



## RISQS Audit Protocol

### Medical Screening 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. Medical Screening Requirements

### 1.1 Management arrangements to deliver effective Medical screening

The Organisation shall ensure it has adequate arrangements in place to enable it to deliver an effective medical assessment 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 that cover:
  - Candidate identification
  - Guidance on medical fitness requirements of Network Rail standards & Railway Group Standards
  - Review of medical assessments by a supervising Occupational Medical Practitioner
  - Recording of assessments and issue of certification
  - Reporting procedures
  - Maintenance, testing and calibration of equipment
  - Managing of updates/changes to Network Rail and Rail Group Standards
- That the Organisation has processes for management of:
  - Competence
  - 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 Occupational Health provider.

## 1.2 Quality Assurance

The company must ensure that its Medical Screening Management System is quality assured (Certification to the ISO9001:2015 standard is preferable but not essential).

- That the company holds a valid ISO 9001:2015 quality certificate issued by a UKAS accredited company.
- The scope of certification should include the provision of occupational health 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.
  - o Through the application of internal auditing.
  - o Findings are recorded, tracked and closed out effectively.
  - o The medical assessment process is subject to internal audit.
  - o The company's internal audit programme should have been defined to ensure that the work of all medical examiners is subject to the audit process annually as a minimum

## 1.3 Rail Standards

The company must ensure that they are in receipt and possession of current applicable Railway Group Standards (RGS) and Network Rail Standards.

- That the organisation has an adequate process for obtaining relevant RGS and Network Rail Standards.
- As a minimum, this should include the following standard; NR/L2/OHS/00124 Competence specific medical fitness requirements and occupational health provider requirements for medical assessments.
- An adequate process exists for receipt of notification of changes to relevant RGS and CS&P.
- Responsibility for the review and implementation of the requirements of rail standards has been clearly identified.
- The review and implementation of requirements is conducted by suitable competent individuals

## 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 and controls key documents and-3-
- That they are readily available to relevant staff. The Auditor will establish these documents include:
- The organisation's own procedures.
  - o Health and Safety Policy.
  - o Railway Group and Network Rail Standards including NR/L2/OHS/00124.
- The Auditor will establish the document control procedures identify:
  - o How documents are approved and reach the point of use.
  - o How changes are identified and recorded.
  - o The process for cancelled or superseded documents including maintenance of an archived copy of superseded documents.

- o Process for review of controlled documents.

## 1.5 Data Protection and Confidentiality

The Organisation shall ensure that it complies with the requirements of the Data Protection Act and The company must ensure that it complies with the requirements of the Data Protection Act and that medical confidentiality is maintained.

- That the organisation holds a current registration under the Data Protection Act
- That the organisation has policies and procedures that ensure compliance with the requirements of the Data Protection Act that cover:
  - o Identification of the type of information held by the organization.
  - o The form that the information is held e.g. electronic, hard copy- disaster recovery arrangements for storage of electronic information.
  - o Process for handling patient requests to access their records.
  - o Release and lawful use of data.
  - o Updating of information held.
  - o Individual's responsibilities.
- That procedures include control measures to protect the confidentiality of patient information and cover:
  - o Employee access to medical records.
  - o Communication of information by telephone, electronic and fax.
  - o **Transportation, storage and disposal** of hard copy medical records to ensure confidentiality, security and disaster recovery in **the event of fire or theft**
  - o **Arrangements for security of computer data, preventing unauthorised access to digital data and authorisation for loading programmes where a computer is used.**

## 1.6 Communication

The company must have arrangements for ensuring that relevant information is communicated within its organisation

- An adequate process exists to communicate changes in internal procedure and policies throughout the Organisation.
- Process should record distribution and receipt.
- A procedure is operated to ensure all staff are advised of:
  - Updates of relevant rail standards.
  - Relevant content of Sentinel and occupational health protocols.
  - Changes to statutory and regulatory requirements

## 1.7 Work Equipment

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

- That there are arrangements to ensure that inspections, calibration, maintenance and replacement of medical equipment are carried out and that records are maintained.
- That equipment calibration and testing records include:
  - Unique identification on all audiometers and sphygmomanometers.
  - A system to identify, report and rectify any faults.
  - A protocol for the testing of audiometers in accordance with manufacturer's instructions.
  - Testing is performed by competent individual or 3rd party.
  - Confirmation that equipment being used is within test date

## 1.8 Insurance

The company must have adequate insurance to undertake Track Safety medical assessments.

- Employer's Liability Minimum cover £5,000,000
- Public Liability Minimum cover £5,000,000
- Professional Indemnity Minimum cover £1,000,000
- N.B. Professional Indemnity cover may be provided through individual membership schemes e.g. MDU and RCN. The Auditor should examine proof of current membership

Auditor note: The Auditor should examine proof of current membership

## 1.9 Induction

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

- New employees are subject to an induction process that covers:
  - Health and safety statutory requirements.
  - Data Protection Act statutory requirements.
  - In-house drugs and alcohol policy.
  - Security procedures.
  - Organisational structure.
  - Roles and Responsibilities.
  - Organisation's policies and procedures.

- That records of induction are held and the record is signed by the inductor and inductee
- 5% of personnel files should be sampled

## 1.10 Employing Competent Personnel

The company must have arrangements for employing competent staff.

- Competence levels meet the minimum requirements identified in [NR/L2/OHS/00124](#)  
[NR/L2/OHS/00124](#)  
Competence specific medical fitness requirements and occupational health provider requirements for medical assessments.
- The Responsible Occupational Health Physician should be able to demonstrate that they are:
  - A registered physician with a licence to practice and accredited specialist in occupational medicine
  - Have the knowledge, experience, skills and understanding relevant to occupational health practice in the railway industry
- That Medical Examiners have received training in performing occupational health assessments either internally or by an external provider and their competence to perform the clinical examinations required to conduct Competence Specific Medical Fitness Assessments has been assessed and recorded.
- That Medical Examiners attending site visits have been issued with Company Identification Cards.
- That the Identification cards as a minimum include:
  - Company Name
  - Name of the officer
  - Telephone contact number
- That training includes awareness training to infrastructure and railway activities and understanding of relevant Railway and Network Rail standards
- Competency records are maintained containing copies of certificates, registrations and relevant training – 5% of employees' competency records should be examined.

## 1.11 Ongoing Competence

The company must have arrangements for the continuous education, training and professional development of staff.

- That Responsible Occupational Health Physicians are subject to GMC revalidation and annual appraisal.
- That Responsible Occupational Health Physicians maintain a portfolio of evidence of continued professional development and ideally participate in a registered CPD scheme through their professional body – certificates of annual submission should be examined.
- Relevancy of material in relation to track safety or safety critical work (Membership of ARIOPS as applicable).
- That Medical Examiners are subject to continuous education, training and professional development.
- Arrangements should include some or all of the following:
  - Participation in relevant CPD Schemes or revalidation to maintain professional registration
  - Clinical appraisal and Peer reviews
  - Refresher training and technology based learning
  - Clinical audit
- That Medical Examiners maintain a portfolio of evidence of continued professional development. Participants' CPD folder should be examined and also include inspection of valid registration document to medical and nursing board (NMC and GMC).

## 1.12 Pre-assessment Checking & Confirmation of Identity of Candidates

The company must have arrangements for the provision of information prior to the medical assessment, pre-assessment checks and confirming the identity of the candidate.

- The Medical Examiner shall confirm that the individual being assessed has a sponsor before a competence specific medical fitness assessment is undertaken.
- That donors are informed to bring suitable means for confirming identity, National Insurance number, visual correction aides 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 within the medical record.
- That the organisation has suitable contingency arrangements for the donor failing to present suitable means of photographic identification.

## 1.13 Obtaining Candidates Information

The company must ensure that it has suitable arrangements in place to obtain relevant information to assist in the medical assessment of the patient.

- The organisation obtains the patient's written consent for Network Rail and or their representatives and their employer/sponsor being notified of the results of the assessment
- The organisation collects and records information to assist in the medical assessment through the use of:
  - Completion of a Medical questionnaires followed by a Patient evaluation through a face to face assessment performed by medical examiner
  - The scope of information gathered – e.g.:
    - Current state of health
    - Medical History
    - Medication
    - Absence from work due to sickness
    - Type of work performed by the candidate e.g. safety critical or shift work
    - Diet and Lifestyle (e.g. exercise, alcohol, tobacco and drug use)
    - Mental Health
- Employment History
- A sample of completed medical records should be examined to ensure the patient's written consent is obtained and medical questionnaires are completed.

## 1.14 Medical Screening Standards

The company must ensure the examinations and screening methods it uses in performing the medical assessment meet the required standards.

- That the medical assessment meets the requirements identified in NR/L2/OHS/00124 Competence specific medical fitness requirements and occupational health provider requirements for medical assessments and includes:
  - Visual Acuity (using 6m Snellen) and the assessment of visual fields
  - Audiometric assessment

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- Colour vision assessed using Ishihara books either 24 or 38 plate, in line with the manufacturer's guidelines for the relevant book, with Testing being done in a non-sequential order.
- Ishihara test plate books shall be closed and stored in their box away from direct sun light when not in use.
- Ishihara test plate books shall be replaced at intervals according to the manufacturer's instructions.
- The medical examiner shall have normal colour vision.
- General Health observations including
  - Height
  - Weight
  - Blood Pressure
  - Urine dipstick test to screen for disease (e.g. diabetes, kidney infection)
- General Health Assessments including
  - Assessment of mobility
  - Assessment of alertness and psychological wellbeing
  - Assessment of speech and ability to communicate

**A sample of completed medical records should be examined to ensure the medical assessment meets the requirements.**

### 1.15 Assessment of Medical Fitness on Network Rail Managed Infrastructure

The company must be able to assess medical fitness for work on or about Network Rail's Managed Infrastructure.

- That the organisation has procedures for the referral of cases, ensuring medical examiners have access to the supervising Occupational Health Physician
- That the organisation has a written code of practice giving guidance on the standards of medical fitness and medical conditions in relation to fitness for work on or about Network Rail's Controlled Infrastructure
- Guidance issued should cover at least:
  - Visual acuity including guidance on laser eye surgery
  - Colour vision
  - Hearing (hearing assessments using audiometry equipment that conforms to British Standard BS EN 60645-1:2015 for pure tone air conduction audiometers. Bone conduction audiometers shall not be used).
  - General Health in accordance with Group 2 DVLA medical standards
  - Urine testing
- Guidance covering the requirements of the medical fitness levels and the role of the following:
  - The use of restrictions and the medical fitness levels to which they can be applied and advice on fitness to undertake specific tasks
  - The age related maximum validity periods and issuing of shorter duration medical certification
  - The recommendation of on-site risk assessment

## 1.16 Recording & Reporting of Results

The company must have arrangements for result reporting of Track Safety Medical Assessments.

- The arrangements form part of a documented procedure and cover:
  - The method of reporting results e.g. how results are communicated and to whom
  - Prompt reporting of medical assessment results. 'Fail' or with restrictions results should be reported the same day to Sentinel and the employer and / or sponsor.
- The company must have arrangements in place for ensuring that medical assessment information/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
  - The completion of the medical certificate including the following:
    - the recording of categories for visual acuity and hearing
    - the recording of wearing of glasses and contact lenses only where they are required to meet the visual acuity standard
    - overriding the default age related expiry date to issue a certificate of shorter duration
    - recording the results and medical fitness level
    - recording the name of the medical examiner who conducted the medical assessment
- The Sentinel database should be accessible and a sample of completed medical certificates examined to ensure certificates meet the requirements for completion and reporting.

## 1.17 Records

The company must have arrangements to ensure records of medical assessments are maintained and controlled in accordance with the Medical Records Act.

- That a record is maintained for each medical assessment that includes the following:
  - Medical history questionnaire or record of patient evaluation performed by medical examiner
  - Results of general health assessment
  - Audiogram and assessment
  - Decision and signature of the examiner
  - Where fitness standard is not met medical record should include:
    - Reason for referral
    - Record of subsequent assessment
    - Decision and signature of the occupational physician
  - That medical assessment records are maintained and available for a period of not less than 10 years
  - That the above records are legible, retrievable and secure
- A sample of completed medical records should be examined to ensure records meet the standards for recording the medical assessment.

## 1.18 Further Evaluation of Patients

The company must have adequate arrangements to manage the further evaluation of patients.

- The arrangements form part of a documented procedure and cover the following:

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- A system for quarantining correctable failures that includes:
  - Establishing current track competence status
  - Assessing the risk of the individual continuing to work under an existing track competence
  - Issuing of interim certificates until further evaluation and reports by other health care professionals are obtained
- Obtaining patient consent for accessing medical records held by other health care professionals to ensure compliance with the Access to Medical Reports Act.