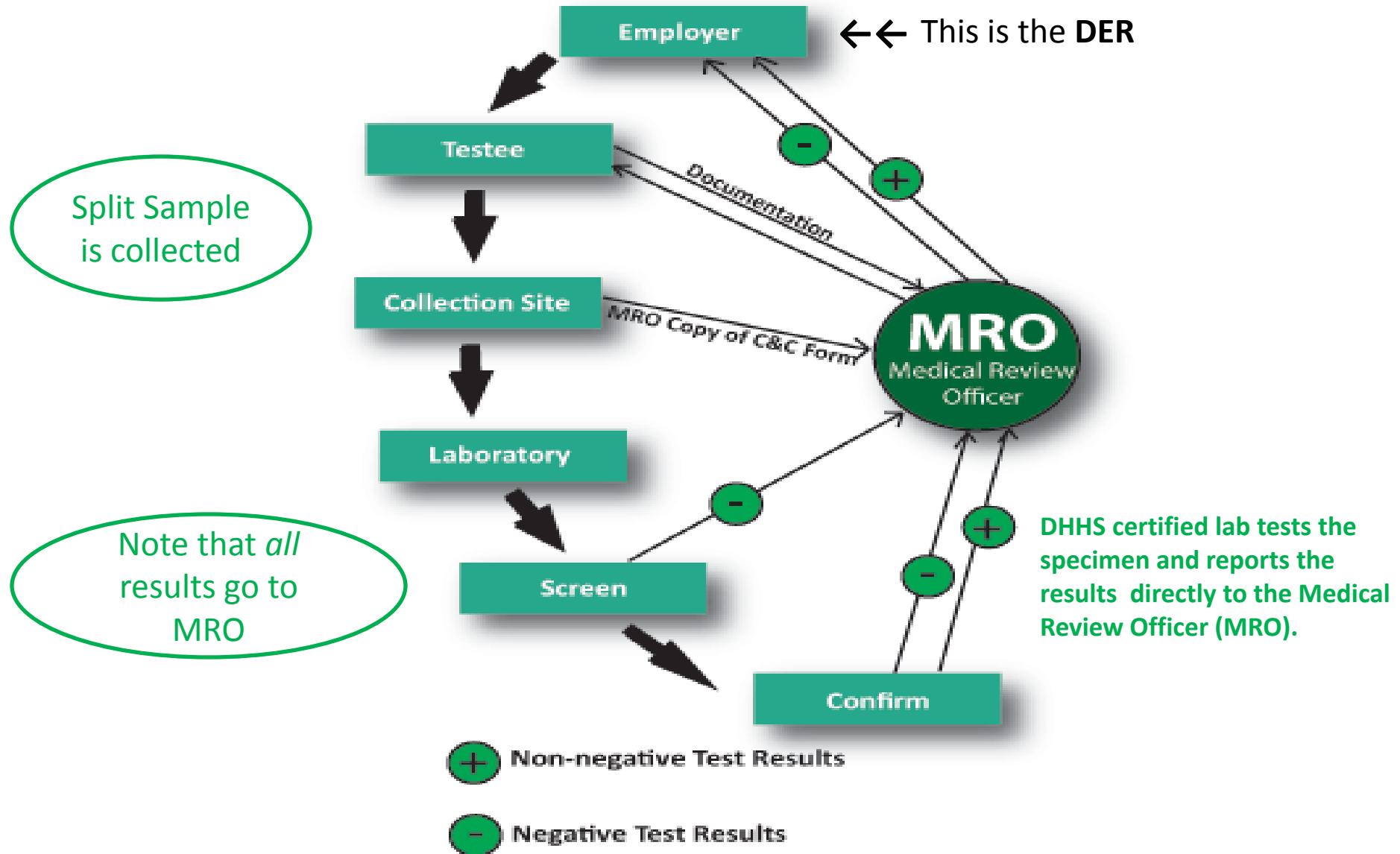
Toxicology, Pharmacology, Pharmacokinetics,
Laboratory Issues

MRO Responsibilities and Regulatory Issues

Clinical Aspects

Collections Procedures

The Drug Testing Process



DER



Has Many Responsibilities

DER

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.

DER

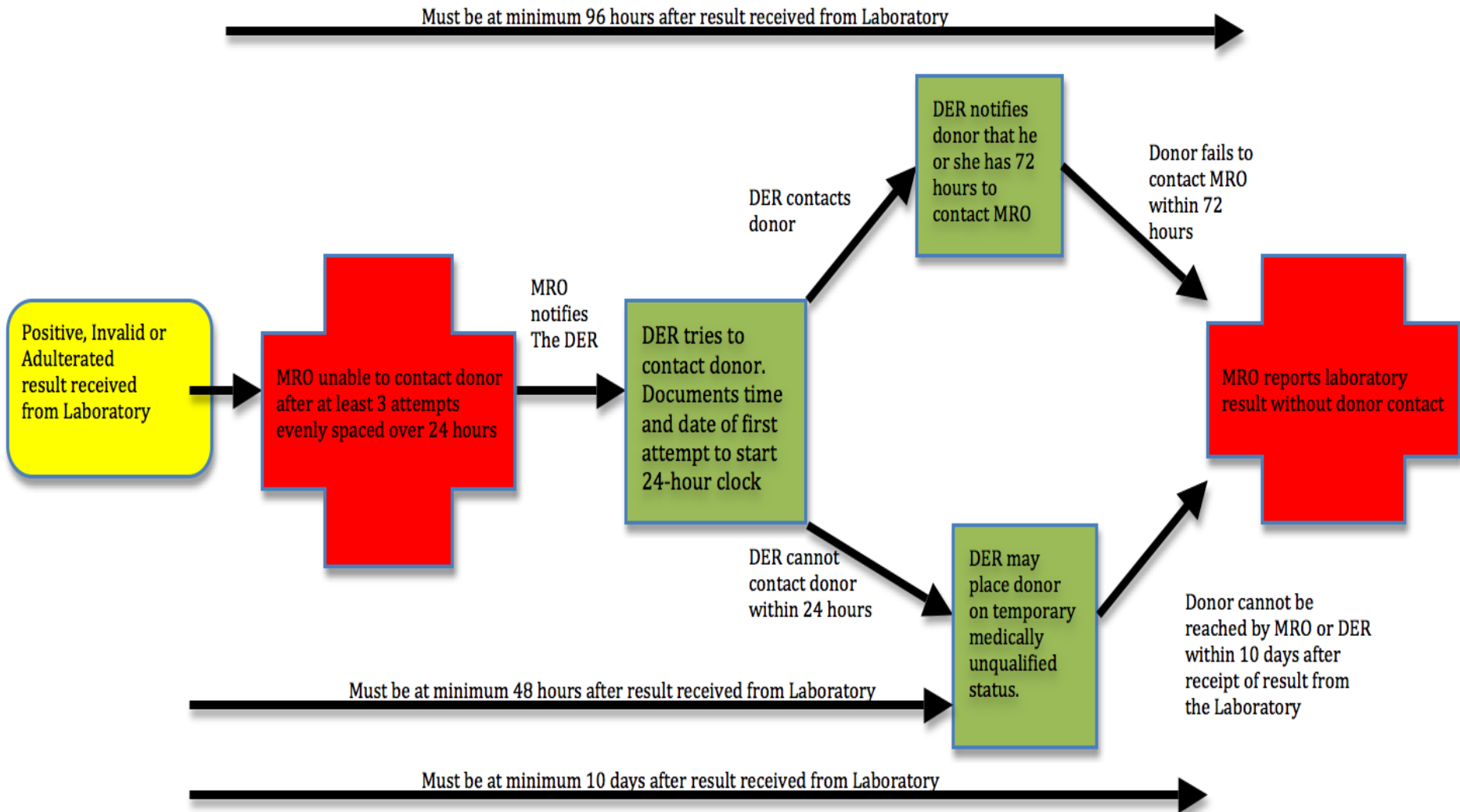


The MRO will verify the results and

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



Timely Flow of Test Results

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

DER

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

Benjamin Gerson, MD

University Services



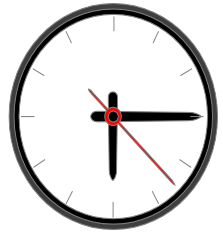
benjamin@userservices.com

01.215.637.6800

The Expectation

Laboratory Reports Today:

Negatives Are Reported Within The Hour: *EVERY DAY*



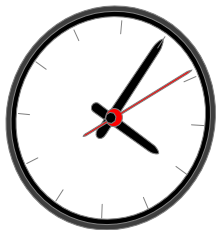
Non-negatives Assigned To MRO: *Throughout The Day, Every Day*

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

MRO in International Testing: Time Differences

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

IF	Creatinine	AND	S.G.	THEN	Lab Reports	AND	MRO Reports
	> 20 mg/dl		Is not measured		Ø		Ø
	≥ 2 mg/dl but < 20 mg/dl		> 1.0010 but < 1.0030		Dilute		Dilute
	≥ 2 mg/dl		≤ 1.0010		Invalid (SCUDO)*		Cancelled Invalid (SCUDO)*
	< 2 mg/dl		> 1.0010 but < 1.0200		Invalid (SCUDO)*		Cancelled Invalid (SCUDO)*
	< 2 mg/dl		≤ 1.0010 or ≥ 1.0200		Substituted		Substituted

*SCUDO = Second Collection Under Direct Observation OK

Contact the DER

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).

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