

ENTERPRISE RISK MANAGEMENT STRATEGIES

for Drug and Alcohol Testing Organizations

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According to the latest Quest Diagnostics Drug Testing Index™ insights, increased use of illicit drugs has driven workforce drug testing positivity to the highest rate in 12 years.¹

Workplace drug testing has seen rapid growth over the last few decades. Some employers have the facilities to provide drug testing services for their own employees, while others contract with drug and alcohol testing services. Positive drug and alcohol test results can have a significant negative impact on the employee, and there are risk considerations for the employer as well. Likewise, drug and alcohol testing organizations have their own risk exposures and legal liability.

Given the range of potential loss exposures, it is important that the drug testing organization has a comprehensive enterprise risk management (ERM) program in place.

An ERM approach to an organization's business-decision-making process can help identify and effectively manage interrelated risks across all of the business's domains that may threaten the successful achievement of an organization's strategic goals and business objectives.

This article will present some examples of potential risk management strategies across several domains of risk for drug testing services to consider. It is beyond the scope of this article to give exhaustive information on federal, state, or local requirements, or how to perform specific aspects of drug testing services.

Potential Risk Management Strategies for Key Aspects of a Drug Testing Operation

DOMAIN: LEGAL/REGULATORY RISKS

Engage legal counsel to assist with any applicable federal, state, and

local laws and regulations for drug testing services.

- *Knowledge of and compliance with the most recent Substance Abuse and Mental Health Services Administration (SAMHSA) and Department of Health and Human Services (HHS) mandatory guidelines for Federal Workplace Drug Testing Programs (effective October 1, 2017)² are important. HHS establishes the scientific and technical guidelines for federal workplace drug testing programs and the standards for certified labs that conduct urine drug testing for federal agencies. As another example, there are requirements for Department of Transportation (DOT) drug testing as well. Although a drug testing facility may not be required to adhere to these federal guidelines, which may not have the effect of law, they can be helpful in designing an organization's own policies and procedures.*
- *Compliance with applicable state and local laws and regulations, such as required laboratory certifications, technical requirements for written notices and confirmatory retest procedures, and limits on the testing methods or mandates on how and when drug testing by employers can be done.*
- *Compliance with applicable federal and state laws for information privacy and security, drug testing, and donor consent regarding release of test results and records and any research activities.*
- *Contract Terms: Some possible terms for consideration may include:*
 - Indemnify and hold harmless language in contracts with employers regarding

their employment decisions based on drug test results.

- Loss of laboratory certification and/or accreditation.
- Right to terminate for no cause.
- Insurance coverage requirements.
- Notification of any information privacy or data security breach.
- Notification of any breach in meeting and maintaining testing standards.

DOMAIN: FINANCIAL RISK

Perform a risk control and risk financing review.

- Engage insurance brokers and carriers to assist in reviewing risk and liability exposures, as well as the various types of insurance coverages that will be needed to adequately treat the risk exposures for the enterprise.

DOMAIN: LEGAL/REGULATORY

Maintain required drug testing laboratory certification and/or accreditation.

- Determine whether a good risk-management strategy for the organization is to obtain and maintain drug testing program certification and/or accreditation, even if not required for the drug testing services that will be provided. For federal employee testing, there is the HHS National Laboratory Certification Program (NLCP), and for accreditation there is the College of American Pathologists (CAP) Forensic Urine Drug Testing (FUDT) program for nonfederal employees. Both are considered a standard of care for drug testing services.

DOMAIN: OPERATIONAL/ CLINICAL RISK

Implement clearly written policies and standard operating procedures (SOPs) consistent with SAMHSA mandatory guidelines, state or local requirements, and industry best practices and standards for the three parts of the drug testing process.

1. Specimen collection:

- Provide specimen donors with information about specimen collection, laboratory analysis, and results reporting processes and responsibilities.
- Adhere to strict SOPs for specimen collection, packaging and shipping, pick up, and chain of custody. These may include, but are not limited to:
 - Timeframe for notice to the donor for specimen collection and testing.
 - Completion of an accurate history of all drugs (including prescribed and OTC), food, and herbals used prior to sample collection.
 - Measures taken to eliminate or detect sample adulteration or substitution.
 - Appropriate accommodation (as may be required under the Americans with Disabilities Act for specimen collection while maintaining compliance with SOPs).
 - Inspections of collection sites/facilities with evidence of compliance with SOPs documented. Known or suspected errors/lapses in specimen collection practices are addressed immediately and reported for further investigation and system-wide corrective action.

2. Specimen laboratory analysis:

- There is a Laboratory Director (or other title) role in place, responsible for the overall operation and administration of the laboratory.
- Determine where initial and confirmatory testing will be performed.
- Confirmatory testing of positive drug test results is done using established, analytical methods that meet a legal standard.

- Highly accurate immunoassays that meet a legal standard are used.
 - A rigorous quality control/quality assurance program is in place.
 - Specimen chain of custody is strictly maintained. Known or suspected errors or lapses in specimen chain of custody practices are addressed immediately and reported for further investigation and system-wide corrective action.
- #### 3. Medical review of results:
- The Medical Review Officer (MRO) role is in place to ensure that test results are properly reviewed and interpreted before verifying the results as positive, and before reporting the results to the contracted employer/federal agency representative. SAMHSA provides guidance in the *2017 MRO Manual*.³
 - The MRO is a qualified, licensed physician certified as an MRO.

DOMAIN: HUMAN CAPITAL RISKS

Personnel

- All job applicants are screened using a process consistent with state and federal employment practices requirements. The organization conducts background checks, including: criminal records (misdemeanors and felonies); Fair Credit Act-authorized inquiries; motor vehicle (DMV) driving record; screening on sex-offender registries; and multi-state background checks.
- All personnel are qualified for their role or function within written job descriptions, and demonstrate competency for their job duties on initial hire and periodically after that.
- The organization consistently and fairly administers a system-wide, drug-free workplace and workplace drug testing program. Information about drug testing and impact on employment is communicated in ads, to potential job applicants, and to current employees.

DOMAIN: HUMAN CAPITAL

Training

- Drug testing service personnel receive documented initial and ongoing training

on their job duties, organizational policies and SOPs, and applicable new laws and regulations in order to demonstrate competency.

DOMAIN: HAZARD RISK

Security

- Facilities for specimen collection, laboratory testing, and results confirmation are safe and secure for donors, staff, and visitors.
- The security and integrity of specimens are maintained. The DOT has published guidance on this.⁴
- Compliance with applicable information privacy and data security regulations and laws, and the confidentiality of donor and drug test information.

DOMAIN: TECHNOLOGY/LEGAL/ REGULATORY RISK

Documentation/Records

- Clearly defined written policies and SOPs for documentation requirements are in place to ensure effective communication regarding the entire drug testing process, results reporting, and to decrease risk exposure for inspections, audits, and other regulatory and legal matters.
- Provide training on documentation expectations, policies, and SOPs.
- Develop an enterprise document release, eDiscovery, and retention and destruction plan.

DOMAIN: TECHNOLOGY/LEGAL/ REGULATORY RISK

Specimen Retention, Storage and Destruction

- Develop enterprise specimen retention, storage and destruction policies and procedures for different specimen types, specimens under legal challenge or hold, and how to maintain specimens for DNA testing, research, or any other purposes.
- Develop a policy and procedure for the release of a donor specimen.

The examples of potential risk management strategies for a drug testing

operation presented above help to illustrate how such a business may consider an ERM approach to proactively and reactively manage risk and liability exposures. ■

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References

- ¹ Quest Diagnostics Drug Testing Index™ insights; <https://www.questdiagnostics.com/home/physicians/health-trends/drug-testing>; accessed 1-22-18.
- ² Substance Abuse and Mental Health Services Administration (SAMHSA), Department of Health and Human Services (HHS) Mandatory Guidelines for Federal Workplace Drug Testing Programs, <https://www.samhsa.gov/workplace/resources>, accessed 1-16-18.
- ³ *Medical Review Officer (MRO) Guidance Manual* for Federal Workplace Drug Testing Programs, Department of Health and Human Services, Substance Abuse and Mental Health Services Administration Center for Substance Abuse Prevention, Division of Workplace Programs. This Medical Review Officer Guidance Manual does not apply to specimens collected and tested under the DOT program https://www.samhsa.gov/sites/default/files/workplace/mro-guidance-manual-oct2017_2.pdf, accessed 1-16-18.
- ⁴ Collection Site Security and Integrity, DOT's 10 Steps to Collection Site Security and Integrity, Office of Drug and Alcohol Policy and Compliance, U.S. Department of Transportation, June 1, 2015.

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