CIVIL SERVICE COMMISSION
CITY AND COUNTY OF SAN FRANCISCO

LONDON N. BREED
MAYOR

Sent via Electronic Mail

September 21, 2023

NOTICE OF CIVIL SERVICE COMMISSION MEETING

SUBJECT: REVIEW OF REQUEST FOR APPROVAL OF PROPOSED PERSONAL SERVICES CONTRACT 41676-23/24; 42481-23/24; 45826-23/24; 32820-23/24; 35159-23/24; 44669-22/23; 41458-23/24; 45295-23/24; 48964-23/24; 48582-22/23; 43319-21/22; 44356-19/20; 32594-15/16; 39913-23/24; 47706-16/17; 47743-17/18; 43527-17/18; 37035-22/23; AND 44886-19/20.

The above matter will be considered by the Civil Service Commission at a hybrid meeting (in-person and virtual) in Room 400, City Hall, 1 Dr. Goodlett Place, San Francisco, California 94102 and through Cisco WebEx to be held on **October 2, 2023, at 2:00 p.m.**

This item will appear on the Ratification Agenda. Please refer to the attached notice for procedural and other information about Commission hearings.

Attendance by you or an authorized representative is recommended. Should you or your representative not attend, the Commission will rule on the information previously submitted and testimony provided at its meeting. All calendared items will be heard and resolved at this time unless good reasons are presented for a continuance.

CIVIL SERVICE COMMISSION

/s/

SANDRA ENG
Executive Officer

Attachments

Cc: Cynthia Avakian, Airport
Jolie Gines, Technology
Shawndrea Hale, Public Utilities Commission
Kelly Hiramoto, Department of Public Health
Lynn Khaw, City Administrator
Joyce Kimotsuki, Controller
Daniel Kwon, Public Utilities Commission
Vincent Lee, Police
Joan Lubamersky, City Administrator
Amy Nuque, Municipal Transportation Agency
Amanda Wentworth, Treasurer/Tax Collector
Peggy Zee, Sheriff
Commission File
Commissioners' Binder
Chron

NOTICE OF COMMISSION HEARING POLICIES AND PROCEDURES

A. Commission Office

The Civil Service Commission office is located at, 25 Van Ness Avenue, Suite 720, San Francisco, CA 94102. The telephone number is (628) 652-1100. The fax number is (628) 652-1109. The email address is civilservice@sfgov.org and the web address is www.sfgov.org/civilservice/. Office hours are from 8:00 a.m. to 5:00 p.m., Monday through Friday.

B. Policy Requiring Written Reports

It is the policy of the Civil Service Commission that except for appeals filed under Civil Service Commission Rule 111A Position-Based Testing, all items appearing on its agenda be supported by a written report prepared by Commission or departmental staff. All documents referred to in any Agenda Document are posted adjacent to the Agenda, or if more than one (1) page in length, available for public inspection and copying at the Civil Service Commission office. Reports from City and County personnel supporting agenda items are submitted in accordance with the procedures established by the Executive Officer. Reports not submitted according to procedures, in the format and quantity required, and by the deadline, will not be calendared.

C. Policy on Written Submissions by Appellants

All written material submitted by appellants to be considered by the Commission in support of an agenda item shall be submitted to the Commission office, no later than 5:00 p.m. on the fourth (4^{th}) business day preceding the Commission meeting for which the item is calendared (ordinarily, on Tuesday). An original copy on 8 1/2-inch X 11 inch paper, three-hole punched on left margin, and page numbered in the bottom center margin, shall be provided. Written material submitted for the Commission's review becomes part of a public record and shall be open for public inspection.

D. Policy on Materials being Considered by the Commission

Copies of all staff reports and materials being considered by the Civil Service Commission are available for public view 72 hours prior to the Civil Service Commission meeting on the Civil Service Commission's website at https://sf.gov/civilservice and in its office located at 25 Van Ness Avenue, Suite 720, San Francisco, CA 94102. If any materials related to an item on this agenda have been distributed to the Civil Service Commission after distribution of the agenda packet, those materials will be available for public inspection at the Civil Service Commission's during normal office hours (8:00 a.m. to 5:00 p.m. Monday through Friday).

E. Policy and Procedure for Hearings to be Scheduled after 5:00 p.m. and Requests for Postponement

A request to hear an item after 5:00 p.m. should be directed to the Executive Officer as soon as possible following the receipt of notification of an upcoming hearing. Requests may be made by telephone at (628) 652-1100 and confirmed in writing or by fax at (628) 652-1109.

A request for a postponement (continuance) to delay an item to another meeting may be directed to the Commission Executive Officer by telephone or in writing. Before acting, the Executive Officer may refer certain requests to another City official for recommendation. Telephone requests must be confirmed in writing prior to the meeting. Immediately following the "Announcement of Changes" portion of the agenda at the beginning of the meeting, the Commission will consider a request for a postponement that has been previously denied. Appeals filed under Civil Service Commission Rule 111A Position-Based Testing shall be considered on the date it is calendared for hearing except under extraordinary circumstances and upon mutual agreement between the appellant and the Department of Human Resources.

F. Policy and Procedure on Hearing Items Out of Order

Requests to hear items out of order are to be directed to the Commission President at the beginning of the agenda. The President will rule on each request. Such requests may be granted with mutual agreement among the affected parties.

G. Procedure for Commission Hearings

All Commission hearings on disputed matters shall conform to the following procedures: The Commission reserves the right to question each party during its presentation and, in its discretion, to modify any time allocations and requirements.

If a matter is severed from the *Consent Agenda* or the *Ratification Agenda*, presentation by the opponent will be for a maximum time limit of five (5) minutes and response by the departmental representative for a maximum time limit of five (5) minutes. Requests by the public to sever items from the [*Consent Agenda* or] *Ratification Agenda* must be provided with justification for the record.

For items on the *Regular Agenda*, presentation by the departmental representative for a maximum time of five (5) minutes and response by the opponent for a maximum time limit of five (5) minutes.
For items on the *Separations Agenda*, presentation by the department followed by the employee or employee's representative shall be for a maximum time limit of ten (10) minutes for each party unless extended by the Commission.
Each presentation shall conform to the following:

1. Opening summary of case (brief overview);
2. Discussion of evidence;
3. Corroborating witnesses, if necessary; and
4. Closing remarks.

The Commission may allocate five (5) minutes for each side to rebut evidence presented by the other side.

H. Policy on Audio Recording of Commission Meetings

As provided in the San Francisco Sunshine Ordinance, all Commission meetings are audio recorded in digital form. These audio recordings of open sessions are available starting on the day after the Commission meeting on the Civil Service Commission website at www.sfgov.org/civilservice/.

I. Speaking before the Civil Service Commission

Speaker cards are not required. The Commission will take public comment on all items appearing on the agenda at the time the item is heard. The Commission will take public comment on matters not on the Agenda, but within the jurisdiction of the Commission during the "Requests to Speak" portion of the regular meeting. Maximum time will be three (3) minutes. A subsequent comment after the three (3) minute period is limited to one (1) minute. The timer shall be in operation during public comment. Upon any specific request by a Commissioner, time may be extended.

J. Public Comment and Due Process

During general public comment, members of the public sometimes wish to address the Civil Service Commission regarding matters that may come before the Commission in its capacity as an adjudicative body. The Commission does not restrict this use of general public comment. To protect the due process rights of parties to its adjudicative proceedings, however, the Commission will not consider, in connection with any adjudicative proceeding, statements made during general public comment. If members of the public have information that they believe to be relevant to a mater that will come before the Commission in its adjudicative capacity, they may wish to address the Commission during the public comment portion of that adjudicative proceeding. The Commission will not consider public comment in connection with an adjudicative proceeding without providing the parties an opportunity to respond.

K. Policy on use of Cell Phones, Pagers and Similar Sound-Producing Electronic Devices at and During Public Meetings

The ringing and use of cell phones, pagers and similar sound-producing electronic devices are prohibited at this meeting. Please be advised that the Chair may order the removal from the meeting room of any person(s) responsible for the ringing or use of a cell phone, pager, or other similar sound-producing electronic devices.

Information on Disability Access

The Civil Service Commission normally meets in Room 400 (Fourth Floor) City Hall, 1 Dr. Carlton B. Goodlett Place. However, meetings not held in this room are conducted in the Civic Center area. City Hall is wheelchair accessible. The closest accessible BART station is the Civic Center, located 2 ½ blocks from City Hall. Accessible MUNI lines serving City Hall are 47 Van Ness Avenue, 9 San Bruno and 71 Haight/Noriega, as well as the METRO stations at Van Ness and Market and at Civic Center. For more information about MUNI accessible services, call (415) 923-6142. Accessible curbside parking has been designated at points in the vicinity of City Hall adjacent to Grove Street and Van Ness Avenue.

The following services are available on request 48 hours prior to the meeting; except for Monday meetings, for which the deadline shall be 4:00 p.m. of the last business day of the preceding week. For American Sign Language interpreters or the use of a reader during a meeting, a sound enhancement system, and/or alternative formats of the agenda and minutes, please contact the Commission office to make arrangements for the accommodation. Late requests will be honored, if possible.

Individuals with severe allergies, environmental illness, multiple chemical sensitivity or related disabilities should call our ADA coordinator at (628) 652-1100 or email civilservice @sfgov.org to discuss meeting accessibility. In order to assist the City's efforts to accommodate such people, attendees at public meetings are reminded that other attendees may be sensitive to various chemical-based products. Please help the City to accommodate these individuals.

Know your Rights under the Sunshine Ordinance (Chapter 67 of the San Francisco Administrative Code)

Government's duty is to serve the public, reaching its decisions in full view of the public. Commissions, boards, councils, and other agencies of the City and County exist to conduct the people's business. This ordinance assures that deliberations are conducted before the people and that City operations are open to the people's review. For more information on your rights under the Sunshine Ordinance or to report a violation of the ordinance, or to obtain a free copy of the Sunshine Ordinance, contact Victor Young, Administrator of the Sunshine Ordinance Task Force, 1 Dr. Carlton B. Goodlett Place, Room 244, San Francisco, CA 94102-4689 at (415) 554-7724, by fax: (415) 554-7854, by e-mail: sotf@sfgov.org, or on the City's website at www.sfgov.org/bdsupvrs/sunshine.

San Francisco Lobbyist Ordinance

Individuals and entities that influence or attempt to influence local legislative or administrative action may be required by the San Francisco Lobbyist Ordinance (San Francisco Campaign and Governmental Conduct Code Section 2.100) to register and report lobbying activity. For more information about the Lobbyist Ordinance, please contact the San Francisco Ethics Commission at 25 Van Ness Ave., Suite 220, San Francisco, CA 94102, telephone (415) 252-3100, fax (415) 252-3112 and web site https://sfethics.org/.

City and County of San Francisco

London Breed
Mayor

Department of Human Resources

Carol Isen
Human Resources Director

Date: September 15, 2023

To: The Honorable Civil Service Commission

Through: Carol Isen
Human Resources Director

From: Joan Lubamersky / Lynn Khaw, GSA
Joyce Kimotsuki, CON
Amy Nuque, MTA
Shawndrea Hale / Daniel Kwon, PUC
Peggy Zee, SHF
Jolie Gines, TIS
Cynthia Avakian, AIR
Vincent Lee, POL
Kelly Hiramoto, DPH
Amanda Wentworth, TTX

Subject: **Personal Services Contracts Approval Request**

This report contains nineteen (19) personal services contracts (PSCs) in accordance with the revised Civil Service Commission (CSC) procedures for processing PSCs that became effective on November 5, 2014.

The services proposed by these contracts have been reviewed by Department of Human Resources (DHR) staff to evaluate whether the requesting departments have complied with City policy and procedures regarding PSCs. The proposed PSCs have been posted on the DHR website for seven (7) calendar days. CSC procedures for processing PSCs require that any appeal of these contracts be filed in the office of the CSC, Executive Officer during the posting period.

No timely appeals have been filed regarding the PSCs contained in this report. These proposed PSCs are being submitted to the CSC for ratification/approval.

DHR has prepared the following cost summary for personal services contracts that have been processed through the Department of Human Resources Fiscal Year 23/24 to date:

Total of this Report	YTD Expedited Approvals FY2023-2024	Total for FY2023-2024
$69,736,000	$321,632,540	$2,558,009,508

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PSC Submissions

POSTING FOR

October 02, 2023

PROPOSED PERSONAL SERVICES CONTRACTS – REGULAR

PSC No	Dept Designation	PSC Amount	Description of Work	PSC Estimated Start Date	PSC Estimated End Date	Type of Approval
41676 - 23/24	GENERAL SERVICES AGENCY - CITY ADMIN	$800,000.00	Contractor will perform natural areas management on Yerba Buena Island to include invasive plant removal and habitat restoration activities using hand and small-tool techniques. This work is to support the Yerba Buena Island (YBI) Habitat Management Plan, following pre-established site priorities developed by the Treasure Island Development Authority (TIDA).	September 30, 2023	September 30, 2027	REGULAR
42481 - 23/24	GENERAL SERVICES AGENCY - CITY ADMIN	$300,000.00	Vendor will perform as-needed specialized toxicological analyses. Tests will be performed for such substances such as synthetic cannabinoids, designer opiates, and bath salts. The Office of the Chief Medical Examiner (OCME) developed several leading analytical methods to detect, quantify and confirm over 450 common drugs of abuse, medications, poisons and novel psychoactive drugs. This is beyond national minimal standards and recommendations for decedents, impaired driving, and sexual assault casework. The capacity to perform these tests in-house has mitigated some of the additional work required during the City's fentanyl drug overdose epidemic. However, an outside accredited laboratory contract is necessary to perform specialized work that OCME cannot do.	December 1, 2023	December 31, 2028	REGULAR

PSC No	Dept Designation	PSC Amount	Description of Work	PSC Estimated Start Date	PSC Estimated End Date	Type of Approval
45826 - 23/24	CONTROLLER	$7,000,000.00	The City seeks responses from Respondents to provide professional services for the following systems: PeopleSoft Financials and Supply Chain Management (FSCM); PeopleSoft Human Capital Management (HCM); PeopleSoft Enterprise Learning Management (ELM); Oracle Business Intelligence Applications (OBIA); Oracle Business Intelligence Enterprise Edition (OBIEE); Potential replacement systems for the above listed products; Potential change in infrastructure used to support the above listed products; and City legacy and related systems. Respondents must be able to provide functional, technical, and project management services for these systems both remotely and on-site at the Office of the Controller's City Hall Office. These services will be used to assist the Controller's Office and other City Departments with system enhancements, modifications, and additional systems support.	November 1, 2023	October 31, 2028	REGULAR
32820 - 23/24	MUNICIPAL TRANSPORTATION AGENCY	$2,500,000.00	The contractor will plan, coordinate, and conduct an in-person survey of the San Francisco Municipal Transportation Agency's (SFMTA) transit riders to collect data on their demographics and transportation practices. The consultant will collect statistically	January 1, 2024	December 31, 2025	REGULAR

PSC No	Dept Designation	PSC Amount	Description of Work	PSC Estimated Start Date	PSC Estimated End Date	Type of Approval
			significant data about customer travel patterns, income levels, ethnic background, language proficiency, and fare media usage both on a temporal and geographic basis. Riders will be surveyed on all routes and modes of transit vehicles, on platforms, and by telephone as necessary. The consultant shall produce a final report that includes a discussion of the survey results and relevant high-level data summaries.			
35159 - 23/24	MUNICIPAL TRANSPORTATION AGENCY	$2,000,000.00	The U.S. Department of Transportation (USDOT) awarded the San Francisco Municipal Transportation Agency (SFMTA) $2 million from the SMART (Strengthening Mobility and Revolutionizing Transportation) grants program to support the SFMTA's Digital Curb project. The SMART grants program funds innovative approaches to using technology to solve transportation problems -- the Digital Curb project will create a first-of-its-kind citywide database and map of all curb locations and regulations, which will provide valuable information for the agency and public, and help achieve the agency's curb management goals. The SFMTA intends to issue an RFP for a Contractor to support the Digital Curb project in assembling curb data for the first time by leveraging existing data and collecting data on the street using innovative digital mapping tools; keeping data up to date via software tools as SFMTA plans legislate, and implements curb regulation changes; and disseminating data via maps, analytical tools, and an open data feed using the Curb Data Specification (CDS) industry standard.	September 15, 2023	September 15, 2025	REGULAR

PSC No	Dept Designation	PSC Amount	Description of Work	PSC Estimated Start Date	PSC Estimated End Date	Type of Approval
			As part of the Digital Curb project, SFMTA will also partner with the Open Mobility Foundation (OMF). OMF is a non-profit organization that develops digital tools for public agencies and manages the CDS standard. OMF will make changes to CDS as necessary to support the Digital Curb project, as well as work with SFMTA and other cities with similar projects to document costs, benefits, lessons learned, and best practices, which will help SFMTA meet its grant obligations to USDOT.			
44669 - 22/23	MUNICIPAL TRANSPORTATION AGENCY	$250,000.00	To provide federally mandated urine analysis for Safety-Sensitive employees with the San Francisco Municipal Transportation Agency (SFMTA).	February 1, 2024	February 1, 2029	REGULAR
41458 - 23/24	PUBLIC UTILITIES COMMISSION	$15,000,000.00	Perform highly specialized engineering tasks that include conducting geotechnical field explorations, investigations, and laboratory testing; hydraulic modeling, seismic vulnerabilities of water treatment facilities and chemical storage tanks, site surveying in remote locations, reliability and maintenance issues with chemical pumps, preparing reports for new and existing facilities; The SFPUC intends to award one (1) contract, not to exceed $15,000,000.	February 1, 2024	January 31, 2035	REGULAR
45295 - 23/24	SHERIFF	$140,000.00	The San Francisco Sheriff's Office proposes to enter into a contract for the garbage collection services for the San Francisco County Jail #3 located in San Bruno, CA, and to comply with the San Bruno Municipal Code 10.20.050, which the City of San Bruno issued an exclusive contract for the collection of garbage.	October 1, 2023	September 30, 2024	REGULAR

PSC No	Dept Designation	PSC Amount	Description of Work	PSC Estimated Start Date	PSC Estimated End Date	Type of Approval
48964 - 23/24	GENERAL SERVICES AGENCY - TECHNOLOGY	$15,000,000.00	Background: The City retired its physical mainframe equipment in 2022. While the City offers its own private City Cloud Platform, it must also offer Public Cloud Service options to those City departments who choose not to leverage the City's Cloud Services. In addition, the City needs Cloud Services from Public Web Services providers for the City to maintain redundancy and disaster recovery services. The Public Cloud Providers are expected to provide Cloud Technical Support and professional services to cover development and production issues for Cloud products and services, along with other key stack components: "How to" questions about Cloud services and features, Best practices to help successfully integrate, deploy, and manage applications in the cloud, Troubleshooting Application Programming Interface (API) and Software Development Kit (SDK) issues, Troubleshooting operational or systemic problems with Cloud resources, Issues with our Management Console or other Cloud tools, Problems detected by Cloud Providers health check tools, and f A number of third-party applications such as Operating System (OS), web servers, email, Virtual Private Network (VPN), databases, and storage configuration	September 1, 2023	December 31, 2030	REGULAR

TOTAL AMOUNT $42,990,000

POSTING FOR

October 02, 2023

PROPOSED PERSONAL SERVICES CONTRACTS –Modifications

PSC Number	Department	Additional Amount	Cumulative Total	Description	Start Date	End Date	Approval Type
48582 - 22/23 - MODIFICATIONS	GENERAL SERVICES AGENCY - CITY ADMIN -- ADM	$8,000,000	$14,000,000	The Office of Contract Administration (OCA) would like to establish contracts for departments to obtain short-term and intermittent security guard services for special events and locations without existing service. Uniformed security guard services will provide a visible presence to the public and City staff while monitoring the grounds/facilities; protecting the safety of persons on sites; protecting the property against fire, theft, damage, and trespass; and investigating and reporting unusual or suspicious activities. These services will be available to all City departments requiring a short turnaround and for short-term duration services. Services will not cover long-term or consistent/regular security guard services.	07/01/2023	08/30/2028	REGULAR
43319 - 21/22 - MODIFICATIONS	AIRPORT COMMISSION -- AIR	$8,000,000	$15,000,000	Professional support services for the Noise Insulation Program (NIP) particularly on the following as-needed tasks: review of County records and updated noise impact boundaries to identify properties that may qualify for noise insulation improvements, outreach efforts to invite potentially eligible homeowners to participate in the NIP, coordination of aircraft noise easement acquisitions and recording, coordination of noise insulation design and	12/31/2026	06/30/2028	REGULAR

PSC Number	Department	Additional Amount	Cumulative Total	Description	Start Date	End Date	Approval Type
				construction work, handling inquiries from property owners regarding eligibility for noise insulation improvements funded by the Federal Aviation Administration (FAA) and the San Francisco International Airport (Airport), and preparation of outlay reports.			
44356 - 19/20 - MODIFICATIONS	AIRPORT COMMISSION -- AIR	$3,500,000	$6,500,000	Complete integrated parking access revenue control system (PARCS) support and maintenance for both hardware and software at the San Francisco International Airport (Airport) public and employee parking facilities. Contractor shall provide all labor, materials, spare parts, software, testing equipment, tools, etc. necessary to perform technical maintenance services for all PARCS equipment and software.	11/28/2025	12/31/2026	REGULAR
32594 - 15/16 - MODIFICATIONS	MUNICIPAL TRANSPORTATION AGENCY -- MTA	$10,000	$110,000	The consultant will provide the services of a Medical Review Officer (MRO) for the San Francisco Municipal Transportation Agency (SFMTA). This is a mandatory service under the Department of Transportation/ Federal Transit Administration (DOT/FTA), TITLE 49: TRANSPORTATION, Code of Federal Regulations, PART 40 – PROCEDURES FOR TRANSPORTATION WORKPLACE DRUG AND ALCOHOL TESTING PROGRAMS (49 CFR Part 40).	07/01/2023	06/30/2025	REGULAR
39913 - 23/24 - MODIFICATIONS	POLICE -- POL	$425,000	$525,000	The contractor will provide background investigation services for civilian and command-level San Francisco Police Department (SFPD) employment applicant positions. The contractor's services will include, but not be limited to, interviewing applicants, investigating records from the	10/01/2023	10/31/2026	REGULAR

PSC Number	Department	Additional Amount	Cumulative Total	Description	Start Date	End Date	Approval Type
				criminal justice system, credit reporting agencies, and Department of Motor Vehicles, and contacting employers and references			
47706 - 16/17 - MODIFICATIONS	PUBLIC HEALTH -- DPH	$5,000,000	$7,590,000	The initial engagement will be in support of a task force established by the Board of Supervisors in preparation for the possible legalization and regulation of adult use and possession of cannabis, the Cannabis State Legalization Task Force, begun in early 2016, to be active for a two-year period. The Task Force is comprised of 22 members, including non-voting representatives of City departments such Planning, Fire, Police, Building Inspection and Public Health and voting members from various sectors, including advocates, business and tourism sector representatives. Services will include assistance in planning; identifying best practices, legal mandates and other relevant information; determining the stakeholder needs; facilitating meetings and handling task force/project documentation and communications; development of findings and recommendations; and making large and small group presentations.	10/01/2023	12/31/2028	REGULAR
47743 - 17/18 - MODIFICATIONS	PUBLIC HEALTH -- DPH	$550,000	$1,512,000	The contractor(s) will provide a behavioral workforce program to prepare students and residents for the behavioral health services workforce by teaching up-to-date, evidenced-based practices. This program will develop and implement a drug and alcohol studies certificate program (currently provided at City College of San Francisco) that will span 2-3 academic	01/01/2024	12/31/2024	REGULAR

PSC Number	Department	Additional Amount	Cumulative Total	Description	Start Date	End Date	Approval Type
				years for counselors employed through Department of Public Health (DPH) Behavioral Health Services (BHS)-funded programs, or those who plan to seek employment with San Francisco agencies. The program will reinforce segments of the DPH BHS's planned education and training "pipeline," with a focus on drawing candidates of varying ethnic and cultural heritages, language backgrounds, sexual orientations/gender identities, and experiences with behavioral health systems. The format will be weekly night classes accessible to working adults and those who may have interrupted academic histories due to family responsibilities and/or time needed for recovery. Enrollment will be aimed to reflect the populations currently served, prioritizing students from diverse communities (e.g., African Americans, Latino/as, Asians, Pacific Islanders, Native Americans and immigrant groups from the neighborhoods of Bayview-Hunters Point, Visitacion Valley, the Mission, Western Addition, Tenderloin and other disenfranchised areas of the city) and marginalized groups (e.g., Lesbian/Gay/Bisexual/Transgender/Queer/ Questioning/Intersex [LGBTQQI], formerly-incarcerated, homeless, etc.).			
43527 - 17/18 - MODIFICATIONS	PUBLIC UTILITIES COMMISSION -- PUC	$200,000	$1,400,000	The work under this agreement includes identifying underutilized and other SFPUC properties that are candidates for revenue enhancement; assessing land economics; assessing project and entitlement feasibility; making entitlement	08/28/ 2023	04/01/ 2027	REGULAR

PSC Number	Department	Additional Amount	Cumulative Total	Description	Start Date	End Date	Approval Type
				applications; building and sustaining local government and community relationships to generate project support; securing necessary local government entitlement approvals outside of San Francisco; analyzing and resolving complex title issues and boundary issues; performing appraisals and providing pre-acquisition and pre-disposition services.			
37035 - 22/23 - MODIFICATIONS	SHERIFF -- SHF	$61,000	$161,000	Coordinate efforts among multiple city agencies to identify and reduce barriers to pre-release Medi-Cal enrollment for persons incarcerated in the San Francisco County jails. Interview stakeholders and map existing Medi-Cal enrollment processes that occur in custody, Identify barriers for enrollment efforts and operational gaps that need to be addressed to implement the pre-release enrollment and suspension processes, including but not limited to IT system modifications, Facilitate meetings and collaborative planning sessions between Sheriff's Office and County Health and Social Service agencies. Identify protocols and IT modifications to strengthen pre-release enrollment, Identify the technology systems and staff needed to more efficiently identify Medi-Cal status at booking, provide enrollment assistance to those in need, while also providing accurate booking and release information to the HSA. Work with partner agencies to develop a comprehensive application for implementation funding which is due to the State Department of Health Care Services	05/01/ 2023	04/20/ 2025	REGULAR

PSC Number	Department	Additional Amount	Cumulative Total	Description	Start Date	End Date	Approval Type
				by December 31, 2022. The initial deliverable of the implementation grant proposal is due no later than December 9, 2022. **Scope Change:** Implementation Assistance, meetings, and Project Management.			
44886 - 19/20 - MODIFICATIONS	TREASURER/TAX COLLECTOR -- TTX	$1,000,000	$2,670,000	The Office of the Treasurer and Tax Collector, Office of Financial Empowerment (OFE) is seeking to expand its one-on-one financial coaching program, Smart Money Coaching (SMC), to reach more residents in low-income communities and in communities with inequitable economic opportunity. The financial coaching service provider would have opportunities to support coaching across the City at City department sites, community-based organizations (CBOs) and other locations identified by the financial coaching service provider in partnership with OFE.	09/01/2023	06/30/2026	REGULAR

TOTAL AMOUNT $26,746,000

Regular/Continuing/Annual Personal Services Contracts

PERSONAL SERVICES CONTRACT SUMMARY ("PSC FORM 1")

Department: GENERAL SERVICES AGENCY - CITY ADMIN -- ADM Dept. Code: ADM

Type of Request: ☑Initial ☐Modification of an existing PSC (PSC # _____)

Type of Approval: ☐Expedited ☑Regular ☐Annual ☐Continuing ☐ (Omit Posting)

Type of Service: Intermittent technical, natural areas management

Funding Source: TIDA departmental budget PSC Duration: 4 years 1 day

PSC Amount: $800,000

1. Description of Work

A. Scope of Work/Services to be Contracted Out:
Contractor will perform natural areas management on Yerba Buena Island to include invasive plant removal and habitat restoration activities using hand and small-tool techniques. This work is to support the Yerba Buena Island (YBI) Habitat Management Plan, following pre-established site priorities developed by the Treasure Island Development Authority (TIDA).

B. Explain why this service is necessary and the consequence of denial:
Service is critical to ensure appropriate repair, restoration and enhancement of critical natural areas lands owned by TIDA. Denial of services will result in accelerated degradation of YBI natural areas lands and overgrowth of non-native plant species. Degradation of YBI native habitat poses compounding threat to existing YBI and Bay Area wildlife communities.

C. Has this service been provided in the past? If so, how? If the service was provided under a previous PSC, attach copy of the most recently approved PSC.
Services have not been provided in the past.

D. Will the contract(s) be renewed?
Unknown.

E. If this is a request for a new PSC in excess of five years, or if your request is to extend (modify) an existing PSC by another five years, please explain why.
not applicable

2. Reason(s) for the Request

A. Indicate all that apply (be specific and attach any relevant supporting documents):

☑ Services required on an as-needed, intermittent, or periodic basis (e.g., peaks in workload).

B. Explain the qualifying circumstances:
Services are as needed and intermittent, approximately 2-3 hours per week.

3. Description of Required Skills/Expertise

A. Specify required skills and/or expertise: Technical expertise in sensitive small-tool removals of invasive plants from native habitat communities, natural resources expertise in identifying and monitoring Bay Area native plant communities and ecosystems.

B. Which, if any, civil service class(es) normally perform(s) this work? 3420, Natural Resource Specialist; 3421, ChfNatural Resource Specialist;

C. Will contractor provide facilities and/or equipment not currently possessed by the City? If so, explain: No.

4. If applicable, what efforts has the department made to obtain these services through available resources within the City?

Work is intermittent and not available from resources within the City.

5. Why Civil Service Employees Cannot Perform the Services to be Contracted Out

A. Explain why civil service classes are not applicable.
The amount of work/need under this Scope of Services is intermittent, approximately 2-3 days per week.

B. If there is no civil service class that could perform the work, would it be practical and/or feasible to adopt a new civil service class to perform this work? Explain. Civil service classes exist that provide some of these services, but services are intermittent, not warranting hiring TIDA staff to do the work.

6. Additional Information

A. Will the contractor directly supervise City and County employee? If so, please include an explanation.
No.

B. Will the contractor train City and County employees and/or is there a transfer of knowledge component that will be included in the contact? If so, please explain what that will entail; if not, explain why not.
No. No training will be provided.

C. Are there legal mandates requiring the use of contractual services?
No.

D. Are there federal or state grant requirements regarding the use of contractual services? If so, please explain and include an excerpt or copy of any such applicable requirement.
No.

E. Has a board or commission determined that contracting is the most effective way to provide this service? If so, please explain and include a copy of the board or commission action.
No.

F. Will the proposed work be completed by a contractor that has a current PSC contract with your department? If so, please explain.
No.

7. Union Notification: On 09/08/2023, the Department notified the following employee organizations of this PSC/RFP request:
Laborers, Local 261

☐ I CERTIFY ON BEHALF OF THE DEPARTMENT THAT THE INFORMATION CONTAINED IN AND ATTACHED TO THIS FORM IS COMPLETE AND ACCURATE:

Name: Joan Lubamersky Phone: 4155544859 Email: joan.lubamersky@sfgov.org

Address: One Carlton B. Goodlett Place Room 362 San Francisco, CA 94012

****

FOR DEPARTMENT OF HUMAN RESOURCES USE

PSC# 41676 - 23/24

DHR Analysis/Recommendation:

Commission Approval Required

DHR Approved for 10/02/2023

Civil Service Commission Action:

Receipt of Union Notification(s)

Lubamersky, Joan (ADM)

From: Theresa Foglio-Ramirez <laborers261@gmail.com>
Sent: Thursday, August 24, 2023 9:46 AM
To: Lubamersky, Joan (ADM)
Cc: DHR-PSCCoordinator, DHR (HRD); Ramon Hernandez
Subject: Re: TIDA PSC 41676

Good morning Joan,
The Union does not object to this PSC moving forward.

On Thu, Aug 24, 2023 at 9:28 AM Lubamersky, Joan (ADM) <joan.lubamersky@sfgov.org> wrote:

> Good morning Theresa.
>
> Would you please let me know if L 261 has any objection to this PSC moving forward.
>
> Thank you.
>
> Joan
>
> Sent from my iPhone
>
> On Aug 24, 2023, at 9:18 AM, Theresa Foglio-Ramirez <laborers261@gmail.com> wrote:
>
> Hi Joan,
> Thank you so much for answering all our questions!
>
> On Tue, Aug 22, 2023 at 3:19 PM Lubamersky, Joan (ADM) <joan.lubamersky@sfgov.org> wrote:
>
> > Hi Theresa
> >
> > I have inquired about this TIDA PSC.
> >
> > This work is not under the Treasure Island PLA which, as I understand, governs the construction and improvements of the Treasure Island Development Project.
> >
> > I would note the following differences comparing our contract and the general parameters of a Covered Project under the Citywide PLA obligations:
> >
> > - Not funded by bond

- the total contract amount ($800,000) is less than the lowest Citywide PLA threshold of $1,000,000
- A professional service Contract, not a construction contract. #7 in the PLA FAQs seems to indicate departments Professional Service Agreements are not under Citywide PLA obligation if not construction design-build?

Please let me know if this responds to your questions.

Thank you.

Best regards,

Joan

Joan Lubamersky - Pronouns: she/her

Office of the City Administrator

One Carlton B. Goodlett Place, Room 362

San Francisco, CA 94102

From: Theresa Foglio-Ramirez <laborers261@gmail.com>
Sent: Friday, August 18, 2023 1:06 PM
To: Lubamersky, Joan (ADM) <joan.lubamersky@sfgov.org>
Cc: DHR-PSCCoordinator, DHR (HRD) <dhr-psccoordinator@sfgov.org>; Ramon Hernandez <ramonliuna261@gmail.com>
Subject: Re: TIDA PSC 41676

Hi Joan,

It stands for Project Labor Agreement.

On Fri, Aug 18, 2023 at 12:37 PM Lubamersky, Joan (ADM) <joan.lubamersky@sfgov.org> wrote:

He Theresa

Would you please tell me what a PLA is?

Thank you.

Joan

Sent from my iPhone

On Aug 18, 2023, at 12:23 PM, Theresa Foglio-Ramirez <laborers261@gmail.com> wrote:

Hi Joan,

Thank you for your patience! Our Business Manager, Ramon Hernandez, has an additional question: Is this PSC covered under the City-Wide PLA or Treasure Island PLA?

On Thu, Aug 10, 2023 at 4:26 PM Lubamersky, Joan (ADM) <joan.lubamersky@sfgov.org> wrote:

> Hello Theresa
>
> I am glad that we connected yesterday morning. On a separate matter, I have asked the DHR PSC staff to assist you in gaining access to the PSC systems. They said they would contact you today.
>
> With regard to PSC 41676 for TIDA, I listed below the points about which you asked and our response.

1. **Federal funds: Is this work reimbursed by Federal funds, or are there any Federal requirements about employment involved? You said that some time ago, perhaps before the MOU, there were issues about Federal vs. local minimum wage. No Federal reimbursement, no Federal funds, and no Federal requirements are involved. The contractor will be subject to City of San Francisco Minimum Compensation Ordinance (MCO) requirements. All wages rates per the contract shall be no less than the Department of Industrial Relations (DIR) predetermined rates, and increases, for Laborer Group 3 per the State of California Labor Code and the San Francisco Administrative Code.**

2. **Is this Journey level work? Is this a workforce development project, such as when the City has pre-apprenticeship job training projects for young people and adults? This PSC does not create a training program. The contractor, TIDA and the local First Hire org, One Treasure Island Job Broker/Construction Training program (TIHDI), will meet to establish natural areas lands management entry-level opportunities to perform scope of services and/or participation in discipline specific-training program that is supportive of One Treasure Island programs opportunities and jobs development mission. TIHDI was created through the development agreements to function like First Hire does for the rest of the City. TIDA will hire a vendor that will inform TIHDI of the work they will do, and TIHDI will send the vendor qualified candidates including for entry level jobs.**

3. **Integrated pest management: Will the work involve use of herbicides? - No**

Please let me know if this responds to your questions or if you have any other concerns.

Thank you.

Best regards,

Joan

Joan Lubamersky - Pronouns: she/her

Office of the City Administrator

One Carlton B. Goodlett Place, Room 362

San Francisco, CA 94102

From: Theresa Foglio <laborers261@gmail.com>
Sent: Tuesday, August 8, 2023 1:35 PM
To: Lubamersky, Joan (ADM) <joan.lubamersky@sfgov.org>
Cc: DHR-PSCCoordinator, DHR (HRD) <dhr-psccoordinator@sfgov.org>; vcourtney <vcourtney@ncdcl.org>
Subject: Re: TIDA PSC 41676

Hello Joan,

8:30 am tomorrow is perfect.

Thank you for your fast response.

On Tue, Aug 8, 2023 at 8:37 AM Lubamersky, Joan (ADM) <joan.lubamersky@sfgov.org> wrote:

> Hello Theresa
>
> May I call you this afternoon at 3:30 pm or tomorrow at 8:30 am?
>
> Joan Lubamersky
>
> Sent from my iPhone
>
> > On Aug 8, 2023, at 7:32 AM, Theresa Foglio <laborers261@gmail.com> wrote:

Hi Joan,

Thank you so much for forwarding this to me! I'm still trying to get someone to fix our access to the PSC system but have not found that magical person to help us yet. The Union would like to meet and discuss PSC-41676.

Thanks again and have a great week!

On Mon, Aug 7, 2023 at 4:42 PM Lubamersky, Joan (ADM) <joan.lubamersky@sfgov.org> wrote:

> To Laborer's Local 261:
>
> Attn: Theresa Foglio
>
> I am writing to you to notify Laborers 261 of a Personal Services Contract involving classifications represented by Laborer's 261. I will copy this email and enter it on the PSC website for PSC 41676.
>
> The DHR PSC system does not recognize classes 3420 and 3421 as valid classifications, so I am not able to do the posting. Since you can't be notified through the PSC system, I am emailing you. I have attached class specs for those positions.
>
> I have attached a copy of PSC 41676 and a copy of the "No Valid Option" screen from the PSC system.
>
> As is the case with PSCs, L261 has 30 days to comment on this PSC if you choose.
>
> Please let me know if you have questions.

Best regards,

Joan

Joan Lubamersky - Pronouns: she/her

Office of the City Administrator

One Carlton B. Goodlett Place, Room 362

San Francisco, CA 94102

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Be Well and Stay Safe!

Theresa Foglio-Ramirez
Public Sector Business Agent
LiUNA!, Local 261
3271 18th Street
San Francisco, CA 94110

(415) 823-7566 cell
(415) 826-4550 office
(415) 826-1948 fax
http://twitter.com/theresafoglio

--

Be Well and Stay Safe!

Theresa Foglio-Ramirez
Public Sector Business Agent
LiUNA!, Local 261
3271 18th Street
San Francisco, CA 94110

(415) 823-7566 cell
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(415) 826-4550 office
(415) 826-1948 fax
http://twitter.com/theresafoglio

Lubamersky, Joan (ADM)

From: Lubamersky, Joan (ADM)
Sent: Monday, August 7, 2023 4:42 PM
To: laborers261@gmail.com
Cc: 'DHR-PSCCoordinator, DHR (dhr-psccoordinator@sfgov.org)'
Subject: TIDA PSC 41676
Attachments: TIDA PSC 41676 No Valid Option.docx; Natural Resource Specialist Class 3420 Spec.docx; Chief fNatural Resource Specialist Class 3421 Spec.docx; PSC 41676 TIDA.pdf

To Laborer's Local 261:

Attn: Theresa Foglio

I am writing to you to notify Laborers 261 of a Personal Services Contract involving classifications represented by Laborer's 261. I will copy this email and enter it on the PSC website for PSC 41676.

The DHR PSC system does not recognize classes 3420 and 3421 as valid classifications, so I am not able to do the posting. Since you can't be notified through the PSC system, I am emailing you. I have attached class specs for those positions.

I have attached a copy of PSC 41676 and a copy of the "No Valid Option" screen from the PSC system.

As is the case with PSCs, L261 has 30 days to comment on this PSC if you choose.

Please let me know if you have questions.

Best regards,

Joan

Joan Lubamersky - Pronouns: she/her
Office of the City Administrator
One Carlton B. Goodlett Place, Room 362
San Francisco, CA 94102

PERSONAL SERVICES CONTRACT SUMMARY ("PSC FORM 1")

Department: GENERAL SERVICES AGENCY - CITY ADMIN -- ADM Dept. Code: ADM

Type of Request: ☑Initial ☐Modification of an existing PSC (PSC # _____)

Type of Approval: ☐Expedited ☑Regular ☐Annual ☐Continuing ☐ (Omit Posting)

Type of Service: As-needed specialized specialized toxicological analyses

Funding Source: General Fund PSC Duration: 5 years 4 weeks

PSC Amount: $300,000

1. Description of Work

A. Scope of Work/Services to be Contracted Out:

Vendor will perform as-needed specialized toxicological analyses. Tests will be performed for such substances such as synthetic cannabinoids, designer opiates, and bath salts. The Office of the Chief Medical Examiner (OCME) developed several leading analytical methods to detect, quantify and confirm over 450 common drugs of abuse, medications, poisons and novel psychoactive drugs. This is beyond national minimal standards and recommendations for decedents, impaired driving, and sexual assault casework. The capacity to perform these tests in-house has mitigated some of the additional work required during the City's fentanyl drug overdose epidemic. However, an outside accredited laboratory contract is necessary to perform specialized work that OCME cannot do.

B. Explain why this service is necessary and the consequence of denial:

The consequences of denial are that specialized tests would not be performed for OCME cases. OCME cases would not include information made possible by testing for nefarious substances outside of the scope of the OCME's internal testing abilities. This includes obscure testing such as heavy metal analysis and the analysis of uncommon sample types such as liver and stomach contents. The OCME does not have the resources to develop a method for these situations, which occur in 1% or less of total casework. Further, to ensure fairness, anonymity, and mitigation of bias, the urine drug testing of new OCME employees is performed by an outside vendor. It is inappropriate for the OCME to test such samples.

C. Has this service been provided in the past? If so, how? If the service was provided under a previous PSC, attach copy of the most recently approved PSC.

By contract.

D. Will the contract(s) be renewed?

The services will continue to be needed. It is likely contract will be renewed.

E. If this is a request for a new PSC in excess of five years, or if your request is to extend (modify) an existing PSC by another five years, please explain why.

For administrative convenience, the department would like the Personal Contract duration to exceed five years for a brief period of time.

2. Reason(s) for the Request

A. Indicate all that apply (be specific and attach any relevant supporting documents):

☑ Short-term or capital projects requiring diverse skills, expertise and/or knowledge.

☑ Services required on an as-needed, intermittent, or periodic basis (e.g., peaks in workload).

☑ Services that require resources that the City lacks (e.g., office space, facilities or equipment with an operator).

B. Explain the qualifying circumstances:
Specialized knowledge, skills and equipment are necessary to perform these as needed tests.

3. Description of Required Skills/Expertise

A. Specify required skills and/or expertise: Ability to analyze toxicological specimens including specialized tests. Must be an American Board of Forensic Toxicology (AFBT) accredited laboratory.

B. Which, if any, civil service class(es) normally perform(s) this work? 2403, Forensic Laboratory Technician; 2456, Asst Forensic Toxicologist 1; 2457, Forensic Toxicologist Supervisor; 2458, Chief Forensic Toxicologist;

C. Will contractor provide facilities and/or equipment not currently possessed by the City? If so, explain: Yes. The contractor has an accredited laboratory including instruments necessary to perform specialized tests.

4. If applicable, what efforts has the department made to obtain these services through available resources within the City?

These services are not available through resources within the City.

5. Why Civil Service Employees Cannot Perform the Services to be Contracted Out

A. Explain why civil service classes are not applicable.
Work is as needed. The City does not have the equipment necessary to perform specialized tests.

B. If there is no civil service class that could perform the work, would it be practical and/or feasible to adopt a new civil service class to perform this work? Explain. City employees currently perform most of the testing performed for OCME cases. Specialized work is to be performed by a vendor as needed.

6. Additional Information

A. Will the contractor directly supervise City and County employee? If so, please include an explanation.
No.

B. Will the contractor train City and County employees and/or is there a transfer of knowledge component that will be included in the contact? If so, please explain what that will entail; if not, explain why not.
No. No training will be provided.

C. Are there legal mandates requiring the use of contractual services?
No.

D. Are there federal or state grant requirements regarding the use of contractual services? If so, please explain and include an excerpt or copy of any such applicable requirement.
No.

E. Has a board or commission determined that contracting is the most effective way to provide this service? If so, please explain and include a copy of the board or commission action.
No.

F. Will the proposed work be completed by a contractor that has a current PSC contract with your department? If so, please explain.
Yes.

7. Union Notification: On 08/07/2023, the Department notified the following employee organizations of this PSC/RFP request:
Architect & Engineers, Local 21

☐ I CERTIFY ON BEHALF OF THE DEPARTMENT THAT THE INFORMATION CONTAINED IN AND ATTACHED TO THIS FORM IS COMPLETE AND ACCURATE:

Name: Joan Lubamersky Phone: 4155544859 Email: joan.lubamersky@sfgov.org

Address: One Carlton B. Goodlett Place Room 362 San Francisco, CA 94102
****

FOR DEPARTMENT OF HUMAN RESOURCES USE

PSC# 42481 - 23/24
DHR Analysis/Recommendation: Civil Service Commission Action:
Commission Approval Required
DHR Approved for 10/02/2023

Receipt of Union Notification(s)

Lubamersky, Joan (ADM)

From: dhr-psccoordinator@sfgov.org on behalf of joan.lubamersky@sfgov.org
Sent: Monday, August 7, 2023 1:14 PM
To: Lubamersky, Joan (ADM); kdavis@ifpte21.org; jharding@ifpte21.org; mweirick@ifpte21.org; dho@ifpte21.org; ewallace@ifpte21.org; ecassidy@ifpte21.com; WendyWong26@yahoo.com; wendywong26@yahoo.com; tmathews@ifpte21.org; kschumacher@ifpte21.org; kpage@ifpte21.org; eerbach@ifpte21.org; l21pscreview@ifpte21.org; Lubamersky, Joan (ADM); DHR-PSCCoordinator, DHR (HRD)
Subject: Receipt of Notice for new PCS over $100K PSC # 42481 - 23/24

RECEIPT for Union Notification for PSC 42481 - 23/24 more than $100k

The GENERAL SERVICES AGENCY - CITY ADMIN -- ADM has submitted a request for a Personal Services Contract (PSC) 42481 - 23/24 for $300,000 for Initial Request services for the period 12/01/2023 – 12/31/2028. Notification of 30 days (60
days for SEIU) is required.

After logging into the system please select link below, view the information and verify receipt:

http://apps.sfgov.org/dhrdrupal/node/21204 For union notification, please see the TO: field of the email to verify receipt. If you do not see all the unions you intended to contact, the PSC Coordinator must change the state back to NOT READY, make sure the classes and unions you want to notify are selected and SAVE. Then VIEW the record and verify the list of unions and emails. EDIT the document again , change the state back START UNION NOTIFICATION and SAVE. You should receive the email with all unions to the TO: field as intended

Additional Attachment(s)

City and County of San Francisco
Office of Contract Administration
Purchasing Division
City Hall, Room 430
1 Dr. Carlton B. Goodlett Place
San Francisco, California 94102-4685

Agreement between the City and County of San Francisco and

NMS Labs

This Agreement is made this First day of June, 2020, in the City and County of San Francisco ("City), State of California, by and between NMS Labs ("Contractor") and City.

Recitals

WHEREAS, the Office of the Chief Medical Examiner ("Department") wishes to acquire the services of NMS Labs to provide specialized toxicological analysis for the Forensic Laboratory Division on an as-needed basis; and,

WHEREAS, this Agreement was competitively procured as required by San Francisco Administrative Code Chapter 21.1 through a Request for Proposal ("RFP") issued on January 6, 2020, in which City selected Contractor as the highest qualified scorer pursuant to the RFP; and

WHEREAS, there is no Local Business Entity ("LBE") subcontracting participation requirement for this Agreement; and

WHEREAS, Contractor represents and warrants that it is qualified to perform the Services required by City as set forth under this Agreement; and

WHEREAS, the City's Civil Service Commission approved Contract number [4123 16/17] on March 6, 2019];

Now, THEREFORE, the parties agree as follows:

Article 1 Definitions

The following definitions apply to this Agreement:

1.1 "Agreement" means this contract document, including all attached appendices, and all applicable City Ordinances and Mandatory City Requirements specifically incorporated into this Agreement by reference as provided herein.

1.2 "City" or "the City" means the City and County of San Francisco, a municipal corporation, acting by and through both its Director of the Office of Contract Administration or the Director's designated agent, hereinafter referred to as "Purchasing" and Office of the Chief Medical Examiner.

1.3 "CMD" means the Contract Monitoring Division of the City.

1.4 "Contractor" or "Consultant" means NMS Labs, 200 Welsh Road, Horsham, PA 19044.

1.5 "Deliverables" means Contractor's work product resulting from the Services provided by Contractor to City during the course of Contractor's performance of the Agreement, including without limitation, the work product described in the “Scope of Services” attached as Appendix A.

1.6 "Effective Date" means the date upon which the City's Controller certifies the availability of funds for this Agreement as provided in Section 3.1.

1.7 "Mandatory City Requirements" means those City laws set forth in the San Francisco Municipal Code, including the duly authorized rules, regulations, and guidelines implementing such laws that impose specific duties and obligations upon Contractor.

1.8 "Party" and "Parties" mean the City and Contractor either collectively or individually.

1.9 "Services" means the work performed by Contractor under this Agreement as specifically described in the "Scope of Services" attached as Appendix A, including all services, labor, supervision, materials, equipment, actions and other requirements to be performed and furnished by Contractor under this Agreement.

Article 2 Term of the Agreement

2.1 The term of this Agreement shall commence on June 1, 2020 and expire on November 30, 2022, unless earlier terminated as otherwise provided herein.

The City has two options to renew the Agreement for a period of three years each. The City may extend this Agreement beyond the expiration date by exercising an option at the City’s sole and absolute discretion and by modifying this Agreement as provided in Section 11.5, “Modification of this Agreement.”

Article 3 Financial Matters

3.1 **Certification of Funds; Budget and Fiscal Provisions; Termination in the Event of Non-Appropriation**. This Agreement is subject to the budget and fiscal provisions of the City’s Charter. Charges will accrue only after prior written authorization certified by the Controller, and the amount of City’s obligation hereunder shall not at any time exceed the amount certified for the purpose and period stated in such advance authorization. This Agreement will terminate without penalty, liability or expense of any kind to City at the end of any fiscal year if funds are not appropriated for the next succeeding fiscal year. If funds are appropriated for a portion of the fiscal year, this Agreement will terminate, without penalty, liability or expense of any kind at the end of the term for which funds are appropriated. City has no obligation to make appropriations for this Agreement in lieu of appropriations for new or other agreements. City budget decisions are subject to the discretion of the Mayor and the Board of Supervisors. Contractor’s assumption of risk of possible non-appropriation is part of the consideration for this Agreement.

THIS SECTION CONTROLS AGAINST ANY AND ALL OTHER PROVISIONS OF THIS AGREEMENT.

3.2 **Guaranteed Maximum Costs**. The City's payment obligation to Contractor cannot at any time exceed the amount certified by City's Controller for the purpose and period stated in such certification. Absent an authorized Emergency per the City Charter or applicable Code, no City representative is authorized to offer or promise, nor is the City required to honor, any offered or promised payments to Contractor under this Agreement in excess of the certified maximum amount without the Controller having first certified the additional promised amount and the Parties having modified this Agreement as provided in Section 11.5, "Modification of this Agreement."

3.3 **Compensation.**

3.3.1 **Payment**. Contractor shall provide an invoice to the City on a monthly basis for Services completed in the immediate preceding month, unless a different schedule is set out in Appendix B, "Calculation of Charges." Compensation shall be made for Services identified in the invoice that the Chief Medical Examiner, in his or her sole discretion, concludes has been satisfactorily performed. Payment shall be made within 30 calendar days of receipt of the invoice, unless the City notifies the Contractor that a dispute as to the invoice exists. In no event shall the amount of this Agreement exceed Three Hundred Thousand Dollars ($300,000). The breakdown of charges associated with this Agreement appears in Appendix B, "Calculation of Charges," attached hereto and incorporated by reference as though fully set forth herein. A portion of payment may be withheld until conclusion of the Agreement if agreed to by both parties as retainage, described in Appendix B. In no event shall City be liable for interest or late charges for any late payments.

3.3.2 **Payment Limited to Satisfactory Services.** Contractor is not entitled to any payments from City until the Office of the Chief Medical Examiner approves Services, including any furnished Deliverables, as satisfying all of the requirements of this Agreement. Approval shall not be unreasonable withheld or delayed. Payments to Contractor by City shall not excuse Contractor from its obligation to replace unsatisfactory Deliverables, including equipment, components, materials, or Services even if the unsatisfactory character of such Deliverables, equipment, components, materials, or Services may not have been apparent or detected at the time such payment was made. Deliverables, equipment, components, materials and Services that do not conform to the requirements of this Agreement may be rejected by City and in such case must be replaced by Contractor without delay at no cost to the City.

3.3.3 **Withhold Payments.** If Contractor fails to provide Services in accordance with Contractor's obligations under this Agreement, the City may withhold any and all payments due Contractor until such failure to perform is cured, and Contractor shall not stop work as a result of City's withholding of payments as provided herein.

3.3.4 **Invoice Format**. Invoices furnished by Contractor under this Agreement must be in a form acceptable to the Controller and City, and must include a unique invoice number. Payment shall be made by City as specified in 3.3.6 or in such alternate manner as the Parties have mutually agreed upon in writing.

3.3.5 **Reserved. (LBE Payment and Utilization Tracking System.)**

3.3.6 **Getting paid by the City for goods and/or services.**

(a) All City vendors receiving new contracts, contract renewals, or contract extensions must sign up to receive electronic payments through the City's Automated

Clearing House (ACH) payments service/provider. Electronic payments are processed every business day and are safe and secure. To sign up for electronic payments, visit www.sfgov.org/ach.

(b) The following information is required to sign up: (i) The enroller must be their company's authorized financial representative, (ii) the company's legal name, main telephone number and all physical and remittance addresses used by the company, (iii) the company's U.S. federal employer identification number (EIN) or Social Security number (if they are a sole proprietor), and (iv) the company's bank account information, including routing and account numbers.

3.4 **Audit and Inspection of Records**. Contractor agrees to maintain and make available to the City, during regular business hours, accurate books and accounting records relating to its Services. Contractor will permit City to audit, examine and make excerpts and transcripts from such books and records, and to make audits of all invoices, materials, payrolls, records or personnel and other data related to all other matters covered by this Agreement, whether funded in whole or in part under this Agreement. Contractor shall maintain such data and records in an accessible location and condition for a period of not fewer than five years after final payment under this Agreement or until after final audit has been resolved, whichever is later. The State of California or any Federal agency having an interest in the subject matter of this Agreement shall have the same rights as conferred upon City by this Section. Contractor shall include the same audit and inspection rights and record retention requirements in all subcontracts.

3.5 **Submitting False Claims**. The full text of San Francisco Administrative Code Chapter 21, Section 21.35, including the enforcement and penalty provisions, is incorporated into this Agreement. Pursuant to San Francisco Administrative Code §21.35, any contractor or subcontractor who submits a false claim shall be liable to the City for the statutory penalties set forth in that section. A contractor or subcontractor will be deemed to have submitted a false claim to the City if the contractor or subcontractor: (a) knowingly presents or causes to be presented to an officer or employee of the City a false claim or request for payment or approval; (b) knowingly makes, uses, or causes to be made or used a false record or statement to get a false claim paid or approved by the City; (c) conspires to defraud the City by getting a false claim allowed or paid by the City; (d) knowingly makes, uses, or causes to be made or used a false record or statement to conceal, avoid, or decrease an obligation to pay or transmit money or property to the City; or (e) is a beneficiary of an inadvertent submission of a false claim to the City, subsequently discovers the falsity of the claim, and fails to disclose the false claim to the City within a reasonable time after discovery of the false claim.

3.6 **Reserved. (Payment of Prevailing Wages)**

Article 4 Services and Resources

4.1 **Services Contractor Agrees to Perform**. Contractor agrees to perform the Services stated in Appendix A, “Scope of Services." Officers and employees of the City are not authorized to request, and the City is not required to reimburse the Contractor for, Services beyond the Scope of Services listed in Appendix A, unless Appendix A is modified as provided in Section 11.5, "Modification of this Agreement."

4.2 **Qualified Personnel**. Contractor shall utilize only competent personnel under the supervision of, and in the employment of, Contractor (or Contractor's authorized subcontractors) to perform the Services. Contractor will comply with City's reasonable requests regarding assignment and/or removal of personnel, but all personnel, including those assigned at City's request, must be supervised by Contractor. Contractor shall commit adequate resources to allow timely completion within the project schedule specified in this Agreement.

4.3 **Subcontracting**.

4.3.1 Contractor may subcontract portions of the Services only upon prior written approval of City. Contractor is responsible for its subcontractors throughout the course of the work required to perform the Services. All Subcontracts must incorporate the terms of Article 10 "Additional Requirements Incorporated by Reference" of this Agreement, unless inapplicable. Neither Party shall, on the basis of this Agreement, contract on behalf of, or in the name of, the other Party. Any agreement made in violation of this provision shall be null and void.

4.4 **Independent Contractor; Payment of Employment Taxes and Other Expenses.**

4.4.1 **Independent Contractor**. For the purposes of this Section 4.4, "Contractor" shall be deemed to include not only Contractor, but also any agent or employee of Contractor. Contractor acknowledges and agrees that at all times, Contractor or any agent or employee of Contractor shall be deemed at all times to be an independent contractor and is wholly responsible for the manner in which it performs the services and work requested by City under this Agreement. Contractor, its agents, and employees will not represent or hold themselves out to be employees of the City at any time. Contractor or any agent or employee of Contractor shall not have employee status with City, nor be entitled to participate in any plans, arrangements, or distributions by City pertaining to or in connection with any retirement, health or other benefits that City may offer its employees. Contractor or any agent or employee of Contractor is liable for the acts and omissions of itself, its employees and its agents. Contractor shall be responsible for all obligations and payments, whether imposed by federal, state or local law, including, but not limited to, FICA, income tax withholdings, unemployment compensation, insurance, and other similar responsibilities related to Contractor's performing services and work, or any agent or employee of Contractor providing same. Nothing in this Agreement shall be construed as creating an employment or agency relationship between City and Contractor or any agent or employee of Contractor. Any terms in this Agreement referring to direction from City shall be construed as providing for direction as to policy and the result of Contractor's work only, and not as to the means by which such a result is obtained. City does not retain the right to control the means or the method by which Contractor performs work under this Agreement. Contractor agrees to maintain and make available to City, upon request and during regular business hours, accurate books and accounting records demonstrating Contractor's compliance with this section. Should City determine that Contractor, or any agent or employee of Contractor, is not performing in accordance with the requirements of this Agreement, City shall provide Contractor with written notice of such failure. Within five (5) business days of Contractor's receipt of such notice, and in accordance with Contractor policy and procedure, Contractor shall remedy the deficiency. Notwithstanding, if City believes that an action of Contractor, or any agent or employee of Contractor, warrants immediate remedial action by Contractor, City shall contact Contractor and provide Contractor in writing with the reason for requesting such immediate action.

4.4.2 **Payment of Employment Taxes and Other Expenses**. Should City, in its discretion, or a relevant taxing authority such as the Internal Revenue Service or the State Employment Development Division, or both, determine that Contractor is an employee for purposes of collection of any employment taxes, the amounts payable under this Agreement shall be reduced by amounts equal to both the employee and employer portions of the tax due (and offsetting any credits for amounts already paid by Contractor which can be applied against this liability). City shall then forward those amounts to the relevant taxing authority. Should a relevant taxing authority determine a liability for past services performed by Contractor for City, upon notification of such fact by City, Contractor shall promptly remit such amount due or arrange with City to have the amount due withheld from future payments to Contractor under this Agreement (again, offsetting any amounts already paid by Contractor which can be applied as a credit against such liability). A determination of employment status pursuant to this Section 4.4 shall be solely limited to the purposes of the particular tax in question, and for all other purposes of this Agreement, Contractor shall not be considered an employee of City. Notwithstanding the foregoing, Contractor agrees to indemnify and save harmless City and its officers, agents and employees from, and, if requested, shall defend them against any and all claims, losses, costs, damages, and expenses, including attorneys' fees, arising from this section.

4.5 **Assignment**. The Services to be performed by Contractor are personal in character and neither this Agreement nor any duties or obligations hereunder may be assigned or delegated by Contractor unless first approved by City by written instrument executed and approved in the same manner as this Agreement. Any purported assignment made in violation of this provision shall be null and void.

4.6 **Warranty**. Contractor warrants to City that the Services will be performed with the degree of skill and care that is required by current, good and sound professional procedures and practices, and in conformance with generally accepted professional standards prevailing at the time the Services are performed so as to ensure that all Services performed are correct and appropriate for the purposes contemplated in this Agreement.

4.7 **Reserved. (Liquidated Damages.)**

Article 5 Insurance and Indemnity

5.1 **Insurance.**

5.1.1 **Required Coverages.** Without in any way limiting Contractor's liability pursuant to the "Indemnification" section of this Agreement, Contractor must maintain in force, during the full term of the Agreement, insurance in the following amounts and coverages:

(a) Workers' Compensation, in statutory amounts, with Employers' Liability Limits not less than $1,000,000 each accident, injury, or illness; and

(b) Commercial General Liability Insurance with limits not less than $1,000,000 each occurrence for Bodily Injury and Property Damage, including Contractual Liability, Personal Injury, Products and Completed Operations; and

(c) Commercial Automobile Liability Insurance with limits not less than $1,000,000 each occurrence, "Combined Single Limit" for Bodily Injury and Property Damage, including Owned, Non-Owned and Hired auto coverage, as applicable.

5.1.2 Commercial General Liability and Commercial Automobile Liability Insurance policies must be endorsed to name as Additional Insured the City and County of San Francisco, its Officers, Agents, and Employees.

(a) Name as Additional Insured the City and County of San Francisco, its Officers, Agents, and Employees.

(b) That such policies are primary insurance to any other insurance available to the Additional Insureds, with respect to any claims arising out of the Agreement, and that insurance applies separately to each insured against whom claim is made of suit is brought.

5.1.3 All policies shall be endorsed to provide thirty (30) days' advance written notice to the City of cancellation for any reason, intended non-renewal, or reduction in coverages. Notices shall be sent to the City address set forth in Section 11.1, entitled "Notices to the Parties."

5.1.4 Should any of the required insurance be provided under a claims-made form, Contractor shall maintain such coverage continuously throughout the term of this Agreement and, without lapse, for a period of three years beyond the expiration of this Agreement, to the effect that, should occurrences during the contract term give rise to claims made after expiration of the Agreement, such claims shall be covered by such claims-made policies.

5.1.5 Should any of the required insurance be provided under a form of coverage that includes a general annual aggregate limit or provides that claims investigation or legal defense costs be included in such general annual aggregate limit, such general annual aggregate limit shall be double the occurrence or claims limits specified above.

5.1.6 Should any required insurance lapse during the term of this Agreement, requests for payments originating after such lapse shall not be processed until the City receives satisfactory evidence of reinstated coverage as required by this Agreement, effective as of the lapse date. If insurance is not reinstated, the City may, at its sole option, terminate this Agreement effective on the date of such lapse of insurance.

5.1.7 Before commencing any Services, Contractor shall furnish to City certificates of insurance and additional insured policy endorsements with insurers with ratings comparable to A-, VIII or higher, that are authorized to do business in the State of California, and that are satisfactory to City, in form evidencing all coverages set forth above. Approval of the insurance by City shall not relieve or decrease Contractor's liability hereunder.

5.1.8 If Contractor will use any subcontractor(s) to provide Services, Contractor shall require the subcontractor(s) to provide all necessary insurance and to name the City and County of San Francisco, its officers, agents and employees and the Contractor as additional insureds.

5.2 **Indemnification**. Contractor shall indemnify and hold harmless City and its officers, agents and employees from, and, if requested, shall defend them from and against any and all claims, demands, losses, damages, costs, expenses, and liability (legal, contractual, or

otherwise) arising from or in any way connected with any: (i) injury to or death of a person, including employees of City or Contractor; (ii) loss of or damage to property; (iii) violation of local, state, or federal common law, statute or regulation, including but not limited to privacy or personally identifiable information, health information, disability and labor laws or regulations; (iv) strict liability imposed by any law or regulation; or (v) losses arising from Contractor's execution of subcontracts not in accordance with the requirements of this Agreement applicable to subcontractors; so long as such injury, violation, loss, or strict liability (as set forth in subsections (i) – (v) above) arises directly or indirectly from Contractor's performance of this Agreement, including, but not limited to, Contractor's use of facilities or equipment provided by City or others, regardless of the negligence of, and regardless of whether liability without fault is imposed or sought to be imposed on City, except to the extent that such indemnity is void or otherwise unenforceable under applicable law, and except where such loss, damage, injury, liability or claim is the result of the active negligence or willful misconduct of City and is not contributed to by any act of, or by any omission to perform some duty imposed by law or agreement on Contractor, its subcontractors, or either's agent or employee. The foregoing indemnity shall include, without limitation, reasonable fees of attorneys, consultants and experts and related costs and City's costs of investigating any claims against the City.

In addition to Contractor's obligation to indemnify City, Contractor specifically acknowledges and agrees that it has an immediate and independent obligation to defend City from any claim which actually or potentially falls within this indemnification provision, even if the allegations are or may be groundless, false or fraudulent, which obligation arises at the time such claim is tendered to Contractor by City and continues at all times thereafter.

Contractor shall indemnify and hold City harmless from all loss and liability, including attorneys' fees, court costs and all other litigation expenses for any infringement of the patent rights, copyright, trade secret or any other proprietary right or trademark, and all other intellectual property claims of any person or persons arising directly or indirectly from the receipt by City, or any of its officers or agents, of Contractor's Services.

Article 6 Liability of the Parties

6.1 **Liability of City**. CITY'S PAYMENT OBLIGATIONS UNDER THIS AGREEMENT SHALL BE LIMITED TO THE PAYMENT OF THE COMPENSATION PROVIDED FOR IN SECTION 3.3.1, "PAYMENT," OF THIS AGREEMENT. NOTWITHSTANDING ANY OTHER PROVISION OF THIS AGREEMENT, IN NO EVENT SHALL CITY BE LIABLE, REGARDLESS OF WHETHER ANY CLAIM IS BASED ON CONTRACT OR TORT, FOR ANY SPECIAL, CONSEQUENTIAL, INDIRECT OR INCIDENTAL DAMAGES, INCLUDING, BUT NOT LIMITED TO, LOST PROFITS, ARISING OUT OF OR IN CONNECTION WITH THIS AGREEMENT OR THE SERVICES PERFORMED IN CONNECTION WITH THIS AGREEMENT.

6.2 **Liability for Use of Equipment**. City shall not be liable for any damage to persons or property as a result of the use, misuse or failure of any equipment used by Contractor, or any of its subcontractors, or by any of their employees, even though such equipment is furnished, rented or loaned by City.

6.3 **Liability for Incidental and Consequential Damages**. Contractor shall be responsible for incidental and consequential damages resulting in whole or in part from Contractor's acts or omissions.

Article 7 Payment of Taxes

7.1 Except for any applicable California sales and use taxes charged by Contractor to City, Contractor shall pay all taxes, including possessory interest taxes levied upon or as a result of this Agreement, or the Services delivered pursuant hereto. Contractor shall remit to the State of California any sales or use taxes paid by City to Contractor under this Agreement. Contractor agrees to promptly provide information requested by the City to verify Contractor's compliance with any State requirements for reporting sales and use tax paid by City under this Agreement.

7.2 Contractor acknowledges that this Agreement may create a "possessory interest" for property tax purposes. Generally, such a possessory interest is not created unless the Agreement entitles the Contractor to possession, occupancy, or use of City property for private gain. If such a possessory interest is created, then the following shall apply:

7.2.1 Contractor, on behalf of itself and any permitted successors and assigns, recognizes and understands that Contractor, and any permitted successors and assigns, may be subject to real property tax assessments on the possessory interest.

7.2.2 Contractor, on behalf of itself and any permitted successors and assigns, recognizes and understands that the creation, extension, renewal, or assignment of this Agreement may result in a "change in ownership" for purposes of real property taxes, and therefore may result in a revaluation of any possessory interest created by this Agreement. Contractor accordingly agrees on behalf of itself and its permitted successors and assigns to report on behalf of the City to the County Assessor the information required by Revenue and Taxation Code section 480.5, as amended from time to time, and any successor provision.

7.2.3 Contractor, on behalf of itself and any permitted successors and assigns, recognizes and understands that other events also may cause a change of ownership of the possessory interest and result in the revaluation of the possessory interest. (see, e.g., Rev. & Tax. Code section 64, as amended from time to time). Contractor accordingly agrees on behalf of itself and its permitted successors and assigns to report any change in ownership to the County Assessor, the State Board of Equalization or other public agency as required by law.

7.2.4 Contractor further agrees to provide such other information as may be requested by the City to enable the City to comply with any reporting requirements for possessory interests that are imposed by applicable law.

Article 8 Termination and Default

8.1 Termination for Convenience

8.1.1 City shall have the option, in its sole discretion, to terminate this Agreement, at any time during the term hereof, for convenience and without cause. City shall exercise this option by giving Contractor at least 30 days written notice of termination. The notice shall specify the date on which termination shall become effective.

8.1.2 Upon receipt of the notice of termination, Contractor shall commence and perform, with diligence, all actions necessary on the part of Contractor to effect the termination of this Agreement on the date specified by City and to minimize the liability of Contractor and City to third parties as a result of termination. All such actions shall be subject to the prior approval of City. Such actions may include any or all of the following, without limitation:

(a) Halting the performance of all Services under this Agreement on the date(s) and in the manner specified by City.

(b) Terminating all existing orders and subcontracts, and not placing any further orders or subcontracts for materials, Services, equipment or other items.

(c) At City's direction, assigning to City any or all of Contractor's right, title, and interest under the orders and subcontracts terminated. Upon such assignment, City shall have the right, in its sole discretion, to settle or pay any or all claims arising out of the termination of such orders and subcontracts.

(d) Subject to City's approval, settling all outstanding liabilities and all claims arising out of the termination of orders and subcontracts.

(e) Completing performance of any Services that City designates to be completed prior to the date of termination specified by City.

(f) Taking such action as may be necessary, or as the City may direct, for the protection and preservation of any property related to this Agreement which is in the possession of Contractor and in which City has or may acquire an interest.

8.1.3 Within 30 days after the specified termination date, Contractor shall submit to City an invoice, which shall set forth each of the following as a separate line item:

8.1.4 In no event shall City be liable for costs incurred by Contractor or any of its subcontractors after the termination date specified by City, except for those costs specifically listed in Section 8.1.3. Such non-recoverable costs include, but are not limited to, anticipated profits on the Services under this Agreement, post-termination employee salaries, post-termination administrative expenses, post-termination overhead or unabsorbed overhead, attorneys' fees or other costs relating to the prosecution of a claim or lawsuit, prejudgment interest, or any other expense which is not reasonable or authorized under Section 8.1.3.

8.1.5 In arriving at the amount due to Contractor under this Section, City may deduct: (i) all payments previously made by City for Services covered by Contractor's final invoice; (ii) any claim which City may have against Contractor in connection with this Agreement; (iii) any invoiced costs or expenses excluded pursuant to the immediately preceding subsection 8.1.4; and (iv) in instances in which, in the opinion of the City, the cost of any Service performed under this Agreement is excessively high due to costs incurred to remedy or replace defective or rejected Services, the difference between the invoiced amount and City's estimate of the reasonable cost of performing the invoiced Services in compliance with the requirements of this Agreement.

8.1.6 City's payment obligation under this Section shall survive termination of this Agreement.

8.2 **Termination for Default; Remedies.**

8.2.1 Each of the following shall constitute an immediate event of default ("Event of Default") under this Agreement:

(a) Contractor fails or refuses to perform or observe any term, covenant or condition contained in any of the following Sections of this Agreement:

3.5	Submitting False Claims.	10.10	Alcohol and Drug-Free Workplace
4.5	Assignment		
Article 5	Insurance and Indemnity	11.10	Compliance with Laws
Article 7	Payment of Taxes	13.1	Nondisclosure of Private, Proprietary or Confidential Information

(b) Contractor fails or refuses to perform or observe any other term, covenant or condition contained in this Agreement, including any obligation imposed by ordinance or statute and incorporated by reference herein, and such default is not cured within ten days after written notice thereof from City to Contractor.

(c) Contractor (i) is generally not paying its debts as they become due; (ii) files, or consents by answer or otherwise to the filing against it of a petition for relief or reorganization or arrangement or any other petition in bankruptcy or for liquidation or to take advantage of any bankruptcy, insolvency or other debtors' relief law of any jurisdiction; (iii) makes an assignment for the benefit of its creditors; (iv) consents to the appointment of a custodian, receiver, trustee or other officer with similar powers of Contractor or of any substantial part of Contractor's property; or (v) takes action for the purpose of any of the foregoing.

(d) A court or government authority enters an order (i) appointing a custodian, receiver, trustee or other officer with similar powers with respect to Contractor or with respect to any substantial part of Contractor's property, (ii) constituting an order for relief or approving a petition for relief or reorganization or arrangement or any other petition in bankruptcy or for liquidation or to take advantage of any bankruptcy, insolvency or other debtors' relief law of any jurisdiction or (iii) ordering the dissolution, winding-up or liquidation of Contractor.

8.2.2 On and after any Event of Default, City shall have the right to exercise its legal and equitable remedies, including, without limitation, the right to terminate this Agreement or to seek specific performance of all or any part of this Agreement. In addition, where applicable, City shall have the right (but no obligation) to cure (or cause to be cured) on behalf of Contractor any Event of Default; Contractor shall pay to City on demand all costs and expenses incurred by City in effecting such cure, with interest thereon from the date of incurrence at the maximum rate then permitted by law. City shall have the right to offset from any amounts due to Contractor under this Agreement or any other agreement between City and Contractor: (i) all damages, losses, costs or expenses incurred by City as a result of an Event of Default; and (ii) any liquidated damages levied upon Contractor pursuant to the terms of this Agreement; and (iii), any damages imposed by any ordinance or statute that is incorporated into this Agreement by reference, or into any other agreement with the City.

8.2.3 All remedies provided for in this Agreement may be exercised individually or in combination with any other remedy available hereunder or under applicable laws, rules and regulations. The exercise of any remedy shall not preclude or in any way be deemed to waive any other remedy. Nothing in this Agreement shall constitute a waiver or limitation of any rights that City may have under applicable law.

8.2.4 Any notice of default must be sent by registered mail to the address set forth in Article 11.

8.3 **Non-Waiver of Rights**. The omission by either party at any time to enforce any default or right reserved to it, or to require performance of any of the terms, covenants, or provisions hereof by the other party at the time designated, shall not be a waiver of any such default or right to which the party is entitled, nor shall it in any way affect the right of the party to enforce such provisions thereafter.

8.4 **Rights and Duties upon Termination or Expiration.**

8.4.1 This Section and the following Sections of this Agreement listed below, shall survive termination or expiration of this Agreement:

3.3.2	Payment Limited to Satisfactory Services		9.1	Ownership of Results
3.3.7(a)	Grant Funded Contracts – Disallowance		9.2	Works for Hire
3.4	Audit and Inspection of Records		11.6	Dispute Resolution Procedure
3.5	Submitting False Claims		11.7	Agreement Made in California; Venue
Article 5	Insurance and Indemnity		11.8	Construction
6.1	Liability of City		11.9	Entire Agreement
6.3	Liability for Incidental and Consequential Damages		11.10	Compliance with Laws
Article 7	Payment of Taxes		11.11	Severability
8.1.6	Payment Obligation		13.1	Nondisclosure of Private, Proprietary of Confidential Information

8.4.2 Subject to the survival of the Sections identified in Section 8.4.1, above, if this Agreement is terminated prior to expiration of the term specified in Article 2, this Agreement shall be of no further force or effect. Contractor shall transfer title to City, and deliver in the manner, at the times, and to the extent, if any, directed by City, any work in progress, completed work, supplies, equipment, and other materials produced as a part of, or acquired in connection with the performance of this Agreement, and any completed or partially completed work which, if this Agreement had been completed, would have been required to be furnished to City.

Article 9 Rights In Deliverables

9.1 **Ownership of Results**. Any interest of Contractor or its subcontractors, in the Deliverables, including any drawings, plans, specifications, blueprints, studies, reports, memoranda, computation sheets, computer files and media or other documents prepared by Contractor or its subcontractors for the purposes of this agreement, shall become the property of and will be transmitted to City. However, unless expressly prohibited elsewhere in this Agreement, Contractor may retain and use copies for reference and as documentation of its experience and capabilities.

9.2 **Works for Hire**. If, in connection with Services, Contractor or its subcontractors creates Deliverables including, without limitation, artwork, copy, posters, billboards, photographs, videotapes, audiotapes, systems designs, software, reports, diagrams, surveys, blueprints, source codes, or any other original works of authorship, whether in digital or any other format, such works of authorship shall be works for hire as defined under Title 17 of the United States Code, and all copyrights in such works shall be the property of the City. If any Deliverables created by Contractor or its subcontractor(s) under this Agreement are ever determined not to be works for hire under U.S. law, Contractor hereby assigns all Contractor's copyrights to such Deliverables to the City, agrees to provide any material and execute any documents necessary to effectuate such assignment, and agrees to include a clause in every subcontract imposing the same duties upon subcontractor(s). With City's prior written approval, Contractor and its subcontractor(s) may retain and use copies of such works for reference and as documentation of their respective experience and capabilities.

Article 10 Additional Requirements Incorporated by Reference

10.1 **Laws Incorporated by Reference**. The full text of the laws listed in this Article 10, including enforcement and penalty provisions, are incorporated by reference into this Agreement. The full text of the San Francisco Municipal Code provisions incorporated by reference in this Article and elsewhere in the Agreement ("Mandatory City Requirements") are available at http://www.amlegal.com/codes/client/san-francisco_ca/ .

10.2 **Conflict of Interest**. By executing this Agreement, Contractor certifies that it does not know of any fact which constitutes a violation of Section 15.103 of the City's Charter; Article III, Chapter 2 of City's Campaign and Governmental Conduct Code; Title 9, Chapter 7 of the California Government Code (Section 87100 *et seq.*), or Title 1, Division 4, Chapter 1, Article 4 of the California Government Code (Section 1090 *et seq.*), and further agrees promptly to notify the City if it becomes aware of any such fact during the term of this Agreement.

10.3 **Prohibition on Use of Public Funds for Political Activity.** In performing the Services, Contractor shall comply with San Francisco Administrative Code Chapter 12G, which prohibits funds appropriated by the City for this Agreement from being expended to participate in, support, or attempt to influence any political campaign for a candidate or for a ballot measure. Contractor is subject to the enforcement and penalty provisions in Chapter 12G.

10.4 **Reserved.**

10.5 **Nondiscrimination Requirements.**

10.5.1 **Non Discrimination in Contracts**. Contractor shall comply with the provisions of Chapters 12B and 12C of the San Francisco Administrative Code. Contractor shall incorporate by reference in all subcontracts the provisions of Sections12B.2(a), 12B.2(c)-(k), and 12C.3 of the San Francisco Administrative Code and shall require all subcontractors to comply with such provisions. Contractor is subject to the enforcement and penalty provisions in Chapters 12B and 12C.

10.5.2 **Nondiscrimination in the Provision of Employee Benefits**. San Francisco Administrative Code 12B.2. Contractor does not as of the date of this Agreement, and will not during the term of this Agreement, in any of its operations in San Francisco, on real property owned by San Francisco, or where work is being performed for the City elsewhere in the United States, discriminate in the provision of employee benefits between employees with

domestic partners and employees with spouses and/or between the domestic partners and spouses of such employees, subject to the conditions set forth in San Francisco Administrative Code Section12B.2.

10.6 **Local Business Enterprise and Non-Discrimination in Contracting Ordinance.** Contractor shall comply with all applicable provisions of Chapter 14B ("LBE Ordinance"). Contractor is subject to the enforcement and penalty provisions in Chapter 14B.

10.7 **Minimum Compensation Ordinance**. Contractor shall pay covered employees no less than the minimum compensation required by San Francisco Administrative Code Chapter 12P. Contractor is subject to the enforcement and penalty provisions in Chapter 12P. By signing and executing this Agreement, Contractor certifies that it complies with Chapter 12P.

10.8 **Health Care Accountability Ordinance**. Contractor shall comply with the requirements of Chapter 12Q. Contractor shall choose and perform one of the Heath Care Accountability options set forth in San Francisco Administrative Code Chapter 12Q.

10.9 **Alcohol and Drug-Free Workplace.** City reserves the right to deny access to, or require Contractor to remove from, City facilities personnel of any Contractor or subcontractor who City has reasonable grounds to believe has engaged in alcohol abuse or illegal drug activity which in any way impairs City's ability to maintain safe work facilities or to protect the health and well-being of City employees and the general public. City shall have the right of final approval for the entry or re-entry of any such person previously denied access to, or removed from, City facilities. Illegal drug activity means possessing, furnishing, selling, offering, purchasing, using or being under the influence of illegal drugs or other controlled substances for which the individual lacks a valid prescription. Alcohol abuse means possessing, furnishing, selling, offering, or using alcoholic beverages, or being under the influence of alcohol.

10.10 **Limitations on Contributions.** By executing this Agreement, Contractor acknowledges its obligations under section 1.126 of the City's Campaign and Governmental Conduct Code, which prohibits any person who contracts with, or is seeking a contract with, any department of the City for the rendition of personal services, for the furnishing of any material, supplies or equipment, for the sale or lease of any land or building, for a grant, loan or loan guarantee, or for a development agreement, from making any campaign contribution to (i) a City elected official if the contract must be approved by that official, a board on which that official serves, or the board of a state agency on which an appointee of that official serves, (ii) a candidate for that City elective office, or (iii) a committee controlled by such elected official or a candidate for that office, at any time from the submission of a proposal for the contract until the later of either the termination of negotiations for such contract or twelve months after the date the City approves the contract. The prohibition on contributions applies to each prospective party to the contract; each member of Contractor's board of directors; Contractor's chairperson, chief executive officer, chief financial officer and chief operating officer; any person with an ownership interest of more than 10% in Contractor; any subcontractor listed in the bid or contract; and any committee that is sponsored or controlled by Contractor. Contractor certifies that it has informed each such person of the limitation on contributions imposed by Section 1.126 by the time it submitted a proposal for the contract, and has provided the names of the persons required to be informed to the City department with whom it is contracting.

10.11 **Reserved. (Slavery Era Disclosure**.)

10.12 **Reserved. (Working with Minors.)**

10.13 **Reserved. (Consideration of Criminal History in Hiring and Employment Decisions.)**

10.14 **Reserved. (Public Access to Nonprofit Records and Meetings.)**

10.15 **Food Service Waste Reduction Requirements.** Contractor shall comply with the Food Service Waste Reduction Ordinance, as set forth in San Francisco Environment Code Chapter 16, including but not limited to the remedies for noncompliance provided therein.

10.16 **Reserved. (Distribution of Beverages and Water.)**

10.17 **Tropical Hardwood and Virgin Redwood Ban**. Pursuant to San Francisco Environment Code Section 804(b), the City urges Contractor not to import, purchase, obtain, or use for any purpose, any tropical hardwood, tropical hardwood wood product, virgin redwood or virgin redwood wood product.

10.18 **Reserved. (Preservative Treated Wood Products.)**

Article 11 General Provisions

11.1 **Notices to the Parties.** Unless otherwise indicated in this Agreement, all written communications sent by the Parties may be by U.S. mail or e-mail, and shall be addressed as follows:

To City: **Office of the Chief Medical Examiner**
Kalima A. Collymore
1 Newhall Street
San Francisco, CA 94124
Email: Kalima.Collymore@sfgov.org

To Contractor: **NMS Labs**
Andrew Nolan
200 Welsh Road
Horsham, PA 19044
Email: Andrew.Nolan@nmslabs.com

Any notice of default must be sent by registered mail. Either Party may change the address to which notice is to be sent by giving written notice thereof to the other Party. If email notification is used, the sender must specify a receipt notice.

11.2 **Compliance with Americans with Disabilities Act**. Contractor shall provide the Services in a manner that complies with the Americans with Disabilities Act (ADA), including but not limited to Title II's program access requirements, and all other applicable federal, state and local disability rights legislation.

11.3 **Reserved. (Incorporation of Recitals.)**

11.4 **Sunshine Ordinance.** Contractor acknowledges that this Agreement and all records related to its formation, Contractor's performance of Services, and City's payment are subject to the California Public Records Act, (California Government Code §6250 et. seq.), and the San Francisco Sunshine Ordinance, (San Francisco Administrative Code Chapter 67). Such

records are subject to public inspection and copying unless exempt from disclosure under federal, state or local law.

11.5 **Modification of this Agreement**. This Agreement may not be modified, nor may compliance with any of its terms be waived, except as noted in Section 11.1, "Notices to Parties," regarding change in personnel or place, and except by written instrument executed and approved in the same manner as this Agreement. Contractor shall cooperate with Department to submit to the Director of CMD any amendment, modification, supplement or change order that would result in a cumulative increase of the original amount of this Agreement by more than 20% (CMD Contract Modification Form).

11.6 **Dispute Resolution Procedure**.

11.6.1 **Negotiation; Alternative Dispute Resolution.** The Parties will attempt in good faith to resolve any dispute or controversy arising out of or relating to the performance of services under this Agreement. If the Parties are unable to resolve the dispute, then, pursuant to San Francisco Administrative Code Section 21.36, Contractor may submit to the Contracting Officer a written request for administrative review and documentation of the Contractor's claim(s). Upon such request, the Contracting Officer shall promptly issue an administrative decision in writing, stating the reasons for the action taken and informing the Contractor of its right to judicial review. If agreed by both Parties in writing, disputes may be resolved by a mutually agreed-upon alternative dispute resolution process. If the parties do not mutually agree to an alternative dispute resolution process or such efforts do not resolve the dispute, then either Party may pursue any remedy available under California law. The status of any dispute or controversy notwithstanding, Contractor shall proceed diligently with the performance of its obligations under this Agreement in accordance with the Agreement and the written directions of the City. Neither Party will be entitled to legal fees or costs for matters resolved under this section.

11.6.2 **Government Code Claim Requirement.** No suit for money or damages may be brought against the City until a written claim therefor has been presented to and rejected by the City in conformity with the provisions of San Francisco Administrative Code Chapter 10 and California Government Code Section 900, et seq. Nothing set forth in this Agreement shall operate to toll, waive or excuse Contractor's compliance with the California Government Code Claim requirements set forth in San Francisco Administrative Code Chapter 10 and California Government Code Section 900, et seq.

11.7 **Agreement Made in California; Venue**. The formation, interpretation and performance of this Agreement shall be governed by the laws of the State of California. Venue for all litigation relative to the formation, interpretation and performance of this Agreement shall be in San Francisco.

11.8 **Construction.** All paragraph captions are for reference only and shall not be considered in construing this Agreement.

11.9 **Entire Agreement**. This contract sets forth the entire Agreement between the parties, and supersedes all other oral or written provisions. This Agreement may be modified only as provided in Section 11.5, "Modification of this Agreement."

11.10 **Compliance with Laws**. Contractor shall keep itself fully informed of the City's Charter, codes, ordinances and duly adopted rules and regulations of the City and of all state, and

federal laws in any manner affecting the performance of this Agreement, and must at all times comply with such local codes, ordinances, and regulations and all applicable laws as they may be amended from time to time.

11.11 **Severability**. Should the application of any provision of this Agreement to any particular facts or circumstances be found by a court of competent jurisdiction to be invalid or unenforceable, then (i) the validity of other provisions of this Agreement shall not be affected or impaired thereby, and (ii) such provision shall be enforced to the maximum extent possible so as to effect the intent of the parties and shall be reformed without further action by the parties to the extent necessary to make such provision valid and enforceable.

11.12 **Cooperative Drafting**. This Agreement has been drafted through a cooperative effort of City and Contractor, and both Parties have had an opportunity to have the Agreement reviewed and revised by legal counsel. No Party shall be considered the drafter of this Agreement, and no presumption or rule that an ambiguity shall be construed against the Party drafting the clause shall apply to the interpretation or enforcement of this Agreement.

11.13 **Order of Precedence.** Contractor agrees to perform the services described below in accordance with the terms and conditions of the Agreement, and the Description of Services listed in Appendix A. Should there be a conflict of terms or conditions, the Agreement and any implementing task orders shall control.

Article 12 Department Specific Terms

12.1 **Reserved**.

Article 13 Data and Security

13.1 **Nondisclosure of Private, Proprietary or Confidential Information.**

13.1.1 **Protection of Private Information.** If this Agreement requires City to disclose "Private Information" to Contractor within the meaning of San Francisco Administrative Code Chapter 12M, Contractor and subcontractor shall use such information only in accordance with the restrictions stated in Chapter 12M and in this Agreement and only as necessary in performing the Services. Contractor is subject to the enforcement and penalty provisions in Chapter 12M.

13.1.2 **Confidential Information.** In the performance of Services, Contractor may have access to City's proprietary or Confidential Information, the disclosure of which to third parties may damage City. If City discloses proprietary or Confidential Information to Contractor, such information must be held by Contractor in confidence and used only in performing the Agreement. Contractor shall exercise the same standard of care to protect such information as a reasonably prudent contractor would use to protect its own proprietary or Confidential Information.

13.2 **Reserved. (Payment Card Industry ("PCI") Requirements.)**

13.3 **Reserved. (Business Associate Agreement.)**

Article 14 MacBride And Signature

14.1 **MacBride Principles - Northern Ireland**. The provisions of San Francisco Administrative Code §12F are incorporated herein by this reference and made part of this Agreement. By signing this Agreement, Contractor confirms that Contractor has read and

understood that the City urges companies doing business in Northern Ireland to resolve employment inequities and to abide by the MacBride Principles, and urges San Francisco companies to do business with corporations that abide by the MacBride Principles.

IN WITNESS WHEREOF, the parties hereto have executed this Agreement on the day first mentioned above.

CITY

Recommended by:

Kenneth Bukowski
Deputy City Administrator
City and County of San Francisco

Approved as to Form:

Dennis J. Herrera
City Attorney

By: _____
David Ries
Deputy City Attorney

Approved:
Sailaja Kurella
Director of the Office of Contract Administration,
and Purchaser, Acting

By: _____
Sailaja Kurella

CONTRACTOR

NMS Labs

Eric F. Rieders
President & ~~CEO~~ COO
200 Welsh Rd.
Horsham, PA 19044

City Supplier Number: **33169**

Appendices
A: Scope of Services
B: Calculation of Charges
C: Insurance Waiver

Appendix A
Scope of Services

1. Description of Services

Contractor agrees to perform the following Services per Sections I-II of the RFP:

In addition to ABFT accreditation, OCME also requires its contracting laboratory to be within the United States and to provide sufficient access to raw data of laboratory results to qualified OCME forensic toxicologists, allowing them to become "Reviewers" of such results. The contracted laboratory must grant OCME direct access to each OCME submitted specimen's chain of custody history, batch posting summary of results, specimens processing history, and other background materials in addition to final analytical results typically provided to the analyst and reviewing staff members of the reference laboratory. This type of analytical-reviewer partnership services would also include access to relevant standard operating procedures, polices and other documentation as necessary in order for OCME forensic toxicologists to approve and sign the reference laboratory's final report for each submitted case. Additional documentations may be required in order satisfy court requirements during judicial proceedings.

San Francisco OCME requires this partnership due to the 2009 US Supreme Court decision of Melendez Diaz v Massachusetts [129 US Supreme Court Reports 2527 (2009)] , where trial defendants have the right to challenge the reviewer of laboratory analytical results. In San Francisco courts, this precedent is routinely exercised, leading to frequent testimony by OCME forensic toxicologists. Because these forensic toxicologists are reviewers for both in-house and reference analytical results, they are able to provide timely and accurate testimony for all samples submitted by the OCME to the contracted laboratory.

All analytical testing must achieve scopes and limits of detection, quantitation and reporting of blood, urine or other biological specimen testing to meet industry recommendations for DUID and DFC casework, and both typically encountered and novel drug scope and concentrations for postmortem casework, with measurements of uncertainties for DUID casework, and completed results and final vendor's toxicology report being available for review on, or before, ten (10) business days of receipt of specimens to the reference laboratory. Subsequently, specimens can be returned within 3 months of reporting, or at request.

Key functional requirements are:

- Current accreditation by the American Board of Forensic Toxicology (ABFT)
- Current ability to provide an online portal, or otherwise, with direct access of all OCME submitted casework, by OCME staff, to the raw data.
- Current ability to facilitate OCME forensic toxicologists to approve and sign the reference laboratory's final report.

- Current ability to provide results that are available for review on, or before, ten (10) business days of receipt of specimens to the reference laboratory.
- Current ability to return all specimens within 3 months of reporting, or immediately at request.

Key detailed features are:

No	Feature Description
1.	Current accreditation by the American Board of Forensic Toxicology (ABFT).
2.	Current ability to provide an online portal, or otherwise, with direct access of all OCME submitted casework, by OCME staff, to the raw data of submitted specimen chain of custody history.
3.	Current ability to provide an online portal, or otherwise, with direct access of all OCME submitted casework, by OCME staff, to the raw data of batch posting summary of results.
4.	Current ability to provide an online portal, or otherwise, with direct access of all OCME submitted casework, by OCME staff, to the raw data of specimen's internal chain of custody and processing history.
5.	Current ability to provide an online portal, or otherwise, with direct access of all OCME submitted casework, by OCME staff, to the raw data of calibration and quality control information and ranges.
6.	Current ability to provide an online portal, or otherwise, with direct access of all OCME submitted casework, by OCME staff, to the raw data of technical or analytical standards of operation.
7.	Current ability to provide an online portal, or otherwise, with direct access of all OCME submitted casework, by OCME staff, to the raw data of quality manual or quality standards of operation.
8.	Current ability to provide an online portal, or otherwise, with direct access of all OCME submitted casework, by OCME staff, to the raw data of physical or digital bench notes.
9.	Current ability to provide an online portal, or otherwise, with direct access of all OCME submitted casework, by OCME staff, to the raw data of any other relevant raw data.
10.	Current ability to save all above mentioned raw data in PDF format and stored on the OCME network.
11.	Current ability to facilitate OCME forensic toxicologists to approve and sign the reference laboratory's final report.

No	Feature Description
12.	Current ability to meet, or exceed, detection of the following drugs and/or metabolites in whole blood specimens pertaining to DUID casework: 6-MAM 1 ng/mL Morphine 5 ng/mL Codeine 5 ng/mL Hydrocodone 5 ng/mL Hydromorphone 1 ng/mL Dihydrocodeine 5 ng/mL Oxycodone 1 ng/mL Oxymorphone 1 ng/mL Methadone 20 ng/mL Fentanyl and metabolite(s) 0.1 ng/mL Buprenorphine and metabolite(s) 0.5 ng/mL Tramadol and metabolite(s) 10 ng/mL
13.	Current ability to meet, or exceed, detection of the following drugs and/or metabolites in whole blood specimens pertaining to DUID casework: THC 1 ng/mL 11-OH THC 1 ng/mL Carboxy THC 5 ng/mL
14.	Current ability to meet, or exceed, detection of the following drugs and/or metabolites in whole blood specimens pertaining to DUID casework: Cocaine and metabolite(s) 20 ng/mL Amphetamines 5 ng/mL Phencyclidine 5 ng/mL Carisoprodol 200 ng/mL MDMA 5 ng/mL Zolpidem 5.0 ng/mL
15.	Current ability to meet, or exceed, detection of the following drugs and/or metabolites in whole blood specimens pertaining to DUID casework: High dose benzodiazepines 20 ng/mL Low dose benzodiazepines 10 ng/mL Barbiturates 200 ng/mL
16.	Current ability to report measurement uncertainties for above-mentioned DUID casework in Feature Items 12 to 15, inclusive.
17.	Current ability to meet the referenced recommendations below of toxicology testing for DFC casework. Specifically, scope and Performance Limits (cutoffs) in urine, and

No	Feature Description
	appropriate scope and cutoffs of blood testing applicable for DFC casework. [SOFT DFC Committee, Drug-Facilitated Crimes Cutoffs, 07/2017, https://www.soft-tox.org/files/MinPerfLimits_DFC2017.pdf]
18.	Current ability to meet the above-mentioned cutoffs in Feature Item 17 by means of the combined use of Enzyme-Linked Immunosorbent Assay (ELISA), Gas Chromatography/Mass Spectrometry (GC/MS), Liquid Chromatography/Mass Spectrometry (LC/MS), and Liquid Chromatography/Time of Flight-Mass Spectrometry (LC/TOF-MS).
19.	Current ability to meet the recommendations of toxicology testing for Medicolegal Death Investigation (MDI) casework. Specifically, scope and cutoffs in blood, and appropriate scope and cutoffs of urine testing applicable for MDI casework. [ASB 119, Standard for the Analytical Scope and Sensitivity of Forensic Toxicology Testing for Medicolegal Death Investigations (OSAC draft, under review)]
20.	Current ability to analyze blood and urine for hundreds of common and novel/new drugs and poisons.
21.	Current ability to analyze for metals such as antimony, arsenic, bismuth, lead, mercury, selenium and thallium in blood and urine.
22.	Current ability to provide results that are available for review on, or before, ten (10) business days of receipt of specimens to the reference laboratory.
23.	Current ability to return specimens within 3 months of reporting, or immediately at request.
24.	Ability to reflex or auto-order on test positive results.
25.	Ability to re-order testing by STAT order.
26.	Alert of insufficient volume for specimen testing.
27.	Appropriate tracking of equipment certification, and to track and monitor calibration schedules for laboratory instruments, scales and balances, pipettes, and related equipment or supplies.
28.	Appropriate systems to track Standard Operating Procedures (SOPs).
29.	Ability to provide all analytical results from all submitted casework over a period of time in a useable excel format.

No	Feature Description
30.	Client support for staff training on initial setup and throughout testing.
31.	Client support for analytical, technical and IT issues.

Additional detailed features are:

- Department employees will prepare biological specimens for shipment to NMS Labs with the prior approval of the Forensic Laboratory Director/Chief Forensic Toxicologist and/or Supervising Forensic Toxicologist.

- Department employees will complete, sign, and include in the shipped package a Requisition form provided by NMS Labs for each case they submit for testing which will describe at minimum the Department case number, specimen type, and specimen accessioning number as well as the analyses ordered.

- Department employees will arrange for NMS Labs' preferred courier service to collect packages from our Department location to take to NMS Labs using NMS Labs' courier account number.

- NMS Labs is to use their approved analytical methods to make the toxicological determinations requested on the Requisition form accompanying each case.

- Department employees will be issued a final report by NMS Labs Client Portal of the requested analyses within ten (10) business days of NMS Labs' receipt of the shipment.

- In cases where Department employees have requested on the Requisition form the return of specimens, NMS Labs will be required to return, at their expense listed in Appendix B, any unused specimens to the Department within four (4) calendar weeks of NMS Labs' receipt of the shipment.

- National Medical Services (NMS) is located in Horsham, Pennsylvania. Services will be provided at NMS Labs' facilities. NMS will be the only service provider. The services will be provided on an as-needed basis.

- The turnaround time of the final reports issued by NMS Labs will be monitored. Results will be evaluated for completeness and consistency.

2. Department Liaison

In performing the Services provided for in this Agreement, Contractor's liaison with the Department will be Luke N. Rodda, Ph.D.

Appendix B
Calculation of Charges

The discounted price list (i.e. attached RFP response TAB 5 – Cost to the Department for Solution Goods and Services) is effective from the initial contract term of three (3) years. Price increases may be implemented during the optional two (3) year extensions upon mutual consent.

For Goods and Services not listed in the abovementioned discounted price list, the regular 'LIST' price issued by the Contractor (i.e. attached "2020 fee schedule for NMS Labs") is effective from the initial contract term through December 31, 2020. Contractor will submit a new discounted price list on January 1, 2021

Appendix C
Insurance Waiver

Attached is the insurance waiver for NMS Labs.

City and County of San Francisco **Department of Human Resources**

PERSONAL SERVICES CONTRACT SUMMARY ("PSC FORM 1")

Department: GENERAL SERVICES AGENCY - CITY ADMIN -- ADM Dept. Code: ADM

Type of Request: ☑ Initial ☐ Modification of an existing PSC (PSC # _____)

Type of Approval: ☐ Expedited ☑ Regular (☐ Omit Posting)

Type of Service: As needed specialized toxicological analyses

Funding Source: General Fund PSC Duration: 3 years

PSC Amount: $500,000 PSC Est. Start Date: 06/01/2017 PSC Est. End Date: 05/31/2020

1. Description of Work

A. Scope of Work:

Specialized toxicological analyses performed by an accredited laboratory. Tests are performed for such substances such as synthetic cannabanoids, designer opiates, and bath salts.

B. Explain why this service is necessary and the consequence of denial:

The Office of the Chief Medical Examiner is required by law to accredit its Forensic Laboratory. At present, there are required toxicology tests which cannot be performed by the Forensic Lab. These tests must be sent to an accredited reference lab for analysis in order to maintain accreditation. The Medical Examiner has brought some tests in house that were earlier contracted out.

C. Has this service been provided in the past. If so, how? If the service was provided via a PSC, provide the most recently approved PSC # and upload a copy of the PSC.

A personal services contract was previously approved (CSC 4123 11.12) for 2012-2017.

D. Will the contract(s) be renewed? Yes, if there continues to be a need for such services.

2. Union Notification: On 02/06/2017, the Department notified the following employee organizations of this PSC/RFP request: Architect & Engineers, Local 21

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FOR DEPARTMENT OF HUMAN RESOURCES USE

PSC# 4123 16/17

DHR Analysis/Recommendation:

Commission Approval Required

DHR Approved for 04/17/2017

04/17/2017

Approved by Civil Service Commission

3. Description of Required Skills/Expertise

A. Specify required skills and/or expertise:
Ability to analyze toxicological specimens. Must be an American Board of Forensic Toxicology (ABFT) accredited laboratory.

B. Which, if any, civil service class(es) normally perform(s) this work?
2403,2456,2457,2458,

C. Will contractor provide facilities and/or equipment not currently possessed by the City? If yes, explain:
Yes, the contractor has its own toxicology laboratory facility with specialized testing instruments.

4. Why Classified Civil Service Cannot Perform

A. Explain why civil service classes are not applicable:
The civil service classes perform the most toxicology testing. The contractor will provide additional testing as needed for specialized tests.

B. Would it be practical to adopt a new civil service class to perform this work? Explain.
No, work is as needed.

5. Additional Information (if "yes", attach explanation)	**YES**	**NO**
A. Will the contractor directly supervise City and County employee?	☐	☑
B. Will the contractor train City and County employee? Employees do not require additional training as work is only for as-needed	☐	☑
C. Are there legal mandates requiring the use of contractual services?	☐	☑
D. Are there federal or state grant requirements regarding the use of contractual services?	☐	☑
E. Has a board or commission determined that contracting is the most effective way to provide this service?	☐	☑
F. Will the proposed work be completed by a contractor that has a current PSC contract with your department?	☐	☑

☑ THE ABOVE INFORMATION IS SUBMITTED AS COMPLETE AND ACCURATE ON BEHALF OF THE DEPARTMENT HEAD ON 03/13/2017 BY:

Name: Joan Lubamersky Phone: 4155544859 Email: joan.lubamersky@sfgov.org

Address: 1 Carlton B. Goodlett Place #362 San Francisco, CA 94102

PERSONAL SERVICES CONTRACT SUMMARY ("PSC FORM 1")

Department: CONTROLLER -- CON Dept. Code: CON

Type of Request: ☑Initial ☐Modification of an existing PSC (PSC # _____)

Type of Approval: ☐Expedited ☑Regular ☐Annual ☐Continuing ☐ (Omit Posting)

Type of Service: Enterprise Resource Planning Systems Support, Maintenance, and Enhancement Services

Funding Source: General & Non General Fund
PSC Amount: $7,000,000 PSC Est. Start Date: 11/01/2023 PSC Est. End Date 10/31/2028

1. Description of Work

A. Scope of Work/Services to be Contracted Out:

The City seeks responses from Respondents to provide professional services for the following systems:

PeopleSoft Financials and Supply Chain Management (FSCM);

PeopleSoft Human Capital Management (HCM);

PeopleSoft Enterprise Learning Management (ELM);

Oracle Business Intelligence Applications (OBIA);

Oracle Business Intelligence Enterprise Edition (OBIEE);

Potential replacement systems for the above listed products;

Potential change in infrastructure used to support the above listed products; and

City legacy and related systems.

Respondents must be able to provide functional, technical, and project management services for these systems both remotely and on-site at the Office of the Controller's City Hall Office.

These services will be used to assist the Controller's Office and other City Departments with system enhancements, modifications, and additional systems support.

B. Explain why this service is necessary and the consequence of denial:
These services will ensure that the Citywide systems listed under Category A are available for over 35,000 City employees and the entire City supplier community. The services include critical upgrades, enhancements, and new functionality that support the effective operation of City departments. Denial would result in negative consequences for the City. This includes delayed projects, critical functionality not being provided to City Departments and other potential negative consequences for the City.

C. Has this service been provided in the past? If so, how? If the service was provided under a previous PSC, attach copy of the most recently approved PSC.
Yes PSC 43296-18.19

D. Will the contract(s) be renewed?
If needed, contracts resulting from this solicitation may be extended.

E. If this is a request for a new PSC in excess of five years, or if your request is to extend (modify) an existing PSC by another five years, please explain why.
not applicable

2. <u>Reason(s) for the Request</u>

A. Indicate all that apply (be specific and attach any relevant supporting documents):

☑ Short-term or capital projects requiring diverse skills, expertise and/or knowledge.

B. Explain the qualifying circumstances:
The City seeks responses from Respondents demonstrating successful functional, technical, and/or project management experience with PeopleSoft Financials and Supply Chain Management (FSCM), PeopleSoft Human Capital Management (HCM), PeopleSoft Enterprise Learning Management (ELM), Oracle Business Intelligence Applications (OBIA), Oracle Business Intelligence Enterprise Edition (OBIEE), potential replacement systems for the above listed products, potential change in infrastructure used to support the above listed products, and City legacy and related systems. These services will be used to assist the Controller's Office and other City Departments with system enhancements, modifications, and additional systems support. Services require expert level knowledge of PeopleSoft and related systems. Services are highly specialized and short term in nature. Knowledge transfer at the end of services provided generally occur so that City staff are able to provide these services going forward.

3. <u>Description of Required Skills/Expertise</u>

A. Specify required skills and/or expertise: Requires expert level functional, technical and project management skills for Oracle PeopleSoft systems, Oracle Business Intelligence, industry leading Human Capital Management, Financial Supply Management Systems, and related City legacy systems. Experience may also include training and knowledge transfer services related to the systems.

B. Which, if any, civil service class(es) normally perform(s) this work? 1052, IS Business Analyst; 1053, IS Business Analyst-Senior; 1054, IS Business Analyst-Principal; 1063, IS Programmer Analyst-Senior; 1064, IS Prg Analyst-Principal; 1070, IS Project Director; 1657, Accountant IV; 1823, Senior Administrative Analyst; 1824, Pr Administrative Analyst; 1825, Prnpl Admin Analyst II; 0931, Manager III; 0932, Manager IV; 0933, Manager V;

C. Will contractor provide facilities and/or equipment not currently possessed by the City? If so, explain: No.

4. If applicable, what efforts has the department made to obtain these services through available resources within the City?

The Office of the Controller conducted an internal review of its staffing and found it did not have the resources to complete this work. The City contacted all the City's CIO Managers. The Department of Technology confirmed it did not have resources to work on this project.

5. Why Civil Service Employees Cannot Perform the Services to be Contracted Out

A. Explain why civil service classes are not applicable.
Services require expert level knowledge of complex technical systems which are highly specialized and primarily utilized on short-term projects. Knowledge transfer at the end of services provided generally occur so that City staff are able to provide these services going forward.

B. If there is no civil service class that could perform the work, would it be practical and/or feasible to adopt a new civil service class to perform this work? Explain. No, the work is short-term and highly specialized in nature.

6. Additional Information

A. Will the contractor directly supervise City and County employee? If so, please include an explanation.
No.

B. Will the contractor train City and County employees and/or is there a transfer of knowledge component that will be included in the contact? If so, please explain what that will entail; if not, explain why not.
Yes. Knowledge transfer and training will occur as a part of all contracts that result from the solicitation. Employees will generally be in the 1054, 1053 and 1064 job classes.

C. Are there legal mandates requiring the use of contractual services?
No.

D. Are there federal or state grant requirements regarding the use of contractual services? If so, please explain and include an excerpt or copy of any such applicable requirement.
No.

E. Has a board or commission determined that contracting is the most effective way to provide this service? If so, please explain and include a copy of the board or commission action.
No.

F. Will the proposed work be completed by a contractor that has a current PSC contract with your department? If so, please explain.
No.

7. Union Notification: On 07/31/2023, the Department notified the following employee organizations of this PSC/RFP request:
Architect & Engineers, Local 21; Municipal Executive Association

☑ I CERTIFY ON BEHALF OF THE DEPARTMENT THAT THE INFORMATION CONTAINED IN AND ATTACHED TO THIS FORM IS COMPLETE AND ACCURATE:

Name: Joyce Kimotsuki Phone: (415) 554-6562 Email: joyce.kimotsuki@sfgov.org

Address: 1 Carlton B. Goodlett Place, #382 San Francisco, CA 94102

****

FOR DEPARTMENT OF HUMAN RESOURCES USE

PSC# 45826 - 23/24

DHR Analysis/Recommendation: Civil Service Commission Action:

Commission Approval Required

Receipt of Union Notification(s)

From:	dhr-psccoordinator@sfgov.org on behalf of joyce.kimotsuki@sfgov.org
To:	Kimotsuki, Joyce (CON); andrea@sfmea.com; Laxamana, Junko (DBI); Criss@sfmea.com; christina@sfmea.com; staff@sfmea.com; kdavis@ifpte21.org; jharding@ifpte21.org; mweirick@ifpte21.org; dho@ifpte21.org; ewallace@ifpte21.org; ecassidy@ifpte21.com; WendyWong26@yahoo.com; wendywong26@yahoo.com; tmathews@ifpte21.org; kschumacher@ifpte21.org; kpage@ifpte21.org; eerbach@ifpte21.org; l21pscreview@ifpte21.org; Miller, Keith (CON); DHR-PSCCoordinator, DHR (HRD)
Subject:	Receipt of Notice for new PCS over $100K PSC # 45826 - 23/24
Date:	Monday, July 31, 2023 3:27:43 PM

RECEIPT for Union Notification for PSC 45826 - 23/24 more than $100k

The CONTROLLER -- CON has submitted a request for a Personal Services Contract
(PSC) 45826 - 23/24 for $7,000,000 for Initial Request services for the period
11/01/2023 – 10/31/2028. Notification of 30 days (60 days for SEIU) is required.

After logging into the system please select link below, view the information and
verify receipt:

http://apps.sfgov.org/dhrdrupal/node/21189 For union notification, please see the TO: field of the email to verify receipt. If you do not see all the unions
you intended to contact, the PSC Coordinator must change the state back to NOT
READY, make sure the classes and unions you want to notify are selected and SAVE. Then VIEW the record and verify the list of unions and emails. EDIT the document again , change the state back START UNION NOTIFICATION and SAVE. You should receive the email with all unions to the TO: field as intended

Additional Attachment(s)

PERSONAL SERVICES CONTRACT SUMMARY ("PSC FORM 1")

Department: CONTROLLER Dept. Code: CON

Type of Request: ☐Initial ☑Modification of an existing PSC (PSC # 43296 - 18/19)

Type of Approval: ☐Expedited ☑Regular ☐Annual ☐Continuing ☐ (Omit Posting)

Type of Service: Enterprise Resource Planning Systems Implementation & Support Services

Funding Source: General & Non General Fund

PSC Original Approved Amount: $7,000,000 PSC Original Approved Duration: 03/06/19 - 12/31/23 (4 years 43 weeks)

PSC Mod#1 Amount: $3,499,000 PSC Mod#1 Duration: 04/21/21-03/31/26 (2 years 12 weeks)

PSC Cumulative Amount Proposed: $10,499,000 PSC Cumulative Duration Proposed: 7 years 3 weeks

1. Description of Work

A. Scope of Work/Services to be Contracted Out:

The City seeks responses from Respondents demonstrating successful functional, technical, and/or project management experience with Oracle PeopleSoft (Financials and Supply Chain Management (FSCM), Human Capital Management (HCM), Enterprise Learning Management (ELM), Oracle Business Intelligence Applications (OBIA),Oracle Business Intelligence Enterprise Edition (OBIEE)), and City legacy and related systems. These services will be used to assist the Controller's Office and other City Departments with system enhancements, modifications and additional systems support.

B. Explain why this service is necessary and the consequence of denial:

These services are critical to ensuring that Citywide systems (SF Financials, SF Procurement, SF People & Pay, SF Learning, SF Reports and Analytics and SF Budget) are available for over 6,000 city users and the entire City supplier community. The services will also help provide critical upgrades, enhancements and new functionality, on PeopleSoft and legacy systems that will support the effective operation of City departments. Denial could result in critical functionality not being available to support City departments.

C. Has this service been provided in the past? If so, how? If the service was provided under a previous PSC, attach copy of the most recently approved PSC.

Yes PSC 41711-1.17

D. Will the contract(s) be renewed?

If needed, contracts resulting from this solicitation may be extended.

E. If this is a request for a new PSC in excess of five years, or if your request is to extend (modify) an existing PSC by another five years, please explain why:

The Controller's Office requests that the PSC cover about 6.25 years since many contracts have options to renew. With consultants, there is a significant learning curve for their understanding and documenting of City and County of San Francisco (City) systems and requirements. The options to renew the contract will also allow the City to address new security and system requirements.

2. Reason(s) for the Request

A. Display all that apply

☑ Short-term or capital projects requiring diverse skills, expertise and/or knowledge.

Explain the qualifying circumstances:

The City seeks responses from Respondents demonstrating successful functional, technical, and/or project management experience with Oracle PeopleSoft (Financials and Supply Chain Management (FSCM), Human Capital Management (HCM), Enterprise Learning Management (ELM), Oracle Business Intelligence Applications (OBIA),Oracle Business Intelligence Enterprise Edition (OBIEE)), and City legacy and related systems. These services will be used to assist the Controller's Office and other City Departments with system enhancements, modifications and additional systems support. Services require expert level knowledge of PeopleSoft and related systems. Services are highly specialized and short term in nature. Knowledge transfer at the end of services provided generally occur so that City staff are able to provide these services going forward.

B. Reason for the request for modification:
Modification is needed to extend the PSC by 2.25 years to 3/31/2026 and to increase the PSC amount by $3,499,000 for consultant services that are critical to ensuring Citywide systems (SF Financials, SF Procurement, SF People & Pay, SF Learning, SF Reports and Analytics and SF Budget) are up to date related to system requirements and security. The services are needed for critical upgrades, enhancements and new functionality. Cumulative time and amount increase is less than 50% of original PSC.

3. Description of Required Skills/Expertise

A. Specify required skills and/or expertise: Requires expert level functional and technical knowledge of Oracle PeopleSoft systems, Oracle Business Intelligence, and related City legacy systems. Experience may also include training and knowledge transfer services related to the systems.

B. Which, if any, civil service class(es) normally perform(s) this work? 1052, IS Business Analyst; 1053, IS Business Analyst-Senior; 1054, IS Business Analyst-Principal; 1064, IS Prg Analyst-Principal; 1070, IS Project Director; 1657, Accountant IV; 1823, Senior Administrative Analyst; 1824, Pr Administrative Analyst; 1825, Prnpl Admin Analyst II; 0931, Manager III; 0932, Manager IV; 0933, Manager V;

C. Will contractor provide facilities and/or equipment not currently possessed by the City? If so, explain: No.

4. If applicable, what efforts has the department made to obtain these services through available resources within the City?

Not Applicable

5. Why Civil Service Employees Cannot Perform the Services to be Contracted Out

A. Explain why civil service classes are not applicable.
Services require expert level knowledge of PeopleSoft and related systems. They are highly specialized and short term in nature. Knowledge transfer at the end of services provided generally occur so that City staff are able to provide these services going forward.

B. If there is no civil service class that could perform the work, would it be practical and/or feasible to adopt a new civil service class to perform this work? Explain: No, the work is short-term and highly specialized in nature.

6. Additional Information

A. Will the contractor directly supervise City and County employee? If so, please include an explanation.
No.

B. Will the contractor train City and County employees and/or is there a transfer of knowledge component that will be included in the contact? If so, please explain what that will entail; if not, explain why not.
Knowledge transfer and training will occur as a part of all contracts that result from the solicitation. Employees will generally be in the 1054, 1053 and 1064 job classes.

C. Are there legal mandates requiring the use of contractual services?
No.

D. Are there federal or state grant requirements regarding the use of contractual services? If so, please explain and include an excerpt or copy of any such applicable requirement.
No.

E. Has a board or commission determined that contracting is the most effective way to provide this service? If so, please explain and include a copy of the board or commission action.
No.

F. Will the proposed work be completed by a contractor that has a current PSC contract with your department? If so, please explain.
Work done by existing contractor and possible new contractors

7. Union Notification: On 04/21/21, the Department notified the following employee organizations of this PSC/RFP request: Professional & Tech Engrs, Local 21; Prof & Tech Eng, Local 21; Municipal Executive Association;

☑ I CERTIFY ON BEHALF OF THE DEPARTMENT THAT THE INFORMATION CONTAINED IN AND ATTACHED TO THIS FORM IS COMPLETE AND ACCURATE:

Name: Joyce Kimotsuki Phone: (415) 554-6562 Email: joyce.kimotsuki@sfgov.org

Address: 1 Carlton B. Goodlett Place, #306, San Francisco, CA 94102

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FOR DEPARTMENT OF HUMAN RESOURCES USE

PSC# 43296 - 18/19
DHR Analysis/Recommendation:
Commission Approval Not Required
Approved by DHR on 04/29/2021

PERSONAL SERVICES CONTRACT SUMMARY ("PSC FORM 1")

Department: MUNICIPAL TRANSPORTATION AGENCY -- MTA Dept. Code: MTA

Type of Request: ☑Initial ☐Modification of an existing PSC (PSC # _____)

Type of Approval: ☐Expedited ☑Regular ☐Annual ☐Continuing ☐ (Omit Posting)

Type of Service: Muni Onboard Customer Survey 2024

Funding Source: Operating Funds PSC Duration: 2 years

PSC Amount: $2,500,000

1. Description of Work

A. Scope of Work/Services to be Contracted Out:

The contractor will plan, coordinate, and conduct an in-person survey of the San Francisco Municipal Transportation Agency's (SFMTA) transit riders to collect data on their demographics and transportation practices. The consultant will collect statistically significant data about customer travel patterns, income levels, ethnic background, language proficiency, and fare media usage both on a temporal and geographic basis. Riders will be surveyed on all routes and modes of transit vehicles, on platforms, and by telephone as necessary. The consultant shall produce a final report that includes a discussion of the survey results and relevant high-level data summaries.

B. Explain why this service is necessary and the consequence of denial:

Federal regulations and guidance require the SFMTA evaluate significant system-wide service and fare changes and proposed improvements at the planning and programming stages to determine whether those changes have a discriminatory impact on low-income/minority customers. We are mandated to conduct an onboard survey every five years at a minimum. The SFMTA is also required to monitor and compare the level and quality of services provided to predominantly minority and low-income areas in order to ensure equitable services system-wide. Denial could result in the SFMTA's inability to be in compliance with the federal regulation and result in a loss of federal funding.

C. Has this service been provided in the past? If so, how? If the service was provided under a previous PSC, attach copy of the most recently approved PSC.

This service was provided in the past through PSC# 44238-15/16.

D. Will the contract(s) be renewed?

No

E. If this is a request for a new PSC in excess of five years, or if your request is to extend (modify) an existing PSC by another five years, please explain why.

not applicable

2. Reason(s) for the Request

A. Indicate all that apply (be specific and attach any relevant supporting documents):

☑ Services required on an as-needed, intermittent, or periodic basis (e.g., peaks in workload).

B. Explain the qualifying circumstances:

The contractor will plan, coordinate, and conduct an in-person survey of the San Francisco Municipal Transportation Agency's (SFMTA) transit riders to collect data on their demographics and transportation practices by deploying a large number of specifically trained field workers on a short-term/temporary basis. The consultant will collect statistically significant data about customer travel patterns, income levels, ethnic background, language proficiency, and fare media usage both on a temporal and geographic basis. Riders will be surveyed on all routes and modes of transit vehicles, on platforms, and by telephone as necessary. The consultant shall produce a final report that includes a detailed analysis and discussion of the survey results and relevant high-level data summaries based on their expertise in this area. The SFMTA will perform this work in accordance with the Metropolitan Transportation Commission (MTC) Resolution no. 3866.

3. Description of Required Skills/Expertise

A. Specify required skills and/or expertise: The consultant must have successfully completed a minimum of one comprehensive ridership demographic survey for a major public transportation agency within the last five years. Must possess technical expertise in data research and analysis that is specific to a major transit system in a similar urban area. Must have the ability to conduct quantitative research in detail; perform person-to-person survey work; provide multi-lingual survey work; tabulate raw data; provide various reports based on data collected; analyze data and present it in a comprehensive summary report; and deliver formal presentations.

B. Which, if any, civil service class(es) normally perform(s) this work? 1312, Public Information Officer; 1804, Statistician; 1823, Senior Administrative Analyst; 1824, Pr Administrative Analyst; 5277, Planner 1; 5502, Project Manager 1;

C. Will contractor provide facilities and/or equipment not currently possessed by the City? If so, explain: We anticipate consultants will be using tablets to collects on-board data.

4. If applicable, what efforts has the department made to obtain these services through available resources within the City?

We have reached out to the teams that would normally be involved in these projects (Transit Planning and Comms) and they have confirmed they do not have capacity.

5. Why Civil Service Employees Cannot Perform the Services to be Contracted Out

A. Explain why civil service classes are not applicable.

This is work that will occur every 5 - 10 years and requires extensive staffing for a limited time period to conduct potentially over 30,000 on-board surveys of the SFMTA customers, many of whom may be limited-English proficient.

B. If there is no civil service class that could perform the work, would it be practical and/or feasible to adopt a new civil service class to perform this work? Explain. No. This survey is a short-term project and the service is only required during the period of regulatory compliance.

6. Additional Information

A. Will the contractor directly supervise City and County employee? If so, please include an explanation. No.

B. Will the contractor train City and County employees and/or is there a transfer of knowledge component that will be included in the contact? If so, please explain what that will entail; if not, explain why not. No. No training is provided as part of the scope of this project.

C. Are there legal mandates requiring the use of contractual services?
No.

D. Are there federal or state grant requirements regarding the use of contractual services? If so, please explain and include an excerpt or copy of any such applicable requirement.
No.

E. Has a board or commission determined that contracting is the most effective way to provide this service? If so, please explain and include a copy of the board or commission action.
No.

F. Will the proposed work be completed by a contractor that has a current PSC contract with your department? If so, please explain.
No.

7. Union Notification: On 08/03/2023, the Department notified the following employee organizations of this PSC/RFP request:
Architect & Engineers, Local 21; Management & Superv Local 21; Prof & Tech Eng, Local 21; Professional & Tech Engrs, Local 21

☑ I CERTIFY ON BEHALF OF THE DEPARTMENT THAT THE INFORMATION CONTAINED IN AND ATTACHED TO THIS FORM IS COMPLETE AND ACCURATE:

Name: Amy NUQUE Phone: 415-646-2802 Email: amy.nuque@sfmta.com

Address: 1 So. Van Ness Avenue, 6th Floor San Francisco, CA 94103
****

FOR DEPARTMENT OF HUMAN RESOURCES USE

PSC# 32820 - 23/24
DHR Analysis/Recommendation:
Commission Approval Required
DHR Approved for 10/02/2023

Civil Service Commission Action:

Receipt of Union Notification(s)

Nuque, Amy

From: dhr-psccoordinator@sfgov.org on behalf of amy.nuque@sfmta.com
Sent: Thursday, August 3, 2023 8:35 PM
To: Nuque, Amy; junko.laxamana@sfgov.org; agarza@ifpte21.org; amakayan@ifpte21.org; kdavis@ifpte21.org; jharding@ifpte21.org; mweirick@ifpte21.org; dho@ifpte21.org; ewallace@ifpte21.org; ecassidy@ifpte21.com; WendyWong26@yahoo.com; wendywong26@yahoo.com; tmathews@ifpte21.org; kschumacher@ifpte21.org; kpage@ifpte21.org; eerbach@ifpte21.org; L21PSCReview@ifpte21.org; Nuque, Amy; dhr-psccoordinator@sfgov.org
Subject: Receipt of Notice for new PCS over $100K PSC # 32820 - 23/24

RECEIPT for Union Notification for PSC 32820 - 23/24 more than $100k

The MUNICIPAL TRANSPORTATION AGENCY -- MTA has submitted a request for a Personal Services Contract (PSC) 32820 - 23/24 for $2,500,000 for Initial Request services for the period 01/01/2024 – 12/31/2025. Notification of 30 days (60 days for SEIU) is required.

After logging into the system please select link below, view the information and verify receipt:

http://apps.sfgov.org/dhrdrupal/node/21200 For union notification, please see the TO: field of the email to verify receipt. If you do not see all the unions you intended to contact, the PSC Coordinator must change the state back to NOT READY, make sure the classes and unions you want to notify are selected and SAVE. Then VIEW the record and verify the list of unions and emails. EDIT the document again , change the state back START UNION NOTIFICATION and SAVE. You should receive the email with all unions to the TO: field as intended

Nuque, Amy

From: Nuque, Amy
Sent: Thursday, August 3, 2023 8:57 PM
To: junko.laxamana@sfgov.org; jharding@ifpte21.org; agarza@ifpte21.org; amakayan@ifpte21.org; kdavis@ifpte21.org; mweirick@ifpte21.org; ewallace@ifpte21.org; WendyWong26@yahoo.com; wendywong26@yahoo.com; tmathews@ifpte21.org; kschumacher@ifpte21.org; L21PSCReview@ifpte21.org; dvickers@iam1414.org; Mjayne@iam1414.org; agonzalez@iam1414.org; speedy4864@aol.com; dhr-psccoordinator@sfgov.org
Subject: RE: Receipt of Notice for new PCS over $100K PSC # 32820 - 23/24

Hi All: Kindly discard the notification below. Union selections were made in error and this request is for Local 21 only.

We apologize for the inconvenience this may have caused.

Thank you,
Amy Nuque
415-646-2802
SFMTA HR-ELR

-----Original Message-----
From: dhr-psccoordinator@sfgov.org <dhr-psccoordinator@sfgov.org> On Behalf Of amy.nuque@sfmta.com
Sent: Thursday, August 3, 2023 1:33 PM
To: Nuque, Amy <Amy.Nuque@sfmta.com>; junko.laxamana@sfgov.org; jharding@ifpte21.org; agarza@ifpte21.org; amakayan@ifpte21.org; kdavis@ifpte21.org; mweirick@ifpte21.org; ewallace@ifpte21.org; WendyWong26@yahoo.com; wendywong26@yahoo.com; tmathews@ifpte21.org; kschumacher@ifpte21.org; L21PSCReview@ifpte21.org; dvickers@iam1414.org; Mjayne@iam1414.org; agonzalez@iam1414.org; speedy4864@aol.com; Nuque, Amy <Amy.Nuque@sfmta.com>; dhr-psccoordinator@sfgov.org
Subject: Receipt of Notice for new PCS over $100K PSC # 32820 - 23/24

RECEIPT for Union Notification for PSC 32820 - 23/24 more than $100k

The MUNICIPAL TRANSPORTATION AGENCY -- MTA has submitted a request for a
Personal Services Contract (PSC) 32820 - 23/24 for $2,500,000 for Initial

Request services for the period 01/01/2024 – 12/31/2025. Notification of 30
days (60 days for SEIU) is required.

After logging into the system please select link below, view the information and
verify receipt:

http://apps.sfgov.org/dhrdrupal/node/21200 For union notification, please see the TO: field of the email to verify receipt. If you do not see all the unions
you intended to contact, the PSC Coordinator must change the state back to NOT
READY, make sure the classes and unions you want to notify are selected and SAVE. Then VIEW the record and verify the list of unions and emails. EDIT the document again , change the state back START UNION NOTIFICATION and SAVE. You should receive the email with all unions to the TO: field as intended

Additional Attachment(s)

PERSONAL SERVICES CONTRACT SUMMARY ("PSC FORM 1")

Department: MUNICIPAL TRANSPORTATION AGENCY Dept. Code: MTA

Type of Request: ☐Initial ☑Modification of an existing PSC (PSC # 44238 - 15/16)

Type of Approval: ☐Expedited ☑Regular ☐Annual ☐Continuing ☐ (Omit Posting)

Type of Service: Ridership Demographic/Travel Behavior Survey and Data Analysis

Funding Source: Operating Budget

PSC Original Approved Amount: $450,000 PSC Original Approved Duration: 04/05/16 - 12/31/17 (1 year 38 weeks)

PSC Mod#1 Amount: $224,000 PSC Mod#1 Duration: 04/05/16-06/30/18 (25 weeks 5 days)

PSC Mod#2 Amount: $276,000 PSC Mod#2 Duration: no duration added

PSC Cumulative Amount Proposed: $950,000 PSC Cumulative Duration Proposed: 2 years 12 weeks

1. Description of Work

A. Scope of Work/Services to be Contracted Out:

The contractor will plan, coordinate, and conduct an in-person survey of the San Francisco Municipal Transportation Agency's (SFMTA) transit riders to collect data on their demographics and transportation practices. The consultant will collect statistically-significant data about customer travel patterns, income levels, ethnic background, language proficiency and fare media usage both on a temporal and geographical basis. Riders will be surveyed on all routes and modes of transit vehicles, on platforms, and by telephone as necessary. The consultant shall produce a final report that includes a discussion of the survey results and relevant high-level data summaries. The SFMTA will perform this work in accordance with the Metropolitan Transportation Commission (MTC) Resolution No. 3866.

B. Explain why this service is necessary and the consequence of denial:

Federal regulations and guidance require that the SFMTA evaluate significant system-wide service and fare changes and proposed improvements at the planning and programming stages to determine whether those changes have a discriminatory impact on low-income/minority customers. The SFMTA is also required to monitor and compare the level and quality of services provided to predominantly minority and low-income areas in order to ensure equitable services system-wide. Denial could result in the SFMTA's inability to compliance with federal regulations and result in a loss of federal funding.

C. Has this service been provided in the past? If so, how? If the service was provided under a previous PSC, attach copy of the most recently approved PSC.

Yes.

D. Will the contract(s) be renewed?

No.

E. If this is a request for a new PSC in excess of five years, or if your request is to extend (modify) an existing PSC by another five years, please explain why:

2. Reason(s) for the Request

A. Display all that apply

☑ Short-term or capital projects requiring diverse skills, expertise and/or knowledge.

☑ Services required on an as-needed, intermittent, or periodic basis (e.g., peaks in workload).

Explain the qualifying circumstances:

This is work that will occur once every 3-5 years and requires extensive staffing for a limited time period to conduct potentially over 30,000 on-board surveys of the SFMTA customers. The consultant must have successfully completed a minimum of one comprehensive ridership demographic survey for a major public transportation

agency within the last five years. Must possess technical expertise in data research and analysis that is specific to a major transit system in a similar urban area. Must have the ability to conduct quantitative research in detail; perform person-to-person survey work; provide multi-lingual survey work; tabulate raw data; provide various reports based on data collected; analyze data and present it in a comprehensive summary report; and deliver formal presentations.

B. Reason for the request for modification:
Additional Cost in order to comply with the Federally-required survey and reporting requirements. There is no change in duration.

3. Description of Required Skills/Expertise

A. Specify required skills and/or expertise: The consultant must have successfully completed a minimum of one comprehensive ridership demographic survey for a major public transportation agency within the last five years. Must possess technical expertise in data research and analysis that is specific to a major transit system in a similar urban area. Must have the ability to conduct quantitative research in detail; perform person-to-person survey work; provide multi-lingual survey work; tabulate raw data; provide various reports based on data collected; analyze data and present it in a comprehensive summary report; and deliver formal presentations.

B. Which, if any, civil service class(es) normally perform(s) this work? 1803, Performance Analyst I; 1804, Statistician; 1805, Performance Analyst II; 1806, Senior Statistician; 1823, Senior Administrative Analyst; 1824, Pr Administrative Analyst;

C. Will contractor provide facilities and/or equipment not currently possessed by the City? If so, explain: No.

4. If applicable, what efforts has the department made to obtain these services through available resources within the City?

Not Applicable

5. Why Civil Service Employees Cannot Perform the Services to be Contracted Out

A. Explain why civil service classes are not applicable.
This is work that will occur once every 3-5 years and requires extensive staffing for a limited time period to conduct potentially over 30,000 on-board surveys of the SFMTA customers, many of whom may be limited-English proficient

B. If there is no civil service class that could perform the work, would it be practical and/or feasible to adopt a new civil service class to perform this work? Explain: No. This survey is a short-term project and the service is only required during the period of regulatory compliance.

6. Additional Information

A. Will the contractor directly supervise City and County employee? If so, please include an explanation.
No.

B. Will the contractor train City and County employees and/or is there a transfer of knowledge component that will be included in the contact? If so, please explain what that will entail; if not, explain why not.
No training is provided with this service as it is only performed on demand every 3-5 years.

C. Are there legal mandates requiring the use of contractual services?
No.

D. Are there federal or state grant requirements regarding the use of contractual services? If so, please explain and include an excerpt or copy of any such applicable requirement.
No.

E. Has a board or commission determined that contracting is the most effective way to provide this service? If so, please explain and include a copy of the board or commission action.
No.

F. Will the proposed work be completed by a contractor that has a current PSC contract with your department? If so, please explain.
Continued work with Metropolitan Transportation Commission.

7. Union Notification: On 10/19/16, the Department notified the following employee organizations of this PSC/RFP request:
SEIU Local 1021; SEIU 1021 Miscellaneous; Professional & Tech Engrs, Local 21;

☑ I CERTIFY ON BEHALF OF THE DEPARTMENT THAT THE INFORMATION CONTAINED IN AND ATTACHED TO THIS FORM IS COMPLETE AND ACCURATE:

Name: Cynthia Hamada Phone: 415.701.5381 Email: cynthia.hamada@sfmta.com

Address: 1 South Van Ness Avenue, 6th Floor, San Francisco, CA 94103
****

FOR DEPARTMENT OF HUMAN RESOURCES USE

PSC# 44238 - 15/16
DHR Analysis/Recommendation: 02/06/2017
Commission Approval Required Approved by Civil Service Commission
02/06/2017 DHR Approved for 02/06/2017

PERSONAL SERVICES CONTRACT SUMMARY ("PSC FORM 1")

Department: MUNICIPAL TRANSPORTATION AGENCY -- MTA Dept. Code: MTA

Type of Request: ☑Initial ☐Modification of an existing PSC (PSC # _____)

Type of Approval: ☐Expedited ☑Regular ☐Annual ☐Continuing ☐ (Omit Posting)

Type of Service: Professional services and software as a service

Funding Source: Grants: Federal (agreement in progress) PSC Duration: 2 years 1 day

PSC Amount: $2,000,000

1. Description of Work

A. Scope of Work/Services to be Contracted Out:

The U.S. Department of Transportation (USDOT) awarded the San Francisco Municipal Transportation Agency (SFMTA) $2 million from the SMART (Strengthening Mobility and Revolutionizing Transportation) grants program to support the SFMTA's Digital Curb project. The SMART grants program funds innovative approaches to using technology to solve transportation problems -- the Digital Curb project will create a first-of-its-kind citywide database and map of all curb locations and regulations, which will provide valuable information for the agency and public, and help achieve the agency's curb management goals.

The SFMTA intends to issue an RFP for a Contractor to support the Digital Curb project in assembling curb data for the first time by leveraging existing data and collecting data on the street using innovative digital mapping tools; keeping data up to date via software tools as SFMTA plans legislate, and implements curb regulation changes; and disseminating data via maps, analytical tools, and an open data feed using the Curb Data Specification (CDS) industry standard.

As part of the Digital Curb project, SFMTA will also partner with the Open Mobility Foundation (OMF). OMF is a non-profit organization that develops digital tools for public agencies and manages the CDS standard. OMF will make changes to CDS as necessary to support the Digital Curb project, as well as work with SFMTA and other cities with similar projects to document costs, benefits, lessons learned, and best practices, which will help SFMTA meet its grant obligations to USDOT.

B. Explain why this service is necessary and the consequence of denial:

In 2020, SFMTA adopted a Curb Management Strategy, and creating a Digital Curb is a key piece in SFMTA's efforts to better manage the curb. When drivers cannot find available curb space, they circle for parking or double-park in a travel lane, slowing down transit and other traffic, creating safety hazards for people walking and biking, and making it difficult for people and goods deliveries to get to their destinations. While San Francisco wants to better manage their curbs, especially in the face of new technology-enabled transportation services, the City lacks detailed foundational data about what the curb regulations are. Creating a Digital Curb would allow City staff, the public, and transportation services such as transportation network companies, delivery services, and automated vehicles to know what the curb regulations are at any time. Additionally, SFMTA has 18 months to spend the USDOT SMART grant funds starting on 9/15/23. Without approval, SFMTA would be unable to bring on partners to support the project and would fail its commitment to USDOT. This would significantly set back SFMTA's Digital Curb project, and compromise the ability of the agency to secure additional federal grants in the future. Furthermore, CDS is the only

internationally-recognized open source standard for the management of urban curb space, and the OMF is the sole steward of CDS.

C. Has this service been provided in the past? If so, how? If the service was provided under a previous PSC, attach copy of the most recently approved PSC.
These services have not been provided in the past – the Digital Curb is an innovative project using new technologies to create a first-of-its-kind citywide dataset on curb regulations.

D. Will the contract(s) be renewed?
No

E. If this is a request for a new PSC in excess of five years, or if your request is to extend (modify) an existing PSC by another five years, please explain why.
not applicable

2. Reason(s) for the Request

A. Indicate all that apply (be specific and attach any relevant supporting documents):

☑ Short-term or capital projects requiring diverse skills, expertise and/or knowledge.

☑ Services that require resources that the City lacks (e.g., office space, facilities or equipment with an operator).

B. Explain the qualifying circumstances:
SFMTA must expend all USDOT grant funds and deliver the project within 18 months. City staff do not have the resources to develop and maintain all of the hardware and software tools necessary to deliver the project, especially within the timeframe mandated by the grant.

3. Description of Required Skills/Expertise

A. Specify required skills and/or expertise: The Digital Curb project requires the following skills and experience: • Developing and supporting hardware and software tools to collect, manage, and analyze curb asset and regulation data as well as train users • Data analytics, system integration, and geographic information systems expertise • Standing up and maintaining application programming interfaces • Experience producing and ingesting data in the Curb Data Specification • Collecting recommended changes based on use cases from a variety of stakeholders to the Curb Data Specification and implementing the best technical solution to support cities' needs • Managing GitHub issues, pull requests and branches • Experience analyzing curb regulation and transportation data for curb management projects is also preferred

B. Which, if any, civil service class(es) normally perform(s) this work? 1042, IS Engineer-Journey; 1043, IS Engineer-Senior; 1044, IS Engineer-Principal; 1823, Senior Administrative Analyst; 1824, Pr Administrative Analyst; 5283, Planner 5; 5288, Transportation Planner II; 5289, Transportation Planner III; 5290, Transportation Planner IV;

C. Will contractor provide facilities and/or equipment not currently possessed by the City? If so, explain:
Yes, the contractor will provide hardware and software tools necessary to collect, maintain, and disseminate curb data.

4. If applicable, what efforts has the department made to obtain these services through available resources within the City?

The Digital Curb project will leverage some software tools already developed and supported by City staff, including GIS and database system infrastructure, and asset management software that SFMTA staff are in the

process of implementing within the agency. However, City staff do not have the resources to develop and support the complex tools and software necessary to implement the entire project within the 18-month period mandated by the grant. Furthermore, CDS is the only internationally-recognized open source standard for the management of urban curb space, and the OMF is the sole steward of CDS.

5. Why Civil Service Employees Cannot Perform the Services to be Contracted Out

A. Explain why civil service classes are not applicable.
Some civil service classifications are applicable; however, the City does not have the staff resources needed to develop and support the necessary tools, especially within the 18-month grant performance period. Furthermore, CDS is the only internationally-recognized open source standard for the management of urban curb space, and the OMF is the sole steward of CDS -- it is infeasible for the City to develop and maintain an industry-standard data specification.

B. If there is no civil service class that could perform the work, would it be practical and/or feasible to adopt a new civil service class to perform this work? Explain. No, there are already applicable civil service classes that could perform some portions of this work. However, the City does not have the resources to support the development of such tools on its own.

6. Additional Information

A. Will the contractor directly supervise City and County employee? If so, please include an explanation.
No.

B. Will the contractor train City and County employees and/or is there a transfer of knowledge component that will be included in the contact? If so, please explain what that will entail; if not, explain why not.
Yes. Yes, training will primarily be provided to Transportation Planners on the tools to maintain curb data and analyze curb data using mapping and visualization tools. Estimated 20 hours of one-time training and ongoing support as needed throughout the project duration.

C. Are there legal mandates requiring the use of contractual services?
No.

D. Are there federal or state grant requirements regarding the use of contractual services? If so, please explain and include an excerpt or copy of any such applicable requirement.
No.

E. Has a board or commission determined that contracting is the most effective way to provide this service? If so, please explain and include a copy of the board or commission action.
No.

F. Will the proposed work be completed by a contractor that has a current PSC contract with your department? If so, please explain.
No.

7. Union Notification: On 08/04/2023, the Department notified the following employee organizations of this PSC/RFP request:
Architect & Engineers, Local 21; Management & Superv Local 21; Prof & Tech Eng, Local 21; Professional & Tech Engrs, Local 21

☑ I CERTIFY ON BEHALF OF THE DEPARTMENT THAT THE INFORMATION CONTAINED IN AND ATTACHED TO THIS FORM IS COMPLETE AND ACCURATE:

Name: Amy NUQUE Phone: 415-646-2802 Email: amy.nuque@sfmta.com

Address: 1 So. Van Ness Avenue, 6th Floor San Francisco, CA 94103

****

FOR DEPARTMENT OF HUMAN RESOURCES USE

PSC# 35159 - 23/24

DHR Analysis/Recommendation:

Commission Approval Required

DHR Approved for 10/02/2023

Civil Service Commission Action:

Receipt of Union Notification(s)

Nuque, Amy

From: dhr-psccoordinator@sfgov.org on behalf of amy.nuque@sfmta.com
Sent: Friday, August 4, 2023 11:33 AM
To: Nuque, Amy; junko.laxamana@sfgov.org; agarza@ifpte21.org; amakayan@ifpte21.org; kdavis@ifpte21.org; jharding@ifpte21.org; mweirick@ifpte21.org; dho@ifpte21.org; ewallace@ifpte21.org; ecassidy@ifpte21.com; WendyWong26@yahoo.com; wendywong26@yahoo.com; tmathews@ifpte21.org; kschumacher@ifpte21.org; kpage@ifpte21.org; eerbach@ifpte21.org; L21PSCReview@ifpte21.org; Nuque, Amy; dhr-psccoordinator@sfgov.org
Subject: Receipt of Notice for new PCS over $100K PSC # 35159 - 23/24

RECEIPT for Union Notification for PSC 35159 - 23/24 more than $100k

The MUNICIPAL TRANSPORTATION AGENCY -- MTA has submitted a request for a Personal Services Contract (PSC) 35159 - 23/24 for $2,000,000 for Initial Request services for the period 09/15/2023 – 09/15/2025. Notification of 30 days (60 days for SEIU) is required.

After logging into the system please select link below, view the information and verify receipt:

http://apps.sfgov.org/dhrdrupal/node/21212 For union notification, please see the TO: field of the email to verify receipt. If you do not see all the unions you intended to contact, the PSC Coordinator must change the state back to NOT READY, make sure the classes and unions you want to notify are selected and SAVE. Then VIEW the record and verify the list of unions and emails. EDIT the document again , change the state back START UNION NOTIFICATION and SAVE. You should receive the email with all unions to the TO: field as intended

PERSONAL SERVICES CONTRACT SUMMARY ("PSC FORM 1")

Department: MUNICIPAL TRANSPORTATION AGENCY -- MTA Dept. Code: MTA

Type of Request: ☑Initial ☐Modification of an existing PSC (PSC # _____)

Type of Approval: ☐Expedited ☑Regular ☐Annual ☐Continuing ☐ (Omit Posting)

Type of Service: Laboratory Drug Testing Services

Funding Source: Operating Funds PSC Duration: 5 years 2 days

PSC Amount: $250,000

1. Description of Work

A. Scope of Work/Services to be Contracted Out:
To provide federally mandated urine analysis for Safety-Sensitive employees with the San Francisco Municipal Transportation Agency (SFMTA).

B. Explain why this service is necessary and the consequence of denial:
This is a required service under the Department of Transportation (DOT)/Federal Transit Administration (FTA) Rules. Denial will jeopardize continued transit agency federal assistance.

C. Has this service been provided in the past? If so, how? If the service was provided under a previous PSC, attach copy of the most recently approved PSC.
Yes, PSC #46107-17/18.

D. Will the contract(s) be renewed?
Yes. At the end of this contract, the SFMTA will issue a Request for Proposal for Laboratory Services as drug testing is expected to continue being a regulatory requirement.

E. If this is a request for a new PSC in excess of five years, or if your request is to extend (modify) an existing PSC by another five years, please explain why.
Laboratory Services such as drug testing are expected to continue being a regulatory requirement.

2. Reason(s) for the Request

A. Indicate all that apply (be specific and attach any relevant supporting documents):

☑ Regulatory or legal requirements, or requirements or mandates of funding source(s) which limit or preclude the use of Civil Service Employees. Include a copy of the applicable requirement or mandate.

B. Explain the qualifying circumstances:
Federal Code 49 CFR Part 40 requires the use of a U.S. Department of Health and Human Services (DHHS) certified lab for all Department of Transportation mandated drug testing.

3. Description of Required Skills/Expertise

A. Specify required skills and/or expertise: The contractor must be a U.S. Department of Health and Human Services (DHHS) certified lab. The City does not have DHHS certified labs.

B. Which, if any, civil service class(es) normally perform(s) this work? none

C. Will contractor provide facilities and/or equipment not currently possessed by the City? If so, explain: Yes. The contractor is a U.S. Department of Health and Human Services (DHHS) certified lab. The City does not have such laboratory services.

4. If applicable, what efforts has the department made to obtain these services through available resources within the City?

Not applicable, the City does not have a U.S. Department of Health and Human Services (DHHS) certified laboratory.

5. Why Civil Service Employees Cannot Perform the Services to be Contracted Out

A. Explain why civil service classes are not applicable.
The contractor must be a U.S. Department of Health and Human Services (DHHS) certified lab. The City does not have DHHS-certified labs or a job class to perform urine analysis.

B. If there is no civil service class that could perform the work, would it be practical and/or feasible to adopt a new civil service class to perform this work? Explain. No - Contract must be a U.S. Department of Health and Human Services (DHHS) certified lab. The City does not have DHHS certified lab and the number of urine analysis needed does not warrant the creation of a new job class.

6. Additional Information

A. Will the contractor directly supervise City and County employee? If so, please include an explanation.
No.

B. Will the contractor train City and County employees and/or is there a transfer of knowledge component that will be included in the contact? If so, please explain what that will entail; if not, explain why not.
No. Urine analysis is a highly specialized task that city employees are not expected to participate in and must be done by federally regulated laboratory staff. Training City and County employees are not relevant to this contract.

C. Are there legal mandates requiring the use of contractual services?
Yes. Yes, 49 CFR Part 40

D. Are there federal or state grant requirements regarding the use of contractual services? If so, please explain and include an excerpt or copy of any such applicable requirement.
No.

E. Has a board or commission determined that contracting is the most effective way to provide this service? If so, please explain and include a copy of the board or commission action.
No.

F. Will the proposed work be completed by a contractor that has a current PSC contract with your department? If so, please explain.
No.

7. Union Notification: On 06/29/2023, the Department notified the following employee organizations of this PSC/RFP request:
all unions were notified

☑ I CERTIFY ON BEHALF OF THE DEPARTMENT THAT THE INFORMATION CONTAINED IN AND ATTACHED TO THIS FORM IS COMPLETE AND ACCURATE:

Name: Amy NUQUE Phone: 415-646-2802 Email: amy.nuque@sfmta.com

Address: San Francisco Municipal Transportation Agency San Francisco, CA 94103

****

FOR DEPARTMENT OF HUMAN RESOURCES USE

PSC# 44669 - 22/23

DHR Analysis/Recommendation:

Commission Approval Required

DHR Approved for 10/02/2023

Civil Service Commission Action:

Receipt of Union Notification(s)

Nuque, Amy

From: dhr-psccoordinator@sfgov.org on behalf of amy.nuque@sfmta.com
Sent: Thursday, June 29, 2023 5:50 PM
To: Nuque, Amy; dho@ifpte21.org; dho@ifpte21.org; dvickers@iam1414.org; SF-DHR-Info@seiu1021.org; SF-DHR-Info@seiu1021.org; sbabaria@cirseiu.org; andrea@sfmea.com; Camaguey@sfmea.com; Camaguey@sfmea.com; cpark@local39.org; cpark@local39.org; khughes@ibew6.org; ewallace@ifpte21.org; ewallace@ifpte21.org; plangrooferslocal40@gmail.com; rooferslocal40@gmail.com; seichenberger@local39.org; dtuttle@oe3.org; dtubble@oe3org; pkim@ifpte21.org; najuawanda.daniels@seiu1021.org; pking@uapd.com; president@sanfranciscodsa.com; max.porter@seiu1021.org; kennethlomba@gmail.com; snaranjo@cirseiu.org; mdennis@twusf.org; rmarenco@twusf.org; Pete Wilson - Union 250A VP; cmoyer@nccrc.org; noah.frigault@sfgov.org; sfdpoa@icloud.com; Mjayne@iam1414.org; Emanuel, Rachel (DEM); laborers261@gmail.com; junko.laxamana@sfgov.org; jennifer.esteen@seiu1021.org; emathurin@cirseiu.org; abush@cirseiu.org; sbabaria@cirseiu.org; anthony@dc16.us; mlobre@sfpoa.org; @sfpoa.org; tracym@sfpoa.org; mleach@ibt856.org; rooferslocal40@gmail.com; sal@local16.org; Criss@sfmea.com; Julie.Meyers@sfgov.org; seichenberger@local39.org; jason.klumb@seiu1021.org; Camaguey@sfmea.com; ablood@cirseiu.org; kcartermartinez@cirseiu.org; ecassidy@ifpte21.com; WendyWong26@yahoo.com; wendywong26@yahoo.com; sarah.wilson@seiu1021.org; kschumacher@ifpte21.org; kpage@ifpte21.org; tjenkins@uapd.com; eerbach@ifpte21.org; tmathews@ifpte21.org; amakayan@ifpte21.org; jb@local16.org; Ricardo.lopez@sfgov.org; Kbasconcillo@sfwater.org; Sandeep.lal@seiu1021.me; pcamarillo_seiu@sbcglobal.net; MRainsford@local39.org; Wendy.Frigillana@seiu1021.org; pscreview@seiu1021.org; pkim@ifpte21.org; agonzalez@iam1414.org; ted.zarzecki@seiu1021.net; leah.berlanga@seiu1021.org; gail@sffdlocal798.org; cityworker@sfcwu.org; davidmkersten@gmail.com; djohnson@opcmialocal300.org; ramonliuna261@gmail.com; ablood@cirseiu.org; pkarinen@nccrc.org; tony@dc16.us; stevek@bac3-ca.org; xiumin.li@seiu1021.org; Sin.Yee.Poon@sfgov.org; smcgarry@nccrc.org; rmitchell@twusf.org; grojo@local39.org; jduritz@uapd.com; staff@sfmea.com; mike@dc16.us; khughes@ibew6.org; L21PSCReview@ifpte21.org; sfsmsa@gmail.com; bart@dc16.us; david.canham@seiu1021.org; jtanner940@aol.com; oashworth@ibew6.org; L21PSCReview@ifpte21.org; laborers261@gmail.com; local200twu; speedy4864@aol.com; Christina@sfmea.com; ecdemvoter@aol.com; thomas.vitale@seiu1021.org; Nuque, Amy; dhr-psccoordinator@sfgov.org
Subject: Receipt of Notice for new PCS over $100K PSC # 44669 - 22/23

RECEIPT for Union Notification for PSC 44669 - 22/23 more than $100k

The MUNICIPAL TRANSPORTATION AGENCY -- MTA has submitted a request for a
Personal Services Contract (PSC) 44669 - 22/23 for $250,000 for Initial
Request
services for the period 02/01/2024 – 02/01/2029. Notification of 30 days

(60
days for SEIU) is required.

After logging into the system please select link below, view the information
and
verify receipt:

http://apps.sfgov.org/dhrdrupal/node/20976 For union notification, please see the TO: field of the email to verify receipt. If you do not see all the
unions
you intended to contact, the PSC Coordinator must change the state back to
NOT
READY, make sure the classes and unions you want to notify are selected and SAVE. Then VIEW the record and verify the list of unions and emails. EDIT the document again , change the state back START UNION NOTIFICATION and SAVE. You should receive the email with all unions to the TO: field as intended

Additional Attachment(s)

Displaying title 49, up to date as of 6/27/2023. Title 49 was last amended 6/22/2023.

Title 49 —Transportation
Subtitle A —Office of the Secretary of Transportation

ENHANCED CONTENT - TABLE OF CONTENTS

PART 40—PROCEDURES FOR TRANSPORTATION WORKPLACE DRUG AND ALCOHOL TESTING PROGRAMS

Authority: 49 U.S.C. 102, 301, 322, 5331, 20140, 31306, and 54101 *et seq.*

Source: 65 FR 79526, Dec. 19, 2000, unless otherwise noted.

EDITORIAL NOTE

Editorial Note: Nomenclature changes to part 40 appear at 73 FR 33329, June 12, 2008.

Subpart A—Administrative Provisions

§ 40.1 Who does this regulation cover?

(a) This part tells all parties who conduct drug and alcohol tests required by Department of Transportation (DOT) agency regulations how to conduct these tests and what procedures to use.

(b) This part concerns the activities of transportation employers, safety-sensitive transportation employees (including self-employed individuals, contractors and volunteers as covered by DOT agency regulations), and service agents.

(c) Nothing in this part is intended to supersede or conflict with the implementation of the Federal Railroad Administration's post-accident testing program (see 49 CFR 219.200).

§ 40.3 What do the terms used in this part mean?

In this part, the terms listed in this section have the following meanings:

Adulterated specimen. A specimen that has been altered, as evidenced by test results showing either a substance that is not a normal constituent for that type of specimen or showing an abnormal concentration of an endogenous substance.

Affiliate. Persons are affiliates of one another if, directly or indirectly, one controls or has the power to control the other, or a third party controls or has the power to control both. Indicators of control include, but are not limited to: interlocking management or ownership; shared interest among family members; shared facilities or equipment; or common use of employees. Following the issuance of a public interest exclusion, an organization having the same or similar management, ownership, or principal employees as the service agent concerning whom a public interest exclusion is in effect is regarded as an affiliate. This definition is used in connection with the public interest exclusion procedures of Subpart R of this part.

Air blank. In evidential breath testing devices (EBTs) using gas chromatography technology, a reading of the device's internal standard. In all other EBTs, a reading of ambient air containing no alcohol.

Alcohol. The intoxicating agent in beverage alcohol, ethyl alcohol or other low molecular weight alcohols, including methyl or isopropyl alcohol.

Alcohol concentration. The alcohol in a volume of breath expressed in terms of grams of alcohol per 210 liters of breath as indicated by a breath test under this part.

Alcohol confirmation test. A subsequent test using an EBT, following a screening test with a result of 0.02 or greater, that provides quantitative data about the alcohol concentration.

Alcohol screening device (ASD). A breath or saliva device, other than an EBT, that is approved by the National Highway Traffic Safety Administration (NHTSA) and appears on ODAPC's Web page for "Approved Screening Devices to Measure Alcohol in Bodily Fluids" because it conforms to the model specifications from NHTSA.

Alcohol screening test. An analytic procedure to determine whether an employee may have a prohibited concentration of alcohol in a breath or saliva specimen.

Alcohol testing site. A place selected by the employer where employees present themselves for the purpose of providing breath or saliva for an alcohol test.

Alcohol use. The drinking or swallowing of any beverage, liquid mixture or preparation (including any medication), containing alcohol.

Aliquot. A fractional part of a specimen used for testing. It is taken as a sample representing the whole specimen.

Alternate specimen. An authorized specimen, other than the type of specimen previously collected or attempted to be collected.

Breath Alcohol Technician (BAT). A person who instructs and assists employees in the alcohol testing process and operates an evidential breath testing device.

Cancelled test. A drug or alcohol test that has a problem identified that cannot be or has not been corrected, or which this part otherwise requires to be cancelled. A cancelled test is neither a positive nor a negative test.

Chain of custody. The procedure used to document the handling of the urine specimen from the time the employee gives the specimen to the collector until the specimen is destroyed. This procedure uses the Federal Drug Testing Custody and Control Form (CCF) as approved by the Office of Management and Budget.

Collection container. A container used to collect a specimen.

Collection site. A place selected by the employer where employees present themselves for the purpose of providing a specimen for a drug test.

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.

Commercial Driver's License Drug and Alcohol Clearinghouse (Clearinghouse). A database, administered by the Federal Motor Carrier Safety Administration, containing records of commercial motor vehicle drivers' violations of controlled substances and alcohol testing program requirements, as set forth in part 382 of this title, as well as their return-to-duty status.

Confirmatory drug test. A second analytical procedure performed on a different aliquot of the original specimen to identify and quantify a specific drug or drug metabolite.

Confirmatory validity test. A second test performed on a different aliquot of the original urine specimen to further support a validity test result.

Confirmed drug test. A confirmation test result received by an MRO from a laboratory.

Consortium/Third-party administrator (C/TPA). A service agent that provides or coordinates the provision of a variety of drug and alcohol testing services to employers. C/TPAs typically perform administrative tasks concerning the operation of the employers' drug and alcohol testing programs. This term includes, but is not limited to, groups of employers who join together to administer, as a single entity, the DOT drug and alcohol testing programs of its members. C/TPAs are not "employers" for purposes of this part.

Continuing education. Training for substance abuse professionals (SAPs) who have completed qualification training and are performing SAP functions, designed to keep SAPs current on changes and developments in the DOT drug and alcohol testing program.

Cutoff. The analytical value (*e.g.,* drug or drug metabolite concentration) used as the decision point to determine a result (*e.g.,* negative, positive, adulterated, invalid, or substituted) or the need for further testing.

Designated employer representative (DER). 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 this part. Service agents cannot act as DERs.

Dilute specimen. A urine specimen with creatinine and specific gravity values that are lower than expected for human urine.

DOT, The Department, DOT Agency. These terms encompass all DOT agencies, including, but not limited to, the Federal Aviation Administration (FAA), the Federal Railroad Administration (FRA), the Federal Motor Carrier Safety Administration (FMCSA), the Federal Transit Administration (FTA), the National Highway Traffic Safety Administration (NHTSA), the Pipeline and Hazardous Materials Safety Administration (PHMSA), and the Office of the Secretary (OST). For purposes of this part, the United States Coast Guard (USCG), in the Department of Homeland Security, is considered to be a DOT agency for drug testing purposes only since the USCG regulation does not incorporate Part 40 for its alcohol testing program. These terms include any designee of a DOT agency.

Drugs. The drugs for which tests are required under this part and DOT agency regulations are marijuana, cocaine, amphetamines, phencyclidine (PCP), and opioids.

Employee. Any person who is designated in a DOT agency regulation as subject to drug testing and/or alcohol testing. The term includes individuals currently performing safety-sensitive functions designated in DOT agency regulations and applicants for employment subject to pre-employment testing. For purposes of drug testing under this part, the term employee has the same meaning as the term “donor” as found on CCF and related guidance materials produced by the Department of Health and Human Services.

Employer. A person or entity employing one or more employees (including an individual who is self-employed) subject to DOT agency regulations requiring compliance with this part. The term includes an employer's officers, representatives, and management personnel. Service agents are not employers for the purposes of this part.

Error Correction Training. Training provided to BATs, collectors, and screening test technicians (STTs) following an error that resulted in the cancellation of a drug or alcohol test. Error correction training must be provided in person or by a means that provides real-time observation and interaction between the instructor and trainee.

Evidential Breath Testing Device (EBT). A device that is approved by the National Highway Traffic Safety Administration (NHTSA) for the evidential testing of breath at the .02 and .04 alcohol concentrations, and appears on ODAPC's Web page for “Approved Evidential Breath Measurement Devices” because it conforms with the model specifications available from NHTSA.

HHS. The Department of Health and Human Services or any designee of the Secretary, Department of Health and Human Services.

Initial drug test. The first test used to differentiate a negative specimen from one that requires further testing for drugs or drug metabolites.

Initial specimen validity test. The first test used to determine if a specimen is adulterated, diluted, substituted, or invalid.

Invalid result. The result reported by an HHS-certified in accordance with the criteria established by HHS when a positive, negative, adulterated, or substituted result cannot be established for a specific drug or specimen validity test.

Laboratory. Any U.S. laboratory certified by HHS under the National Laboratory Certification Program as meeting the minimum standards set by HHS; or, in the case of foreign laboratories, a laboratory approved for participation by DOT under this part.

Limit of Detection (LOD). The lowest concentration at which the analyte (*e.g.,* drug or drug metabolite) can be identified.

Limit of Quantitation (LOQ). For quantitative assays, the lowest concentration at which the identity and concentration of the analyte (*e.g.,* drug or drug metabolite) can be accurately established.

Medical Review Officer (MRO). A person who is a licensed physician and 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.

Negative result. The result reported by an HHS-certified laboratory to an MRO when a specimen contains no drug or the concentration of the drug is less than the cutoff concentration for the drug or drug class and the specimen is a valid specimen.

Non-negative specimen. A specimen that is reported as adulterated, substituted, positive (for drug(s) or drug metabolite(s)), or invalid.

Office of Drug and Alcohol Policy and Compliance (ODAPC). The office in the Office of the Secretary, DOT, that is responsible for coordinating drug and alcohol testing program matters within the Department and providing information concerning the implementation of this part.

Oral fluid specimen. A specimen that is collected from an employee's oral cavity and is a combination of physiological fluids produced primarily by the salivary glands. An oral fluid specimen is considered to be a direct observation collection for all purposes of this part.

Oxidizing adulterant. A substance that acts alone or in combination with other substances to oxidize drugs or drug metabolites to prevent the detection of the drug or drug metabolites, or affects the reagents in either the initial or confirmatory drug test.

Primary specimen. In drug testing, the specimen bottle that is opened and tested by a first laboratory to determine whether the employee has a drug or drug metabolite in his or her system; and for the purpose of specimen validity testing. The primary specimen is the portion of the donor's subdivided specimen designated as the primary ("A") specimen by the collector to distinguish it from the split ("B") specimen, as defined in this section.

Positive result. The result reported by an HHS-certified laboratory when a specimen contains a drug or drug metabolite equal to or greater than the cutoff concentrations.

Qualification Training. The training required in order for a collector, BAT, MRO, SAP, or STT to be qualified to perform their functions in the DOT drug and alcohol testing program. Qualification training may be provided by any appropriate means (*e.g.,* classroom instruction, internet application, CD-ROM, video).

Reconfirmed. The result reported for a split (Bottle B) specimen when the second HHS-certified laboratory corroborates the original result reported for the primary (Bottle A) specimen.

Refresher Training. The training required periodically for qualified collectors, BATs, and STTs to review basic requirements and provide instruction concerning changes in technology (*e.g.,* new testing methods that may be authorized) and amendments, interpretations, guidance, and issues concerning this part and DOT agency drug and alcohol testing regulations. Refresher training can be provided by any appropriate means (*e.g.,* classroom instruction, internet application, CD-ROM, video).

Rejected for testing. The result reported by an HHS-certified laboratory when no tests are performed for a specimen because of a fatal flaw or a correctable flaw that is not corrected.

Screening Test Technician (STT). A person who instructs and assists employees in the alcohol testing process and operates an ASD.

Secretary. The Secretary of Transportation or the Secretary's designee.

Service agent. Any person or entity, other than an employee of the employer, who provides services to employers and/or employees in connection with DOT drug and alcohol testing requirements. This includes, but is not limited to, collectors, BATs and STTs, laboratories, MROs, substance abuse professionals, and C/TPAs. To act as service agents, persons and organizations must meet DOT qualifications, if applicable. Service agents are not employers for purposes of this part.

Shipping container. A container that is used for transporting and protecting specimen bottles and associated documents from the collection site to the laboratory.

Specimen. Fluid, breath, or other material collected from an employee at the collection site for the purpose of a drug or alcohol test.

Specimen bottle. The bottle that, after being sealed and labeled according to the procedures in this part, is used to hold a primary ("A") or split ("B") specimen during transportation to the laboratory. In the context of oral fluid testing, it may be referred to as a "vial," "tube," or "bottle."

Split specimen. In drug testing, the specimen that is sent to a first laboratory and stored with its original seal intact, and which is transported to a second laboratory for retesting at the employee's request following MRO verification of the primary specimen as positive, adulterated or substituted.

Split specimen collection. A collection in which the single specimen collected is divided into two separate specimen bottles, the primary specimen (Bottle A) and the split specimen (Bottle B).

SSN or Employee ID No. This number serves as a unique identifier that must be used on the Federal Drug Testing Custody and Control Form (CCF) or Alcohol Testing Form (ATF) for a donor, on the MRO's reports, on SAP reports, or on other documents that are required under this part. For all purposes of this part, this term means: only the Commercial Driver's License (CDL) Number and State of issuance for drivers tested under the authority of the Federal Motor Carrier Safety Administration (FMCSA); and, for all drivers and other safety-sensitive employees tested under the authority of the other DOT agencies, this can be the individual's actual Social Security Number, a unique identifier issued by the employer, a State-issued identification card number, a State-issued driver's license number (including a CDL number) or any other State-issued or federally-issued identification number.

Stand-down. The practice of temporarily removing an employee from the performance of safety-sensitive functions based only on a report from a laboratory to the MRO of a confirmed positive test for a drug or drug metabolite, an adulterated test, or a substituted test, before the MRO has completed verification of the test result.

Substance Abuse Professional (SAP). A person who evaluates employees who have violated a DOT drug and alcohol regulation and makes recommendations concerning education, treatment, follow-up testing, and aftercare.

Substituted specimen. An employee's specimen not consistent with a normal human specimen, as determined by HHS (*e.g.,* a urine specimen, with creatinine and specific gravity values that are so diminished, or so divergent that they are not consistent with normal human urine).

Undiluted (neat) oral fluid. An oral fluid specimen to which no other solid or liquid has been added. For example: A collection device that uses a diluent (or other component, process, or method that modifies the volume of the testable specimen) must collect at least 1 mL of undiluted (neat) oral fluid.

Urine specimen. Urine collected from an employee at the collection site for the purpose of a drug test.

Verified test. A drug test result or validity testing result from an HHS-certified laboratory that has undergone review and final determination by the MRO.

[65 FR 79526, Dec. 19, 2000, as amended at 66 FR 41950, Aug. 9, 2001; 71 FR 49384, Aug. 23, 2006; 71 FR 55347, Sept. 22, 2006; 73 FR 35969, June 25, 2008; 75 FR 49861, Aug. 16, 2010; 76 FR 59577, Sept. 27, 2011; 80 FR 19553, Apr. 13, 2015; 81 FR 52365, Aug. 8, 2016; 82 FR 52243, Nov. 13, 2017; 88 FR 27636, May 2, 2023]

§ 40.5 Who issues authoritative interpretations of this regulation?

ODAPC and the DOT Office of General Counsel (OGC) provide written interpretations of the provisions of this part. These written DOT interpretations are the only official and authoritative interpretations concerning the provisions of this part. DOT agencies may incorporate ODAPC/OGC interpretations in written guidance they issue concerning drug and alcohol testing matters. Only Part 40 interpretations issued after August 1, 2001, are considered valid.

§ 40.7 How can you get an exemption from a requirement in this regulation?

(a) If you want an exemption from any provision of this part, you must request it in writing from the Office of the Secretary of Transportation, under the provisions and standards of 49 CFR part 5. You must send requests for an exemption to the following address: Department of Transportation, Deputy Assistant General Counsel for Regulation and Enforcement, 1200 New Jersey Avenue, SE., Washington, DC 20590.

(b) Under the standards of 49 CFR part 5, we will grant the request only if the request documents special or exceptional circumstances, not likely to be generally applicable and not contemplated in connection with the rulemaking that established this part, that make your compliance with a specific provision of this part impracticable.

(c) If we grant you an exemption, you must agree to take steps we specify to comply with the intent of the provision from which an exemption is granted.

(d) We will issue written responses to all exemption requests.

Subpart B—Employer Responsibilities

§ 40.11 What are the general responsibilities of employers under this regulation?

(a) As an employer, you are responsible for meeting all applicable requirements and procedures of this part.

(b) You are responsible for all actions of your officials, representatives, and agents (including service agents) in carrying out the requirements of the DOT agency regulations.

(c) All agreements and arrangements, written or unwritten, between and among employers and service agents concerning the implementation of DOT drug and alcohol testing requirements are deemed, as a matter of law, to require compliance with all applicable provisions of this part and DOT agency drug and alcohol testing regulations. Compliance with these provisions is a material term of all such agreements and arrangements.

§ 40.13 How do DOT drug and alcohol tests relate to non-DOT tests?

(a) DOT tests must be completely separate from non-DOT tests in all respects.

(b) DOT tests must take priority and must be conducted and completed before a non-DOT test is begun. When conducting a urine DOT drug test, you must discard any excess urine left over from a DOT test and collect a separate urine void for the subsequent non-DOT test.

(c) Except as provided in paragraph (d) of this section, you must not perform any tests on DOT specimens other than those tests specifically authorized by this part or DOT agency regulations. For example, you must not test a DOT specimen for additional drugs. In addition, a laboratory is prohibited from making a DOT specimen available for a DNA test or other types of specimen identity testing.

(d) When a DOT urine drug test collection is conducted as part of a physical examination required by DOT agency regulations, it is permissible to conduct medical tests related to this physical examination (*e.g.,* for glucose) on any specimen remaining in the collection container after the DOT portion has been sealed into the specimen bottles.

(e) A non-DOT drug or alcohol test administered, as part of a physical examination, is not a DOT drug or alcohol test for purposes of this part and/or related DOT agency drug and alcohol testing rules, if that test was performed to determine if an employee is medically qualified for a license or certificate. Consequently, the results of such a test do not have consequences under this part.

(f) No one is permitted to change or disregard the results of DOT tests based on the results of non-DOT tests. For example, as an employer you must not disregard a verified positive DOT drug test result because the employee presents a negative test result from a blood or urine specimen collected by the employee's physician or a DNA test result purporting to question the identity of the DOT specimen.

(g) As an employer, you must not use the CCF or the ATF in your non-DOT drug and alcohol testing programs. This prohibition includes the use of the DOT forms with references to DOT programs and agencies crossed out. You also must always use the CCF and ATF for all your DOT-mandated drug and alcohol tests.

(h) No one is permitted to conduct a DOT drug or alcohol test on an individual who is not a DOT-regulated employee, as defined by the DOT agency regulations.

[65 FR 79526, Dec. 19, 2000, as amended at 88 FR 27637, May 2, 2023]

§ 40.14 What collection information must employers provide to collectors?

As an employer, or an employer's service agent—for example a C/TPA, you must ensure the collector has the following information when conducting a urine specimen collection for you:

(a) Full name of the employee being tested.

(b) SSN or Employee ID No.

(c) Laboratory name and address (can be pre-printed on the CCF).

(d) Employer name, address, phone number, and fax number (can be pre-printed on the CCF at Step 1–A).

(e) DER information required at § 40.35 of this part.

(f) MRO name, address, phone number, and fax number (can be pre-printed on the CCF at Step 1–B).

(g) The DOT Agency which regulates the employee's safety-sensitive duties (the checkmark can pre-printed in the appropriate box on the CCF at Step 1–D).

(h) Test reason, as appropriate: Pre-employment; Random; Reasonable Suspicion/Reasonable Cause; Post-Accident; Return-to-Duty; and Follow-up.

(i) Whether the test is to be observed or not (see § 40.67 of this part).

(j) (Optional) C/TPA name, address, phone, and fax number (can be pre-printed on the CCF).

(k) Specimen type to be collected (*i.e.,* oral fluid or urine).

[75 FR 59107, Sept. 27, 2010, as amended at 88 FR 27637, May 2, 2023]

§ 40.15 May an employer use a service agent to meet DOT drug and alcohol testing requirements?

(a) As an employer, you may use a service agent to perform the tasks needed to comply with this part and DOT agency drug and alcohol testing regulations, consistent with the requirements of Subpart Q and other applicable provisions of this part.

(b) As an employer, you are responsible for ensuring that the service agents you use meet the qualifications set forth in this part (*e.g.,* § 40.121 for MROs). You may require service agents to show you documentation that they meet the requirements of this part (*e.g.,* documentation of MRO qualifications required by § 40.121(e)).

(c) You remain responsible for compliance with all applicable requirements of this part and other DOT drug and alcohol testing regulations, even when you use a service agent. If you violate this part or other DOT drug and alcohol testing regulations because a service agent has not provided services as our rules require, a DOT agency can subject you to sanctions. Your good faith use of a service agent is not a defense in an enforcement action initiated by a DOT agency in which your alleged noncompliance with this part or a DOT agency drug and alcohol regulation may have resulted from the service agent's conduct.

(d) As an employer, you must not permit a service agent to act as your DER.

§ 40.17 Is an employer responsible for obtaining information from its service agents?

Yes, as an employer, you are responsible for obtaining information required by this part from your service agents. This is true whether or not you choose to use a C/TPA as an intermediary in transmitting information to you. For example, suppose an applicant for a safety-sensitive job takes a pre-employment drug test, but there is a significant delay in your receipt of the test result from an MRO or C/TPA. You must not assume that “no news is good news” and permit the applicant to perform safety-sensitive duties before receiving the result. This is a violation of the Department's regulations.

§ 40.19 [Reserved]

§ 40.21 May an employer stand down an employee before the MRO has completed the verification process?

(a) As an employer, you are prohibited from standing employees down, except consistent with a waiver a DOT agency grants under this section.

(b) You may make a request to the concerned DOT agency for a waiver from the prohibition of paragraph (a) of this section. Such a waiver, if granted, permits you to stand an employee down following the MRO's receipt of a laboratory report of a confirmed positive test for a drug or drug metabolite, an adulterated test, or a substituted test pertaining to the employee.

(1) For this purpose, the concerned DOT agency is the one whose drug and alcohol testing rules apply to the majority of the covered employees in your organization. The concerned DOT agency uses its applicable procedures for considering requests for waivers.

(2) Before taking action on a waiver request, the concerned DOT agency coordinates with other DOT agencies that regulate the employer's other covered employees.

(3) The concerned DOT agency provides a written response to each employer that petitions for a waiver, setting forth the reasons for the agency's decision on the waiver request.

(c) Your request for a waiver must include, as a minimum, the following elements:

(1) Information about your organization:

(i) Your determination that standing employees down is necessary for safety in your organization and a statement of your basis for it, including any data on safety problems or incidents that could have been prevented if a stand-down procedure had been in place;

(ii) Data showing the number of confirmed laboratory positive, adulterated, and substituted test results for your employees over the two calendar years preceding your waiver request, and the number and percentage of those test results that were verified positive, adulterated, or substituted by the MRO;

(iii) Information about the work situation of the employees subject to stand-down, including a description of the size and organization of the unit(s) in which the employees work, the process through which employees will be informed of the stand-down, whether there is an in-house MRO, and whether your organization has a medical disqualification or stand-down policy for employees in situations other than drug and alcohol testing; and

(iv) A statement of which DOT agencies regulate your employees.

(2) Your proposed written company policy concerning stand-down, which must include the following elements:

(i) Your assurance that you will distribute copies of your written policy to all employees that it covers;

(ii) Your means of ensuring that no information about the confirmed positive, adulterated, or substituted test result or the reason for the employee's temporary removal from performance of safety-sensitive functions becomes available, directly or indirectly, to anyone in your organization (or subsequently to another employer) other than the employee, the MRO and the DER;

(iii) Your means of ensuring that all covered employees in a particular job category in your organization are treated the same way with respect to stand-down;

(iv) Your means of ensuring that a covered employee will be subject to stand-down only with respect to the actual performance of safety-sensitive duties;

(v) Your means of ensuring that you will not take any action adversely affecting the employee's pay and benefits pending the completion of the MRO's verification process. This includes continuing to pay the employee during the period of the stand-down in the same way you would have paid him or her had he or she not been stood down;

(vi) Your means of ensuring that the verification process will commence no later than the time an employee is temporarily removed from the performance of safety-sensitive functions and that the period of stand-down for any employee will not exceed five days, unless you are informed in writing by the MRO that a longer period is needed to complete the verification process; and

(vii) Your means of ensuring that, in the event that the MRO verifies the test negative or cancels it—

(A) You return the employee immediately to the performance of safety-sensitive duties;

(B) The employee suffers no adverse personnel or financial consequences as a result;

(C) For a verified negative result, the employee will not be required to submit an alternate specimen for the same testing action. For a cancelled result, the employee could be required to submit an alternate specimen on a re-collection; and

(D) You maintain no individually identifiable record that the employee had a confirmed laboratory positive, adulterated, or substituted test result (*i.e.*, you maintain a record of the test only as a negative or cancelled test).

(d) The Administrator of the concerned DOT agency, or his or her designee, may grant a waiver request only if he or she determines that, in the context of your organization, there is a high probability that the procedures you propose will effectively enhance safety and protect the interests of employees in fairness and confidentiality.

(1) The Administrator, or his or her designee, may impose any conditions he or she deems appropriate on the grant of a waiver.

(2) The Administrator, or his or her designee, may immediately suspend or revoke the waiver if he or she determines that you have failed to protect effectively the interests of employees in fairness and confidentiality, that you have failed to comply with the requirements of this section, or that you have failed to comply with any other conditions the DOT agency has attached to the waiver.

(e) You must not stand employees down in the absence of a waiver, or inconsistent with the terms of your waiver. If you do, you are in violation of this part and DOT agency drug testing regulations, and you are subject to enforcement action by the DOT agency just as you are for other violations of this part and DOT agency rules.

[65 FR 79526, Dec. 19, 2000, as amended at 88 FR 27637, May 2, 2023]

§ 40.23 What actions do employers take after receiving verified test results?

(a) 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 test result. Do not wait to receive the written report or the result of a split specimen test.

(b) As an employer who receives a verified adulterated or substituted drug test result, you must consider this a refusal to test and immediately remove the employee involved from performing safety-sensitive functions. You must take this action on receiving the initial report of the verified adulterated or substituted test result. Do not wait to receive the written report or the result of a split specimen test.

(c) As an employer who receives an alcohol test result of 0.04 or higher, you must immediately remove the employee involved from performing safety-sensitive functions. If you receive an alcohol test result of 0.02–0.039, you must temporarily remove the employee involved from performing safety-sensitive functions, as provided in applicable DOT agency regulations. Do not wait to receive the written report of the result of the test.

(d) As an employer, when an employee has a verified positive, adulterated, or substituted test result, or has otherwise violated a DOT agency drug and alcohol regulation, you must not return the employee to the performance of safety-sensitive functions until or unless the employee successfully completes the return-to-duty process of Subpart O of this part.

(e) As an employer who receives a drug test result indicating that the employee's specimen was dilute, take action as provided in § 40.197.

(f) As an employer who receives a drug test result indicating that the employee's test was cancelled because it was invalid and that a second collection must take place under direct observation—

(1) You must immediately direct the employee to provide a new specimen under direct observation (either an oral fluid specimen or a urine specimen under direct observation).

(2) You must not attach consequences to the finding that the test was invalid other than collecting a new specimen under direct observation.

(3) You must not give any advance notice of this test requirement to the employee.

(4) You must instruct the collector to note on the CCF the same reason (*e.g.,* random test, post-accident test) and DOT Agency (e.g., check DOT and FMCSA) as for the original collection.

(5) You must ensure that the collector conducts the collection under direct observation (either an oral fluid specimen or a urine specimen under direct observation).

(g) As an employer who receives a cancelled test result when a negative result is required (*e.g.,* pre-employment, return-to-duty, or follow-up test), you must direct the employee to provide another specimen immediately.

(h) As an employer, you may also be required to take additional actions required by DOT agency regulations (*e.g.,* FAA rules require some positive drug tests to be reported to the Federal Air Surgeon).

(i) As an employer, you must not alter a drug or alcohol test result transmitted to you by an MRO, BAT, or C/TPA.

[65 FR 79526, Dec. 19, 2000, as amended at 71 FR 49384, Aug. 23, 2006; 73 FR 35970, June 25, 2008; 75 FR 59107, Sept. 27, 2010; 88 FR 27637, May 2, 2023]

§ 40.25 Must an employer check on the drug and alcohol testing record of employees it is intending to use to perform safety-sensitive duties?

(a)

(1) Yes, as an employer, you must, after obtaining an employee's written consent, request the information about the employee listed in paragraphs (b) through (j) of this section. This requirement applies only to employees seeking to begin performing safety-sensitive duties for you for the first time (*i.e.,* a new hire, an employee transferring into a safety-sensitive position). If the employee refuses to provide this written consent, you must not permit the employee to perform safety-sensitive functions.

(2) If you are an employer regulated by FMCSA, you must comply with the requirements of this section by using the FMCSA's Drug and Alcohol Clearinghouse in accordance with 49 CFR 382.71(a). In addition, you must continue to comply with the requirements of this § 40.25 when checking an employee's testing history with employers regulated by a DOT operating administration other than FMCSA.

(3) If you are an employer regulated by FMCSA, with a prospective employee subject to drug and alcohol testing with a DOT agency other than FMCSA, you must continue to request the information about the employee listed in paragraphs (b) through (j) of this section. For example, if you are an employer regulated by both FMCSA and PHMSA, and you are hiring an employee to perform functions regulated by both DOT agencies, then you must query FMCSA's Clearinghouse to satisfy FMCSA's requirements and you must request the information listed in paragraphs (b) through (j) of this section to satisfy PHMSA's requirements.

(b) You must request the information listed in this paragraph (b) from DOT-regulated employers who have employed the employee during any period during the two years before the date of the employee's application or transfer:

(1) Alcohol tests with a result of 0.04 or higher alcohol concentration;

(2) Verified positive drug tests;

(3) Refusals to be tested (including verified adulterated or substituted drug test results);

(4) Other violations of DOT agency drug and alcohol testing regulations; and

(5) With respect to any employee who violated a DOT drug and alcohol regulation, documentation of the employee's successful completion of DOT return-to-duty requirements (including follow-up tests). If the previous employer does not have information about the return-do-duty process (*e.g.,* an employer who did not hire an employee who tested positive on a pre-employment test), you must seek to obtain this information from the employee.

(c) The information obtained from a previous employer includes any drug or alcohol test information obtained from previous employers under this section or other applicable DOT agency regulations.

(d) If feasible, you must obtain and review this information before the employee first performs safety-sensitive functions. If this is not feasible, you must obtain and review the information as soon as possible. However, you must not permit the employee to perform safety-sensitive functions after 30 days from the date on which the employee first performed safety-sensitive functions, unless you have obtained or made and documented a good faith effort to obtain this information.

(e) If you obtain information that the employee has violated a DOT agency drug and alcohol regulation, you must not use the employee to perform safety-sensitive functions unless you also obtain information that the employee has subsequently complied with the return-to-duty requirements of Subpart O of this part and DOT agency drug and alcohol regulations.

(f) You must provide to each of the employers from whom you request information under paragraph (b) of this section written consent for the release of the information cited in paragraph (a) of this section.

(g) The release of information under this section must be in any written form (*e.g.,* fax, e-mail, letter) that ensures confidentiality. As the previous employer, you must maintain a written record of the information released, including the date, the party to whom it was released, and a summary of the information provided.

(h) If you are an employer from whom information is requested under paragraph (b) of this section, you must, after reviewing the employee's specific, written consent, immediately release the requested information to the employer making the inquiry.

(i) As the employer requesting the information required under this section, you must maintain a written, confidential record of the information you obtain or of the good faith efforts you made to obtain the information. You must retain this information for three years from the date of the employee's first performance of safety-sensitive duties for you.

(j) As the employer, you must also ask the employee whether he or she has tested positive, or refused to test, on any pre-employment drug or alcohol test administered by an employer to which the employee applied for, but did not obtain, safety-sensitive transportation work covered by DOT agency drug and alcohol testing rules during the past two years. If the employee admits that he or she had a positive test or a refusal to test, you must not use the employee to perform safety-sensitive functions for you, until and unless the employee documents successful completion of the return-to-duty process (see paragraphs (b)(5) and (e) of this section).

[65 FR 79526, Dec. 19, 2000, as amended at 88 FR 27637, May 2, 2023]

§ 40.26 What form must an employer use to report Management Information System (MIS) data to a DOT agency?

As an employer, when you are required to report MIS data to a DOT agency, you must use the U.S. Department of Transportation Drug and Alcohol Testing MIS Data Collection Form to report that data. You must use the form and instructions referenced at appendix J to part 40. You must submit the MIS report in accordance with rule requirements (*e.g.,* dates for submission; selection of companies required to submit, and method of reporting) established by the DOT agency regulating your operation.

[84 FR 16773, Apr. 23, 2019, as amended at 88 FR 27638, May 2, 2023]

§ 40.27 May an employer require an employee to sign a consent or release in connection with the DOT drug and alcohol testing program?

No, as an employer, you must not require an employee to sign a consent, release, waiver of liability, or indemnification agreement with respect to any part of the drug or alcohol testing process covered by this part (including, but not limited to, collections, laboratory testing, MRO and SAP services).

[66 FR 41950, Aug. 9, 2001]

Subpart C—Urine Collection Personnel

§ 40.31 Who may collect specimens for DOT drug testing?

(a) Collectors meeting the requirements of this subpart are the only persons authorized to collect urine specimens for DOT drug testing.

(b) A urine collector must meet training requirements of § 40.33.

(c) An oral fluid collector must meet the training requirements of § 40.35.

(d) To avoid the appearance of a conflict of interest, if you are the immediate supervisor of the employee being tested, you must not act as the collector when that employee is tested, unless no other collector is available and you are permitted to do so under DOT agency drug and alcohol regulations.

(e) You must not act as the collector for the employee being tested if you work for a HHS-certified laboratory (*e.g.,* as a technician or accessioner) and could link the employee with a urine specimen, drug testing result, or laboratory report.

(f) Employees are not permitted to be their own collector.

(1) An employee who is a qualified collector is not permitted to be their own collector; another qualified collector must perform the collection in accordance with this part.

(2) To avoid a potential conflict of interest, a collector must not be related to the employee being tested (*e.g.,* spouse, ex-spouse, relative) or a close personal friend.

[65 FR 79526, Dec. 19, 2000, as amended at 88 FR 27637, May 2, 2023]

§ 40.33 What training requirements must a collector meet for urine collection?

To be permitted to act as a urine collector in the DOT drug testing program, you must meet each of the requirements of this section:

(a) ***Basic information.*** You must be knowledgeable about this part, the current "DOT Urine Specimen Collection Procedures Guidelines," and DOT agency regulations applicable to the employers for whom you perform collections. DOT agency regulations, the DOT Urine Specimen Collection Procedures Guidelines, and other materials are available from ODAPC (Department of Transportation, 1200 New Jersey Avenue SE., Washington DC, 20590, 202–366–3784, or on the ODAPC Web site (*https://www.transportation.gov/odapc*). You must keep current on any changes to these materials. You must subscribe to the ODAPC list-serve at: *https://www.transportation.gov/odapc/get-odapc-email-updates.*

(b) ***Qualification training.*** You must receive qualification training meeting the requirements of this paragraph. Qualification training must provide instruction on the following subjects:

(1) All steps necessary to complete a collection correctly and the proper completion and transmission of the CCF;

(2) "Problem" collections (*e.g.,* situations like "shy bladder" and attempts to tamper with a specimen);

(3) Fatal flaws, correctable flaws, and how to correct problems in collections; and

(4) The collector's responsibility for maintaining the integrity of the collection process, ensuring the privacy of employees being tested, ensuring the security of the specimen, and avoiding conduct or statements that could be viewed as offensive or inappropriate;

(c) ***Initial Proficiency Demonstration.*** Following your completion of qualification training under paragraph (b) of this section, you must demonstrate proficiency in collections under this part by completing five consecutive error-free mock collections.

(1) The five mock collections must include two uneventful collection scenarios, one insufficient quantity of urine scenario, one temperature out of range scenario, and one scenario in which the employee refuses to sign the CCF and initial the specimen bottle tamper-evident seal.

(2) Another person must monitor and evaluate your performance, in person or by a means that provides real-time observation and interaction between the instructor and trainee, and attest in writing that the mock collections are "error-free." This person must be a qualified collector who has demonstrated necessary knowledge, skills, and abilities by—

(i) Regularly conducting DOT drug test collections for a period of at least a year;

(ii) Conducting collector training under this part for a year; or

(iii) Successfully completing a "train the trainer" course.

(d) You must meet the requirements of paragraphs (b) and (c) of this section before you begin to perform collector functions.

(e) ***Refresher training.*** No less frequently than every five years from the date on which you satisfactorily complete the requirements of paragraphs (b) and (c) of this section, you must complete refresher training that meets all the requirements of paragraphs (b) and (c) of this section.

(f) ***Error correction training.*** If you make a mistake in the collection process that causes a test to be cancelled (*i.e.,* a fatal or uncorrected flaw), you must undergo error correction training. This training must occur within 30 days of the date you are notified of the error that led to the need for retraining. Errors that cause cancellation but occur outside

the collection process (*e.g.,* when a specimen is crushed or otherwise damaged during the transportation process, or is lost in transit), the cancellation would not be the result of an error by the collector during the collection process and does not require the collector to be retrained.

(1) Error correction training must be provided and your proficiency documented in writing by a person who meets the requirements of paragraph (c)(2) of this section.

(2) Error correction training is required to cover only the subject matter area(s) in which the error that caused the test to be cancelled occurred.

(3) As part of the error correction training, you must demonstrate your proficiency in the collection procedures of this part by completing three consecutive error-free mock collections. The mock collections must include one uneventful scenario and two scenarios related to the area(s) in which your error(s) occurred. The person providing the training must monitor and evaluate your performance and attest in writing that the mock collections were "error-free."

(g) ***Documentation.*** You must maintain documentation showing that you currently meet all requirements of this section. You must provide this documentation on request to DOT agency representatives and to employers and C/TPAs who are using or negotiating to use your services.

[65 FR 79526, Dec. 19, 2000; 66 FR 3885, Jan. 17, 2001, as amended at 66 FR 41950, Aug. 9, 2001; 82 FR 52244, Nov. 13, 2017; 88 FR 27638, May 2, 2023]

§ 40.35 What training requirements must a collector meet for oral fluid collection?

To be permitted to act as an oral fluid collector in the DOT drug testing program, you must meet each of the requirements of this section:

(a) ***Basic information.*** You must be knowledgeable about this part, the current "DOT Oral Fluid Specimen Collection Procedures Guidelines," and DOT agency regulations applicable to the employers for whom you perform collections. DOT agency regulations, guidelines, and other materials are available from ODAPC (Department of Transportation, 1200 New Jersey Avenue SE, Washington DC, 20590, 202–366–3784, or on the ODAPC website (*https://www.transportation.gov/odapc*). You must keep current on any changes to these materials. You must subscribe to the ODAPC list-serve at: *https://www.transportation.gov/odapc/get-odapc-email-updates.*

(b) ***Qualification training.*** You must receive qualification training meeting the requirements of this paragraph (b). Qualification training must provide instruction on the following subjects:

(1) Training on the testing procedures of this part;

(2) Training to proficiency in the operation of the particular oral fluid collection device(s) you will be using.

(3) All steps necessary to complete a collection correctly and the proper completion and transmission of the CCF;

(4) "Problem" collections (*e.g.,* situations like "dry mouth" and attempts to tamper with a specimen);

(5) Fatal flaws, correctable flaws, and how to correct problems in collections; and

(6) The collector's responsibility for maintaining the integrity of the collection process, ensuring the privacy of employees being tested, ensuring the security of the specimen, and avoiding conduct or statements that could be viewed as offensive or inappropriate.

(c) ***Initial proficiency demonstration.*** Following your completion of qualification training under paragraph (b) of this section, you must demonstrate proficiency in collections under this part by completing five consecutive error-free mock collections for each device you will use.

(1) The five mock collections for each device must include one uneventful collection scenario, one insufficient specimen quantity scenario; one scenario in which the employee has something in their mouth that might interfere with the collection; one scenario in which the employee attempts to tamper with the specimen; and one scenario in which the employee refuses to sign the CCF. For each of the five mock collections, the collector must check the expiration date of the device, show it to the employee, and record the date on the CCF used. The collector must ensure, when applying the labels, they do not cover the expiration dates.

(2) Another person must monitor and evaluate your performance, in person or by a means that provides real-time observation and interaction between you and the qualified collector, who must attest in writing that the mock collections are "error-free." This person must be a qualified collector who has demonstrated necessary knowledge, skills, and abilities by—

(i) Regularly conducting DOT drug test collections for a period of at least one year;

(ii) Conducting collector training under this part for at least one year; or

(iii) Successfully completing a "train the trainer" course.

(d) ***Schedule for qualification training and initial proficiency demonstration.*** You must meet the requirements of paragraphs (b) and (c) of this section before you begin to perform collector functions.

(e) ***Refresher training.*** No less frequently than every five years from the date on which you satisfactorily complete the requirements of paragraphs (b) and (c) of this section, you must complete refresher training that meets all the requirements of paragraphs (b) and (c).

(f) ***Error correction training.*** If you make a mistake in the collection process that causes a test to be cancelled (*i.e.,* a fatal or uncorrected flaw), you must undergo error correction training. This training must occur within 30 days of the date you are notified of the error that led to the need for retraining.

(1) Error correction training must be provided and your proficiency documented in writing by a person who meets the requirements of paragraph (c)(2) of this section.

(2) Error correction training is required to cover only the subject matter area(s) in which the error that caused the test to be cancelled occurred.

(3) As part of the error correction training, you must demonstrate your proficiency in the collection procedures of this part by completing three consecutive error-free mock collections. The mock collections must include one uneventful scenario and two scenarios related to the area(s) in which your error(s) occurred. The person providing the training must monitor and evaluate your performance and attest in writing that the mock collections were "error-free."

(g) ***Documentation.*** You must maintain documentation showing that you currently meet all requirements of this section. You must provide this documentation on request to DOT agency representatives and to employers and C/TPAs who are using or negotiating to use your services.

[88 FR 27638, May 2, 2023]

§ 40.36 What information about the DER must employers provide to collectors?

As an employer, you must provide to collectors the name and telephone number of the appropriate DER (and C/TPA, where applicable) to contact about any problems or issues that may arise during the testing process.

[65 FR 79526, Dec. 19, 2000. Redesignated at 88 FR 27639, May 2, 2023]

Subpart D—Collection Sites, Forms, Equipment and Supplies Used in DOT Urine and Oral Fluid Collections

§ 40.40 What form is used to document a DOT collection?

(a) The Federal Drug Testing Custody and Control Form (CCF) must be used to document every collection required by the DOT drug testing program. You may view this form on the Department's website (*https://www.transportation.gov/odapc*) or the HHS website (*https://www.workplace.samhsa.gov*).

(b) You must not use a non-Federal form or an expired CCF to conduct a DOT collection. As a laboratory, C/TPA or other party that provides CCFs to employers, collection sites, or other customers, you must not provide copies of an expired CCF to these participants. You must also affirmatively notify these participants that they must not use an expired CCF.

(c) As a participant in the DOT drug testing program, you are not permitted to modify or revise the CCF except as follows:

(1) You may include, in the area outside the border of the form, other information needed for billing or other purposes necessary to the collection process.

(2) The CCF must include the names, addresses, telephone numbers and any other appropriate contact information (*e.g.,* an email address of the employer and the MRO), including the DER's name and contact information. All of this information must be preprinted, typed, or handwritten. Fax numbers may be included but are not required. The MRO information must include the physician's name and address, as opposed to only a generic clinic, health care organization, company name, or post office box. This information is required, and an employer, collector, service agent or any other party is prohibited from omitting it. In addition, a C/TPA's name, address, telephone and fax numbers, and any other appropriate contact information should be included, but is not required. The employer may use a C/TPA's address in place of its own, but must continue to include its name, telephone and fax numbers, and any other appropriate contact information.

(3) As an employer you may preprint the box in Step 1–D of the CCF for the DOT agency under whose authority the test will occur.

(4) As a collector, you may use a CCF with your name, address, telephone number, and fax number preprinted, but under no circumstances may you sign the form before the collection event. If a collection takes place at a clinic, the actual address of the clinic should be used, not a corporate address of the collection company. If the collection takes place onsite at the employer, the employer's address must be noted as the collection site address. If the collection takes place in a "mobile unit" or at an accident site, the collector must enter the actual location address of the collection or as near an approximation as possible. The collector must ensure that the required collector telephone number is the number that the laboratory, MRO, or employer may use to directly contact the individual collector and/or the collector's supervisor during the collection site's business hours. The collector must not provide a number for a call center.

(5) When using an electronic CCF, you must establish adequate confidentiality and security measures to ensure that confidential employee records are not available to unauthorized persons. This includes protecting the physical security of records, access controls, and computer security measures to safeguard confidential data in electronic form.

(d) Under no circumstances may the CCF transmit personal identifying information about an employee (other than a SSN or Employee ID No.) to a laboratory.

(e) As an employer, you may use an equivalent foreign-language version of the CCF approved by ODAPC. You may use such a non-English language form only in a situation where both the employee and collector understand and can use the form in that language.

(f) An employer who uses an electronic CCF must ensure that the collection site, the primary and split laboratories, and MRO have compatible systems, and that the employee and any other program participants in the testing process will receive a legible copy of the CCF.

[65 FR 79526, Dec. 19, 2000, as amended at 66 FR 41950, Aug. 9, 2001; 75 FR 59107, Sept. 27, 2010; 76 FR 59577, Sept. 27, 2011; 80 FR 19553, Apr. 13, 2015; 82 FR 52244, Nov. 13, 2017. Redesignated and amended at 88 FR 27639, May 2, 2023]

§ 40.41 May employers use the CCF for non-Federal collections or non-Federal forms for DOT collections?

(a) No, as an employer, you are prohibited from using the CCF for non-Federal collections. You are also prohibited from using non-Federal forms for DOT collections. Doing either subjects you to enforcement action under DOT agency regulations.

(b)

(1) In the rare case where the collector, either by mistake or as the only means to conduct a test under difficult circumstances (*e.g.,* post-accident or reasonable suspicion test with insufficient time to obtain the CCF), uses a non-Federal form for a DOT collection, the use of a non-Federal form does not present a reason for the laboratory to reject the specimen for testing or for an MRO to cancel the result.

(2) The use of the non-Federal form is a "correctable flaw." As an MRO, to correct the problem you must follow the procedures of § 40.205(b)(2).

[65 FR 79526, Dec. 19, 2000, as amended at 66 FR 41950, Aug. 9, 2001. Redesignated and amended at 88 FR 27639, June 1, 2023]

§ 40.42 Where does a urine collection for a DOT drug test take place?

(a) A urine collection for a DOT drug test must take place in a collection site meeting the requirements of this section.

(b) If you are operating a collection site, you must ensure that it meets the security requirements of § 40.43.

(c) If you are operating a collection site, you must have all necessary personnel, materials, equipment, facilities and supervision to provide for the collection, temporary storage, and shipping of urine specimens to a laboratory, and a suitable clean surface for writing.

(d) Your collection site must include a facility for urination described in either paragraph (e) or paragraph (f) of this section.

(e) The first, and preferred, type of facility for urination that a collection site may include is a single-toilet room, having a full-length privacy door, within which urination can occur.

(1) No one but the employee may be present in the room during the collection, except for the observer in the event of a directly observed collection.

(2) You must have a source of water for washing hands, that, if practicable, should be external to the closed room where urination occurs. If an external source is not available, you may meet this requirement by securing all sources of water and other substances that could be used for adulteration and substitution (*e.g.,* water faucets, soap dispensers) and providing moist towelettes outside the closed room.

(f) The second type of facility for urination that a collection site may include is a multistall restroom.

(1) Such a site must provide substantial visual privacy (*e.g.,* a toilet stall with a partial-length door) and meet all other applicable requirements of this section.

(2) If you use a multi-stall restroom, you must either—

(i) Secure all sources of water and other substances that could be used for adulteration and substitution (*e.g.,* water faucets, soap dispensers) and place bluing agent in all toilets or secure the toilets to prevent access; or

(ii) Conduct all collections in the facility as monitored collections (see § 40.69 for procedures). This is the only circumstance in which you may conduct a monitored collection.

(3) No one but the employee may be present in the multistall restroom during the collection, except for the monitor in the event of a monitored collection or the observer in the event of a directly observed collection.

(g) A collection site may be in a medical facility, a mobile facility (*e.g.,* a van), a dedicated collection facility, or any other location meeting the requirements of this section.

[65 FR 79526, Dec. 19, 2000. Redesignated at 88 FR 27639, May 2, 2023]

§ 40.43 What steps must operators of collection sites and collectors take to protect the security and integrity of urine collections?

(a) Collectors and operators of collection sites must take the steps listed in this section to prevent unauthorized access that could compromise the integrity of collections.

(b) As a collector, you must do the following before each collection to deter tampering with specimens:

(1) Secure any water sources or otherwise make them unavailable to employees (*e.g.,* turn off water inlet, tape handles to prevent opening faucets);

(2) Ensure that the water in the toilet is blue;

(3) Ensure that no soap, disinfectants, cleaning agents, or other possible adulterants are present;

(4) Inspect the site to ensure that no foreign or unauthorized substances are present;

(5) Tape or otherwise secure shut any movable toilet tank top, or put bluing in the tank;

(6) Ensure that undetected access (*e.g.,* through a door not in your view) is not possible;

(7) Secure areas and items (*e.g.,* ledges, trash receptacles, paper towel holders, under-sink areas) that appear suitable for concealing contaminants; and

(8) Recheck items in paragraphs (b)(1) through (7) of this section following each collection to ensure the site's continued integrity.

(c) If the collection site uses a facility normally used for other purposes, like a public rest room or hospital examining room, you must, as a collector, also 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. Limited-access signs must be posted.

(d) As a collector, you must take the following additional steps to ensure security during the collection process:

(1) To avoid distraction that could compromise security, you are limited to conducting a collection for only one employee at a time. However, during the time one employee is in the period for drinking fluids in a "shy bladder" situation (see § 40.193(b)), you may conduct a collection for another employee.

(2) To the greatest extent you can, keep an employee's collection container within view of both you and the employee between the time the employee has urinated and the specimen is sealed.

(3) Ensure you are the only person in addition to the employee who handles the specimen before it is poured into the bottles and sealed with tamper-evident seals.

(4) In the time between when the employee gives you the specimen and when you seal the specimen, remain within the collection site.

(5) Maintain personal control over each specimen and CCF throughout the collection process.

(e) If you are operating a collection site, you must implement a policy and procedures to prevent unauthorized personnel from entering any part of the site in which urine specimens are collected or stored.

(1) Only employees being tested, collectors and other collection site workers, DERs, employee and employer representatives authorized by the employer (*e.g.,* employer policy, collective bargaining agreement), and DOT agency representatives are authorized persons for purposes of this paragraph (e).

(2) Except for the observer in a directly observed collection or the monitor in the case of a monitored collection, you must not permit anyone to enter the urination facility in which employees provide specimens.

(3) You must ensure that all authorized persons are under the supervision of a collector at all times when permitted into the site.

(4) You or the collector may remove any person who obstructs, interferes with, or causes a delay in the collection process.

(f) If you are operating a collection site, you must minimize the number of persons handling specimens.

§ 40.44 What materials are used to collect urine specimens?

For each DOT drug test, you must use a collection kit meeting the requirements of Appendix A of this part.

[65 FR 79526, Dec. 19, 2000. Redesignated at 88 FR 27639, May 2, 2023]

§ 40.45 What materials are used to send urine specimens to the laboratory?

(a) Except as provided in paragraph (b) of this section, you must use a shipping container that adequately protects the specimen bottles from shipment damage in the transport of specimens from the collection site to the laboratory.

(b) You are not required to use a shipping container if a laboratory courier hand-delivers the specimens from the collection site to the laboratory.

[65 FR 79526, Dec. 19, 2000. Redesignated at 88 FR 27639, May 2, 2023]

§ 40.47 Where does an oral fluid collection for a DOT drug test take place?

(a) An oral fluid collection for a DOT drug test must take place in a collection site meeting the requirements of this section.

(b) If you are operating an oral fluid collection site:

(1) You must ensure that it meets the security requirements of § 40.48;

(2) The site may be a permanent or temporary facility located either at the work site or at a remote site;

(3) The site may be in a medical facility, a mobile facility (*e.g.,* a van), a dedicated collection facility, or any other location meeting the requirements of this section; and

(4) You must have all necessary personnel, materials, equipment, and facilities that include privacy and supervision to provide for the collection, temporary storage, and shipping of specimens to a laboratory, and a suitable clean surface for writing.

(c) If a collection site is not accessible and there is an immediate requirement to collect an oral fluid specimen (*e.g.,* an accident investigation), another site may be used for the collection, if the collection is performed by a collector who has been trained to collect oral fluid specimens in accordance with this part and the manufacturer's procedures for the collection device.

[88 FR 27640, May 2, 2023]

§ 40.48 What steps must operators of collection sites and collectors take to protect the security and integrity of oral fluid collections?

(a) Collectors and operators of collection sites must take the steps listed in this section to prevent unauthorized access that could compromise the integrity of collections.

(b) As a collector, you must do the following before each collection to deter tampering with specimens:

(1) Ensure that access to collection materials and specimens is effectively restricted;

(2) Ensure that undetected access (*e.g.,* through a door not in your view) is not possible; and

(3) Ensure the security of the facility during the collection process to maintain privacy to the employee and prevent distraction of the collector. Limited-access signs must be posted.

(c) As a collector, you must take the following additional steps to ensure security during the collection process:

(1) To avoid distraction that could compromise security, you are limited to conducting a collection for only one employee at a time. However, during the time one employee is in the period for drinking fluids in a “dry mouth” situation (*see* § 40.72(b)(1)), you may conduct a collection for another employee as long as the employee with “dry mouth” remains supervised.

(2) To the greatest extent practicable, keep an employee's collection container within view of both you and the employee between the time the employee has provided the oral fluid specimen and the specimen is sealed.

(3) Ensure you are the only person in addition to the employee who handles the specimen before it is sealed with tamper-evident seals.

(4) In the time between when the employee gives you the specimen and when you seal the specimen, remain within the collection site.

(5) Maintain personal control over each specimen and CCF throughout the collection process.

(d) If you are operating a collection site, you must implement a policy and procedures to prevent unauthorized personnel from entering any part of the site in which oral fluid specimens are collected or stored.

(1) Only employees being tested, collectors and other collection site workers, DERs, employee and employer representatives authorized by the employer (*e.g.,* employer policy, collective bargaining agreement), and DOT agency representatives are authorized persons for purposes of this paragraph (d).

(2) You must ensure that all authorized persons are under the supervision of a collector at all times when permitted into the site.

(3) You or the collector may remove any person who obstructs, interferes with, or causes a delay in the collection process.

(e) If you are operating a collection site, you must minimize the number of persons handling specimens.

[88 FR 27640, May 2, 2023]

§ 40.49 What materials are used to collect oral fluid specimens?

For each DOT drug test, you must use a collection device meeting the requirements of appendix B of this part.

[88 FR 27640, May 2, 2023]

§ 40.51 What materials are used to send oral fluid specimens to the laboratory?

(a) Except as provided in paragraph (b) of this section, you must use a shipping container that adequately protects the specimen bottles from damage in the transport of specimens from the collection site to the laboratory.

(b) You are not required to use a shipping container if a laboratory courier hand-delivers the specimens from the collection site to the laboratory.

[88 FR 27640, May 2, 2023]

Subpart E—Specimen Collections

§ 40.61 What are the preliminary steps in the drug testing collection process?

As the collector, you must take the following steps before actually beginning a collection:

(a) When a specific time for an employee's test has been scheduled, or the collection site is at the employee's work site, and the employee does not appear at the collection site at the scheduled time, contact the DER to determine the appropriate interval within which the DER has determined the employee is authorized to arrive. If the employee's arrival is delayed beyond that time, you must notify the DER that the employee has not reported for testing, the DER must determine whether the employee has refused to test (*see* §§ 40.191(a)(1) and 40.355(i)). In a situation where a C/TPA has notified an owner/operator or other individual employee to report for testing (other than for a pre-employment test) and the employee does not appear, the C/TPA must determine whether the employee has refused to test (*see* §§ 40.191(a)(1) and 40.355(j)).

(b) Ensure that, when the employee enters the collection site, you begin the testing process without undue delay. For example, you must not wait because the employee says he or she is not ready or is unable to urinate or because an authorized employer or employee representative is delayed in arriving.

(1) If the employee is also going to take a DOT alcohol test, you must ensure, to the greatest extent practicable, that the alcohol test is completed before the drug testing collection process begins.

> *Example to paragraph (b)(1):* An employee enters the test site for both a drug and an alcohol test. Normally, the collector would wait until the BAT had completed the alcohol test process before beginning the drug test process. However, there are some situations in which an exception to this normal practice would be reasonable. One such situation might be if several people were waiting for the BAT to conduct alcohol tests, but a drug testing collector in the same facility were free. Someone waiting might be able to complete a drug test without unduly delaying his or her alcohol test. Collectors and BATs should work together, however, to ensure that post-accident and reasonable suspicion alcohol tests happen as soon as possible (*e.g.,* by moving the employee to the head of the line for alcohol tests).

(2) If the employee needs medical attention (*e.g.,* an injured employee in an emergency medical facility who is required to have a post-accident test), do not delay this treatment to collect a specimen.

(3) You must not collect a specimen from an unconscious employee to conduct a drug test under this part.

(4) You must not catheterize a conscious employee for purposes of a urine test. However, you must inform an employee who normally voids through self-catheterization that the employee is required to provide a specimen in that manner. If an employee normally voids through self-catheterization, but declines to do so for the urine test, the collector should notify the DER of the circumstances, so that the actual employer can determine whether the situation constitutes a refusal to test by the employee.

(c) Require the employee to provide positive identification. You must see a photo ID issued by the employer (other than in the case of an owner-operator or other self-employed individual) or a Federal, state, or local government (*e.g.,* a driver's license). You may not accept faxes or photocopies of identification. Positive identification by an employer representative (not a co-worker or another employee being tested) is also acceptable. If the employee cannot produce positive identification, you must contact a DER to verify the identity of the employee.

(d) If the employee asks, provide your identification to the employee. Your identification must include your name and your employer's name, but does not have to include your picture, address, or telephone number.

(e) Explain the basic collection procedure to the employee, and notify the employee that instructions for completing the CCF can be found at the HHS (*https://www.samhsa.gov/workplace*) and DOT (*https://www.transportation.gov/odapc*) websites.

(f) Direct the employee to remove outer clothing (*e.g.,* coveralls, jacket, coat, hat) that could be used to conceal items or substances that could be used to tamper with a specimen. You must also direct the employee to leave these garments and any briefcase, purse, or other personal belongings with you or in a mutually agreeable location. You must advise the employee that failure to comply with your directions constitutes a refusal to test.

(1) If the employee asks for a receipt for any belongings left with you, you must provide one.

(2) You must allow the employee to keep his or her wallet.

(3) You must not ask the employee to remove other clothing (*e.g.,* shirts, pants, dresses, underwear), to remove all clothing, or to change into a hospital or examination gown (unless the urine collection is being accomplished simultaneously with a DOT agency-authorized medical examination).

(4) You must direct the employee to empty his or her pockets and display the items in them to ensure that no items are present which could be used to adulterate the specimen. If nothing is there that can be used to adulterate a specimen, the employee can place the items back into his or her pockets. As the employee, you must allow the collector to make this observation.

(5) If, in your duties under paragraph (f)(4) of this section, you find any material that could be used to tamper with a specimen, you must:

(i) Determine if the material appears to be brought to the collection site with the intent to alter the specimen, and, if it is, either conduct a directly observed urine collection using direct observation procedures (*see* § 40.67) or an oral fluid specimen collection, make a note on the CCF and continue with collection process; or

(ii) Determine if the material appears to be inadvertently brought to the collection site (*e.g.,* eye drops), secure and maintain it until the collection process is completed and conduct a normal (*i.e.,* unobserved) collection.

(g) You must instruct the employee not to list medications that he or she is currently taking on the CCF. (The employee may make notes of medications on the back of the employee copy of the form for his or her own convenience, but these notes must not be transmitted to anyone else.)

[65 FR 79526, Dec. 19, 2000, as amended at 88 FR 27640, May 2, 2023]

§ 40.63 What steps does the collector take in the collection process before the employee provides a urine specimen?

As the collector, you must take the following steps before the employee provides the urine specimen:

(a) Ensure all items under Step 1 of the CCF are complete and accurate (*e.g.,* if Step 1.D is not checked, put a check mark for the "Specify DOT Agency" under the authority of which the test will take place; if the address where the collection is actually taking place is not in Step 1.G, update that.)

(b) Instruct the employee to wash and dry his or her hands at this time. You must tell the employee not to wash his or her hands again until after delivering the specimen to you. You must not give the employee any further access to water or other materials that could be used to adulterate or dilute a specimen.

(c) Select, or allow the employee to select, an individually wrapped or sealed collection container from collection kit materials. Either you or the employee, with both of you present, must unwrap or break the seal of the collection container. You must not unwrap or break the seal on any specimen bottle at this time. You must not allow the employee to take anything from the collection kit into the room used for urination except the collection container.

(d) Direct the employee to go into the room used for urination, provide a specimen of at least 45 mL, not flush the toilet, and return to you with the specimen as soon as the employee has completed the void.

(1) Except in the case of an observed or a monitored collection (see §§ 40.67 and 40.69), neither you nor anyone else may go into the room with the employee.

(2) As the collector, you may set a reasonable time limit for voiding.

(e) You must pay careful attention to the employee during the entire collection process to note any conduct that clearly indicates an attempt to tamper with a specimen (*e.g.,* substitute urine in plain view or an attempt to bring into the collection site an adulterant or urine substitute). If you detect such conduct, you must require that a collection take place immediately under direct observation (*see* § 40.67) and complete Step 2 by noting the conduct in the "Remarks" line of the CCF and the fact that the collection was observed by checking the "Observed" box. You must also, as soon as possible, inform the DER and collection site supervisor that a collection took place under direct observation and the reason for doing so.

[65 FR 79526, Dec. 19, 2000, as amended at 75 FR 59107, Sept. 27, 2010; 88 FR 27641, May 2, 2023]

§ 40.65 What does the collector check for when the employee presents a urine specimen?

As a collector, you must check the following when the employee gives the collection container to you:

(a) ***Sufficiency of specimen.*** You must check to ensure that the specimen contains at least 45 mL of urine.

(1) If it does not, you must follow "shy bladder" procedures (see § 40.193(b)).

(2) When you follow "shy bladder" procedures, you must discard the original specimen, unless another problem (*i.e.,* temperature out of range, signs of tampering) also exists.

(3) You are never permitted to combine urine collected from separate voids to create a specimen.

(4) You must discard any excess urine.

(b) ***Temperature.*** You must check the temperature of the specimen no later than four minutes after the employee has given you the specimen.

(1) The acceptable temperature range is 32–38 °C/90–100 °F.

(2) You must determine the temperature of the specimen by reading the temperature strip attached to the collection container.

(3) If the specimen temperature is within the acceptable range, you must mark the "Yes" box on the CCF (Step 2).

(4) If the specimen temperature is outside the acceptable range, you must mark the "No" box and enter in the "Remarks" line (Step 2) your findings about the temperature.

(5) If the specimen temperature is outside the acceptable range, you must immediately conduct a new urine collection using direct observation procedures (*see* § 40.67) or an oral fluid collection.

(6) In a case where a specimen is collected under direct observation because of the temperature being out of range, you must process both the original specimen and the specimen collected using direct observation (including oral fluid) and send the two sets of specimens to their respective laboratories. This is true even in a

case in which the original specimen has insufficient volume and the temperature is out of range. You must also, as soon as possible, inform the DER and collection site supervisor that a collection took place under direct observation and the reason for doing so.

(7) In a case where the employee refuses to provide another specimen (see § 40.191(a)(3)) or refuses to provide another specimen under direct observation (see § 40.191(a)(4)), you must notify the DER. As soon as you have notified the DER, you must discard any specimen the employee has provided previously during the collection procedure.

(c) ***Signs of tampering.*** You must inspect the specimen for unusual color, presence of foreign objects or material, or other signs of tampering (*e.g.,* if you notice any unusual odor).

(1) If it is apparent from this inspection that the employee has tampered with the specimen (*e.g.,* blue dye in the specimen, excessive foaming when shaken, or smell of bleach), you must immediately conduct a new urine collection using direct observation procedures (*see* § 40.67) or an oral fluid collection.

(2) In a case where a specimen is collected under direct observation because of showing signs of tampering, you must process both the original specimen and the specimen collected using direct observation and send the two sets of specimens to the laboratory. This is true even in a case in which the original specimen has insufficient volume but it shows signs of tampering. You must also, as soon as possible, inform the DER and collection site supervisor that a collection took place under direct observation and the reason for doing so.

(3) In a case where the employee refuses to provide a specimen under direct observation (see § 40.191(a)(4)), you must discard any specimen the employee provided previously during the collection procedure. Then you must notify the DER as soon as practicable.

[65 FR 79526, Dec. 19, 2000, as amended at 66 FR 41950, Aug. 9, 2001; 88 FR 27641, May 2, 2023]

§ 40.67 When and how is a directly observed urine collection conducted?

(a) As an employer, you must direct an immediate collection under direct observation with no advance notice to the employee, if:

(1) The laboratory reported to the MRO that a specimen is invalid, and the MRO reported to you that there was not an adequate medical explanation for the result;

(2) The MRO reported to you that the original positive, adulterated, or substituted result had to be cancelled because the test of the split specimen could not be performed; or

(3) The laboratory reported to the MRO that the specimen was negative-dilute with a creatinine concentration greater than or equal to 2 mg/dL but less than or equal to 5 mg/dL, and the MRO reported the specimen to you as negative-dilute and that a second collection must take place under direct observation (see § 40.197(b)(1)).

(4) You realize a collection under direct observation was required but was not conducted or the service agent informs you that a direct observation should have been collected but was not (*see* paragraph (n) of this section).

(b) As an employer, you must direct a collection under direct observation of an employee if the drug test is a return-to-duty test or a follow-up test.

(c) As a collector, you must immediately conduct a collection under direct observation if:

(1) You are directed by the DER to do so (see paragraph (a) of this section); or

(2) You observed materials brought to the collection site or the employee's conduct clearly indicates an attempt to tamper with a specimen (see §§ 40.61(f)(5)(i) and 40.63(e)); or

(3) The temperature on the original specimen was out of range (*see* § 40.65(b)(5));

(4) The original specimen appeared to have been tampered with (*see* § 40.65(c)(1)); or

(5) The test reason is return-to-duty or follow-up.

(d)

(1) As the employer, you must explain to the employee the reason for a directly observed collection under paragraph (a) or (b) of this section.

(2) As the collector, you must explain to the employee the reason, if known, under this part for a directly observed collection.

(e) As the collector, you must complete a new CCF for the directly observed collection.

(1) You must mark the “reason for test” block (Step 1) the same as for the first collection.

(2) You must check the “Observed, (Enter Remark)” box and enter the reason (see paragraphs (c)(2) through (4) of this section) in the “Remarks” line (Step 2).

(f) In a case where two sets of specimens are being sent to the laboratory because of suspected tampering with the specimen at the collection site, enter on the “Remarks” line of the CCF (Step 2) for each specimen a notation to this effect (*e.g.,* collection 1 of 2, or 2 of 2) and the specimen ID number of the other specimen.

(g) As the collector, you must ensure that the observer is the same gender as the employee.

(1) You must never permit an opposite gender person to act as the observer.

(2) The observer can be a different person from the collector and need not be a qualified collector.

(3) If a same gender collector cannot be found or in circumstances of nonbinary or transgender employees:

(i) If the employer has a standing order to allow oral fluid testing in such situations, the collector will follow that order;

(ii) If there is no standing order from the employer, the collector must contact the DER and either conduct an oral fluid test if the collection site is able to do so, or send the employee to a collection site acceptable to the employer for the oral fluid test.

(h) As the collector, if someone else is to observe the collection (*e.g.,* in order to ensure a same gender observer), you must verbally instruct that person to follow procedures at paragraphs (i) and (j) of this section. If you, the collector, are the observer, you too must follow these procedures.

(i) As the observer, you must request the employee to raise his or her shirt, blouse, or dress/skirt, as appropriate, above the waist; and lower clothing and underpants to show you, by turning around, that they do not have a prosthetic device. After you have determined that the employee does not have such a device, you may permit the employee to return clothing to its proper position for observed urination.

(j) As the observer, you must watch the employee urinate into the collection container. Specifically, you are to watch the urine go from the employee's body into the collection container.

(k) As the observer but not the collector, you must not take the collection container from the employee, but you must observe the specimen as the employee takes it to the collector.

(l) As the collector, when someone else has acted as the observer, you must include the observer's name in the “Remarks” line of the CCF (Step 2).

(m) As the employee, if you decline to allow a directly observed collection required or permitted under this section to occur, this is a refusal to test.

(n) As a service agent, when you learn that a directly observed collection should have been collected but was not, you must inform the employer that it must direct the employee to have an immediate recollection under direct observation.

[65 FR 79526, Dec. 19, 2000, as amended at 66 FR 41950, Aug. 9, 2001; 68 FR 31626, May 28, 2003; 69 FR 64867, Nov. 9, 2004; 73 FR 35970, June 25, 2008; 73 FR 50223, Aug. 26, 2008; 73 FR 62910, Oct. 22, 2008; 73 FR 70284, Nov. 20, 2008; 74 FR 37952, July 30, 2009; 82 FR 52244, Nov. 13, 2017; 88 FR 27641, May 2, 2023]

§ 40.69 How is a monitored urine collection conducted?

(a) As stated in § 40.42(f)(2), if you are conducting a urine collection in a multi-stall restroom and you cannot secure all sources of water and other substances that could be used for adulteration and substitution, you must conduct a monitored collection. This is the only circumstance in which you must conduct a monitored collection.

(b) As the collector, you must secure the room being used for the monitored collection so that no one except the employee and the monitor can enter it until after the collection has been completed.

(c) As the collector, you must ensure that the monitor is the same gender as the employee, unless the monitor is a medical professional (e.g., nurse, doctor, physician's assistant, technologist, or technician licensed or certified to practice in the jurisdiction in which the collection takes place). The monitor can be a different person from the collector and need not be a qualified collector.

(d) As the collector, if someone else is to monitor the collection (e.g., in order to ensure a same-gender monitor), you must verbally instruct that person to follow the procedures of paragraphs (d) and (e) of this section. If you, the collector, are the monitor, you must follow these procedures.

(e) As the monitor, you must not watch the employee urinate into the collection container. If you hear sounds or make other observations indicating an attempt to tamper with a specimen, there must be an additional collection under direct observation. *See* §§ 40.63(e), 40.65(c), and 40.67(c)(2)(3)).

(f) As the monitor, you must ensure that the employee takes the collection container directly to the collector as soon as the employee has exited the enclosure.

(g) As the collector, when someone else has acted as the monitor, you must note that person's name in the “Remarks” line of the CCF (Step 2).

(h) As the employee being tested, if you decline to permit a collection authorized under this section to be monitored, it is a refusal to test.

[65 FR 79526, Dec. 19, 2000, as amended at 66 FR 41951, Aug. 9, 2001; 88 FR 27641, May 2, 2023]

§ 40.71 How does the collector prepare the urine specimen?

(a) All collections under DOT agency drug testing regulations must be split specimen collections.

(b) As the collector, you must take the following steps, in order, after the employee brings the urine specimen to you. You must take these steps in the presence of the employee.

(1) After the collection, check the box on the CCF (Step 2) indicating that this was a “Urine” and “Split” specimen collection.

(2) You, not the employee, must first pour at least 30 mL of urine from the collection container into one specimen bottle, to be used for the primary specimen.

(3) You, not the employee, must then pour at least 15 mL of urine from the collection container into the second specimen bottle to be used for the split specimen.

(4) You, not the employee, must place and secure (*i.e.,* tighten or snap) the lids/caps on the bottles.

(5) You, not the employee, must seal the bottles by placing the tamper-evident bottle seals over the bottle caps/lids and down the sides of the bottles.

(6) You, not the employee, must then write the date on the tamper-evident bottle seals.

(7) You must then ensure that the employee initials the tamper-evident bottle seals for the purpose of certifying that the bottles contain the specimens he or she provided. If the employee fails or refuses to do so, you must note this in the “Remarks” line of the CCF (Step 2) and complete the collection process.

(8) You must discard any urine left over in the collection container after both specimen bottles have been appropriately filled and sealed. There is one exception to this requirement: you may use excess urine to conduct clinical tests (e.g., protein, glucose) if the collection was conducted in conjunction with a physical examination required by a DOT agency regulation. Neither you nor anyone else may conduct further testing (such as adulteration testing) on this excess urine and the employee has no legal right to demand that the excess urine be turned over to the employee.

[65 FR 79526, Dec. 19, 2000, as amended at 66 FR 41951, Aug. 9, 2001; 88 FR 27641, May 2, 2023]

§ 40.72 What steps does the collector take in the collection process before the employee provides an oral fluid specimen?

(a) The collector requests that the employee open the employee's mouth, and the collector inspects the oral cavity to ensure that it is free of any items that could impede or interfere with the collection of an oral fluid specimen (*e.g.*, candy, gum, food, or tobacco) or could be used to adulterate, substitute, or alter the specimen.

(1) If the collector finds indication(s) of anything identified above, the collector will ask the employee to lift their tongue and/or separate their cheek from their gum to permit full inspection. If this occurs, the employee may cleanse his or her hands, but must not decline the collector's request for further inspection.

(2) If the employee claims that he or she has a medical condition that prevents opening his or her mouth for inspection, the collector follows the procedure described in § 40.193(a).

(3) If the collector observes materials brought to the collection site or the employee's conduct clearly indicates an attempt to adulterate, substitute, or alter the specimen, the collector must terminate the collection, note the circumstances in the Remarks section of the CCF, and report the circumstances to the DER, so that the employer can decide whether to deem the situation a refusal in accordance with § 40.191(a).

(b) If an item is present that might impede or interfere with the collection of an oral fluid specimen, the collector must request the employee remove the item.

(1) If the employee removes any item that could impede or interfere with the collection of an oral fluid specimen, the employee has abnormally colored saliva, or the employee claims to have “dry mouth,” then the collector must give the employee water, up to 8 ounces, to rinse their mouth. The employee may drink the water. The collector must then wait 10 minutes before beginning the specimen collection.

(2) If the employee refuses to remove the item or rinse, the collector must terminate the collection, note the circumstances in the Remarks section of the CCF, and report the information to the DER to test as described in § 40.191(a)(8) (failure to cooperate), so that the employer can decide whether to deem the situation a refusal.

(c) If there is nothing of concern in the oral cavity and no “dry mouth” condition, the collector starts a 10-minute wait period and proceeds with the steps below before beginning the specimen collection as described in § 40.73.

(d) During the 10-minute wait period:

(1) Review with the employee the procedures required for a successful oral fluid specimen collection as stated in the manufacturer's instructions for the specimen collection device.

(2) Complete all items under Step 1 of the CCF, and for clarification:

(i) In Step 1.D of the CCF, the collector must put a check mark for the “Specify DOT Agency” under whose authority the test will take place.

(ii) In Step 1.G of the CCF for the “Collection Site Address”, the collector must provide the address where the collection took place.

(3) The collector will provide, or the employee may select, a specimen collection device that is clean, unused, and wrapped/sealed in original packaging.

(i) The collector will check the expiration date on the device or the package containing the device and show it to the employee.

(ii) The collector must not use the device after its expiration date.

(iii) The collector must open the specimen collection device in view of the employee.

(4) The collector will complete Step 2 of the CCF.

(i) Check “Oral Fluid”,

(ii) For “Oral Fluid: Split Type” check “Subdivided”, and

(iii) Check “Each Device Within Expiration Date?” after ensuring the device is within its expiration date.

(5) The collector will enter the Split Specimen Device Expiration Date in Step 4 of the CCF. Since the collector will use one oral fluid device that will collect a single specimen, which is then subdivided in the presence of the donor, only one entry in Step 4 is to be made for the device expiration date.

(6) The collector must instruct the employee to use hand sanitizer or wash and dry his or her hands.

(e) To the greatest extent practicable, the collector must keep the employee's unwrapped collection device within view of both the collector and the employee, between the time the employee has provided a specimen and the specimen is sealed.

[88 FR 27642, May 2, 2023]

§ 40.73 How is an oral fluid specimen collected?

(a) The collector must be present and maintain visual contact with the employee during the procedures outlined in this section.

(b) The collector must note any unusual behavior or appearance of the employee on the CCF. If the collector detects any conduct that clearly indicates an attempt to tamper with a specimen (*e.g.,* an attempt to bring into the collection site an adulterant or oral fluid substitute), the collector must terminate the collection and report the information to the DER so that the employer can decide whether to deem the situation a refusal.

(c) The employee and collector must complete the specimen collection in accordance with the manufacturer's instructions for the collection device.

(1) Under the observation of the collector, the employee is responsible for positioning the specimen collection device for collection.

(2) The collector must ensure the collection is performed correctly (*i.e.,* using the oral fluid device in the manner described by its manufacturer), that the collection device is working properly, and that a sufficient specimen volume is collected.

(3) If the employee states that he or she is unable to provide an oral fluid specimen or provides an insufficient specimen during the collection process, the collector must continue to make one attempt to collect, after an insufficient specimen, the collector follows the procedure in § 40.193.

(4) The collector must inspect the specimen for unusual color, presence of foreign objects or material, or other signs of tampering. If it is apparent from this inspection that the employee has tampered with the specimen, the collector must conduct a new collection.

(i) Document any unusual characteristics referenced above in the Remarks section of the CCF.

(ii) Proceed with obtaining the new oral fluid specimen from the donor. Note on the new CCF that this is another collection for the same testing event (*i.e.,* Document in the remarks section that this is Specimen 2 of 2 and include the Specimen ID number of the other specimen). Make the same notation on the CCF of the suspect specimen.

[88 FR 27642, May 2, 2023]

§ 40.74 How does the collector prepare the oral fluid specimens?

(a) The collector follows the manufacturer's instructions to package the split specimen collections.

(b) A volume of at least 1 mL of undiluted (neat) oral fluid is collected for the specimen designated as “Bottle A”, and a volume of at least 1 mL of undiluted (neat) oral fluid is collected for the specimen designated as “Bottle B”, or an otherwise sufficient amount of oral fluid is collected to permit an HHS-certified laboratory to analyze the specimen(s).

(c) In the presence of the employee, the collector places a tamper-evident seal from the CCF over the cap of each specimen container, taking care not to obstruct the expiration date on the collection containers. The collector must record the date of the collection on the tamper-evident seals, after they are affixed to the specimen containers.

(d) The collector instructs the employee to initial the tamper-evident seals on each specimen container. If the employee declines to do so, the collector must note this in the "Remarks" line of the CCF (Step 2) and complete the collection process.

[88 FR 27642, May 2, 2023]

§§ 40.75-40.78 [Reserved]

§ 40.79 How is the collection process completed?

(a) As the collector, when using the paper CCF, you must do the following things to complete the collection process. You must complete the steps called for in paragraphs (a)(1) through (7) of this section in the employee's presence.

(1) Direct the employee to read and sign the certification statement on Copy 2 of the CCF and provide all information required in Step 5. If the employee declines to sign the CCF or to provide any of the required information, you must note this in the "Remarks" line (Step 2) of the CCF and complete the collection. If the employee declines to fill out any information, you must, as a minimum, print the employee's name in the appropriate place.

(2) Complete the chain of custody on the CCF (Step 4) by printing your name (note: you may pre-print your name), recording the time and date of the collection, signing the statement, and entering the name of the delivery service transferring the specimen to the laboratory,

(3) Ensure that all copies of the CCF are legible and complete.

(4) Remove Copy 5 of the CCF and give it to the employee.

(5) Place the specimen bottles and Copy 1 of the CCF in the appropriate pouches of the plastic bag.

(6) Secure both pouches of the plastic bag.

(7) Advise the employee that he or she may leave the collection site.

(8) To prepare the sealed plastic bag containing the specimens and CCF for shipment you must:

(i) Place the sealed plastic bag in a shipping container (*e.g.,* standard courier box) designed to minimize the possibility of damage during shipment. (More than one sealed plastic bag can be placed into a single shipping container if you are doing multiple collections.)

(ii) Seal the container as appropriate.

(iii) If a laboratory courier hand-delivers the specimens from the collection site to the laboratory, prepare the sealed plastic bag for shipment as directed by the courier service.

(9) Send Copy 2 of the CCF to the MRO and Copy 4 to the DER. You must fax or otherwise transmit these copies to the MRO and DER within 24 hours or during the next business day. Keep Copy 3 for at least 30 days, unless otherwise specified by applicable DOT agency regulations.

(b) As a collector, when using other forms of the CCF as approved by the Office of Management and Budget, you must follow the procedures approved for that form.

(c) As a collector or collection site, you must ensure that each specimen you collect is shipped to a laboratory as quickly as possible, but in any case, within 24 hours or during the next business day.

[65 FR 79526, Dec. 19, 2000, as amended at 71 FR 49384, Aug. 23, 2006; 80 FR 19553, Apr. 13, 2015. Redesignated and amended at 88 FR 27641, 27643, May 2, 2023]

Subpart F—Drug Testing Laboratories

§ 40.81 What laboratories may be used for DOT drug testing?

(a) As a drug testing laboratory located in the U.S., you are permitted to participate in DOT drug testing only if you are certified by HHS under the National Laboratory Certification Program (NLCP) for each specimen testing methodology performed required under this part.

(b) As a drug testing laboratory located in Canada or Mexico which is not certified by HHS under the NLCP, you are permitted to participate in DOT drug testing only if:

(1) The DOT, based on a written recommendation from HHS, has approved your laboratory as meeting HHS laboratory certification standards or deemed your laboratory fully equivalent to a laboratory meeting HHS laboratory certification standards for all testing required under this part; or

(2) The DOT, based on a written recommendation from HHS, has recognized a Canadian or Mexican certifying organization as having equivalent laboratory certification standards and procedures to those of HHS, and the Canadian or Mexican certifying organization has certified your laboratory under those equivalent standards and procedures.

(c) As a laboratory participating in the DOT drug testing program, you must comply with the requirements of this part. You must also comply with all applicable requirements of HHS in testing DOT specimens, whether or not the HHS requirements are explicitly stated in this part.

(d) If DOT determines that you are in noncompliance with this part, you could be subject to PIE proceedings under Subpart R of this part. If the Department issues a PIE with respect to you, you are ineligible to participate in the DOT drug testing program even if you continue to meet the requirements of paragraph (a) or (b) of this section.

[65 FR 79526, Dec. 19, 2000, as amended at 88 FR 27643, May 2, 2023]

§ 40.82 What drugs do laboratories test for?

As a laboratory, you must test for the following five drugs or classes of drugs in a DOT drug test. You must not test "DOT specimens" for any other drugs.

(a) Marijuana metabolites.

(b) Cocaine metabolites.

(c) Amphetamines.

(d) Opioids.

(e) Phencyclidine (PCP).

[82 FR 52244, Nov. 13, 2017. Redesignated at 88 FR 27643, May 2, 2023]

§ 40.83 How do laboratories process incoming specimens?

As the laboratory, you must do the following when you receive a DOT specimen:

(a) You are authorized to receive only Copy 1 of the CCF. You are not authorized to receive other copies of the CCF or any copies of the alcohol testing form.

(b) You must comply with applicable provisions of the HHS Guidelines concerning accessioning and processing drug specimens.

(c) You must inspect each specimen and CCF for the following "fatal flaws":

(1) There is no CCF;

(2) In cases where a specimen has been collected, there is no specimen submitted with the CCF;

(3) There is no printed collector's name and no collector's signature;

(4) Two separate collections are performed using one CCF;

(5) The specimen ID numbers on the specimen bottle and the CCF do not match;

(6) The specimen bottle seal is broken or shows evidence of tampering, unless a split specimen can be redesignated (see paragraph (h) of this section);

(7) There is an insufficient amount of specimen in the primary bottle for analysis, unless the specimens can be redesignated (see paragraph (h) of this section).

(8) For an oral fluid collection, the collector used an expired device at the time of collection.

(9) For an oral fluid collection, if the collector failed to enter the expiration date in Step 4 of the CCF and the laboratory is unable to determine the expiration date by inspecting Bottles A and B.

(d) When you find a specimen meeting the criteria of paragraph (c) of this section, you must document your findings and stop the testing process. Report the result in accordance with § 40.97(a)(3) .

(e) You must inspect each CCF for the presence of the collector's signature on the certification statement in Step 4 of the CCF. Upon finding that the signature is omitted, document the flaw and continue the testing process.

(1) In such a case, you must retain the specimen for a minimum of 5 business days from the date on which you initiated action to correct the flaw.

(2) You must then attempt to correct the flaw by following the procedures of § 40.205(b)(1).

(3) If the flaw is not corrected, report the result as rejected for testing in accordance with § 40.97(a)(3).

(f) If you determine that the urine specimen temperature was not checked and the “Remarks” line did not contain an entry regarding the temperature being outside of range, you must then attempt to correct the problem by following the procedures of § 40.208.

(1) In such a case, you must continue your efforts to correct the problem for five business days, before you report the result.

(2) When you have obtained the correction, or five business days have elapsed, report the result in accordance with § 40.97(a).

(g) If you determine that a CCF that fails to meet the requirements of § 40.40(a) (e.g., a non-Federal form or an expired Federal form was used for the collection), you must attempt to correct the use of the improper form by following the procedures of § 40.205(b)(2).

(1) In such a case, you must retain the specimen for a minimum of 5 business days from the date on which you initiated action to correct the problem.

(2) If the problem(s) is not corrected, you must reject the test and report the result in accordance with § 40.97(a)(3).

(h) If the CCF is marked indicating that a split specimen collection was collected and if the split specimen does not accompany the primary, has leaked, or is otherwise unavailable for testing, you must still test the primary specimen and follow appropriate procedures outlined in § 40.175(b) regarding the unavailability of the split specimen for testing.

(1) The primary specimen and the split specimen can be redesignated (*i.e.,* Bottle B is redesignated as Bottle A, and vice-versa) if:

(i) The primary specimen appears to have leaked out of its sealed bottle and the laboratory believes a sufficient amount of specimen exists in the split specimen to conduct all appropriate primary laboratory testing; or

(ii) The primary specimen is labeled as Bottle B, and the split specimen as Bottle A; or

(iii) The laboratory opens the split specimen instead of the primary specimen, the primary specimen remains sealed, and the laboratory believes a sufficient amount of specimen exists in the split specimen to conduct all appropriate primary laboratory testing; or

(iv) The primary specimen seal is broken but the split specimen remains sealed and the laboratory believes a sufficient amount of specimen exists in the split specimen to conduct all appropriate primary laboratory testing.

(2) In situations outlined in paragraph (h)(1) of this section, the laboratory shall mark through the “A” and write “B,” then initial and date the change. A corresponding change shall be made to the other bottle by marking through the “B” and writing “A,” and initialing and dating the change.

(i) A notation shall be made on Copy 1 of the CCF (Step 5a) and on any laboratory internal chain of custody documents, as appropriate, for any fatal or correctable flaw.

[65 FR 79526, Dec. 19, 2000, as amended at 66 FR 41951, Aug. 9, 2001; 71 FR 49384, Aug. 23, 2006; 73 FR 35970, June 25, 2008; 75 FR 59107, Sept. 27, 2010; 82 FR 52244, Nov 13, 2017; 88 FR 27643, May 2, 2023]

§ 40.84 How long does the laboratory retain specimens after testing?

(a) As a laboratory testing the primary specimen, you must retain a specimen that was reported with positive, adulterated, substituted, or invalid results for a minimum of one year.

(b) You must keep such a specimen in secure, long-term, frozen storage in accordance with HHS requirements.

(c) Within the one-year period, the MRO, the employee, the employer, or a DOT agency may request in writing that you retain a specimen for an additional period of time (*e.g.,* for the purpose of preserving evidence for litigation or a safety investigation). If you receive such a request, you must comply with it. If you do not receive such a request, you may discard the specimen at the end of the year.

(d) If you have not sent the split specimen to another laboratory for testing, you must retain the split specimen for an employee's test for the same period of time that you retain the primary specimen and under the same storage conditions.

(e) As the laboratory testing the split specimen, you must meet the requirements of paragraphs (a) through (d) of this section with respect to the split specimen.

[65 FR 79526, Dec. 19, 2000. Redesignated at 88 FR 27643, May 2, 2023]

§ 40.85 What are the cutoff concentrations for urine drug tests?

(a) As a laboratory, you must use the cutoff concentrations displayed in the following table for initial and confirmatory drug tests. All cutoff concentrations are expressed in nanograms per milliliter (ng/mL). The table follows:

Initial test analyte	Initial test cutoff[1]	Confirmatory test analyte	Confirmatory test cutoff concentration
Marijuana metabolites (THCA)[2]	50 ng/mL[3]	THCA	15 ng/mL.
Cocaine metabolite (Benzoylecgonine)	150 ng/mL[3]	Benzoylecgonine	100 ng/mL.
Codeine/ Morphine	2000 ng/mL	Codeine Morphine	2000 ng/mL. 2000 ng/mL.
Hydrocodone/ Hydromorphone	300 ng/mL	Hydrocodone Hydromorphone	100 ng/mL. 100 ng/mL.
Oxycodone/ Oxymorphone	100 ng/mL	Oxycodone Oxymorphone	100 ng/mL. 100 ng/mL.
6-Acetylmorphine	10 ng/mL	6-Acetylmorphine	10 ng/mL.
Phencyclidine	25 ng/mL	Phencyclidine	25 ng/mL.
Amphetamine/ Methamphetamine	500 ng/mL	Amphetamine Methamphetamine	250 ng/mL. 250 ng/mL.

Initial test analyte	Initial test cutoff[1]	Confirmatory test analyte	Confirmatory test cutoff concentration
MDMA[4]/MDA[5]	500 ng/mL	MDMA MDA	250 ng/mL. 250 ng/mL.

[1] For grouped analytes (i.e., two or more analytes that are in the same drug class and have the same initial test cutoff):

Immunoassay: The test must be calibrated with one analyte from the group identified as the target analyte. The cross-reactivity of the immunoassay to the other analyte(s) within the group must be 80 percent or greater; if not, separate immunoassays must be used for the analytes within the group.

Alternate technology: Either one analyte or all analytes from the group must be used for calibration, depending on the technology. At least one analyte within the group must have a concentration equal to or greater than the initial test cutoff or, alternatively, the sum of the analytes present (i.e., equal to or greater than the laboratory's validated limit of quantification) must be equal to or greater than the initial test cutoff.

[2] An immunoassay must be calibrated with a target analyte.

[3] *Alternate technology (THCA and Benzoylecgonine):* When using an alternate technology initial test for the specific target analytes of THCA and Benzoylecgonine, the laboratory must use the same cutoff for the initial and confirmatory tests (i.e., 15 ng/mL for THCA and 100ng/mL for Benzoylecgonine).

[4] Methylenedioxymethamphetamine (MDMA).

[5] Methylenedioxyamphetamine (MDA).

(b) On an initial drug test, you must report a result below the cutoff concentration as negative. If the result is at or above the cutoff concentration, you must conduct a confirmation test.

(c) On a confirmation drug test, you must report a result below the cutoff concentration as negative and a result at or above the cutoff concentration as confirmed positive.

(d) You must report quantitative values for morphine or codeine at 15,000 ng/mL or above.

[65 FR 79526, Dec. 19, 2000, as amended at 75 FR 49862, Aug. 16, 2010; 77 FR 26473, May 4, 2012; 82 FR 52244, Nov. 13, 2017. Redesignated and amended at 88 FR 27643, May 2, 2023]

§ 40.86 What is urine validity testing, and are laboratories required to conduct it?

(a) Specimen validity testing is the evaluation of the specimen to determine if it is consistent with normal human urine. The purpose of validity testing is to determine whether certain adulterants or foreign substances were added to the urine, if the urine was diluted, or if the specimen was substituted.

(b) As a laboratory, you must conduct validity testing.

[65 FR 79526, Dec. 19, 2000, as amended at 66 FR 41951, Aug. 9, 2001; 73 FR 35970, June 25, 2008. Redesignated at 88 FR 27643, May 2, 2023]

§ 40.87 What validity tests must laboratories conduct on primary urine specimens?

As a laboratory, when you conduct validity testing under § 40.86, you must conduct it in accordance with the requirements of this section.

(a) You must determine the creatinine concentration on each primary specimen. You must also determine its specific gravity if you find the creatinine concentration to be less than 20 mg/dL.

(b) You must determine the pH of each primary specimen.

(c) You must perform one or more validity tests for oxidizing adulterants on each primary specimen.

(d) You must perform additional validity tests on the primary specimen when the following conditions are observed:

(1) Abnormal physical characteristics;

(2) Reactions or responses characteristic of an adulterant obtained during initial or confirmatory drug tests (*e.g.*, non-recovery of internal standards, unusual response); or

(3) Possible unidentified interfering substance or adulterant.

(e) If you determine that the specimen is invalid and HHS guidelines direct you to contact the MRO, you must contact the MRO and together decide if testing the primary specimen by another HHS certified laboratory would be useful in being able to report a positive or adulterated test result.

[65 FR 79526, Dec. 19, 2000, as amended at 69 FR 64867, Nov. 9, 2004. Redesignated and amended at 88 FR 27643, May 2, 2023]

§ 40.88 What criteria do laboratories use to establish that a urine specimen is dilute or substituted?

(a) As a laboratory, you must consider the primary specimen to be dilute when:

(1) The creatinine concentration is greater than or equal to 2 mg/dL but less than 20 mg/dL, and

(2) The specific gravity is greater than 1.0010 but less than 1.0030 on a single aliquot.

(b) As a laboratory, you must consider the primary specimen to be substituted when the creatinine concentration is less than 2 mg/dL and the specific gravity is less than or equal to 1.0010 or greater than or equal to 1.0200 on both the initial and confirmatory creatinine tests and on both the initial and confirmatory specific gravity tests on two separate aliquots.

[69 FR 64867, Nov. 9, 2004. Redesignated at 88 FR 27643, May 2, 2023]

§ 40.89 What are the adulterant cutoff concentrations for initial and confirmation urine tests?

(a) As a laboratory, you must use the cutoff concentrations for the initial and confirmation adulterant testing as required by the HHS Mandatory Guidelines and you must use two separate aliquots—one for the initial test and another for the confirmation test.

(b) As a laboratory, you must report results at or above the cutoffs (or for pH, at or above or below the values, as appropriate) as adulterated and provide the numerical value that supports the adulterated result.

[73 FR 35970, June 25, 2008. Redesignated at 88 FR 27643, May 2, 2023]

§ 40.90 What criteria do laboratories use to establish that a urine specimen is invalid?

(a) As a laboratory, you must use the invalid test result criteria for the initial and confirmation testing as required by the HHS Mandatory Guidelines, and you must use two separate aliquots—one for the initial test and another for the confirmation test.

(b) As a laboratory, for a specimen having an invalid result for one of the reasons outlined in the HHS Mandatory Guidelines, you must contact the MRO to discuss whether sending the specimen to another HHS certified laboratory for testing would be useful in being able to report a positive or adulterated result.

(c) As a laboratory, you must report invalid results in accordance with the invalid test result criteria as required by the HHS Guidelines and provide the numerical value that supports the invalid result, where appropriate, such as pH.

(d) As a laboratory, you must report the reason a test result is invalid.

[73 FR 35970, June 25, 2008. Redesignated at 88 FR 27643, May 2, 2023]

§ 40.91 What are the cutoff concentrations for oral fluid drug tests?

As a laboratory, you must use the cutoff concentrations displayed in the following table for initial and confirmatory drug tests for oral fluid specimens. All cutoff concentrations are expressed in nanograms per milliliter (ng/mL). The table follows:

Table 1 to § 40.91—Oral Fluid Testing Cutoff Concentrations

Initial test analyte	Initial test cutoff[1]	Confirmatory test analyte	Confirmatory test cutoff concentration
Marijuana (THC)[2]	4 ng/mL[3]	THC	2 ng/mL.
Cocaine/Benzoylecgonine	15 ng/mL	Cocaine Benzoylecgonine	8 ng/mL. 8 ng/mL.
Codeine/Morphine	30 ng/mL	Codeine Morphine	15 ng/mL. 15 ng/mL.
Hydrocodone/Hydromorphone	30 ng/mL	Hydrocodone Hydromorphone	15 ng/mL. 15 ng/mL.
Oxycodone/Oxymorphone	30 ng/mL	Oxycodone Oxymorphone	15 ng/mL. 15 ng/mL.
6-Acetylmorphine	4 ng/mL[3]	6-Acetylmorphine	2 ng/mL.
Phencyclidine	10 ng/mL	Phencyclidine	10 ng/mL.
Amphetamine/Methamphetamine	50 ng/mL	Amphetamine Methamphetamine	25 ng/mL. 25 ng/mL.
MDMA[4]/MDA[5]	50 ng/mL	MDMA MDA	25 ng/mL. 25 ng/mL.

[1] For grouped analytes (*i.e.,* two or more analytes that are in the same drug class and have the same initial test cutoff):

Immunoassay: The test must be calibrated with one analyte from the group identified as the target analyte. The cross reactivity of the immunoassay to the other analyte(s) within the group must be 80 percent or greater; if not, separate immunoassays must be used for the analytes within the group.

Alternate technology: Either one analyte or all analytes from the group must be used for calibration, depending on the technology. At least one analyte within the group must have a concentration equal to or greater than the initial test cutoff or, alternatively, the sum of the analytes present (*i.e.,* with concentrations equal to or greater than the laboratory's validated limit of quantification) must be equal to or greater than the initial test cutoff.

[2] An immunoassay must be calibrated with the target analyte.

[3] *Alternate technology (THC and 6-AM):* The confirmatory test cutoff must be used for an alternate technology initial test that is specific for the target analyte (*i.e.,* 2 ng/mL for THC, 2 ng/mL for 6-AM).

[4] Methylenedioxymethamphetamine (MDMA).

[5] Methylenedioxyamphetamine (MDA).

[88 FR 27643, May 2, 2023]

§ 40.92 What is oral fluid validity testing, and are laboratories required to conduct it?

(a) Specimen validity testing is the evaluation of the specimen to determine if it is consistent with normal human oral fluid. The purpose of validity testing is to determine whether certain adulterants or foreign substances were added to the oral fluid, if the oral fluid was altered.

(b) If a specimen exhibits abnormal characteristics (*e.g.,* unusual odor or color), causes reactions or responses characteristic of an adulterant during initial or confirmatory drug tests (*e.g.,* non-recovery of internal standard, unusual response), or contains an unidentified substance that interferes with the confirmatory analysis, then you may conduct validity testing.

(c) If you determine that the specimen is invalid and HHS guidelines direct you to contact the MRO, you must contact the MRO and together decide if testing the primary specimen by another HHS-certified laboratory would be useful in being able to report a positive or adulterated test result.

[88 FR 27643, May 2, 2023]

§ 40.93 What validity tests must laboratories conduct on primary oral fluid specimens?

As a laboratory, if you conduct validity testing under § 40.92, you must conduct it in accordance with the requirements of this section.

(a) You may test for a biomarker such as albumin or immunoglobulin G (IgG) or a test for a specific adulterant.

(b) You must follow the applicable HHS requirements for any additional validity testing.

[88 FR 27643, May 2, 2023]

§ 40.97 What do laboratories report and how do they report it?

(a) As a laboratory, when reporting a result of any kind, you must report the specimen type.

(b) You must also report the results for each primary specimen, which will fall into one of the following three categories. As a laboratory, you must report the actual results (and not the categories):

(1) ***Category 1: Negative results.*** As a laboratory, when you find a specimen to be negative, you must report the test result as being one of the following, as applicable:

(i) Negative, or

(ii) For urine only, negative-dilute, with numerical values for creatinine and specific gravity.

(2) ***Category 2: Non-negative results.*** As a laboratory, when you find a specimen to be non-negative, you must report the test result as being one or more of the following, as applicable:

(i) Positive, with drug(s)/metabolite(s) noted, with numerical values for the drug(s) or drug metabolite(s).

(ii) Adulterated, with adulterant(s) noted, with confirmatory test values (when applicable), and with remarks(s);

(iii) For urine only, positive-dilute, with drug(s)/metabolite(s) noted, with numerical values for the drug(s) or drug metabolite(s) and with numerical values for creatinine and specific gravity;

(iv) For urine only, substituted, with confirmatory test values for creatinine and specific gravity; or

(v) For urine only, invalid result, with remark(s). Laboratories will report actual values for pH results.

(vi) For oral fluid only, invalid result, with remark(s). Laboratories must report numerical values of the specimen validity test results that support a specimen reported as invalid.

(3) ***Category 3: Rejected for testing.*** As a laboratory, when you reject a specimen for testing, you must report the result as being Rejected for Testing, with remark(s).

(c) As a laboratory, you must report laboratory results directly, and only, to the MRO at his or her place of business. You must not report results to or through the DER or a service agent (*e.g.,* a C/TPA).

(1) Negative results: You must fax, courier, mail, or electronically transmit a legible image or copy of the fully completed Copy 1 of the CCF which has been signed by the certifying scientist, or you may provide the laboratory results report electronically (*i.e.,* computer data file).

(i) If you elect to provide the laboratory results report, you must include the following elements, as a minimum, in the report format:

(A) Laboratory name and address;

(B) Employer's name (you may include I.D. or account number);

(C) Medical review officer's name;

(D) Specimen I.D. number;

(E) SSN or Employee ID from Step 1C of the CCF, if provided;

(F) Reason for test, if provided;

(G) Collector's name and telephone number;

(H) Date of the collection;

(I) For oral fluid only, collection device expiration date;

(J) Date received at the laboratory;

(K) Date certifying scientist released the results;

(L) Certifying scientist's name;

(M) Results (*e.g.,* positive, adulterated) as listed in paragraph (a) of this section; and

(N) Remarks section, with an explanation of any situation in which a correctable flaw has been corrected.

(ii) You may release the laboratory results report only after review and approval by the certifying scientist. It must reflect the same test result information as contained on the CCF signed by the certifying scientist. The information contained in the laboratory results report must not contain information that does not appear on the CCF.

(iii) The results report may be transmitted through any means that ensures accuracy and confidentiality. You, as the laboratory, together with the MRO, must ensure that the information is adequately protected from unauthorized access or release, both during transmission and in storage (*e.g., see* § 40.351).

(2) Non-negative and Rejected for Testing results: You must fax, courier, mail, or electronically transmit a legible image or copy of the fully completed Copy 1 of the CCF that has been signed by the certifying scientist. In addition, you may provide the electronic laboratory results report following the format and procedures set forth in paragraphs (b)(1)(i) and (ii) of this section.

(d) In transmitting laboratory results to the MRO, you, as the laboratory, together with the MRO, must ensure that the information is adequately protected from unauthorized access or release, both during transmission and in storage. If the results are provided by fax or other electronic means, the electronic communication must be accessible only to authorized individuals.

(e) You must transmit test results to the MRO in a timely manner, preferably the same day that review by the certifying scientist is completed.

(f)

(1) You must provide quantitative values for confirmed positive drug test results to the MRO.

(2) You must provide numerical values that support the adulterated (when applicable) or substituted result, without a request from the MRO.

(3) You must also provide the MRO numerical values for creatinine and specific gravity for the negative-dilute urine test result, without a request from the MRO.

(g) You must provide quantitative values for confirmed positive morphine and/or codeine urine results at or below 15,000 ng/mL, and for confirmed positive morphine or codeine oral fluid results at or below 150 ng/mL.

[88 FR 27644, May 2, 2023]

§ 40.101 What relationship may a laboratory have with an MRO?

(a) As a laboratory, you may not enter into any relationship with an MRO that creates a conflict of interest or the appearance of a conflict of interest with the MRO's responsibilities for the employer. You may not derive any financial benefit by having an employer use a specific MRO.

(b) The following are examples of relationships between laboratories and MROs that the Department regards as creating conflicts of interest, or the appearance of such conflicts. This following list of examples is not intended to be exclusive or exhaustive:

(1) The laboratory employs an MRO who reviews test results produced by the laboratory;

(2) The laboratory has a contract or retainer with the MRO for the review of test results produced by the laboratory;

(3) The laboratory designates which MRO the employer is to use, gives the employer a slate of MROs from which to choose, or recommends certain MROs;

(4) The laboratory gives the employer a discount or other incentive to use a particular MRO;

(5) The laboratory has its place of business co-located with that of an MRO or MRO staff who review test results produced by the laboratory; or

(6) The laboratory permits an MRO, or an MRO's organization, to have a financial interest in the laboratory.

§ 40.107 Who may inspect laboratories?

As a laboratory, you must permit an inspection, with or without prior notice, by ODAPC, a DOT agency, or a DOT-regulated employer that contracts with the laboratory for drug testing under the DOT drug testing program, or the designee of such an employer.

§ 40.109 What documentation must the laboratory keep, and for how long?

(a) As a laboratory, you must retain all records pertaining to each employee urine specimen for a minimum of two years.

(b) As a laboratory, you must also keep for two years employer-specific data required in § 40.111.

(c) Within the two-year period, the MRO, the employee, the employer, or a DOT agency may request in writing that you retain the records for an additional period of time (*e.g.,* for the purpose of preserving evidence for litigation or a safety investigation). If you receive such a request, you must comply with it. If you do not receive such a request, you may discard the records at the end of the two-year period.

§ 40.111 When and how must a laboratory disclose statistical summaries and other information it maintains?

(a) As a laboratory, you must transmit an aggregate statistical summary, by employer, of the data listed in appendix D of this part with respect to each specimen type for which you conduct tests to the employer on a semi-annual basis.

(1) The summary must not reveal the identity of any employee.

(2) In order to avoid sending data from which it is likely that information about an employee's test result can be readily inferred, you must not send a summary if the employer has fewer than five aggregate tests results.

(3) The summary must be sent by January 20 of each year for July 1 through December 31 of the prior year.

(4) The summary must also be sent by July 20 of each year for January 1 through June 30 of the current year.

(b) When the employer requests a summary in response to an inspection, audit, or review by a DOT agency, you must provide it unless the employer had fewer than five aggregate test results. In that case, you must send the employer a report indicating that not enough testing was conducted to warrant a summary. You may transmit the summary or report by hard copy, fax, or other electronic means.

(c) You must also release information to appropriate parties as provided in §§ 40.329 and 40.331.

(d) As a laboratory, you must transmit an aggregate statistical summary listed in appendix E of this part for each specimen type for which you conduct testing to DOT on a semi-annual basis. The summary must be sent by January 31 of each year for July 1 through December 31 of the prior year. It must be sent by July 31 of each year for January 1 through June 30 of the current year. If you withdraw or are removed from NLCP's laboratory certification during a reporting period, you must provide the aggregate statistical summary to the DOT-regulated employers and to ODAPC for the last reporting period in which you conducted DOT-regulated testing.

[65 FR 79526, Dec. 19, 2000, as amended at 73 FR 35971, June 25, 2008; 88 FR 27645, May 2, 2023]

§ 40.113 Where is other information concerning laboratories found in this regulation?

You can find more information concerning laboratories in several sections of this part:

§ 40.3—Definition.
§ 40.13—Prohibition on making specimens available for other purposes.
§ 40.31—Conflicts of interest concerning collectors.
§ 40.47—Laboratory rejections of test for improper form.
§ 40.125—Conflicts of interest concerning MROs.
§ 40.175—Role of first laboratory in split specimen tests.
§ 40.177—Role of second laboratory in split specimen tests (drugs).
§ 40.179—Role of second laboratory in split specimen tests (adulterants).
§ 40.181—Role of second laboratory in split specimen tests (substitution).
§§ 40.183–40.185—Transmission of split specimen test results to MRO.
§§ 40.201–40.205—Role in correcting errors.
§ 40.329—Release of information to employees.
§ 40.331—Limits on release of information.
§ 40.355—Role with respect to other service agents.

Subpart G—Medical Review Officers and the Verification Process

§ 40.121 Who is qualified to act as an MRO?

To be qualified to act as an MRO in the DOT drug testing program, you must meet each of the requirements of this section:

(a) ***Credentials.*** You must be a licensed physician (Doctor of Medicine or Osteopathy). If you are a licensed physician in any U.S., Canadian, or Mexican jurisdiction and meet the other requirements of this section, you are authorized to perform MRO services with respect to all covered employees, wherever they are located. For example, if you are licensed as an M.D. in one state or province in the U.S., Canada, or Mexico, you are not limited to performing MRO functions in that state or province, and you may perform MRO functions for employees in other states or provinces without becoming licensed to practice medicine in the other jurisdictions.

(b) ***Basic knowledge.*** You must be knowledgeable in the following areas:

(1) You must be knowledgeable about and have clinical experience in controlled substances abuse disorders, including detailed knowledge of alternative medical explanations for laboratory confirmed drug test results.

(2) You must be knowledgeable about issues relating to adulterated and substituted specimens as well as the possible medical causes of specimens having an invalid result.

(3) You must be knowledgeable about this part, the DOT MRO Guidelines, and the DOT agency regulations applicable to the employers for whom you evaluate drug test results, and you must keep current on any changes to these materials. You must subscribe to the ODAPC list-serve at *https://www.transportation.gov/odapc/get-odapc-email-updates.* DOT agency regulations, DOT MRO Guidelines, and other materials are available from ODAPC (Department of Transportation, 1200 New Jersey Avenue SE, Washington, DC 20590, 202–366–3784), or on the ODAPC Web site (*http://www.transportation.gov/odapc*).

(c) ***Qualification training.*** You must receive qualification training meeting the requirements of this paragraph (c).

(1) Qualification training must provide instruction on the following subjects:

(i) Collection procedures for specimens;

(ii) Chain of custody, reporting, and recordkeeping;

(iii) Interpretation of drug and validity tests results;

(iv) The role and responsibilities of the MRO in the DOT drug testing program;

(v) The interaction with other participants in the program (*e.g.,* DERs, SAPs); and

(vi) Provisions of this part and DOT agency rules applying to employers for whom you review test results, including changes and updates to this part and DOT agency rules, guidance, interpretations, and policies affecting the performance of MRO functions, as well as issues that MROs confront in carrying out their duties under this part and DOT agency rules.

(2) Following your completion of qualification training under paragraph (c)(1) of this section, you must satisfactorily complete an examination administered by a nationally-recognized MRO certification board or subspecialty board for medical practitioners in the field of medical review of DOT-mandated drug tests. The examination must comprehensively cover all the elements of qualification training listed in paragraph (c)(1) of this section.

(3) You must meet the requirements of paragraphs (a), (b), and (c) of this section before you begin to perform MRO functions.

(d) ***Requalification training.*** During each five-year period from the date on which you satisfactorily completed the examination under paragraph (c)(2) of this section, you must complete requalification training.

(1) This requalification training must meet the requirements of the qualification training under paragraph (c)(1) of this section.

(2) Following your completion of requalification training, you must satisfactorily complete an examination administered by a nationally-recognized MRO certification board or subspecialty board for medical practitioners in the field of medical review of DOT-mandated drug tests. The examination must comprehensively cover all the elements of qualification training listed in paragraph (c)(1) of this section.

(e) ***Documentation.*** You must maintain documentation showing that you currently meet all requirements of this section. You must provide this documentation on request to DOT agency representatives and to employers and C/TPAs who are using or negotiating to use your services.

[65 FR 79526, Dec. 19, 2000, as amended at 66 FR 41951, Aug. 9, 2001; 75 FR 49862, Aug. 16, 2010; 82 FR 52245, Nov. 13, 2017; 88 FR 27645, May 2, 2023]

§ 40.123 What are the MRO's responsibilities in the DOT drug testing program?

As an MRO, you have the following basic responsibilities:

(a) Acting as an independent and impartial “gatekeeper” and advocate for the accuracy and integrity of the drug testing process.

(b) Providing a quality assurance review of the drug testing process for the specimens under your purview. This includes, but is not limited to:

(1) Ensuring the review of the CCF on all specimen collections for the purposes of determining whether there is a problem that may cause a test to be cancelled (see §§ 40.199–40.203). As an MRO, you are not required to review laboratory internal chain of custody documentation. No one is permitted to cancel a test because you have not reviewed this documentation;

(2) Providing feedback to employers, collection sites and laboratories regarding performance issues where necessary; and

(3) Reporting to and consulting with the ODAPC or a relevant DOT agency when you wish DOT assistance in resolving any program issue. As an employer or service agent, you are prohibited from limiting or attempting to limit the MRO's access to DOT for this purpose and from retaliating in any way against an MRO for discussing drug testing issues with DOT.

(c) You must determine whether there is a legitimate medical explanation for confirmed positive, adulterated, substituted, and invalid results from the laboratory.

(d) While you provide medical review of employees' test results, this part does not deem that you have established a doctor-patient relationship with the employees whose tests you review.

(e) You must act to investigate and correct problems where possible and notify appropriate parties (*e.g.,* HHS, DOT, employers, service agents) where assistance is needed, (*e.g.,* cancelled or problematic tests, incorrect results).

(f) You must ensure the timely flow of test results and other information to employers.

(g) You must protect the confidentiality of the drug testing information.

(h) You must perform all your functions in compliance with this part and other DOT agency regulations.

[65 FR 79526, Dec. 19, 2000, as amended at 82 FR 52245, Nov. 13, 2017; 88 FR 27645, May 2, 2023]

§ 40.125 What relationship may an MRO have with a laboratory?

As an MRO, you may not enter into any relationship with an employer's laboratory that creates a conflict of interest or the appearance of a conflict of interest with your responsibilities to that employer. You may not derive any financial benefit by having an employer use a specific laboratory. For examples of relationships between laboratories and MROs that the Department views as creating a conflict of interest or the appearance of such a conflict, see § 40.101(b).

§ 40.127 What are the MRO's functions in reviewing negative test results?

As the MRO, you must do the following with respect to negative drug test results you receive from a laboratory, prior to verifying the result and releasing it to the DER:

(a) Review Copy 2 of the CCF to determine if there are any fatal or correctable errors that may require you to initiate corrective action or to cancel the test (see §§ 40.199 and 40.203).

(b) Review the negative laboratory test result and ensure that it is consistent with the information contained on the CCF.

(c) Before you report a negative test result, you must have in your possession the following documents:

(1) Copy 2 of the CCF, a legible copy of it, or any other CCF copy containing the employee's signature; and

(2) A legible copy (fax, photocopy, image) of Copy 1 of the CCF or the electronic laboratory results report that conveys the negative laboratory test result.

(d) If the copy of the documentation provided to you by the collector or laboratory appears unclear, you must request that the collector or laboratory send you a legible copy.

(e) On Copy 2 of the CCF, place a check mark in the “Negative” box (Step 6), provide your name, and sign, initial, or stamp and date the verification statement.

(f) Report the result in a confidential manner (see §§ 40.163–40.167).

(g) Staff under your direct, personal supervision may perform the administrative functions of this section for you, but only you can cancel a test. If you cancel a laboratory-confirmed negative result, check the “Test Cancelled” box (Step 6) on Copy 2 of the CCF, make appropriate annotation in the “Remarks” line, provide your name, and sign,

initial or stamp and date the verification statement.

(1) On specimen results that are reviewed by your staff, you are responsible for assuring the quality of their work.

(2) You are required to personally review at least 5 percent of all CCFs reviewed by your staff on a quarterly basis, including all results that required a corrective action. However, you need not review more than 500 negative results in any quarter of all specimen types combined.

(3) Your review must, as a minimum, include the CCF, negative laboratory test result, any accompanying corrective documents, and the report sent to the employer. You must correct any errors that you discover. You must take action as necessary to ensure compliance by your staff with this part and document your corrective action. You must attest to the quality assurance review by initialing the CCFs that you review.

(4) You must make these CCFs easily identifiable and retrievable by you for review by DOT agencies.

[65 FR 79526, Dec. 19, 2000, as amended at 66 FR 41951, Aug. 9, 2001; 88 FR 27645, May 2, 2023]

§ 40.129 What are the MRO's functions in reviewing laboratory confirmed non-negative drug test results?

(a) As the MRO, you must do the following with respect to confirmed positive, adulterated, substituted, or invalid results you receive from a laboratory, before you verify the result and release it to the DER:

(1) Review Copy 2 of the CCF to determine if there are any fatal or correctable errors that may require you to cancel the test (see §§ 40.199 and 40.203). Staff under your direct, personal supervision may conduct this administrative review for you, but only you may verify or cancel a test.

(2) Review Copy 1 of the CCF and ensure that it is consistent with the information contained on Copy 2, that the test result is legible, and that the certifying scientist signed the form. You are not required to review any other documentation generated by the laboratory during their analysis or handling of the specimen (*e.g.,* the laboratory internal chain of custody).

(3) If the copy of the documentation provided to you by the collector or laboratory appears unclear, you must request that the collector or laboratory send you a legible copy.

(4) Except in the circumstances spelled out in § 40.133 , conduct a verification interview. This interview must include direct contact in person or by telephone between you and the employee. You may initiate the verification process based on the laboratory results report.

(5) Verify the test result, consistent with the requirements of §§ 40.135 through 40.145, 40.159, and 40.160, as:

(i) Negative; or

(ii) Cancelled; or

(iii) Positive, and/or refusal to test because of adulteration or substitution.

(b) Before you report a verified negative, positive, refusal to test because of adulteration or substitution, you must have in your possession the following documents:

(1) Copy 2 of the CCF, a legible copy of it, or any other CCF copy containing the employee's signature; and

(2) A legible copy (fax, photocopy, image) of Copy 1 of the CCF, containing the certifying scientist's signature.

(c) With respect to verified positive test results, place a checkmark in the “Positive” box in Step 6 on Copy 2 of the CCF, indicate the drug(s)/metabolite(s) verified positive, and sign and date the verification statement.

(d) If you cancel a laboratory confirmed positive, adulterated, substituted, or invalid result, check the “test cancelled” box (Step 6) on Copy 2 of the CCF, make appropriate annotation in the “Remarks” line, sign, provide your name, and date the verification statement.

(e) Report the result in a confidential manner (see §§ 40.163–40.167).

(f) With respect to adulteration or substitution test results, check the “refusal to test because:” box (Step 6) on Copy 2 of the CCF, check the “Adulterated” or “Substituted” box, as appropriate, make appropriate annotation in the “Remarks” line, sign and date the verification statement.

(g) As the MRO, your actions concerning reporting confirmed positive, adulterated, or substituted results to the employer before you have completed the verification process are also governed by the stand-down provisions of § 40.21 .

(1) If an employer has a stand-down policy that meets the requirements of § 40.21 , you may report to the DER that you have received an employee's laboratory confirmed positive, adulterated, or substituted test result, consistent with the terms of the waiver the employer received. You must not provide any further details about the test result (*e.g.,* the name of the drug involved).

(2) If the employer does not have a stand-down policy that meets the requirements of § 40.21, you must not inform the employer that you have received an employee's laboratory confirmed positive, adulterated, or substituted test result until you verify the test result. For example, as an MRO employed directly by a company, you must not tell anyone on the company's staff or management that you have received an employee's laboratory confirmed test result.

[65 FR 79526, Dec. 19, 2000, as amended at 66 FR 41952, Aug. 9, 2001; 73 FR 35971, June 25, 2008; 75 FR 59107, Sept. 27, 2010; 88 FR 27645, May 2, 2023]

§ 40.131 How does the MRO or DER notify an employee of the verification process after receiving laboratory confirmed non-negative drug test results?

(a) When, as the MRO, you receive a confirmed positive, adulterated, substituted, or invalid test result from the laboratory, you must contact the employee directly (*i.e.,* actually talk to the employee), on a confidential basis, to determine whether the employee wants to discuss the test result. In making this contact, you must explain to the employee that, if he or she declines to discuss the result, you will verify the test as positive or as a refusal to test because of adulteration or substitution, as applicable.

(b) As the MRO, staff under your personal supervision may conduct this initial contact for you.

(1) This staff contact must be limited to scheduling the discussion between you and the employee and explaining the consequences of the employee's declining to speak with you (*i.e.,* that the MRO will verify the test without input from the employee). If the employee declines to speak with you, the staff person must document the employee's decision, including the date and time.

(2) A staff person must not gather any medical information or information concerning possible explanations for the test result.

(3) A staff person may advise an employee to have medical information (*e.g.,* prescriptions, information forming the basis of a legitimate medical explanation for a confirmed positive test result) ready to present at the interview with the MRO.

(4) Since you are required to speak personally with the employee, face-to-face or on the phone, your staff must not inquire if the employee wishes to speak with you.

(c) As the MRO, you or your staff must make reasonable efforts to reach the employee at the day and evening telephone numbers listed on the CCF. Reasonable efforts include, as a minimum, three attempts, spaced reasonably over a 24-hour period, to reach the employee at the day and evening telephone numbers listed on the CCF. If you or your staff cannot reach the employee directly after making these efforts, you or your staff must take the following steps:

(1) Document the efforts you made to contact the employee, including dates and times. If both phone numbers are incorrect (*e.g.,* disconnected, wrong number), you may take the actions listed in paragraph (c)(2) of this section without waiting the full 24-hour period.

(2) Contact the DER, instructing the DER to contact the employee.

(i) You must simply direct the DER to inform the employee to contact you.

(ii) You must not inform the DER that the employee has a confirmed positive, adulterated, substituted, or invalid test result.

(iii) You must document the dates and times of your attempts to contact the DER, and you must document the name of the DER you contacted and the date and time of the contact.

(d) As the DER, you must attempt to contact the employee immediately, using procedures that protect, as much as possible, the confidentiality of the MRO's request that the employee contact the MRO. If you successfully contact the employee (i.e., actually talk to the employee), you must document the date and time of the contact, and inform the MRO. You must inform the employee that he or she should contact the MRO immediately. You must also inform the employee of the consequences of failing to contact the MRO within the next 72 hours (see § 40.133(a)(2)).

(1) As the DER, you must not inform anyone else working for the employer that you are seeking to contact the employee on behalf of the MRO.

(2) If, as the DER, you have made all reasonable efforts to contact the employee but failed to do so, you may place the employee on temporary medically unqualified status or medical leave. Reasonable efforts include, as a minimum, three attempts, spaced reasonably over a 24-hour period, to reach the employee at the day and evening telephone numbers listed on the CCF.

(i) As the DER, you must document the dates and times of these efforts.

(ii) If, as the DER, you are unable to contact the employee within this 24-hour period, you must leave a message for the employee by any practicable means (*e.g.,* voice mail, e-mail, letter) to contact the MRO and inform the MRO of the date and time of this attempted contact.

[65 FR 79526, Dec. 19, 2000, as amended at 66 FR 41952, Aug. 9, 2001; 68 FR 31626, May 28, 2003; 69 FR 64867, Nov. 9, 2004]

§ 40.133 Without interviewing the employee, under what circumstances may the MRO verify a test result as positive, or as a refusal to test because of adulteration or substitution, or as cancelled because the test was invalid?

(a) As the MRO, you normally may verify a confirmed positive test (for any drug or drug metabolite, including opiates), or as a refusal to test because of adulteration or substitution, only after interviewing the employee as provided in §§ 40.135–40.145 . However, there are three circumstances in which you may verify such a result without an interview:

(1) You may verify a test result as a positive or refusal to test, as applicable, if the employee expressly declines the opportunity to discuss the test with you. You must maintain complete documentation of this occurrence, including notation of informing, or attempting to inform, the employee of the consequences of not exercising the option to speak with the you.

(2) You may verify a test result as a positive or refusal to test, as applicable, if the DER has successfully made and documented a contact with the employee and instructed the employee to contact you and more than 72 hours have passed since the time the DER contacted the employee.

(3) You may verify a test result as a positive or refusal to test, as applicable, if neither you nor the DER, after making and documenting all reasonable efforts, has been able to contact the employee within ten days of the date on which the MRO receives the confirmed test result from the laboratory.

(b) As the MRO, you may verify an invalid test result as cancelled (with instructions to recollect immediately under direct observation) without interviewing the employee, as provided at § 40.159:

(1) If the employee expressly declines the opportunity to discuss the test with you;

(2) If the DER has successfully made and documented a contact with the employee and instructed the employee to contact you and more than 72 hours have passed since the time the DER contacted the employee; or

(3) If neither you nor the DER, after making and documenting all reasonable efforts, has been able to contact the employee within ten days of the date on which you received the confirmed invalid test result from the laboratory.

(c) As the MRO, after you verify a test result as a positive or as a refusal to test under this section, you must document the date and time and reason, following the instructions in § 40.163. For a cancelled test due to an invalid result under this section, you must follow the instructions in § 40.159(a)(5).

(d) As the MRO, after you have verified a test result under this section and reported the result to the DER, you must allow the employee to present information to you within 60 days of the verification to document that serious illness, injury, or other circumstances unavoidably precluded contact with the MRO and/or DER in the times provided. On the basis

of such information, you may reopen the verification, allowing the employee to present information concerning whether there is a legitimate medical explanation of the confirmed test result.

[65 FR 79526, Dec. 19, 2000, as amended at 73 FR 35971, June 25, 2008]

§ 40.135 What does the MRO tell the employee at the beginning of the verification interview?

(a) As the MRO, you must tell the employee that the laboratory has determined that the employee's test result was positive, adulterated, substituted, or invalid, as applicable. You must also tell the employee of the drugs for which his or her specimen tested positive, or the basis for the finding of adulteration or substitution.

(b) You must explain the verification interview process to the employee and inform the employee that your decision will be based on information the employee provides in the interview.

(c) You must explain that, if further medical evaluation is needed for the verification process, the employee must comply with your request for this evaluation and that failure to do so is equivalent of expressly declining to discuss the test result.

(d) As the MRO, you must warn an employee who has a confirmed positive, adulterated, substituted or invalid result that you are required to provide to third parties drug test result information and medical information affecting the performance of safety-sensitive duties that the employee gives you in the verification process without the employee's consent (see § 40.327).

(1) You must give this warning to the employee before obtaining any medical information as part of the verification process.

(2) For purposes of this paragraph (d), medical information includes information on medications or other substances affecting the performance of safety-sensitive duties that the employee reports using or medical conditions the employee reports having.

(3) For purposes of this paragraph (d), the persons to whom this information may be provided include the employer, a SAP evaluating the employee as part of the return to duty process (see § 40.293(g)), DOT, another Federal safety agency (*e.g.,* the NTSB), or any state safety agency as required by state law.

(e) You must also advise the employee that, before informing any third party about any medication the employee is using pursuant to a legally valid prescription consistent with the Controlled Substances Act, you will allow 5 business days from the date you report the verified negative result for the employee to have the prescribing physician contact you to determine if the medication can be changed to one that does not make the employee medically unqualified or does not pose a significant safety risk. If, in your reasonable medical judgment, a medical qualification issue or a significant safety risk remains after you communicate with the employee's prescribing physician or after 5 business days, whichever is shorter, you must follow § 40.327. If, as the MRO, you receive information that eliminates the medical qualification issue or significant safety risk, you must transmit this information to any third party to whom you previously provided information under § 40.327.

[65 FR 79526, Dec. 19, 2000, as amended at 66 FR 41952, Aug. 9, 2001; 82 FR 52245, Nov. 13, 2017; 88 FR 27645, May 2, 2023]

§ 40.137 On what basis does the MRO verify test results involving marijuana, cocaine, amphetamines, semi-synthetic opioids, or PCP?

(a) As the MRO, you must verify a confirmed positive test result for marijuana, cocaine, amphetamines, semi-synthetic opioids (*i.e.,* hydrocodone, hydromorphone, oxycodone, and oxymorphone), and/or PCP unless the employee presents a legitimate medical explanation for the presence of the drug(s)/metabolite(s) in his or her system. In determining whether an employee's legally valid prescription consistent with the Controlled Substances Act for a substance in these categories constitutes a legitimate medical explanation, you must not question whether the prescribing physician should have prescribed the substance.

(b) You must offer the employee an opportunity to present a legitimate medical explanation in all cases.

(c) The employee has the burden of proof that a legitimate medical explanation exists. The employee must present information meeting this burden at the time of the verification interview. As the MRO, you have discretion to extend the time available to the employee for this purpose for up to five days before verifying the test result, if you

determine that there is a reasonable basis to believe that the employee will be able to produce relevant evidence concerning a legitimate medical explanation within that time.

(d) If you determine that there is a legitimate medical explanation, you must verify the test result as negative. Otherwise, you must verify the test result as positive.

(e) In determining whether a legitimate medical explanation exists, you may consider the employee's use of a medication from a foreign country. You must exercise your professional judgment consistently with the following principles:

(1) There can be a legitimate medical explanation only with respect to a substance that is obtained legally in a foreign country.

(2) There can be a legitimate medical explanation only with respect to a substance that has a legitimate medical use. Use of a drug of abuse (*e.g.*, heroin, PCP, marijuana) or any other substance (see § 40.151(f) and (g)) that cannot be viewed as having a legitimate medical use can never be the basis for a legitimate medical explanation, even if the substance is obtained legally in a foreign country.

(3) Use of the substance can form the basis of a legitimate medical explanation only if it is used consistently with its proper and intended medical purpose.

(4) Even if you find that there is a legitimate medical explanation under this paragraph (e) and verify a test negative, you may have a responsibility to raise fitness-for-duty considerations with the employer (see § 40.327).

[65 FR 79526, Dec. 19, 2000, as amended at 82 FR 52245, Nov. 13, 2017]

§ 40.139 On what basis does the MRO verify test results involving 6-acetylmorphine, codeine, and morphine?

As the MRO, you must proceed as follows when you receive a laboratory confirmed positive opiate result:

(a) If the laboratory confirms the presence of 6-acetylmorphine (6–AM) in the specimen, you must verify the test result positive.

(b) In the absence of 6–AM, if the laboratory confirms the presence of either morphine or codeine equal to or above 15,000 ng/mL (in urine) or equal to or above 150 ng/mL (in oral fluid), you must verify the test result as positive, unless the employee presents a legitimate medical explanation for the presence of the drug or drug metabolite in his or her system, as in the case of other drugs (see § 40.137). Consumption of food products (*e.g.*, poppy seeds) must not be considered a legitimate medical explanation for the employee having morphine or codeine at these concentrations.

(c) For all other codeine and morphine positive results, you must verify a confirmed positive test result only if you determine that there is clinical evidence, in addition to the test, of unauthorized use of any opium, opiate, or opium derivative (*i.e.*, morphine, codeine, or heroin).

(1) As an MRO, it is your responsibility to use your best professional and ethical judgement and discretion to determine whether there is clinical evidence of unauthorized use of opiates. Examples of information that you may consider in making this judgement include, but are not limited to, the following:

(i) Recent needle tracks;

(ii) Behavioral and psychological signs of acute opiate intoxication or withdrawal;

(iii) Clinical history of unauthorized use recent enough to have produced the laboratory test result;

(iv) Use of a medication from a foreign country. See § 40.137(e) for guidance on how to make this determination.

(2) In order to establish the clinical evidence referenced in paragraphs (c)(1)(i) and (ii) of this section, personal observation of the employee is essential.

(i) Therefore, you, as the MRO, must conduct, or cause another physician to conduct, a face-to-face examination of the employee.

(ii) No face-to-face examination is needed in establishing the clinical evidence referenced in paragraph (c)(1)(iii) or (iv) of this section.

(3) To be the basis of a verified positive result for codeine or morphine, the clinical evidence you find must concern a drug that the laboratory found in the specimen. (For example, if the test confirmed the presence of codeine, and the employee admits to unauthorized use of hydrocodone, you must not verify the test positive for codeine. The admission must be for the substance that was found through the actual drug test.)

(4) As the MRO, you have the burden of establishing that there is clinical evidence of unauthorized use of opiates referenced in this paragraph (c). If you cannot make this determination (e.g., there is not sufficient clinical evidence or history), you must verify the test as negative. The employee does not need to show you that a legitimate medical explanation exists if no clinical evidence is established.

[77 FR 26473, May 4, 2012, as amended at 82 FR 52245, Nov. 13, 2017; 88 FR 27645, May 2, 2023]

§ 40.141 How does the MRO obtain information for the verification decision?

As the MRO, you must do the following as you make the determinations needed for a verification decision:

(a) You must conduct a medical interview. You must review the employee's medical history and any other relevant biomedical factors presented to you by the employee. You may direct the employee to undergo further medical evaluation by you or another physician.

(b) If the employee asserts that the presence of a drug or drug metabolite in his or her specimen results from taking prescription medication (*i.e.,* a legally valid prescription consistent with the Controlled Substances Act), you must review and take all reasonable and necessary steps to verify the authenticity of all medical records the employee provides.

(1) You may contact the employee's physician or other relevant medical personnel for further information.

(i) If you decide to contact the employee's pharmacy to authenticate whether the prescription offered by the employee was filled by the pharmacy, you or staff under your operational control can contact the pharmacy.

(ii) If you utilize staff to perform the inquiry in paragraph (b)(1)(i) of this section, you must ensure operational control over the hiring, firing, evaluation of the staff and you must oversee the performance of the function of contacting a pharmacy to authenticate specific prescription(s) (*e.g.,* outline or script what the staff will ask the pharmacy; occasionally monitor calls to assure quality control; or other methods to ensure the staff are properly conducting the calls with the pharmacies).

(2) You may request an HHS-certified laboratory with validated protocols (*see* § 40.81(c)) to conduct testing for D,L stereoisomers of amphetamine and methamphetamine or testing for tetrahydrocannabivarin (THC–V) when verifying lab results, as you determine necessary.

[65 FR 79526, Dec. 19, 2000, as amended at 82 FR 52245, Nov. 13, 2017; 88 FR 27645, May 2, 2023]

§ 40.143 [Reserved]

§ 40.145 On what basis does the MRO verify test results involving adulteration or substitution?

(a) As an MRO, when you receive a laboratory report that a specimen is adulterated or substituted, you must treat that report in the same way you treat the laboratory's report of a confirmed positive for a drug or drug metabolite.

(b) You must follow the same procedures used for verification of a confirmed positive test for a drug or drug metabolite (see §§ 40.129–40.135, 40.141, 40.151), except as otherwise provided in this section.

(c) In the verification interview, you must explain the laboratory findings to the employee and address technical questions or issues the employee may raise.

(d) You must offer the employee the opportunity to present a legitimate medical explanation for the laboratory findings with respect to presence of the adulterant in, or the creatinine and specific gravity findings for, the specimen.

(e) The employee has the burden of proof that there is a legitimate medical explanation.

(1) To meet this burden in the case of an adulterated specimen, the employee must demonstrate that the adulterant found by the laboratory entered the specimen through physiological means.

(2) To meet this burden in the case of a substituted specimen, the employee must demonstrate that he or she did produce or could have produced urine through physiological means, meeting the creatinine concentration criterion of less than 2 mg/dL and the specific gravity criteria of less than or equal to 1.0010 or greater than or equal to 1.0200 (see § 40.93(b)).

(3) The employee must present information meeting this burden at the time of the verification interview. As the MRO, you have discretion to extend the time available to the employee for this purpose for up to five days before verifying the specimen, if you determine that there is a reasonable basis to believe that the employee will be able to produce relevant evidence supporting a legitimate medical explanation within that time.

(f) As the MRO or the employer, you are not responsible for arranging, conducting, or paying for any studies, examinations or analyses to determine whether a legitimate medical explanation exists.

(g) As the MRO, you must exercise your best professional judgment in deciding whether the employee has established a legitimate medical explanation.

(1) If you determine that the employee's explanation does not present a reasonable basis for concluding that there may be a legitimate medical explanation, you must report the test to the DER as a verified refusal to test because of adulteration or substitution, as applicable.

(2) If you believe that the employee's explanation may present a reasonable basis for concluding that there is a legitimate medical explanation, you must direct the employee to obtain, within the five-day period set forth in paragraph (e)(3) of this section, a further medical evaluation. This evaluation must be performed by a licensed physician (the “referral physician”), acceptable to you, with expertise in the medical issues raised by the employee's explanation. (The MRO may perform this evaluation if the MRO has appropriate expertise.)

(i) As the MRO or employer, you are not responsible for finding or paying a referral physician. However, on request of the employee, you must provide reasonable assistance to the employee's efforts to find such a physician. The final choice of the referral physician is the employee's, as long as the physician is acceptable to you.

(ii) As the MRO, you must consult with the referral physician, providing guidance to him or her concerning his or her responsibilities under this section. As part of this consultation, you must provide the following information to the referral physician:

(A) That the employee was required to take a DOT drug test, but the laboratory reported that the specimen was adulterated or substituted, which is treated as a refusal to test;

(B) The consequences of the appropriate DOT agency regulation for refusing to take the required drug test;

(C) That the referral physician must agree to follow the requirements of paragraphs (g)(3) through (g)(4) of this section; and

(D) That the referral physician must provide you with a signed statement of his or her recommendations.

(3) As the referral physician, you must evaluate the employee and consider any evidence the employee presents concerning the employee's medical explanation. You may conduct additional tests to determine whether there is a legitimate medical explanation. Any additional drug tests must be performed in an HHS-certified laboratory.

(4) As the referral physician, you must then make a written recommendation to the MRO about whether the MRO should determine that there is a legitimate medical explanation. As the MRO, you must seriously consider and assess the referral physician's recommendation in deciding whether there is a legitimate medical explanation.

(5) As the MRO, if you determine that there is a legitimate medical explanation, you must cancel the test and inform ODAPC in writing of the determination and the basis for it (*e.g.,* referral physician's findings, evidence produced by the employee).

(6) As the MRO, if you determine that there is not a legitimate medical explanation, you must report the test to the DER as a verified refusal to test because of adulteration or substitution.

(h) The following are examples of types of evidence an employee could present to support an assertion of a legitimate medical explanation for a substituted urine result.

(1) Medically valid evidence demonstrating that the employee is capable of physiologically producing urine meeting the creatinine and specific gravity criteria of § 40.93(b).

(i) To be regarded as medically valid, the evidence must have been gathered using appropriate methodology and controls to ensure its accuracy and reliability.

(ii) Assertion by the employee that his or her personal characteristics (*e.g.,* with respect to race, gender, weight, diet, working conditions) are responsible for the substituted result does not, in itself, constitute a legitimate medical explanation. To make a case that there is a legitimate medical explanation, the employee must present evidence showing that the cited personal characteristics actually result in the physiological production of urine meeting the creatinine and specific gravity criteria of § 40.93(b).

(2) Information from a medical evaluation under paragraph (g) of this section that the individual has a medical condition that has been demonstrated to cause the employee to physiologically produce urine meeting the creatinine and specific gravity criteria of § 40.93(b).

(i) A finding or diagnosis by the physician that an employee has a medical condition, in itself, does not constitute a legitimate medical explanation.

(ii) To establish there is a legitimate medical explanation, the employee must demonstrate that the cited medical condition actually results in the physiological production of urine meeting the creatinine and specific gravity criteria of § 40.93(b).

[65 FR 79526, Dec. 19, 2000, as amended at 68 FR 31626, May 28, 2003; 69 FR 64867, Nov. 9, 2004; 88 FR 27646, May 2, 2023]

§ 40.147 [Reserved]

§ 40.149 May the MRO change a verified drug test result?

(a) As the MRO, you may change a verified test result only in the following situations:

(1) When you have reopened a verification that was done without an interview with an employee (see § 40.133(d)).

(2) If you receive information, not available to you at the time of the original verification, demonstrating that the laboratory made an error in identifying (*e.g.,* a paperwork mistake) or testing (*e.g.,* a false positive or negative) the employee's primary or split specimen. For example, suppose the laboratory originally reported a positive test result for Employee X and a negative result for Employee Y. You verified the test results as reported to you. Then the laboratory notifies you that it mixed up the two test results, and X was really negative and Y was really positive. You would change X's test result from positive to negative and contact Y to conduct a verification interview.

(3) If, within 60 days of the original verification decision—

(i) You receive information that could not reasonably have been provided to you at the time of the decision demonstrating that there is a legitimate medical explanation for the presence of drug(s)/metabolite(s) in the employee's specimen; or

(ii) You receive credible new or additional evidence that a legitimate medical explanation for an adulterated or substituted result exists.

> *Example to paragraph (a)(3):* If the employee's physician provides you a valid prescription that he or she failed to find at the time of the original verification, you may change the test result from positive to negative if you conclude that the prescription provides a legitimate medical explanation for the drug(s)/ metabolite(s) in the employee's specimen.

(4) If you receive the information in paragraph (a)(3) of this section after the 60-day period, you must consult with ODAPC prior to changing the result.

(5) When you have made an administrative error and reported an incorrect result.

(b) If you change the result, you must immediately notify the DER in writing, as provided in §§ 40.163–40.165.

(c) You are the only person permitted to change a verified test result, such as a verified positive test result or a determination that an individual has refused to test because of adulteration or substitution. This is because, as the MRO, you have the sole authority under this part to make medical determinations leading to a verified test (e.g., a determination that there was or was not a legitimate medical explanation for a laboratory test result). For example, an arbitrator is not permitted to overturn the medical judgment of the MRO that the employee failed to present a legitimate medical explanation for a positive, adulterated, or substituted test result of his or her specimen.

[65 FR 79526, Dec. 19, 2000, as amended at 66 FR 41952, Aug. 9, 2001; 73 FR 35971, June 25, 2008]

§ 40.151 What are MROs prohibited from doing as part of the verification process?

As an MRO, you are prohibited from doing the following as part of the verification process:

(a) You must not consider any evidence (verbal or written information) from any drug tests that are not collected or tested in accordance with this part. For example, if an employee tells you he went to his own physician, provided a urine specimen, sent it to a laboratory, and received a negative test result, you are required to ignore this test result.

(b) It is not your function to make decisions about factual disputes between the employee and the collector concerning matters occurring at the collection site that are not reflected on the CCF (*e.g.,* concerning allegations that the collector left the area or left open collection containers where other people could access them.)

(c) It is not your function to determine whether the employer should have directed that a test occur. For example, if an employee tells you that the employer misidentified her as the subject of a random test, or directed her to take a reasonable suspicion or post-accident test without proper grounds under a DOT agency drug or alcohol regulation, you must inform the employee that you cannot play a role in deciding these issues.

(d) It is not your function to consider explanations of confirmed positive, adulterated, or substituted test results that would not, even if true, constitute a legitimate medical explanation. For example, an employee may tell you that someone slipped amphetamines into her drink at a party, that she unknowingly ingested a marijuana brownie, or that she traveled in a closed car with several people smoking crack. MROs are unlikely to be able to verify the facts of such passive or unknowing ingestion stories. Even if true, such stories do not present a legitimate medical explanation. Consequently, you must not declare a test as negative based on an explanation of this kind.

(e) You must not verify a test negative based on information that a physician recommended that the employee use a drug listed in Schedule I of the Controlled Substances Act. (*e.g.,* under a state law that purports to authorize such recommendations, such as the "medical marijuana" laws that some states have adopted).

(f) You must not accept an assertion of consumption or other use of a hemp or other non-prescription marijuana-related product as a basis for verifying a marijuana test negative. You also must not accept such an explanation related to consumption of coca teas as a basis for verifying a cocaine test result as negative. Consuming or using such a product is not a legitimate medical explanation.

(g) You must not accept an assertion that there is a legitimate medical explanation for the presence of PCP, 6–AM, MDMA, or MDA in a specimen.

(h) You must not accept, as a legitimate medical explanation for an adulterated specimen, an assertion that soap, bleach, or glutaraldehyde entered a specimen through physiological means. There are no physiological means through which these substances can enter a specimen.

(i) You must not accept, as a legitimate medical explanation for a substituted specimen, an assertion that an employee can produce a urine specimen for which the creatinine level is below the laboratory's limit of detection. There are no physiological means through which a person can produce a urine specimen having this characteristic.

[65 FR 79526, Dec. 19, 2000, as amended at 66 FR 41952, Aug. 9, 2001; 75 FR 49863, Aug. 16, 2010; 88 FR 27646, May 2, 2023]

§ 40.153 How does the MRO notify employees of their right to a test of the split specimen?

(a) As the MRO, when you have verified a drug test as positive for a drug or drug metabolite, or as a refusal to test because of adulteration or substitution, you must notify the employee of his or her right to have the split specimen tested. You must also notify the employee of the procedures for requesting a test of the split specimen.

(b) You must inform the employee that he or she has 72 hours from the time you provide this notification to him or her to request a test of the split specimen.

(c) You must tell the employee how to contact you to make this request. You must provide telephone numbers or other information that will allow the employee to make this request. As the MRO, you must have the ability to receive the employee's calls at all times during the 72 hour period (*e.g.,* by use of an answering machine with a "time stamp" feature when there is no one in your office to answer the phone).

(d) You must tell the employee that if he or she makes this request within 72 hours, the employer must ensure that the test takes place, and that the employee is not required to pay for the test from his or her own funds before the test takes place. You must also tell the employee that the employer may seek reimbursement for the cost of the test (see § 40.173).

(e) You must tell the employee that additional tests of the specimen *e.g.,* DNA tests) are not authorized.

§ 40.155 What does the MRO do when a negative or positive test result is also dilute?

(a) When the laboratory reports that a specimen is dilute, you must, as the MRO, report to the DER that the specimen, in addition to being negative or positive, is dilute.

(b) You must check the "dilute" box (Step 6) on Copy 2 of the CCF.

(c) When you report a dilute specimen to the DER, you must explain to the DER the employer's obligations and choices under § 40.197, to include the requirement for an immediate recollection under direct observation if the creatinine concentration of a negative-dilute specimen was greater than or equal to 2mg/dL but less than or equal to 5mg/dL.

(d) If the employee's recollection under direct observation, in paragraph (c) of this section, results in another negative-dilute, as the MRO, you must:

(1) Review the CCF to ensure that there is documentation that the recollection was directly observed.

(2) If the CCF documentation shows that the recollection was directly observed as required, report this result to the DER as a negative-dilute result.

(3) If CCF documentation indicates that the recollection was not directly observed as required, do not report a result but again explain to the DER that there must be an immediate recollection under direct observation.

[65 FR 79526, Dec. 19, 2000, as amended at 66 FR 41952, Aug. 9, 2001; 68 FR 31626, May 28, 2003; 69 FR 64867, Nov. 9, 2004; 73 FR 35971, June 25, 2008]

§ 40.157 [Reserved]

§ 40.159 What does the MRO do when a drug test result is invalid?

(a) As the MRO, when the laboratory reports that the test result is an invalid result, you must do the following:

(1) Discuss the laboratory results with a certifying scientist to determine if the primary specimen should be tested at another HHS-certified laboratory. If the laboratory did not contact you as required by §§ 40.91(e) and 40.96(b), you must contact the laboratory.

(2) If you and the laboratory have determined that no further testing is necessary, contact the employee and inform the employee that the specimen was invalid. In contacting the employee, use the procedures set forth in § 40.131.

(3) After explaining the limits of disclosure (see §§ 40.135(d) and 40.327), you must determine if the employee has a medical explanation for the invalid result. You must inquire about the medications the employee may have taken.

(4) If the employee gives an explanation that is acceptable, you must:

(i) Place a check mark in the “Test Cancelled” box (Step 6) on Copy 2 of the CCF and enter “Invalid Result” and “direct observation collection not required” on the “Remarks” line.

(ii) Report to the DER that the test is cancelled, the reason for cancellation, and that no further action is required unless a negative test result is required (*i.e.,* pre-employment, return-to-duty, or follow-up tests).

(iii) If a negative test result is required and the medical explanation concerns a situation in which the employee has a permanent or long-term medical condition that precludes him or her from providing a valid specimen, as the MRO, you must follow the procedures outlined at § 40.160 for determining if there is clinical evidence that the individual is an illicit drug user.

(5) If the employee is unable to provide an explanation and/or a valid prescription for a medication that interfered with the immunoassay test but denies having adulterated the specimen, you must:

(i) Place a check mark in the “Test Cancelled” box (Step 6) on Copy 2 of the CCF and enter “Invalid Result” and “direct observation collection required” on the “Remarks” line.

(ii) Report to the DER that the test is cancelled, the reason for cancellation, and that a second collection must take place immediately under direct observation. Recommend to the employer that an alternate specimen should be collected if practicable (*e.g.,* oral fluid, if the specimen was urine).

(iii) Instruct the employer to ensure that the employee has the minimum possible advance notice that he or she must go to the collection site.

(6) When the test result is invalid because pH is greater than or equal to 9.0 but less than or equal to 9.5 and the employee has no other medical explanation for the pH, you should consider whether there is evidence of elapsed time and increased temperature that could account for the pH value.

(i) You are authorized to consider the temperature conditions that were likely to have existed between the time of collection and transportation of the specimen to the laboratory, and the length of time between the specimen collection and arrival at the laboratory.

(ii) You may talk with the collection site and laboratory to discuss time and temperature issues, including any pertinent information regarding specimen storage.

(iii) If you determine that time and temperature account for the pH value, you must cancel the test and take no further action, as provided at paragraph (a)(4) of this section.

(iv) If you determine that time and temperature fail to account for the pH value, you must cancel the test and direct another collection under direct observation, as provided at paragraph (a)(5) of this section.

(b) You may only report an invalid test result when you are in possession of a legible copy of Copy 1 of the CCF. In addition, you must have Copy 2 of the CCF, a legible copy of it, or any other copy of the CCF containing the employee's signature.

(c) If the employee admits to having adulterated or substituted the specimen, you must, on the same day, write and sign your own statement of what the employee told you. You must then report a refusal to test in accordance with § 40.163 .

(d) If the employee admits to using a drug, you must, on the same day, write and sign your own statement of what the employee told you. You must then report that admission to the DER for appropriate action under DOT Agency regulations. This test will be reported as cancelled with the reason noted.

(e) If the employee's recollection (required at paragraph (a)(5) of this section) results in another invalid result for the same reason as reported for the first specimen, as the MRO, you must:

(1) Review the CCF to ensure that there is documentation that the recollection was directly observed.

(2) If the CCF review indicates that the recollection was directly observed as required, document that the employee had another specimen with an invalid result for the same reason.

(3) Follow the recording and reporting procedures at (a)(4)(i) and (ii) of this section.

(4) If a negative result is required (i.e., pre-employment, return-to-duty, or follow-up tests), follow the procedures at § 40.160 for determining if there is clinical evidence that the individual is an illicit drug user.

(5) If the recollection was not directly observed as required, do not report a result but again explain to the DER that there must be an immediate recollection under direct observation.

(f) If the employee's recollection (required at paragraph (a)(5) of this section) results in another invalid result for a different reason than that reported for the first specimen, as the MRO, you must:

(1) Review the CCF to ensure that there is documentation that the recollection was directly observed.

(2) If the CCF review indicates that the recollection was directly observed as required, document that the employee had another specimen with an invalid result for a different reason.

(3) As the MRO, you should not contact the employee to discuss the result, but rather direct the DER to conduct an immediate recollection under direct observation without prior notification to the employee.

(4) If the CCF documentation indicates that the recollection was not directly observed as required, do not report a result but again explain to the DER that there must be an immediate recollection under direct observation.

(g) If, as the MRO, you receive a laboratory invalid result in conjunction with a positive, adulterated, and/or substituted result and you verify any of those results as being a positive and/or refusal to test, you do not report the invalid result unless the split specimen fails to reconfirm the result(s) of the primary specimen.

[65 FR 79526, Dec. 19, 2000, as amended at 73 FR 35972, June 25, 2008; 75 FR 49863, Aug. 16, 2010; 88 FR 27646, May 2, 2023]

§ 40.160 What does the MRO do when a valid test result cannot be produced and a negative result is required?

(a) If a valid test result cannot be produced and a negative result is required, (under § 40.159 (a)(5)(iii) and (e)(4)), as the MRO, you must determine if there is clinical evidence that the individual is currently an illicit drug user. You must make this determination by personally conducting, or causing to be conducted, a medical evaluation. In addition, if appropriate, you may also consult with the employee's physician to gather information you need to reach this determination.

(b) If you do not personally conduct the medical evaluation, as the MRO, you must ensure that one is conducted by a licensed physician acceptable to you.

(c) For purposes of this section, the MRO or the physician conducting the evaluation may conduct an alternative test (e.g., blood) as part of the medically appropriate procedures in determining clinical evidence of drug use.

(d) If the medical evaluation reveals no clinical evidence of drug use, as the MRO, you must report this to the employer as a negative test result with written notations regarding the medical examination. The report must also state why the medical examination was required (i.e., either the basis for the determination that a permanent or long-term medical condition exists or because the recollection under direct observation resulted in another invalid result for the same reason, as appropriate) and for the determination that no signs and symptoms of drug use exist.

(1) Check “Negative” (Step 6) on the CCF.

(2) Sign and date the CCF.

(e) If the medical evaluation reveals clinical evidence of drug use, as the MRO, you must report the result to the employer as a cancelled test with written notations regarding the results of the medical examination. The report must also state why the medical examination was required (i.e., either the basis for the determination that a permanent or long-term medical condition exists or because the recollection under direct observation resulted in another invalid result for the same reason, as appropriate) and state the reason for the determination that signs and symptoms of drug use exist. Because this is a cancelled test, it does not serve the purpose of an actual negative test result (i.e., the employer is not authorized to allow the employee to begin or resume performing safety-sensitive functions, because a negative test result is needed for that purpose).

[73 FR 35972, June 25, 2008]

§ 40.161 What does the MRO do when a drug test specimen is rejected for testing?

As the MRO, when the laboratory reports that the specimen is rejected for testing (*e.g.,* because of a fatal or uncorrected flaw), you must do the following:

(a) Place a check mark in the “Test Cancelled” box (Step 6) on Copy 2 (or a legible copy of Copy 3–5) of the CCF and enter the reason on the “Remarks” line. If you do not have Copy 2 (or a legible copy of Copy 3–5), then enter “Test Cancelled” and the reason for the cancellation on a report in the format required under § 40.163(c).

(b) Report to the DER that the test is cancelled and the reason for cancellation, and that no further action is required unless a negative test is required (*e.g.*, in the case of a pre-employment, return-to-duty, or follow-up test).

(c) You may only report a test cancelled because of a “rejected for testing” laboratory result when you are in possession of a legible copy of Copy 1 of the CCF. In addition, you must have Copy 2 of the CCF, a legible copy of it, or any other copy of the CCF containing the employee's signature. If you do not have Copy 2 (or a legible copy of Copy 3–5), then enter “Test Cancelled” and the reason for the cancellation on a report in the format required under § 40.163(c).

[65 FR 79526, Dec. 19, 2000, as amended at 88 FR 27646, May 2, 2023]

§ 40.162 What must MROs do with multiple verified results for the same testing event?

(a) If the testing event is one in which there was one specimen collection with multiple verified non-negative results, as the MRO, you must report them all to the DER. For example, if you verified the specimen as being positive for marijuana and cocaine and as being a refusal to test because the specimen was also adulterated, as the MRO, you should report the positives and the refusal to the DER.

(b) If the testing event was one in which two separate specimen collections (e.g., a specimen out of temperature range and the subsequent observed collection) were sent to the laboratory, as the MRO, you must:

(1) If both specimens were verified negative, report the result as negative.

(2) If either of the specimens was verified negative and the other was verified as one or more non-negative(s), report the non-negative result(s) only. For example, if you verified one specimen as negative and the other as a refusal to test because the second specimen was substituted, as the MRO you should report only the refusal to the DER.

(i) If the first specimen is reported as negative, but the result of the second specimen has not been reported by the laboratory, as the MRO, you should hold—not report—the result of the first specimen until the result of the second specimen is received.

(ii) If the first specimen is reported as non-negative, as the MRO, you should report the result immediately and not wait to receive the result of the second specimen.

(3) If both specimens were verified non-negative, report all of the non-negative results. For example, if you verified one specimen as positive and the other as a refusal to test because the specimen was adulterated, as the MRO, you should report the positive and the refusal results to the DER.

(c) As an exception to paragraphs (a) and (b) of this section, as the MRO, you must follow procedures at § 40.159(g) when any verified non-negative result is also invalid.

[73 FR 35972, June 25, 2008, as amended at 82 FR 52245, Nov. 13, 2017]

§ 40.163 How does the MRO report drug test results?

(a) As the MRO, it is your responsibility to report all drug test results to the employer.

(b) You may use a signed or stamped and dated legible photocopy of Copy 2 of the CCF to report test results.

(c) If you do not report test results using Copy 2 of the CCF for this purpose, you must provide a written report (e.g., a letter) for each test result. This report must, as a minimum, include the following information:

(1) Full name, as indicated on the CCF, of the employee tested;

(2) Specimen ID number from the CCF and the SSN or employee ID No.;

(3) Reason for the test, if indicated on the CCF (e.g., random, post-accident);

(4) Date of the collection;

(5) Date you received Copy 2 of the CCF;

(6) Result of the test (i.e., positive, negative, dilute, refusal to test, test cancelled) and the date the result was verified by the MRO;

(7) For verified positive tests, the drug(s)/metabolite(s) for which the test was positive;

(8) For cancelled tests, the reason for cancellation; and

(9) For refusals to test, the reason for the refusal determination (e.g., in the case of an adulterated test result, the name of the adulterant).

(d) As an exception to the reporting requirements of paragraph (b) and (c) of this section, the MRO may report negative results using an electronic data file.

(1) If you report negatives using an electronic data file, the report must contain, as a minimum, the information specified in paragraph (c) of this section, as applicable for negative test results.

(2) In addition, the report must contain your name, address, and phone number, the name of any person other than you reporting the results, and the date the electronic results report is released.

(e) If you use a written report as provided in paragraph (c) of this section to report results, you must retain a copy of the written report. If you use the electronic data file to report negatives, as provided in paragraph (d) of this section, you must retain a retrievable copy of that report in a format suitable for inspection and audit by a DOT representative. In either case, you must keep the completed Copy 2 of the CCF. When completing Copy 2, either the MRO must sign and date it (for both negatives and non-negatives) or MRO staff must stamp and date it (for negatives only).

(f) You must not use Copy 1 of the CCF to report drug test results.

(g) You must not provide quantitative values to the DER or C/TPA for drug or validity test results. However, you must provide the test information in your possession to a SAP who consults with you (see § 40.293(g)).

(h) You must maintain reports and records related to negatives and cancelled results for one year; you must maintain reports and records related to positives and refusals for five years, unless otherwise specified by applicable DOT agency regulations.

[66 FR 41952, Aug. 9, 2001, as amended at 75 FR 49863, Aug. 16, 2010; 75 FR 59107, Sept. 27, 2010; 76 FR 59578, Sept. 27, 2011; 88 FR 27646, May 2, 2023]

§ 40.165 To whom does the MRO transmit reports of drug test results?

(a) As the MRO, you must report all drug test results to the DER, except in the circumstances provided for in § 40.345 .

(b) If the employer elects to receive reports of results through a C/TPA, acting as an intermediary as provided in § 40.345 , you must report the results through the designated C/TPA.

§ 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).

[65 FR 79526, Dec. 19, 2000, as amended at 66 FR 41953, Aug. 9, 2001]

§ 40.169 Where is other information concerning the role of MROs and the verification process found in this regulation?

You can find more information concerning the role of MROs in several sections of this part:

§ 40.3—Definition.
§§ 40.47–40.49—Correction of form and kit errors.
§ 40.67—Role in direct observation and other atypical test situations.
§ 40.83—Laboratory handling of fatal and correctable flaws.
§ 40.97—Laboratory handling of test results and quantitative values.
§ 40.99—Authorization of longer laboratory retention of specimens.
§ 40.101—Relationship with laboratories; avoidance of conflicts of interest.
§ 40.171—Request for test of split specimen.
§ 40.187—Action concerning split specimen test results.
§ 40.193—Role in “shy bladder” situations.
§ 40.195—Role in cancelling tests.
§§ 40.199–40.203—Documenting errors in tests.
§ 40.327—Confidentiality and release of information.
§ 40.347—Transfer of records.
§ 40.353—Relationships with service agents.

[65 FR 79526, Dec. 19, 2000, as amended at 82 FR 52245, Nov. 13, 2017]

Subpart H—Split Specimen Tests

§ 40.171 How does an employee request a test of a split specimen?

(a) As an employee, when the MRO has notified you that you have a verified positive drug test and/or refusal to test because of adulteration or substitution, you have 72 hours from the time of notification to request a test of the split specimen. The request may be verbal or in writing. If you make this request to the MRO within 72 hours, you trigger the requirements of this section for a test of the split specimen. There is no split specimen testing for an invalid result.

(b)

(1) If, as an employee, you have not requested a test of the split specimen within 72 hours, you may present to the MRO information documenting that serious injury, illness, lack of actual notice of the verified test result, inability to contact the MRO (e.g., there was no one in the MRO's office and the answering machine was not working), or other circumstances unavoidably prevented you from making a timely request.

(2) As the MRO, if you conclude from the employee's information that there was a legitimate reason for the employee's failure to contact you within 72 hours, you must direct that the test of the split specimen take place, just as you would when there is a timely request.

(c) When the employee makes a timely request for a test of the split specimen under paragraphs (a) and (b) of this section, you must, as the MRO, immediately provide written notice to the laboratory that tested the primary specimen, directing the laboratory to forward the split specimen to a second HHS-certified laboratory. You must also document the date and time of the employee's request.

[65 FR 79526, Dec. 19, 2000, as amended at 73 FR 35972, June 25, 2008]

§ 40.173 Who is responsible for paying for the test of a split specimen?

(a) As the employer, you are responsible for making sure (e.g., by establishing appropriate accounts with laboratories for testing split specimens) that the MRO, first laboratory, and second laboratory perform the functions noted in §§ 40.175–40.185 in a timely manner, once the employee has made a timely request for a test of the split specimen.

(b) As the employer, you must not condition your compliance with these requirements on the employee's direct payment to the MRO or laboratory or the employee's agreement to reimburse you for the costs of testing. For example, if you ask the employee to pay for some or all of the cost of testing the split specimen, and the employee is unwilling or unable to do so, you must ensure that the test takes place in a timely manner, even though this means that you pay for it.

(c) As the employer, you may seek payment or reimbursement of all or part of the cost of the split specimen from the employee (e.g., through your written company policy or a collective bargaining agreement). This part takes no position on who ultimately pays the cost of the test, so long as the employer ensures that the testing is conducted as required and the results released appropriately.

§ 40.175 What steps does the first laboratory take with a split specimen?

(a) As the laboratory at which the primary and split specimen first arrive, you must check to see whether the split specimen is available for testing.

(b) If the split specimen is unavailable or appears insufficient, you must then do the following:

(1) Continue the testing process for the primary specimen as you would normally. Report the results for the primary specimen without providing the MRO information regarding the unavailable split specimen.

(2) Upon receiving a letter from the MRO instructing you to forward the split specimen to another laboratory for testing, report to the MRO that the split specimen is unavailable for testing. Provide as much information as you can about the cause of the unavailability.

(c) As the laboratory that tested the primary specimen, you are not authorized to open the split specimen under any circumstances (except when the split specimen is redesignated as provided in § 40.83).

(d) When you receive written notice from the MRO instructing you to send the split specimen to another HHS-certified laboratory, you must forward the following items to the second laboratory:

(1) The split specimen in its original specimen bottle, with the seal intact;

(2) A copy of the MRO's written request; and

(3) A copy of Copy 1 of the CCF, which identifies the drug(s)/metabolite(s) or the validity criteria to be tested for.

(e) You must not send to the second laboratory any information about the identity of the employee. Inadvertent disclosure does not, however, cause a fatal flaw.

(f) This subpart does not prescribe who gets to decide which HHS-certified laboratory is used to test the split specimen. That decision is left to the parties involved.

§ 40.177 What does the second laboratory do with the split specimen when it is tested to reconfirm the presence of a drug or drug metabolite?

(a) As the laboratory testing the split specimen, you must test the split specimen for the drug(s)/drug metabolite(s) confirmed in the primary specimen.

(b) You must conduct this test without regard to the cutoff concentrations of § 40.85 or § 40.91, as applicable.

(c) If the test fails to reconfirm the presence of the drug(s)/drug metabolite(s) that were reported in the primary specimen, you must conduct validity tests in an attempt to determine the reason for being unable to reconfirm the presence of the drug(s)/metabolite(s). You should conduct the same validity tests as you would conduct on a primary specimen set forth in § 40.87 or § 40.93, as applicable.

(d) In addition, if the test fails to reconfirm the presence of the drug(s)/ drug metabolite(s) reported in the primary specimen, you may send the specimen or an aliquot of it for testing at another HHS-certified laboratory that has the capability to conduct another reconfirmation test.

[65 FR 79526, Dec. 19, 2000, as amended at 73 FR 35972, June 25, 2008; 88 FR 27646, May 2, 2023]

§ 40.179 What does the second laboratory do with the split specimen when it is tested to reconfirm an adulterated test result?

(a) As the laboratory testing the split specimen, you must test the split specimen for the adulterant detected in the primary specimen, using the confirmatory test for the adulterant and using criteria in § 40.89 or § 40.93, as applicable and confirmatory cutoff levels required by the HHS Mandatory Guidelines.

(b) In addition, if the test fails to reconfirm the adulterant result reported in the primary specimen, you may send the specimen or an aliquot of it for testing at another HHS-certified laboratory that has the capability to conduct another reconfirmation test.

[73 FR 35973, June 25, 2008, as amended at 88 FR 27646, May 2, 2023]

§ 40.181 What does the second laboratory do with the split specimen when it is tested to reconfirm a substituted test result?

As the laboratory testing a urine split specimen, you must test the split specimen using the confirmatory tests for creatinine and specific gravity, using the criteria set forth in § 40.88.

[88 FR 27646, May 2, 2023]

§ 40.183 What information do laboratories report to MROs regarding split specimen results?

(a) As the laboratory responsible for testing the split specimen, you must report split specimen test results by checking the “Reconfirmed” box and/or the “Failed to Reconfirm” box (Step 5(b)) on Copy 1 of the CCF, as appropriate, and by providing clarifying remarks using current HHS Mandatory Guidelines requirements.

(b) As the laboratory certifying scientist, enter your name, sign, and date the CCF.

[65 FR 79526, Dec. 19, 2000, as amended at 73 FR 35972, June 25, 2008]

§ 40.185 Through what methods and to whom must a laboratory report split specimen results?

(a) As the laboratory testing the split specimen, you must report laboratory results directly, and only, to the MRO at his or her place of business. You must not report results to or through the DER or another service agent (e.g., a C/TPA).

(b) You must fax, courier, mail, or electronically transmit a legible image or copy of the fully-completed Copy 1 of the CCF, which has been signed by the certifying scientist.

(c) You must transmit the laboratory result to the MRO immediately, preferably on the same day or next business day as the result is signed and released.

§ 40.187 What does the MRO do with split specimen laboratory results?

As the MRO, the split specimen laboratory results you receive will fall into five categories. You must take the following action, as appropriate, when a laboratory reports split specimen results to you.

(a) ***Category 1:*** The laboratory reconfirmed one or more of the primary specimen results. As the MRO, you must report to the DER and the employee the result(s) that was/were reconfirmed.

(1) In the case of a reconfirmed positive test(s) for drug(s) or drug metabolite(s), the positive is the final result.

(2) In the case of a reconfirmed adulterated or substituted result, the refusal to test is the final result.

(3) In the case of a combination positive and refusal to test results, the final result is both positive and refusal to test.

(b) ***Category 2:*** The laboratory failed to reconfirm all of the primary specimen results because, as appropriate, drug(s)/drug metabolite(s) were not detected; adulteration criteria were not met; and/or substitution criteria were not met. As the MRO, you must report to the DER and the employee that the test must be cancelled.

(1) As the MRO, you must inform ODAPC of the failure to reconfirm using the format in appendix F to this part.

(2) In a case where the split failed to reconfirm because the substitution criteria were not met and the split specimen creatinine concentration was equal to or greater than 2mg/dL but less than or equal to 5mg/dL, as the MRO, you must, in addition to step (b)(1) of this paragraph, direct the DER to ensure the immediate collection of another specimen from the employee under direct observation, with no notice given to the employee of this collection requirement until immediately before the collection.

(3) In a case where the split failed to reconfirm and the primary specimen's result was also invalid, direct the DER to ensure the immediate collection of another specimen from the employee under direct observation, with no notice given to the employee of this collection requirement until immediately before the collection.

(c) ***Category 3:*** The laboratory failed to reconfirm all of the primary specimen results, and also reported that the split specimen was invalid, adulterated, and/or substituted.

(1) In the case where the laboratory failed to reconfirm all of the primary specimen results and the split was reported as invalid, as the MRO, you must:

(i) Report to the DER and the employee that the test must be cancelled and the reason for the cancellation.

(ii) Direct the DER to ensure the immediate collection of another specimen from the employee under direct observation, with no notice given to the employee of this collection requirement until immediately before the collection.

(iii) Inform ODAPC of the failure to reconfirm using the format in appendix F to this part.

(2) In the case where the laboratory failed to reconfirm any of the primary specimen results, and the split was reported as adulterated and/or substituted, as the MRO, you must:

(i) Contact the employee and inform the employee that the laboratory has determined that his or her split specimen is adulterated and/or substituted, as appropriate.

(ii) Follow the procedures of § 40.145 to determine if there is a legitimate medical explanation for the laboratory finding of adulteration and/or substitution, as appropriate.

(iii) If you determine that there is a legitimate medical explanation for the adulterated and/or substituted test result, report to the DER and the employee that the test must be cancelled; and inform ODAPC of the failure to reconfirm using the format in appendix F to this part.

(iv) If you determine that there is not a legitimate medical explanation for the adulterated and/or substituted test result, you must take the following steps:

(A) Report the test to the DER and the employee as a verified refusal to test. Inform the employee that he or she has 72 hours to request a test of the primary specimen to determine if the adulterant found in the split specimen is also present in the primary specimen and/or to determine if the primary specimen meets appropriate substitution criteria.

(B) Except when the request is for a test of the primary specimen and is being made to the laboratory that tested the primary specimen, follow the procedures of §§ 40.153, 40.171, 40.173, 40.179, 40.181, and 40.185, as appropriate.

(C) As the laboratory that tests the primary specimen to reconfirm the presence of the adulterant found in the split specimen and/or to determine that the primary specimen meets appropriate substitution criteria, report your result to the MRO on a photocopy (faxed, mailed, scanned, couriered) of Copy 1 of the CCF.

(D) If the test of the primary specimen reconfirms the adulteration and/or substitution finding of the split specimen, as the MRO you must report the result as a refusal to test as provided in paragraph (a)(2) of this section.

(E) If the test of the primary specimen fails to reconfirm the adulteration and/or substitution finding of the split specimen, as the MRO you must cancel the test, following procedures in paragraph (b) of this section.

(d) ***Category 4:*** The laboratory failed to reconfirm one or more but not all of the primary specimen results, and also reported that the split specimen was invalid, adulterated, and/or substituted. As the MRO, in the case where the laboratory reconfirmed one or more of the primary specimen result(s), you must follow procedures in paragraph (a) of this section and:

(1) Report that the split was also reported as being invalid, adulterated, and/or substituted (as appropriate).

(2) Inform the DER to take action only on the reconfirmed result(s).

(e) ***Category 5:*** The split specimen was not available for testing or there was no split laboratory available to test the specimen. As the MRO, you must:

(1) Report to the DER and the employee that the test must be cancelled and the reason for the cancellation;

(2) Direct the DER to ensure the immediate recollection of another specimen from the employee under direct observation, with no notice given to the employee of this collection requirement until immediately before the collection; and

(3) Notify ODAPC of the failure to reconfirm using the format in appendix F to this part.

(f) For all split specimen results, as the MRO you must in Step 7 of Copy 2 of the CCF:

(1) Report split specimen test results by checking the “Reconfirmed” box and/or the “Failed to Reconfirm” box, or the “Test Cancelled” box, as appropriate.

(2) , Enter your name, sign, and date.

(3) Send a legible copy of Copy 2 of the CCF (or a signed and dated letter, see § 40.163) to the employer and keep a copy for your records. Transmit the document as provided in § 40.167.

[73 FR 35973, June 25, 2008, as amended at 75 FR 59108, Sept. 27, 2010; 88 FR 27646, May 2, 2023]

§ 40.189 Where is other information concerning split specimens found in this regulation?

You can find more information concerning split specimens in several sections of this part:

§ 40.3—Definition.
§ 40.65—Quantity of split specimen.
§ 40.67—Directly observed test when split specimen is unavailable.
§§ 40.71–40.73—Collection process for split specimens.
§ 40.83—Laboratory accessioning of split specimens.
§ 40.99—Laboratory retention of split specimens.
§ 40.153—MRO notice to employees on tests of split specimen.
§§ 40.193 and 40.201—MRO actions on insufficient or unavailable split specimens.
Appendix D to Part 40—Report format for split specimen failure to reconfirm.

[65 FR 79526, Dec. 19, 2000, as amended at 82 FR 52245, Nov. 13, 2017]

Subpart I—Problems in Drug Tests

§ 40.191 What is a refusal to take a DOT drug test, and what are the consequences?

(a) As an employee, you have refused to take a drug test if you:

(1) Fail to appear for any test (except a pre-employment test) within a reasonable time, as determined by the employer, consistent with applicable DOT agency regulations, after being directed to do so by the employer. This includes the failure of an employee (including an owner-operator) to appear for a test when called by a C/TPA (see § 40.61(a));

(2) Fail to remain at the testing site until the testing process is complete. Provided that an employee who leaves the collection site before the testing process commences (*see* § 40.63(c) or § 40.72(e), as applicable) for a pre-employment test is not deemed to have refused to test. The collector is not required to inform an employee that the failure to remain at the collection site is a refusal. If an employee leaves prior to the completion of the testing process, per § 40.355(i) the employer must decide whether the employee's actions constitute a refusal;

(3) Fail to provide a specimen for any drug test required by this part or DOT agency regulations. Provided that an employee who does not provide a specimen because he or she has left the testing site before the testing process commences (*see* § 40.63(c) or § 40.72(e), as applicable) for a pre-employment test is not deemed to have refused to test. The collector is not required to inform an employee that the failure to remain at the collection site is a refusal. If an employee leaves prior to the completion of the testing process, per § 40.355(i) the employer must decide whether the employee's actions constitute a refusal;

(4) In the case of a directly observed or monitored urine collection in a drug test, fail to permit the observation or monitoring of an employee's provision of a specimen (*see* §§ 40.67(m) and 40.69(g));

(5) Fail to provide a sufficient amount of specimen when directed, and it has been determined, through a required medical evaluation, that there was no adequate medical explanation for the failure (*see* § 40.193(d)(2));

(6) Fail or decline to take an additional drug test the employer or collector has directed you to take (*see,* for instance, § 40.197(b) as applicable);

(7) Fail to undergo a medical examination or evaluation, as directed by the MRO as part of the verification process, or as directed by the DER under § 40.193(c). In the case of a pre-employment drug test, the employee is deemed to have refused to test on this basis only if the pre-employment test is conducted following a contingent offer of employment. If there was no contingent offer of employment, the MRO will cancel the test;

(8) Fail to cooperate with any part of the testing process (*e.g.,* refuse to empty pockets when directed by the collector, behave in a confrontational way that disrupts the collection process, fail to wash hands after being directed to do so by the collector, fail to remove objects from mouth, fail to permit inspection of the oral cavity, or fail to complete a rinse when requested);

(9) For an observed urine collection, fail to follow the observer's instructions to raise your clothing above the waist, lower clothing and underpants, and to turn around to permit the observer to determine if you have any type of prosthetic or other device that could be used to interfere with the collection process;

(10) Possess or wear a prosthetic or other device that could be used to interfere with the collection process; or

(11) Admit to the collector or MRO that you adulterated or substituted the specimen.

(b) As an employee, if the MRO reports that you have a verified adulterated or substituted test result, you have refused to take a drug test.

(c) As an employee, if you refuse to take a drug test, you incur the consequences specified under DOT agency regulations for a violation of those DOT agency regulations. The consequences specified under DOT agency regulations for a refusal cannot be overturned or set aside by an arbitration, grievance, State court or other non-Federal forum that adjudicates the personnel decisions the employer has taken against the employee.

(d) As a collector or an MRO, when an employee refuses to participate in the part of the testing process in which you are involved, you must terminate the portion of the testing process in which you are involved, document the refusal on the CCF (including, in the case of the collector, printing the employee's name on Copy 2 of the CCF), immediately notify the DER by any means (e.g., telephone or secure fax machine) that ensures that the refusal notification is immediately received. As a referral physician (e.g., physician evaluating a “shy bladder” condition or a claim of a legitimate medical explanation in a validity testing situation), you must notify the MRO, who in turn will notify the DER.

(1) As the collector, you must note the actions that may constitute a refusal in the “Remarks” line (Step 2), and sign and date the CCF. The collector does not make the final decision about whether the employee's conduct constitutes a refusal to test; the employer has the sole responsibility to decide whether a refusal occurred, as stated in § 40.355(i), the employer has a non-delegable duty to make the decision about whether the employee has refused to test.

(2) As the MRO, you must note the refusal by checking the “Refusal to Test” box in Step 6 on Copy 2 of the CCF, checking whether the specimen was adulterated or substituted and, if adulterated, noting the adulterant/reason. If there was another reason for the refusal, check “Other” in Step 6 on Copy 2 of the CCF, and note the reason next to the “Other” box and on the “Remarks” lines, as needed. You must then sign and date the CCF.

(e) As an employee, when you refuse to take a non-DOT test or to sign a non-DOT form, you have not refused to take a DOT test. There are no consequences under DOT agency regulations for refusing to take a non-DOT test.

[65 FR 79526, Dec. 19, 2000, as amended at 66 FR 41953, Aug. 9, 2001; 68 FR 31626, May 28, 2003; 71 FR 49384, Aug. 23, 2006; 73 FR 35974, June 25, 2008; 75 FR 59108, Sept. 27, 2010; 88 FR 27647, May 2, 2023]

§ 40.193 What happens when an employee does not provide a sufficient amount of specimen for a drug test?

(a) If an employee does not provide a sufficient amount of specimen to permit a drug test (*i.e.,* 45 mL of urine in a single void, or 2mL oral fluid in a single sampling, as applicable) you, as the collector, must provide another opportunity to the employee to do so. In accordance with the employer's instructions, this can be done using the same specimen type as the original collection or this can be done by a collector qualified to use an alternate specimen collection for this purpose.

(1) If you change to an alternate specimen collection at this point (*i.e.,* from urine to oral fluid; or from oral fluid to urine), the next collection begins under § 40.61(e) for urine or § 40.72 for oral fluid collection.

(i) If you proceed with an alternate specimen collection, discard the insufficient specimen and proceed with the next specimen collection.

(ii) If you proceed with an alternate specimen collection, discard the CCF for the insufficient specimen and begin a new CCF for the next specimen collection with a notation in the remarks section of the new CCF.

(b)

(1) As the collector, you must do the following when continuing with a urine specimen collection under this section:

(i) Discard the insufficient specimen, except where the insufficient specimen was out of temperature range or showed evidence of adulteration or tampering (*see* § 40.65(b) and (c)).

(ii) Urge the employee to drink up to 40 ounces of fluid, distributed reasonably through a period of up to three hours, or until the individual has provided a sufficient urine specimen, whichever occurs first. It is not a refusal to test if the employee declines to drink. Document on the Remarks line of the CCF (Step 2), and inform the employee of the time at which the three-hour period begins and ends.

(iii) If the employee refuses to make the attempt to provide a new urine specimen or leaves the collection site before the collection process is complete, you must discontinue the collection, note that fact on the “Remarks” line of the CCF (Step 2), and immediately notify the DER of the conduct as provided in § 40.191(e)(1); the employer decides whether the situation is deemed to be a refusal.

(iv) If the employee has not provided a sufficient specimen within three hours of the first unsuccessful attempt to provide the specimen, you must discontinue the collection, note the fact on the “Remarks” line of the CCF (Step 2), and immediately notify the DER. You must also discard any specimen the employee previously provided, including any specimen that is “out of temperature range” or shows signs of tampering. In the remarks section of the CCF that you will distribute to the MRO and DER, note the fact that the employee provided an “out of temperature range specimen” or “specimen that shows signs of tampering” and that it was discarded because the employee did not provide a second sufficient specimen.