



RISQS Audit Protocol

Alcohol & Drugs module

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Preface

This protocol meets the RISQS Board Industry Minimum Requirements for Prequalification.

The audit is intended to facilitate the validation of information submitted by Supplier's on to the RISQS platform at the prequalification stage and to assess additional areas of compliance as required by Infrastructure Managers and the RISQS Board. Audits take place upon initial entry to the scheme, on a periodic basis and where there are relevant changes to the Organisation's information within RISQS. Auditors and Auditees (i.e. organisation subject to audit) are required to familiarise themselves with the content of the audit and its requirements prior to the audit commencing.

Guidance Notes

The questions and guidance notes within this document are applicable to all suppliers with the exception of those questions and bullet points' denoted (*TfL requirement*) which apply only to suppliers specifically limiting their scope of works to Transport for London (TfL) infrastructure.

Assessment Requirements

1. Alcohol & Drugs Testing Requirements

1.1 Arrangements to deliver effective Alcohol & Drugs screening

The company must have adequate arrangements in place to deliver an effective Alcohol and Drugs screening service.

That the organisation has a defined internal management structure with roles and responsibilities identified. That the organisation has a documented management system that includes procedures covering:

- Candidate identification
- Chain of custody
- Collection procedures
- Result reporting
- Managing of updates/changes to Rail Standards
- That the organisation has processes for management of:
 - Competence
 - Screening results and records
- That the organisation (if 5 or more employees) has a Health and Safety Policy and emergency arrangements that cover evacuation in the event of a fire.
- That fire risk assessments are conducted and recorded and the arrangements for ensuring health and safety extend to all facilities operated by the organisation.

1.2 Management System Quality Assurance

The company must ensure that its Alcohol & Drugs Collection/Testing Management System is quality assured.

- Preferably ISO 9001:2015 quality certificate issued by a UKAS accredited company
- The scope of certification should include the provision of drugs and alcohol screening services
- Examine the most recent 3rd party surveillance visit report and establish that no significant shortfalls were identified and that all non-conformances have been addressed and closed out within a reasonable time period.
- That the organisation measures compliance against its own management system i.e. Through the application of internal auditing
- Findings are recorded, tracked and closed out effectively
- The chain of custody process is subject to internal audit.
- The audit programme should be defined to ensure that all staff conducting chain of custody collections are subject to the audit process annually assured

1.3 Rail Standards

The company must have arrangements for ensuring that they are in receipt and possession of current Railway Group Standards (RGS) and Network Rail Standards.

- The Auditor will review arrangements and establish these documents are controlled and readily available to relevant staff.
- That the organisation has an adequate process for obtaining relevant RGS and Network Rail Standards
- Competence of those who carry out the review

1.4 Document Control

The company must have arrangements for the identification of all documents that are required to be controlled.

- That the organisation has a 'Document Control Procedure' that identifies the key documents required to be controlled. This must include:
 - The organisation's own procedures
 - Health and safety Policy
 - Railway Group Standards
 - Network Rail Standards and Procedures
- The document control procedure should identify:
- How documents are approved and reach the point of use
- How changes are identified and recorded
- The process for cancelled or superseded documents including maintenance of an archived copy of superseded documents.
- Process for review of controlled documents

1.5 Communication

The company must have arrangements that ensure relevant information is communicated within its organisation.

- An adequate process exists to communicate changes in internal procedure and policies throughout the organization
- The process is documented
- What procedure is operated to ensure all staff are advised of:
 - Updates of relevant rail and Network Rail company standards
 - Content of Sentinel and other relevant publications
 - Changes to statutory and regulatory requirements

1.6 Health and Safety Compliance

The organisation must ensure the workplace safety of its staff and comply with Health and Safety Legislation.

- That the organisation has a Health and Safety Policy including arrangements that cover:
 - Conducting risk assessments
 - Conducting COSHH Assessments
 - Emergency procedures e.g. covering fire & first aid
- A suitable and sufficient risk assessment for the hazards presented by the laboratories work activities has been conducted and recorded - (Reg 3 MHSWA Reg's)
- COSHH assessments exist for the hazardous substances being used – (COSHH Reg's)
- That staff undertaking such duties have been informed of the hazards and the preventative and protective measures to control the risk

1.7 Safety of Collection Officers

The company must have arrangements to ensure the safety of its collection officers.

- The organisation has performed and recorded a suitable and sufficient risk assessment for hazards presented to collection officers undertaking their activities. Hazards may include:
 - Lone working
 - Biological hazard
 - That collection officers undertaking such duties have been informed of the hazards and the preventative and protective measures required to control the risk
 - Measures should include suitable emergency and communication arrangements that ensure the organisation can locate its collection officers
 - The organisation has undertaken and recorded a COSHH assessment for the handling of biological fluids.

1.8 Insurance

The company must have adequate insurance to undertake Occupational Alcohol & Drugs screening.

- Employers Liability Minimum cover £5,000,000
- Public Liability Minimum cover £5,000,000
- Professional Indemnity Minimum cover £1,000,000

1.9 Security of Laboratory Premises

The company must ensure the security of its premises.

- That the laboratory has a robust security system to ensure that no unauthorized personnel gain access to the laboratory processes or to areas where samples or records are stored. Measures should include:
 - Unescorted access to secured areas must be restricted to authorized individuals only
 - Records to document the entry and exit of all visitors to the secured laboratory areas
 - A record of all staff who are authorized to enter the secure laboratory areas

1.10 Induction

The company must ensure that all new employees receive a formal documented induction.

- New employees are subject to an induction process that covers:
 - Health, safety & environmental statutory and regulatory requirements
 - Data Protection Act statutory requirements
 - In-house drugs and alcohol policy
 - Security procedures
 - Organisational structure
 - Roles and Responsibilities
 - Understanding of railway and infrastructure operations through an awareness training and briefing on all relevant rail documents
- That records of induction are held and the record is signed by the inductor and inductee.
- 5% of personnel files should be sampled

1.11 Selection of Competent Laboratory Staff

The company must have arrangements in place for the initial selection of competent staff.

- Competence levels have been defined for all key roles including:
 - Laboratory analyst
 - Authorizing scientist
 - Laboratory Manager
 - Those fulfilling role of expert witness
 - Quality Manager
 - Health, Safety and Environment Manager
- That careful selection and recruitment procedures are adopted
 - References are taken up and recorded
 - Competence and training records are maintained - Records should be examined

1.12 Training of Laboratory Staff

The company must ensure that laboratory staff undertaking workplace alcohol & drug testing are competent to do so.

- That training covers:
 - The laboratories processes and procedures
 - Chain of custody procedures
 - Quality control practices
 - Theory and practice of all analytical methods and procedures

- That training is assessed and recorded
- How continued competency is ensured through the review of work performance and on-going training e.g.
 - Participation in suitable CPD schemes
 - Annual appraisal
 - Peer review

1.13 Training of Collection Officers

The company must have arrangements for ensuring collection officers are competent to fulfil their duties.

- Collection officers have received appropriate training and fully understand Chain of Custody procedures
- Collection officers have been assessed whilst conducting a chain of custody collection and a record of the assessment maintained
- Competency Training covers drugs and alcohol screening within the rail industry e.g.
 - role of Sentinel
 - certification issued,
 - requirements of rail standards
- Competency records are maintained – 5% of collection Officers competency records should be sampled
 - Competency must be reviewed on an annual basis through **competence assessment whilst conducting a chain of custody collection**

1.14 Integrity of Collection Officers

The company must have measures to ensure the integrity of its collection officers.

- What measures the organisation has in place to ensure the integrity of its collection officers. These should include:
 - Take up and recording of references prior to employment
 - Issue of contract or terms of employment
 - Transgressions subject to a formal disciplinary process
 - Supervision and monitoring
 - 5% of personnel files should be sampled for recording of references and copies of contract or terms of employment
 - In accordance with best practice the organisation should have an in-house alcohol & drugs policy
 - Annual screening of own staff

1.15 Identification of Collection Officers

The company must have arrangements in place enabling any collection officer to readily demonstrate their competency and authorization

- That collection officers have been issued with Company Identification Cards if working away from base. That the identification cards as a minimum include:
 - Company Name
 - Name of the officer
 - Identification photo
 - Telephone contact number

- That collection officers have been issued with a certificate of competence and briefed that they must carry it and produce it when requested as required by NR/L2/OHS/00120
- That the collection officers have been briefed on the organisations arrangements in the event of a challenge by the donor regarding the collection officer's competence and contingency arrangements should the donor not be satisfied

1.16 Laboratory Criteria

The laboratory must perform drug testing that meets the requirements of relevant Network Rail Company Standards.

- That the laboratory's method of testing meets the requirements of NR/L2/OHS/00120 i.e.
 - Initial screening by immunoassay
 - Confirmatory drug testing by GC-MS or LC-MS testing
 - Urine validity testing to identify substitution, dilution and adulteration
 - Drug screening should identify persons in an unfit state through the use of drugs in accordance with Network Rail Alcohol & Drugs Standard NR/L1/OHS/051 and include urine screening for the following drugs:
 - Amphetamine
 - Benzodiazepines
 - Cannabis
 - Cocaine
 - MDMA
 - Methadone
 - Opiates
 - Propoxyphene
 - Alcohol

What contingency arrangements does the laboratory have minimize the risk and impact of unplanned events e.g. failure of equipment or power supply

1.17 Donor Identity

The company must have arrangements for confirming the identity of the donor.

- That donors are informed to bring suitable means for confirming identity, ~~and~~ National Insurance number and details of any medication prior to attending screening appointments
- That the organisation's procedures should identify suitable means for confirming the identity and National Insurance Number of the donor e.g. Sentinel Card, or other photo identification e.g. Passport, Driving licence or company identification card.
- That the confirmation of identity and national insurance number is recorded in the chain of custody documentation
- That the organisation has contingency arrangements for the donor failing to present suitable means of photographic identification to ensure that screening takes place

1.18 Pre-screening information to Donors

The company must have arrangements to ensure donors have received relevant information prior to sample donation.

- Arrangements form part of a documented procedure

- Information provided on the Donor Advice Sheet covers:
 - Instructions for collecting the sample
 - Importance of disclosing all medication before the sample is collected including:
 - Injections – including dental given or taken during the previous 14 days
 - Prescribed medicines
 - Proprietary medicines
 - Reason for the second sample
 - A list of the specific drug groups to be tested for that includes the following:
 - Amphetamine
 - Benzodiazepines
 - Cannabis
 - MDMA
 - Methadone
 - Opiates
 - Propoxyphene
 - Cocaine
 - Actions taken in the event of a positive result
- A chain of custody document gives:
 - The donors informed consent for the testing
The donors consent to Network Rail and or their representatives and their employer/sponsor being notified of the results

1.19 Collection Kits

The company must ensure that sample collection kits are fit for purpose

- Collection kits are supplied in sealed bags that include:
 - Sufficient printed barcode labels to identify the donor's samples and all copies of the chain of custody form
 - Security seals for the donor's sample with space for the donor's signature/initials
 - Packaging components that satisfy current mail and courier regulations including:
 - Watertight primary receptacle capable of withstanding, without leakage, an internal pressure which produces a pressure differential of not less than 95kPa
 - Watertight secondary packaging
 - Rigid outer packaging with laboratory address
 - Absorbent packing between the primary and secondary receptacle sufficient to absorb the entire contents of the primary receptacle(s)
 - Tamper evident seals

1.20 Chain of Custody

The company must have arrangements for establishing a Chain of Custody Procedure

- That the organisation has a documented chain of custody procedure that is as robust as the recommended Chain of Custody Procedure in NR/L2/OHS/00120
- That procedures include the following measures:
- Establishing a secure screening area
- Screening area to be checked and any possible contaminants or diluents removed
- Donor to remove outer clothing
- Donor to wash hands and scrub their nails
- Selection from choice of sealed collection kits
- Wash basin taps to be sealed with tape
- Dye block in place in WC cistern
- Instruction not to flush the toilet until the specimen is handed over to the collection officer
- Personnel access restricted until specimens are secured

- That samples are subject to testing and examination by the collection officer to ensure integrity of the specimen and the results recorded on chain of custody documentation. Information recorded should include:
 - Inadequate volume of urine
 - Temperature of the urine
 - Abnormal appearance of the urine
- Where dipstick testing of the sample is performed, procedures should ensure:
 - Testing is performed on the residual sample in the donor cup
 - The organisation has arrangements for handling abnormal results
 - Process respects the dignity of the donor and allows individual privacy during urination
- The organisation has protocols for managing donors who:
 - Are willing but unable to provide a sample
 - Refuse to consent or undergo testing

1.21 Laboratory Chain of Custody

The laboratories must ensure suitable arrangements for establishing and maintaining the chain of custody.

- The chain of custody form records the following information:
 - Donors name and national insurance number
 - Donors consent to the testing of the sample
 - Collection Officer's confirmation of donor identity
 - Temperature of the sample
 - Location, date and time of the collection
 - Chain of custody number
 - Collection officers signature
- That there are robust chain of custody procedures for the specimen throughout the life cycle of the analysis that provides an 'audit trail' for each sample and any aliquots, identifying the location and the identity of the analyst working with them
- There are control measures to minimize the risk of mix up of specimens

1.22 Testing Location

The company must have arrangements to ensure a suitable location for testing

- That any dedicated/regular donor facilities include:
 - Table or work surface for writing
 - Lockable storage or arrangements for donor's valuables
 - 2 chairs
 - Table or work surface for processing urine specimens
 - Toilet with door
- That the donor facilities can be made secure during the chain of custody collection
- That there are adequate arrangements for assessing and setting up a suitable collection area when sample collection is conducted at temporary donor facilities e.g. at the donors work place. Arrangements should take into account the following:
 - WC with access and egress through one door only

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- Hand washing facilities
- Secured windows if at ground level
- Secure work area for processing documentation and urine specimens
- Lockable storage for donor's valuables and collected samples
- Assessment of suitability of temporary donor facilities should be recorded

1.23 Random Screening on Behalf of the Employer

The company must have arrangements for managing random screening programmes on behalf of the employer (where offered).

- That the process for the random selection of donors and screening intervals is random, transparent, and fair and includes the following:
 - Arrangements form part of a documented procedure
 - Sufficient numbers of donor are selected to make up for staff absences
 - Collection officers are independent from the selection process
 - How the employer is informed of the identity of the selected donor(s) and the scheduling of the screening..

1.24 'For Cause' Screening

The company must have adequate arrangements for providing a For-cause screening service. (Note: Question only applies to organisations providing For-cause testing).

- Arrangements for the provision of a for-cause screening service that include the following:
 - A call-out system to provide 24 hour cover
 - Defined geographical area of service
 - Sufficient numbers of collection officers strategically located to cover the geographical area
 - A target attendance time of 2 hours from the initial contact
 - That the organisation monitors its attendance times and collates and reviews the data and is adequately meeting the 2 hour target

1.25 Records of Analysis

The company must ensure that records relating to the analysis of samples are maintained

- That the records should include:
 - Calibration data and any calculations used in determining the test results
 - Quality control results
 - Reagent and QC lot numbers
 - Equipment maintenance log

The Auditor should randomly select 1 positive screening result and examine the test data for this and the resulting confirmatory test

1.26 Laboratory Quality Control of Alcohol & Drugs Tests

The company must ensure that quality control systems are in place for drugs and alcohol tests

- That all the relevant types of drug are covered by the QC material
- That QC material of an appropriate medium and level is used
- That acceptable analytical performance of QC material has been identified
- How QC results are analysed to assess satisfactory performance
- That procedures cover the action to be taken when QC performance falls outside specifications
 - That QC performance is regularly reviewed

1.27 External Quality Assurance

The company must be able to demonstrate its performance in external Quality Assurance Schemes

- The laboratory participates in blind analysis testing as required by Railway Group Standard GE/RT8070 Drugs and Alcohol
- That the external Quality Assurance Scheme covers Drugs of Abuse
- That the laboratory has achieved satisfactory performance within the scheme

1.28 Laboratory Specimen Storage

The company must ensure suitable arrangements for the storage of specimens

- Specimens should be stored within the secure laboratory area until disposal
- Positive samples should be suitably stored to maintain their integrity
- Positive samples are retained in long term storage for a minimum period of 1 year

1.29 Work Equipment

The company must ensure that all equipment used meets manufacturer's specifications for maintenance, testing and calibration.

- That there are arrangements to ensure that inspections, calibration and maintenance of equipment are carried out and that records are maintained.
- That equipment calibration and testing and records include:
 - Unique identification on all breathalysers
 - A system exists to identify, report and rectify any faults
 - Testing is performed by competent individual or 3rd party
 - Equipment is maintained in good working order and shall be serviced as specified under the manufacturers specification

1.30 Breath Alcohol Testing

The company must have arrangements in place to ensure breath alcohol testing meets the requirements of NR/L2/OHS/00120.

- That testing is performed using a Home Office type approved device that provides an evidential immediate printed result.
- That the organisation has a documented breath alcohol testing procedure that includes the following:
 - Preparation of the donor including:
 - Instructions for collecting the sample, informing the donor of the implications of failure to provide a breath test and the consequences of the results
 - Establishing the time elapsed since the donor last smoked or took anything by mouth
 - Obtaining the donor's informed consent for the testing and consent to Network Rail and or their representatives and their employer/sponsor being notified of the results.
 - Instructions regarding obtaining a sample including:
 - The collection officer and donor signing the printed results,

- The actions in event of a positive including retesting using a new mouthpiece, after a 15 minute interval following a detectable reading
 - Basic maintenance of the alcometer
- That positive for alcohol results are defined using the levels identified in RGS GE/RT8070 Drugs and Alcohol i.e. More than 13 mg in 100ml of breath or More than 29 mg per 100ml equivalent blood alcohol.

1.31 Interpretation of Results – Laboratory Mandatory Cut-offs

The company must demonstrate knowledge of the mandated cut-offs to be used in the interpretation of analytical results.

- The screening and confirmation cut-off concentrations for urinary drugs are identified and take in to account:
 - The analytical method
 - Guidelines on work place drug testing

1.32 Reporting of Laboratory Results

The company must have arrangements for the reporting of laboratory results

- Result reporting is undertaken by competent individuals
- There are control measures to minimize the risk of transcription errors
- Interpretation and authorisation of positive result should be performed by a competent toxicologist and reports should be endorsed by the competent toxicologist
- The arrangements form part of a documented procedure and cover:
 - The method of reporting Pass and Fail results e.g. how results are communicated and to whom
 - Same day reporting of positive results
 - Reporting of diluted or suspected adulterated samples
 - Reporting of results consistent with declared and undeclared medication

1.33 Reporting of Results

The company must have adequate arrangements for the reporting of results

- The arrangements form part of a documented procedure and cover:
 - The method of reporting Pass and Fail results e.g. how results are communicated and to whom
 - Reporting of non-attendance to a drugs screening appointment
 - Reporting of willing but unable to provide a suitable specimen
 - Reporting of refusals to undergo testing
 - All non-negative laboratory results are reviewed by a competent Medical Review Officer before final confirmation of test result.
 - To whom results are to be reported e.g.: employer / sponsor / Network Rail and or their representatives
 - Prompt reporting of positive and 'No Result' categories of results – should be reported immediately to Sentinel and the employer / sponsor.
 - Certificate PRO number
 - Positive result including substance found
- All laboratory results are reviewed by a competent Medical Review Officer before final confirmation of test result.

1.34 Updating of Result to Sentinel

The company must have arrangements in place for ensuring that Alcohol & Drugs Screening results are uploaded on to Sentinel.

- The company must have arrangements in place for ensuring that drug and alcohol screening results are uploaded to Sentinel, including:
 - How to search for the individual's record within the database
 - The process to be followed where information on the database is incorrect
 - Completion of the drug and alcohol screening certificate
- Reports correctly identify the type of screen as Pre-employment (PE), Random (R), Unannounced Random (UR) or For-Cause (FC).

The Sentinel database should be accessible and a sample of completed drug and alcohol certificates examined to ensure certificates meet the requirements for completion and timescales for reporting.

1.35 Records of Results to Sentinel

The company must ensure adequate records of drug screening results are maintained

- That a record is maintained for each screen that includes the following:
 - Copy of the chain of custody form
 - Copy of the laboratory report
 - Copies of breath alcohol printed results signed by the collection officer and the donor
 - Copies of any comments made by the Medical Review Officer
- That drugs and alcohol screening records are maintained for a period of not less than 10 years
- That the above records are legible, retrievable and secure

A sample of completed drug screening records should be examined to ensure records are correct and complete and include a record of medical review where applicable

1.36 Monitoring

The company must have arrangements in place to monitor its performance.

- That the organisation has a system for logging all the drugs and alcohol screens it conducts
- That the organisation has arrangements for reporting and recording chain of custody errors. Arrangements should include the identification of suitable corrective and preventative actions and close-out of actions should be recorded. The Auditor should examine any chain of custody errors for the previous 12 month period and record the total number

1.37 Medical Review

The company must have arrangements to ensure the medical review of positive laboratory findings

- That the organisation's procedures ensure all positive results undergo medical review

- That the process aims to establish that any declared medication is the result of legitimate use
- That results are managed in accordance with the requirements identified in the rail standard NR/L2/OHS/00120
- Medical review is performed by a competent medical review officer
- The sponsor or employer is advised when medication is not compatible with safety critical working

1.38 Challenged Samples

The company must have adequate arrangements for the management of challenged samples

- That the organisation has a documented procedure for the management of challenged samples
- Process ensures that the second sample is released in accordance with a chain of custody procedure following authorisation by the donor and the employer/sponsor
- Donors are provided with instructions on how to challenge positive results and a list of approved laboratories for testing of the second sample