



**Pipeline and Hazardous Materials Safety Administration
Office of Pipeline Safety**

**Substance Abuse Program:
Comprehensive Audit and Inspection Protocol Form
Specimen Collection Sites**

**Form No.: 3.1.7
Revision 1**

June 1, 2012

*Replaces and Provides Comprehensive
Anti-Drug Program and Alcohol Misuse Program
HQ Inspection Forms*

Protocol Area O: Specimen Collection Sites

Service Provider Profile and General Audit Information

| | | | | | |
|---|--------------------------------------|-------------------------|---|-------------------|--|
| Company Name of Service Provider: | | | | | |
| Official Address | | | | | |
| Business Tax ID Number | | | | | |
| Operator/Contractor Name and Op ID or Business Tax ID number utilizing the above Service Provider: | | | | | |
| Operator's/Contractor's DER or Substance Abuse Program Mgr /: | | | | Phone No.: | |
| Service Provider Company Contact Information | | | Service Provider's Official Representative Contact | | |
| Doing Business As or Affiliated Company Name | | | Contact Name: | | |
| Ph. No.: | | | Ph. No.: | | |
| Fax No.: | | | Fax No.: | | |
| Web Site or Email | | | Email | | |
| Mailing Address: (If different from official address) | | | Lead Auditor or Inspector: | Name: | |
| | | | | Agency: | |
| | | | Date of Audit or Inspection: | | |
| Technician Interviewed | Qualification Expiration Date | Telephone Number | Comment | | |
| | | | | | |
| | | | | | |

| Key Persons | Name/Title | Phone/Email Address |
|---|-------------------|----------------------------|
| Primary Service Provider Representative Interviewed or Providing Information | | |
| Others Interviewed, Providing Information or Present at Audit: | | |
| | | |
| | | |

Government or Other Official Representatives Participating:

| Name/Title | Office/Organization | Phone/Email Address |
|-------------------|----------------------------|----------------------------|
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Substance Abuse Program Protocols

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O.01 Urine Collection Personnel

Verify that training and usage of personnel is in compliance with the applicable requirements of Part 40.

O.01.a. Does the operator ensure that, unless no other collector is available, an immediate supervisor of an employee does not serve as a collection site person [§40.31(c)]?

| O.01.a. Inspection Results (type an X in exactly one cell below) | | Inspection Notes |
|--|---|-------------------------|
| <input type="checkbox"/> | No Issue Identified | |
| <input type="checkbox"/> | Potential Issue Identified (explain) | |
| <input type="checkbox"/> | N/A (explain) | |
| <input type="checkbox"/> | Not Inspected | |

O.01.b. Do collectors meet the training requirements of §40.33 and is documentation available showing that currently all requirements are met [§40.33(g)]?

| O.01.b. Inspection Results (type an X in exactly one cell below) | | Inspection Notes |
|--|---|-------------------------|
| <input type="checkbox"/> | No Issue Identified | |
| <input type="checkbox"/> | Potential Issue Identified (explain) | |
| <input type="checkbox"/> | N/A (explain) | |
| <input type="checkbox"/> | Not Inspected | |

O.01.c. Does the operator provide error correction training as required by §40.33(f) and does the training occur within 30 days of the date of notification of the error that led to the need for training?

| O.01.c. Inspection Results (type an X in exactly one cell below) | | Inspection Notes |
|--|---|-------------------------|
| <input type="checkbox"/> | No Issue Identified | |
| <input type="checkbox"/> | Potential Issue Identified (explain) | |
| <input type="checkbox"/> | N/A (explain) | |
| <input type="checkbox"/> | Not Inspected | |

O.02 Collection Sites, Forms and Supplies

Verify that collection sites, forms and supplies are in compliance with the applicable physical and security requirements of Part 40.

O.02.a. Has the employer designated a collection site that meets the requirements of §40.41.

| O.02.a. Inspection Results (type an X in exactly one cell below) | | Inspection Notes |
|--|---|-------------------------|
| <input type="checkbox"/> | No Issue Identified | |
| <input type="checkbox"/> | Potential Issue Identified (explain) | |
| <input type="checkbox"/> | N/A (explain) | |
| <input type="checkbox"/> | Not Inspected | |

O.02.b. If the collection site uses a facility normally used for other purposes, are procedures in place to ensure before the collection that: (1) access to collection materials and specimens is effectively restricted; and (2) the facility is secured against access during the procedure to ensure privacy to the employee and prevent distraction of the collector? Also, are limited-access signs posted [§40.43(c)]?

| O.02.b. Inspection Results (type an X in exactly one cell below) | | Inspection Notes |
|--|---|-------------------------|
| <input type="checkbox"/> | No Issue Identified | |
| <input type="checkbox"/> | Potential Issue Identified (explain) | |
| <input type="checkbox"/> | N/A (explain) | |
| <input type="checkbox"/> | Not Inspected | |

O.02.c. Are procedures in place to assure the collector maintains personal control over each specimen and CCF throughout the collection process and to prevent unauthorized personnel from entering any part of the site in which urine specimens are collected or stored [§40.43(d)(5) and §40.43(e)]?

| O.02.c. Inspection Results (type an X in exactly one cell below) | | Inspection Notes |
|--|---|-------------------------|
| <input type="checkbox"/> | No Issue Identified | |
| <input type="checkbox"/> | Potential Issue Identified (explain) | |
| <input type="checkbox"/> | N/A (explain) | |
| <input type="checkbox"/> | Not Inspected | |

O.02.d. Is the current Federal Drug Testing Custody and Control Form (CCF) or equivalent being used [§40.45]?

| O.02.d. Inspection Results (type an X in exactly one cell below) | | Inspection Notes |
|--|---|-------------------------|
| <input type="checkbox"/> | No Issue Identified | |
| <input type="checkbox"/> | Potential Issue Identified (explain) | |
| <input type="checkbox"/> | N/A (explain) | |
| <input type="checkbox"/> | Not Inspected | |

O.02.e. Is a collection kit used that meets the requirements of Appendix A to Part 40 [§40.49]?

| O.02.e. Inspection Results (type an X in exactly one cell below) | | Inspection Notes |
|--|---|-------------------------|
| <input type="checkbox"/> | No Issue Identified | |
| <input type="checkbox"/> | Potential Issue Identified (explain) | |
| <input type="checkbox"/> | N/A (explain) | |
| <input type="checkbox"/> | Not Inspected | |

O.03 Urine Specimen Collections

Verify that procedures for collection of urine specimens are in compliance with the applicable requirements of Part 40.

O.03.a. Do collection site personnel explain the basic collection procedure to the employee, including showing the employee the instructions on the back of the CCF [§40.61(e)]?

| O.03.a. Inspection Results (type an X in exactly one cell below) | | Inspection Notes |
|--|---|-------------------------|
| <input type="checkbox"/> | No Issue Identified | |
| <input type="checkbox"/> | Potential Issue Identified (explain) | |
| <input type="checkbox"/> | N/A (explain) | |
| <input type="checkbox"/> | Not Inspected | |

O.03.b. Do collection site personnel provide the donor with an individually wrapped or sealed collection container from the collection kit materials [§40.63(c)]?

| O.03.b. Inspection Results (type an X in exactly one cell below) | | Inspection Notes |
|--|---|-------------------------|
| <input type="checkbox"/> | No Issue Identified | |
| <input type="checkbox"/> | Potential Issue Identified (explain) | |
| <input type="checkbox"/> | N/A (explain) | |
| <input type="checkbox"/> | Not Inspected | |

O.03.c. Are precautions taken to ensure that unadulterated specimens are obtained and correctly identified that meet the following requirements:

- Bluing agents in toilet tank and all water sources secure [§40.43(b)(1) and (2)]
- Individual positively identified (photo ID, etc.) [§40.61(c)]
- Proper authority contacted if individual fails to arrive at the assigned time [§40.61(a)]
- The donor shall remove any unnecessary outer garments. Purses or briefcases shall remain with outer garments [§40.61(f)].
- Donor shall wash and dry his/her hands [§40.63(b)].
- To the greatest extent possible, the collector must keep an employee's collection container within view of both himself/herself and the employee between the time the employee has urinated and the specimen is sealed [§40.43(d)(2)]
- Any unusual behavior noted on the CCF [§40.63(e)]

| O.03.c. Inspection Results (type an X in exactly one cell below) | | Inspection Notes |
|--|---|-------------------------|
| <input type="checkbox"/> | No Issue Identified | |
| <input type="checkbox"/> | Potential Issue Identified (explain) | |
| <input type="checkbox"/> | N/A (explain) | |
| <input type="checkbox"/> | Not Inspected | |

O.03.d. Are procedures being followed at the collection site after the specimen has been provided in compliance with the requirements of §40.65

| O.03.d. Inspection Results (type an X in exactly one cell below) | | Inspection Notes |
|--|---|-------------------------|
| <input type="checkbox"/> | No Issue Identified | |
| <input type="checkbox"/> | Potential Issue Identified (explain) | |
| <input type="checkbox"/> | N/A (explain) | |
| <input type="checkbox"/> | Not Inspected | |

O.03.e. Have provisions been made if the donor is unable to provide at least 45 milliliters of urine [§40.65(a)]?

| O.03.e. Inspection Results (type an X in exactly one cell below) | | Inspection Notes |
|--|---|-------------------------|
| <input type="checkbox"/> | No Issue Identified | |
| <input type="checkbox"/> | Potential Issue Identified (explain) | |
| <input type="checkbox"/> | N/A (explain) | |
| <input type="checkbox"/> | Not Inspected | |

O.03.f. Are procedures in place for immediately collecting urine specimens under direct observation for the situations identified in §40.67(c)

1. As of August 31, 2009, verify that all collections for return-to-duty and follow-up testing were performed under DER directed direct observation [§40.67(b)]

| O.03.f. Inspection Results (type an X in exactly one cell below) | | Inspection Notes |
|--|---|-------------------------|
| <input type="checkbox"/> | No Issue Identified | |
| <input type="checkbox"/> | Potential Issue Identified (explain) | |
| <input type="checkbox"/> | N/A (explain) | |
| <input type="checkbox"/> | Not Inspected | |

O.03.g. Are same gender collection personnel used if a collection is monitored under direct observation by non-medical personnel [§40.69(g)]

| O.03.g. Inspection Results (type an X in exactly one cell below) | | Inspection Notes |
|--|---|-------------------------|
| <input type="checkbox"/> | No Issue Identified | |
| <input type="checkbox"/> | Potential Issue Identified (explain) | |
| <input type="checkbox"/> | N/A (explain) | |
| <input type="checkbox"/> | Not Inspected | |

O.03.h. Is the CCF properly executed by authorized collection site personnel upon receipt and transfer of a urine specimen [§40.73(a)]

| O.03.h. Inspection Results (type an X in exactly one cell below) | | Inspection Notes |
|--|---|-------------------------|
| <input type="checkbox"/> | No Issue Identified | |
| <input type="checkbox"/> | Potential Issue Identified (explain) | |
| <input type="checkbox"/> | N/A (explain) | |
| <input type="checkbox"/> | Not Inspected | |

| Protocol Area O - Documents Reviewed | | | |
|---|------------|-------------|-----------------------|
| Document Number | Rev | Date | Document Title |
| | | | |
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