



The following has been reviewed and is published by the Substance Abuse Program Administrator's Association and its International Committee as a benefit of Membership with the permission of its Authors and subject to the Authors' Copyright.

The following review is not offered as business, legal or scientific advice but is instead offered for informational purposes. First Advantage Corporation is not a law firm or medical provider and does not offer business, medical or scientific advice. The following review is therefore not intended as a substitute for the legal advice of an attorney knowledgeable of the user's individual circumstances or to provide scientific advice. First Advantage Corporation makes no assurances regarding the accuracy, completeness, currency or utility of the following information. Legislative, regulatory and case law developments regularly impact on general research and the science in this area is evolving rapidly.

By:

Josephine Elizabeth Kenney, J.D.
Senior Vice President of Compliance
Occupational Health Group
Employment Screening Services Division
First Advantage
Josephine.Kenney@fadv.com

Benjamin Gerson, MD
Medical Director.
University Services

July 13, 2009

Reviewed and published by the Substance Abuse Program Administrator's Association and its International Committee as a benefit of Membership.

The Role of the Medical Review Officer (MRO) in International Workplace Drug Testing

Executive Summary

Although the role of the Medical Review Officer (MRO) is well established in United States Workplace Drug Testing Programs, such is not the case internationally. This review will summarize the information that is generally or currently known or is available in the Drug and Alcohol Testing Industry on the role of the Medical Review Officer internationally. It is important to note at the outset that the acceptance of the role of the Medical Review Officer in workplace drug testing programs is not addressed or acknowledged in many Countries.



The Role of the MRO Globally

In a review of 200 countries, a Drug and Alcohol Industry research team found information on the role of the Medical Review Officer in only 36 countries or 18% of the 200 countries researched. This is because the information available through accepted legal research practices is insufficient due to the need for practical in country information. Although the authors acknowledge that more detailed information is needed from legal counsel in each Country in the Global Community in order to truly understand and monitor the evolution of the role of the Medical Review, the following is meant to start the discussion.

In Austria, Belgium, Finland, France and Germany there appears to be a role for the occupational health physician in the review of workplace drug test review. Under Finland's Occupational Health Care Act, only a health care professional can determine a test is needed. Authorization to test from an occupational health physician is also required in France, Lithuania, Netherlands, Norway, Slovakia, Slovenia, and possibly Ireland. By contrast, in the United Kingdom, occupational health physicians are discouraged from being involved in workplace drug testing, including test review, because it is believed that the occupational health physician's role will damage the trust of the workforce. In Germany, a company's physician should not conduct the test or provide Medical Review Officer review because medical secrecy restrictions limit the use of the information.

The occupational health physician's role in the foregoing countries is a little different than the role of the MRO in the United States because the objective of the occupational health physician's test review is to report on the fitness for duty of the donor. The purpose of the fitness for duty review arises from a concern for balancing two objectives fairly, firstly, workplace security, and secondly, the protection of personal information.

Although currently undergoing revision, in 2002 the Laboratory Committee of EA (European co-operation for Accreditation) approved a document prepared by the European Workplace Drug Testing Society (EWDTS) entitled "European Laboratory Guidelines for Legally Defensible Workplace Drug Testing." The guidelines contained therein are based on the UK Guidelines drawn up by a steering group consisting of several UK analytical laboratories.

The stated purpose of the European Guidelines is to establish "best practice" procedures for the:

1. collection of urine samples,
2. laboratory analysis, and
3. subsequent interpretation of the results.



However, the Guidelines are clear that, while they suggest best practices, they are not intended to be binding regulations for all testing situations and circumstances. “The European Guidelines are designed to establish best practice procedures whilst allowing individual countries to operate within the requirements of national customs and legislation.” Therefore, the detail within the appendices to the Guidelines may vary from country to country.

The Guidelines are based on the “general principles that have been established internationally.” They are designed to ensure that the entire drug testing process is conducted to give accurate and reliable information about a donor's drug use.” Though some of the terminology may be different, much of what is found in the Guidelines will look familiar with those found in U.S. federal drug testing guidelines and regulations, as well as individual state laws.

For example, the Guidelines discuss chain-of-custody protocols during the collection process, ensuring the integrity of a sample received at a laboratory (including validity testing), screening and confirmation testing (GC/MS, LC/MS), and result interpretation via a lab toxicologist and a qualified “medical practitioner” or Medical Review Officer. The Guidelines also cover results reporting, long-term specimen storage, and record keeping.

In Canada, the role of the MRO is very similar to that in the United States. Brazil has also taken an approach to MRO practice similar to that in the United States and Canada. However, in Brazil, the MRO seems to play an expanded role relative to involvement with the employers conducting testing, their unions, and the larger community.

No information was found on the role of the Medical Review Officer in the remaining countries. Further, no information on the current status of workplace drug testing was available for a large number of the countries researched.

Additional Considerations

Beyond the foregoing, additional considerations for Medical Review practice include: 1) the impact of time differences on communications, 2) language differences, 3) seasonal and holiday variations, 4) electronic privacy and security laws, especially data transmission and storage laws that may prohibit the flow of data from between one country to another country, 5) review considerations unique to a particular country and 6) MRO training.

The role of the MRO is not widely understood or recognized outside of North America for the most part as noted previously. Many North American based multinational companies maintain the MRO role in their testing programs in all locations. The MRO role usually is based on the U.S. DOT model with modifications driven by local



requirements in the particular country testing to the extent that those requirements are understood and practical logistical necessities.

1) Adequate telecommunications capability is an important consideration. Both quality and availability are important.

Twenty-four hour a day, preferably 7 day a week availability of the MRO may be needed when a centralized MRO service is being provided for an organization that requires interviews in various time zones due to the time differences country to country. Some organizations will not require daily availability.

2) Language capability must be planned. Organizations that rely on a local physician may not have this challenge although local dialects may be a problem because the dialect differences may make communication more difficult. Those providing support from a centralized location must have planned for this. The best solution is to have a qualified MRO who is a native speaker. This may be achieved in many locations whether domestic or abroad. The next best approach is to have support staff directly controlled by or part of the same organization as the MRO who are able to serve as interpreters. These support staff may be native speakers or have gained proficiency based on other experience or training. Also acceptable is to use a commercial service that may be accessed on demand to provide a simultaneous translator. Clearly there will be limitations based on local circumstance and the particular language need.

3) Seasonal and holiday variations country to country impact the review process because they result in communication challenges and can delay the MRO review process.

4) Electronic privacy and security laws, especially data transmission and storage laws that may prohibit the flow of data from between one country to another country must be considered relative to the MRO global practice because these laws present practical considerations that must be addressed based on each country's particular requirements.

5) Panels, or drugs tested may vary from country to country and must be understood and considered as part of the MRO review process internationally. This is because drug usage and preferences can vary greatly from country to country. Even in the United States a study from the Substance Abuse and Mental Health Services Administration (SAMHSA) found that the prevalence of illicit drug use and drug preferences varies widely among the states. Hughes, A., Sathe, N., & Spagnola, K. (2009). *State Estimates of Substance Use from the 2006-2007 National Surveys on Drug Use and Health* (Office of Applied Studies, Substance Abuse and Mental Health Services Administration, NSDUH Series H-35, HHS Publication No. SMA 09-4362). Rockville, MD.



In providing MRO support in various countries the MRO must anticipate how to handle certain situations that may or may not arise based on the historical experience in North America. Some of these resolutions are well established when providing MRO review in North America but may not be established for practice elsewhere. As a best practice, it is important that employers establish a policy that is consistent with local law and regulations prior to program implementation. By so doing, the MRO can review a specific result in compliance with employer's policy and program.

Another aspect of providing MRO support in various regions is to anticipate how to handle certain situations that may or may not arise based on domestic experience. Some of these resolutions are well established when providing MRO review in North America but may not be established for practice elsewhere. It is best to have a company establish a policy, consistent with local regulations in advance.

Some examples of substances that may require special consideration are Coca Teas, Betel nuts, Khat and Daun Ketum. There are also others such as herbals and .some botanicals, etc.

Coca teas

Coca leaves may be chewed or a tea made from the leaves may be consumed. Coca tea, also called mate de coca, is an herbal tea made using the leaves of the coca plant. The leaves of the coca plant contain several alkaloids including cocaine. The tea is often packaged in individual servings as tea bags which contain approximately 1 g of plant material. When the cocaine is removed, the amount of cocaine is small enough for the product to legally sell in the USA. A cup of coca tea prepared from one gram of coca leaves contains approximately 4.21 mg of cocaine. Consumption of tea made from Cocoa leaves will cause a positive urine drug test.

Betel nuts

The nut contains a substance called arecoline which is a mild stimulant that affects the central nervous system. This alkaloid is said to improve learning and memory as well as to counteract intestinal parasites. Excessive use causes inebriation and dizziness. Long term use damages the teeth and soft tissue of the mouth.

Khat

Khat contains the alkaloids cathinone, a stimulant related to amphetamine which causes excitement, loss of appetite and euphoria. In 1980 the World Health Organization classified khat as a drug of abuse that can produce mild to moderate psychological



dependence. It is schedule I in the United States. Khat leaves are chewed. Cathine and cathinone are released and absorbed through the mouth and the stomach. The effects begin to subside after about 90 minutes to 3 hours, but can last 24 hours. At the end of a khat session, the user may experience a depressive mood, irritability, loss of appetite, and difficulty sleeping.

Daun Ketum

The active substance of ketum, also called kratom, is the alkaloid mitragynine. The plant is indigenous to Malaysia, growing mostly wild in the northern part of the peninsula, from Kedah to as far as Thailand. Mitragynine is an opioid agonist, having an affinity for opioid receptors in the brain. These receptors influence mood and anxiety. Mitragynine binds to these receptors and gives a euphoric-like feeling, just like opiates such as heroin and opium. The big difference between kratom and opiates is that mitragynine prefers delta opioid receptors, while opiates bind to mu opioid receptors. At higher doses, mitragynine increasingly stimulates mu receptors. This is believed to be the reason that kratom has a stimulating effect at lower doses and narcotic effects at higher doses.

Also, to be considered and planned for in advance in the absence of a valid prescription for a specific product/substance and which may or may not constitute valid medical use are:

- Foodstuffs (e.g. food containing marijuana, poppy seeds, or other non-food additives)
- Vitamins and Dietary Supplements
- Hemp Oil Products
- Inhaled Substances

Frequently encountered in United States Department of Transportation testing is pharmaceutical THC, brand name Marinol. Marinol (dronabinol), a Schedule III of the Controlled Substances Act and WHO Schedule IV of the Convention, is prescribed as an appetite stimulant, primarily for AIDS and chemotherapy patients. The MRO must be prepared as how to handle this.

Also important to mention is anticipation of shy bladder, alcohol, chain of custody concerns, adulteration. Additionally, to use some industry terminology, the MRO might have to be involved in shy lung [inability to provide a breath sample] and shy mouth [inability to provide a saliva sample] situations. It is beyond the scope of this article to review this issue country by country. However, different perspectives on this issue must be considered when designing a workplace testing program regardless of the country in which the program is being administered.

6) MRO training of those performing the MRO function in various countries is highly



recommended. MRO certification as defined in the United States is not a requirement with few exceptions; always be certain of local requirements. The person performing the MRO duties may be the company's local country based physician or may be based in the United States, again influenced by applicable regulations and company policies.

The Role of the Medical Review Officer in the United States

As noted in the Executive Summary to this Review, under United States federal testing guidelines, Medical Review Officer review is required and the MRO must personally conduct the donor interview. The federal guidelines take precedence over state law requirements for employers and employees required to comply with United States Department of Transportation regulations. Also, many State Laws in the United States mandate the use of a Medical Review Officer in some form of fashion. The following explanation of role of the Medical Review Officer in the United States as a starting point for future discussion of test result review internationally.

What is a Medical Review Officer in the United States?

United States Federal guidelines and Drug and Alcohol Testing Industry standards define Medical Review Officer as follows:

A Medical Review Officer (MRO) is a licensed physician (medical doctor or doctor of osteopathy) qualified to act as an MRO by possessing:

- (a) credentials,
- (b) basic knowledge, and
- (c) receiving qualification training.

If, unlike the federal guidelines, state law does not require MRO training, it is nonetheless recommended. Such training should be equivalent to that required by the federal drug testing programs for U.S. Department of Transportation safety sensitive employees as set forth in 49 CFR Part 40. It is important to recognize that a number of state laws and or implementing regulations **actually require** the use of an MRO.

Why is the use of an MRO perceived as "a must have" in Workplace Drug Testing in the United States?

- The MRO plays a key role in ensuring fair and accurate laboratory test review and verification.
- Regardless of testing methodology used by a particular organization, (*urine, point of collection urine, Intercept oral fluids, point-of-collection oral fluids, or hair testing*), the role of the MRO is a critical tool for proactive legal risk reduction.



- The MRO is the gatekeeper protecting the critical checks and balances between the employer's compliance, health, safety and security, legal risk mitigation objectives. However, the employer's interests must be balanced with those of the applicant/employee. These include fundamental legal rights, protections and employer's compliance with federal and state law as well as applicable regulations and ordinances. The foregoing relate to drug and alcohol testing program fairness, privacy, confidentiality, applicable state and/or federal constitutional and civil rights protections, American with Disability (ADA), Health Insurance Portability and Accountability Act (HIPAA) and employment/labor law.
- As the gatekeeper holding the key to fundamental program fairness, the MRO not only ensures the accuracy and integrity of the process but the MRO serves as an advocate for the accuracy and integrity of the process.
- Whether testing is being conducted under federal guidelines or as part of a non-mandated Drug Free Workplace program, Drug and Alcohol Testing Industry best practice recognizes the critical role of the Medical Review Officer.
- Federal testing programs **require** the use of an MRO.
- **Unknown to many employers in the United States is that many States require the use of an MRO or some equivalent as well.**

Specifically, the following sixteen (16) states (Alabama, Alaska, Arkansas, Florida, Hawaii, Idaho, Iowa, Louisiana, Maryland, Missouri, Montana, New Mexico, Ohio, Oklahoma, Tennessee, and Vermont) each have a law that includes language that must be considered regarding the role and responsibilities of the Medical Review Officer in the review and verification of workplace drug tests.

Twenty-Six (26) states do not require MRO review. Those states are: Delaware, District of Columbia, Illinois, Indiana, Kansas, Maine, Massachusetts, Michigan, Minnesota, Mississippi, Nebraska, Nevada, New Hampshire, New Jersey, North Carolina, Oregon, Pennsylvania, Rhode Island, South Carolina, South Dakota, Texas, Utah, Virginia, Washington, West Virginia, Wisconsin and Wyoming.

California and Connecticut each has a statute that requires MRO review under federal guidelines for a particular employer or workforce group. Connecticut's law is voluntary but California's law is mandatory. The drug testing law in **Puerto Rico** seems to presume that an MRO will be personally conducting the MRO interview.

New York has a State Regulation relative to the use of an MRO that must be considered. **Kentucky** has a State Regulation relative to the use of an MRO that also must be considered for workers in State operated Mental Health facilities.



The use of an MRO is not required but is recommended under **Arizona's** voluntary law.

Although the use of an MRO is not required under **Colorado, Georgia and North Dakota's** statutes, the use of an MRO may support a denial of benefits in such administrative action. It is recommended that the MRO personally conduct the interview in the foregoing states in order to ensure that the test result is given maximum weight in such an action. Under **Ohio's** voluntary workers compensation premium reduction law, MRO review is required for follow up testing. The law does not require that the MRO personally conduct the donor interview.

There are some states that specifically require the MRO to personally conduct the donor interview or to follow the federal guidelines that require the MRO to personally conduct the donor interview. These include mandatory statutes in **Montana, Vermont and Puerto Rico**, a group of states in which an MRO is required in special circumstances only, **California, Connecticut and Kentucky**, and **states in which MRO is required under a voluntary statute, Alabama, Arkansas, Florida, Idaho, Missouri, New Mexico and Tennessee**. As noted in the Executive Summary to this Review, under federal testing guidelines, MRO review is required and the MRO must personally

conduct the donor interview. The federal guidelines supercede take precedence over state law requirements for employers and employees required to comply with United States Department of Transportation regulations.

A number of states do not address whether a trained individual, other than the MRO, but under the MRO's supervision, may conduct the donor interview. These states are **Hawaii, Iowa, Louisiana, Maryland, Oklahoma, Alaska**, and **Ohio**. However, most of the statutes that reference or define the role and responsibilities of the MRO implicitly assume or directly state that the MRO is responsible for the final determination of the test result.

Conclusion

The role of the Medical Review Officer internationally may evolve differently than the role of the Medical Review Officer in the United States based on practical, cultural and legal considerations. It would be presumptuous, impractical and likely imprudent to assume that the United States' Medical Review Officer process will be the best model for international test review. Rather, the Medical Review Officer process in the United States could be a good starting point for the global community as it looks at workplace drug testing.