UIMC Railway medical guidelines

Guidelines for medical fitness of railway personnel in safety critical functions

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PREFACE

The original working group was established in 1999 to define minimum interoperability criteria for European railway staff concerning medical fitness. The group considered mainly two interoperating occupations, i.e. train drivers and other train crew.

The original minimum criteria were meant to be a model for further development in the field of railway related medical fitness and aptitude, and to form a recommendation to the Community of European Railways (CER) concerning medical fitness of staff taking part in interoperability.

The editorial group intended to periodically evaluate and update these recommendations. In 2012 an update was executed by a group of three railway medical experts. The UIMC asked them to update these guidelines to reflect relevant changes in the last 10 years by checking international and national guidelines together with a brief survey of recent literature. Modern medical insights, new treatments and a method for risk assessment are now integrated into these updated minimum interoperability criteria. A provisional version of the update was presented at the 2012 UIMC conference in Helsinki. This version was also sent to all the UIMC members for comments. The comments were discussed in a special meeting in Utrecht in 2013 by several delegates and at a further meeting in Bern in 2014 to finalize the guidance. In 2019 we revised the chapters on psychiatric disorders and on misuse of alcohol, drugs and psychotropic substances.

The majority of criteria formulated in these guidelines are based on expert opinion and consensus of experts from around the globe because of the lack of high quality studies concerning the relationship between diseases and railway safety.

General remarks

There are two risk groups in operating services demanding partially different criteria. It is in the responsibility of the railway company to define in which group each role is placed.

***Group A*:** high safety risk, i.e. a single person's responsibility for traffic safety not fully compensated by technical means

***Group B*:** safety risk, i.e. responsibility for operational safety controlled by group work, supervision by another skilled person or by technical equipment that can maintain a sufficient safety level.

The disqualifying criteria are divided into two categories: strong and relative. The strong criteria are fixed and independent of other criteria. The relative criteria should be judged in relation to the other criteria. For example: having an ICD is a strong

disqualifier while a body mass index > 30 kg/m^2 is a relative disqualifier and should be evaluated in conjunction with other criteria such as blood pressure, etc.

The minimum interoperability criteria for medical fitness are those required for serving staff. The version of 2001 was based on fitness criteria which have proved to be valid in different European countries. In the update of 2013 the basis of these minimum criteria has been extended to those of Australia and Canada. The update includes a new general introduction to risk assessment which can be used for national or local development of specific medical criteria and an update of the chapters concerning Cardiovascular disorders, Neurological diseases (including OSA and syncope) and Diabetes mellitus.

The purpose of these guidelines is to establish minimum standards for interoperability. Individual railway companies may choose to have stricter standards.

It is possible, after careful assessment and in co-operation with certified railway occupational physicians and the appropriate medical specialist, to make exceptions to the minimum criteria set out in these guidelines.

For the ease of reading this document, the railway worker is referred in the male gender, as “he”.

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Medical fitness standards

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1. INTRODUCTION

The basic purpose for these minimal interoperability medical fitness standards is to minimize the risk of railway accidents. Within the framework of railway safety, the functional capabilities (vision, hearing, adequate cognitive functioning and physical capacity) of the railway worker and the risk of sudden incapacity caused by diseases are important factors.

For group A one must not be suffering from any medical condition or be taking any medication, drugs or substances which are likely to cause[1]:

- sudden loss of consciousness
- impairment of cognitive functioning
- impairment of safety – relevant sensory functions
- sudden incapacity
- impairment or loss of balance or coordination
- limitation of mobility or coordination needed for specific tasks

For group B one must not be suffering from any medical condition or be taking any medication, drugs or substances which are likely to cause[2]:

- impairment of cognitive functioning
- impairment of safety – relevant sensory functions

The criteria for the sensory functions such as vision and hearing are determined by the technical circumstances. For vision the distances at which a worker must see clearly, which colors are used and the contrast situation determine the criteria.

For hearing the signal-noise relation is the most important determinant.

Every (physical) medical condition or disease can also affect the cognitive and/or mental functioning. The impact on cognitive functioning depends on the nature and severity of the disease and the age of the employee. Cognitive functioning has many aspects such as perception, alertness and concentration, information processing, reasoning and executive functioning. In these cases, a (neuro-) psychological assessment is recommended and should be considered, in some cases this assessment is even mandatory.

The employee with any disease must, if declared fit for safety duties, have a good understanding of the disease and have the capacity to act adequately in case of the appearance of symptoms. He should receive instructions to stop his safety critical tasks at the first signs of an impending disturbance of functioning.

References:

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2. RISK ASSESSMENT CALCULATION

The level of acceptable risk of sudden incapacity caused by diseases is difficult to define. Even under a "vision zero accidents" approach one must be aware that the risk of human failure can never be zero. By "vision zero accidents" is meant the often impossible demand of societies or politicians to realize a 100% human safety situation. The society or politicians have to agree what level of risk of an accident is acceptable. For example, in the Netherlands the Human Environment and Transport Inspectorate (IL&T)[3] has established the level of risk of an incident (e.g. speeding through a red signal) at 1:10.000 drivers per year caused by medical incapacity. This corresponds with worldwide standards for all kinds of traffic modalities.

To transform this risk into medical fitness standards for workers with diseases which can cause sudden incapacity we recommend adopting a "risk of harm" formula based on the model of the Canadian Cardiovascular Society (CCS) to quantify the level of risk for drivers[4].

This formula incorporates four components:

1. Time spent driving (TD)
2. Type of railway system (RS)
3. Risk of sudden incapacity (SCI)
4. The probability that such an event will result in a fatal or injury-producing accident (Ac)

The railway specific risk of harm (RH) can be assessed by this formula:

RH = TD x RS x SCI x Ac

- TD: The Time spent Driving for professional train drivers is approximately 15-25% of the total years' time.
- RS: The type of railway system represents the impact of the train. The CCS set the factor for heavy trucks as 1. This same value can be used for trains although the impact of a train is higher than that of heavy trucks but because of the advanced technical safety devices in trains RS will also approach the value 1.
- SCI: The risk of sudden incapacity varies depending on the disease and relating factors such as provoking triggers and the individual ability to cope and adequately react to oncoming problems and symptoms. In the general "healthy" population the SCI is ± 1% per year.
- Ac: The probability that such an event will result in harm to others can be found in accidents statistics. For road traffic the Ac is ± 2%.

Putting these numbers in the formula for professional truck drivers the RH = 0.25 (TD) x 1 (V) x 0.01 (SCI) x 0.02 (Ac) = 0.00005 or 1 in 20.000 drivers will cause harm to others in a period of one year.

For train drivers this risk of harm will be lower because while the working hours are 25% of their total years' time, the actual driving time is 60-70% of this working time. That makes the Time spent driving (TD) ± 15%. The probability that such an event will result in harm to others (Ac), although not known for railway traffic, will be lower also. Taking into account that the accepted risk for train drivers is set 1 in 10.000, the risk of sudden incapacity (SCI) can be higher and still result in the same low risk of harm (RH). So the risk of sudden incapacity (SCI) can safely be set at 2 - 4%, depending on local values of TD and Ac.

One may conclude that the impact of sudden incapacity of a train driver (harm to people and material) depends mainly on the risk of sudden incapacity (SCI) and on the working conditions e.g. the time at risk, the circumstances like technical safety devices, train velocity, material and the number of people present in the train and stations. This means that with each assessment of the individual risk level individual factors and circumstantial factors will play a role in the assessment.

With this individual risk of sudden incapacity during a period of one year in mind the minimum interoperability medical fitness standards have been updated for the chapters on Cardiovascular disorders, Neurology and Diabetes Mellitus.

When the working conditions change the fitness criteria have to be adapted.

In order to react properly in case of sudden symptoms a worker with a disease which can cause incapacity must have a certain understanding of his disease and of the responsibility of railway safety matters. This is compulsory for every disease which can influence the railway safety.

Another important factor is the experience of the worker. There is the paradox between the healthy, inexperienced working youngsters and the less healthy, but more experienced older workers. A study of pilots showed a higher accident rate for healthy young pilots compared with a lower accident rate for less healthy older ones[5].

This means one should be more stringent for the initial assessment and could be more lenient for the recurrent assessment if this is permitted by the legal framework within which the railway company operates.

The initial assessment consists of a medical history, height, weight, blood pressure, blood/urine glucose, ECG, vision, hearing and a general physical and mental examination.

One Scandinavian study suggests that periodic assessment before the age of forty is not evidence based. In cases which are indicated in the following chapters of these medical fitness standards, periodic assessment is advisable.

After the age of forty a minimum frequency of five years for medical assessment is recommended and a shorter interval according to age, depending on the age-related prevalence of diseases and adhering to the requirements of national and international regulation.

Every railway company is advised to adapt the medical fitness criteria to suit their current railway safety situation taking into account the components of the risk of harm formula and their national and international legislation.

3. CARDIOVASCULAR DISORDERS

General remarks

In general, cardiovascular diseases account for 8 percent of all disease- related accidents. In 25 percent of these cases it concerns people who were unaware of having a cardiovascular disease[1].

The employee with a cardiac disease must, if declared fit for safety duties, have a good disease understanding and capacity to act adequately in case of the appearance of symptoms. He should receive instructions to stop performing safety tasks at the first signs of an impending incapacity.

Coronary heart disease is the most common form of cardiovascular disorders. The underlying atherothrombotic processes are related to several risk factors and can be influenced by cardiovascular risk management. The major risk factors that determine an individual's cardiovascular risk are smoking status, blood pressure, age, gender, lipid profile, obesity, sedentary life-style, diabetes, a positive family history for cardiovascular disease, OSA and kidney disease.

It is of utmost importance to lower the cardiovascular risk in patients with established cardiovascular diseases by means of individually tailored medication and sustained lifestyle changes. Stopping smoking and good physical fitness are most effective for risk reduction. These aspects should be incorporated into the medical fitness assessment.

There are two prominent and currently widely used risk models to determine the individual cardiovascular risk. For European populations SCORE (Systemic Coronary Risk Evaluation Project) (in annex A), has been developed and for Outside-Europe populations the Framingham Risk Score has been developed. SCORE only predicts the 10-year's risk of dying from a cardiovascular disease (i.e. only mortality) while Framingham predicts the combined 10 –year risk for morbidity and mortality [2,3,4]. In both risk models, populations at risk are classified in the category "high" or "very high". In these guidelines the category "high" is used to indicate the possibility of an impact on the fitness for safety duties.

Group A

For an adequate assessment of the fitness of group A employees who have cardiac disease, actual information is needed on diagnosis, physical fitness, symptoms, left ventricular function, the presence or absence of ischemia, the presence or absence of arrhythmias, ECG, co-morbidity, cardiovascular risk profile, OSA, and medication use[2].

When an employee with one of the following cardiac disorders is declared fit for high safety tasks, a periodic evaluation should be conducted. This includes at least an oral history or questionnaire, risk factors assessment, a resting ECG and an adequate stress test.

Additional diagnostic investigations such as Holter monitoring, echocardiography or other cardiac imaging modalities or more invasive procedures should be undertaken where there remain doubts about the employees' medical fitness for driving.

Impaired cognitive functioning caused by cardiovascular disorders should be looked for. When in doubt a (neuro)psychological investigation should be considered.

Group B

Whilst employees with cardiac diseases within this group may be physically fit for their duty, their cognitive function may be affected. This is particularly true for advanced age. When in doubt a (neuro)psychological investigation should be considered.

3.1. Coronary heart disease

Coronary heart disease includes all patients with chronic angina pectoris and/or acute coronary syndromes (unstable angina pectoris, STEMI and N-STEMI) and/or a history of PCI or CABG.

It is well known that a patient with a coronary heart disease will benefit from a cardiac rehabilitation programme. If this programme pays specific attention to the job characteristics it will facilitate return to safety work[5,6].

Group A

Group A employees can safely resume their duty following onset of coronary heart disease provided there are no disqualifying criteria[7].

<u>Strong disqualifying criteria</u>

- Any persisting symptoms
- Left ventricular ejection fraction < 40%
- (Silent) ischemia provoked by a stress test
- Residual stenosis of > 50 % in the left main stem or proximal and middle LAD, RCA or RCX and at other places a stenosis > 50% only with proven ischaemia or a FFR (Fractional Flow Reserve) < 0.80 (Please note: this does not mean angiography is mandatory for (re)licensing purposes)[8].
- Poor-compliance with medical treatment
- Other disqualifying factors (see relevant chapters)

Relative disqualifying criteria

- Physical fitness < 7 MET* (8 MET is recommended for age < 50)[9]
- Left ventricular ejection fraction < 50%
- Inadequately treated cardiovascular risk factors (see table 1)
- Inadequately treated OSA

Remarks

Special attention should be given to cognitive functioning in relation to age[10,11].

Resuming work

6 weeks after (N)STEMI, PCI and 12 weeks after CABG provided the assessment phase is concluded satisfactorily, the resumption of work can begin, supervised by a certified railway doctor. After an elective PCI the period before resuming work can be shorter. Cardiac rehabilitation is strongly recommended as well as gradually resuming non-safety related work during the cardiac rehabilitation. Periodic reassessment is required. Its frequency depends on age, severity of the coronary heart disease and risk profile.

Group B

Strong disqualifying criteria

- Persisting symptoms NYHA classes III and IV (see Annex B)

Relative disqualifying criteria

- NYHA class II with symptoms provoked by professional activities

Remarks

The assessment must take into account the level of control of cardiovascular risks (see Table 1).

** MET : 7 MET is equivalent to going up three flights of stairs and 8 MET four flights of stairs.*

Table 1

ESC recommendations for optimal cardiovascular risk profile in patients with established coronary heart disease[a].

- Smoking cessation among smokers
- Regular physical activity
- BMI < 25 kg/m^2
- Waist circumference < 94 cm (men)
  < 80 cm (women)
- Blood pressure < 140/90 mmHg
- Total cholesterol < 4,5 mmol/l (175 mg/dl)
- LDL cholesterol < 2,5 mmol/l (100 mg/dl)
- Among patients with type 2 diabetes
  Fasting glycemia < 7,0 mmol/l (125 mg/dl)
  HbA1c < 6.5%

[a] European Guidelines on cardiovascular disease prevention in clinical practice Eur Heart J. 2012 Jul;33(13):1635-701.

Note: Although the ESC target values for patients with established coronary heart disease and diabetes mellitus are recommended for preventing recurrence of new cardiac events, it may not be optimal for safety duties because of the higher risk of hypoglycemia. See chapter on diabetes mellitus for the optimal recommended values of fasting glycaemia and HbA1c.

3.2. Peripheral arterial disease[12,13]

Group A

When, after cardiological investigations have been completed, there are no signs of relevant coronary artery disease, no restrictions are necessary, provided that the peripheral arterial disease is stabilized, the cardiovascular risk is not high and mobility is not affected.

In case of atherosclerosis or dilatation of the thoracic or abdominal aorta, an annual imaging assessment is mandatory to adequately identify potential deterioration of aortic disease.
After successful PTA, grafting or repair, when no evidence of residual disease or other disqualifying condition exists, a return to high safety duties can be considered after clinical assessment.

<u>Strong disqualifying criteria</u>

- An aortic aneurysm is present with a diameter > 4,5 cm in the thoracic aorta or > 5 cm in the abdominal aorta.

Relative disqualifying criteria

- A high cardiovascular risk

Remarks

When, after careful examination, the employee could be declared fit for safety duties special attention should be given to cognitive functioning. Special attention is required for blood pressure control in patients with peripheral vascular disease (for hypertension see relevant chapter).

3.3. Hypertension (see annex C)

The European Guideline on Hypertension[14] recommends office measurements for screening and diagnosis of hypertension. The diagnosis must be based on at least two blood pressure measurements per visit and on at least two visits. The home and ambulatory BP measurements are additional methods. It is important to realize that there are different cut-off points for the definition of hypertension depending on the method of measurement. If indicated 24hr ambulatory BP-monitoring (ABPM) can be helpful, especially during a driving day, and considering the different cut-off points. When hypertension is diagnosed the 10-years cardiovascular risk must be assessed.

Group A

Strong disqualifying criteria

- Immediately when blood pressure ≥ 200/110 mmHg (with or without treatment)
- Persistent blood pressure ≥ 180/110 mm Hg (with or without treatment)
- Blood pressure > 140/90 mmHg combined with secondary organ damage such as left ventricular hypertrophy with STT-abnormalities on the ECG and/or damage of the kidney
- Resistant hypertension. Hypertension is usually defined as resistant or refractory to treatment when a therapeutic plan which includes attention to lifestyle measures and the prescription of at least three antihypertensive drugs (including a diuretic) in adequate doses has failed to lower systolic and diastolic blood pressure ≤ 140/90, provided that poor compliance is excluded[14]. Further investigation is needed for other causes (secondary hypertension)

Relative disqualifying criteria

- Blood pressure > 140/90 mmHg combined with a high 10 year cardiovascular risk

Remarks

If the blood pressure is normalized, high safety duties can be resumed provided that a periodic assessment of the blood pressure and cardiovascular risk will be carried out.

Special attention should be given to cognitive functioning, especially with long existing, not well or untreated, hypertension[15,16,17,18].

Group B

Relative disqualifying criteria

- Blood pressure ≥ 180/110 mmHg (with or without treatment)
- Blood pressure > 140/90 mmHg combined with a high 10-year cardiovascular risk. (with or without treatment)
- Blood pressure > 140/90 mmHg combined with secondary organ damage like left ventricular hypertrophy with STT- abnormalities on the ECG and/or damage of the kidney
- Resistant hypertension. Hypertension is usually defined resistant or refractory to treatment when a therapeutic plan that has included attention to lifestyle measures and the prescription of at least three drugs (including a diuretic) in adequate doses has failed to lower systolic and diastolic blood pressure ≤ 140/90 mmHg, provided noncompliance is excluded[14]. Further investigation is needed for other causes (secondary hypertension)

Remarks

Special attention should be given to cognitive functioning, especially with long existing, not well or untreated, hypertension[15,16,17,18].

3.4. Heart failure

Whenever possible the cause of heart failure should be diagnosed and adequately treated. The underlying cause of heart failure can have a high risk of clinical deterioration/SCD even under optimal medical treatment (normally meeting ICD criteria) and can thus be a reason for disqualification – a very thorough investigation and risk estimation must be undertaken.

Group A

Strong disqualifying criteria

- Any persisting symptoms
- Left ventricular ejection fraction < 40%
- (Silent) ischemia provoked by a stress test

- (Orthostatic) hypotension
- Elevated BNP values (if measured) > 500 pg/ml
- Persisting and hemodynamically relevant arrhythmias

Relative disqualifying criteria

- Physical fitness < 7 MET (8 MET is recommended for age < 50)
- The underlying cause of heart failure can be a reason for disqualification

Remarks

Unless there is a clear cause of heart failure and this cause has been cured, for employees who had heart failure and are free of symptoms (NYHA class I) special attention should be paid to cognitive functioning in relation to age[19,20,21].

After (re)qualification, annual clinical assessment of left ventricular function, physical fitness and Holter monitoring is recommended.

Group B

Strong disqualifying criteria

- Persisting symptoms NYHA classes III and IV

Relative disqualifying criteria

- NYHA class II with symptoms provoked by professional activities

Remarks

For employees who have had heart failure and are free of symptoms (NYHA class I) or have persistent minor symptoms (NYHA class II) special attention should be paid to cognitive functioning[19,20,21].

3.5. Cardiomyopathies

Group A

Strong disqualifying criteria

- Proven dilated cardiomyopathy and obstructive hypertrophic cardiomyopathy are incompatible with high safety duties.

Remarks

In mild cases i.e. preserved left ventricular function, no history of significant arrhythmias, no familiar history of sudden cardiac death and physical fitness > 7 MET (8 MET is recommended for age < 50) authorization can be given only after consulting a cardiologist and careful evaluation.

Group B

For group B there are no disqualifying criteria except mentioned in the chapters concerning heart failure and arrhythmias.

3.6. Heart transplantation

Fitness must be assessed individually; annual cardiac assessment is mandatory because of the elevated risk of coronary heart disease in transplants.

3.7. Cardiac congenital diseases in adults

Nowadays many children with congenital cardiac diseases had early repair and survive for a long time. They can often live a normal life but after the age of forty there is an elevated risk of complications such as arrhythmias, heart failure or sudden cardiac death[22]. Although individual assessment is advised there are still some disqualifying disorders.

In exceptional cases of long lasting stable physical condition and no signs of possible cardiac complications/deterioration of cardiac function, the employee can be declared fit for high safety duties. Special attention should be given to cognitive functioning[23,24,25,26,27].

Group A

Strong disqualifying disorders

- Tetralogy of Fallot, including after repair
- Transposition of the great arteries, including after repair
- Ebstein anomaly, including after repair
- Univentricular heart, including after repair
- Coarctatio aortae if repair was carried out after the age of 12 or abnormal blood pressure at rest and during exercise
- Atrium septum defect if the relation between the pulmonary and body circulation > 2:1 or abnormal right pressures are present
- Ventricle septum defect if the relation between the pulmonary and body circulation > 2:1 or an abnormal heart size exists or after operation main conduction disturbances exist

Group B

For group B there are no disqualifying criteria except mentioned in the chapters concerning heart failure and arrhythmias.

Extra attention to cognitive functioning is indicated.

3.8. Valvular heart diseases

Group A

All valvular heart diseases (congenital or acquired) must be carefully evaluated by a cardiologist. The assessment must include the dimensions and mass of the left ventricle, the pressure gradient and the ejection fraction. Concomitant arrhythmias should be sought and excluded.

Significant aortic, pulmonary or mitral stenosis and aortic or mitral regurgitation are normally incompatible with high safety duties unless, after surgery, there is documented preserved biventricular ventricular function and no other signs of developing dysfunction or significant pressure or volume overload.

Valvular surgery requires a careful evaluation and periodic follow-up before one can resume high safety duties.

<u>Strong disqualifying criteria</u>

- Any persisting symptoms
- Reduced hemodynamics
- Left ventricular ejection fraction < 40%
- Right ventricular dilatation or impaired right ventricular function
- Persisting and hemodynamically relevant arrhythmias
- Abnormal blood pressure (hypertension, hypotension)
- Pulmonary arterial hypertension
- Cerebral complications
- Poor compliance with cardiac medication
- Other disqualifying factors (see relevant chapters)

<u>Relative disqualifying criteria</u>

- Physical fitness < 7 MET (8 MET is recommended for age < 50)

Group B

For group B there are no disqualifying criteria except employees meeting the criteria mentioned in the chapters heart failure and arrhythmias.

3.9. Arrhythmias and conduction abnormalities

General

In cases of documented or suspected potentially dangerous/symptomatic arrhythmias and/or conduction abnormalities, additional cardiac investigations must be carried out to establish an individual risk assessment. Underlying heart diseases must be excluded and potential triggers must be determined. If after initiation of successful treatment, the employee is declared fit for (high) safety duties annual evaluation must be performed.

Group A

Strong disqualifying criteria

- Any persisting or relapsing symptoms
- Left ventricular ejection fraction < 40%
- Inadequately treated
- Poor compliance with cardiac medication
- Other disqualifying factors (see relevant chapters)

Relative disqualifying criteria

- Physical fitness < 7 MET (8 MET is recommended for age < 50)

Supraventricular arrhythmias

Group A

Additional strong disqualifying criteria for atrial fibrillation

- Persistent heart rate > 100/min
- BP > 140/90 mmHg documented by ambulatory 24h-BP-measurement
- CHA_2DS_2VASc score > 0 and inadequately treated to prevent embolism with respectively acetylsalicylic, coumarin derivates or the new generation antithrombotics (depending on the $CHAD_2S_2VASc$ score) and the HAS-BLED score > 3[28,29] (see annex D)

Remarks

After cardioversion without an underlying disease, high safety duties should be prohibited for a month. Special attention should be given to cognitive functioning in relation to age[30].

Group B

Although employees controlled by group work or supervision by another skilled person are fit for their duties, they must get instructions to temporarily stop their safety critical tasks during the manifestation of a paroxysmal arrhythmia. Special attention should be given to cognitive functioning in relation to age [30].

Ventricular arrhythmias

Group A

Strong disqualifying criteria

- Sustained ventricular tachycardia unless thorough cardiological testing shows no elevated risk of recurrence.
- Employees fulfilling criteria for ICD implantation.

Group B

Employees must get instructions to temporarily stop their safety critical tasks during the manifestation of a paroxysmal arrhythmia.

Cardiac arrest

A survivor of a cardiac arrest can be declared fit for (high) safety duties if the cardiac arrest has been caused by a clear reversible triggering event (i.e. myocardial infarction, massive pulmonary embolism, etc.) that has been treated successfully and favorable long term outcome can be assumed after successful treatment of the underlying disease. For both groups A and B, when a survivor of a cardiac arrest could, after careful examination, be declared fit for (high) safety duties (that means no elevated risk of recurrence and no disqualifying factors mentioned in the relevant chapters), a (neuro)psychological assessment is mandatory because 50% of survivors of a cardiac arrest have cognitive impairment[31] which can influence their functioning in railway safety tasks.

Group A

Strong disqualifying criteria

- Elevated risk of recurrence of malignant arrhythmias or myocardial infarction

- Cognitive impairment
- Employees fulfilling criteria for ICD implantation.
- Other disqualifying factors (e.g. underlying cardiac disease, etc. see relevant chapters)

Group B

Strong disqualifying criteria

- Cognitive impairment

Conduction abnormalities

Group A

Additional disqualifying criteria for sinus dysfunction (sick sinus)

- Pauses > 4 sec in the non-sleeping period as well as pauses which cause hemodynamic disturbances.

Additional disqualifying criteria for LBBB

- QRS width > 165 msec
- Left axis deviation

Remarks

After qualification periodic assessments are necessary to monitor disease progression towards higher degree blocks.

AV blocks

Additional disqualifying criteria for AV blocks

- 2^{e} degree AV block type Mobitz 2
- 3^{e} degree AV block

Pre-excitation syndromes (e.g. WPW)

Group A

Strong disqualifying criteria

- Any symptoms
- High risk of arrhythmias
- Anterograde refractory period < 270 msec

Remarks

After a successful catheter ablation resumption of high safety duties may be allowed.

Pacemakers (PM)

Group A

Strong disqualifying criteria

- Any persisting symptoms
- Totally dependent on the pacemaker
- Risk of serious malfunction by interfering electromagnetic fields in the working environment of the employee (depending on the characteristics of the pacemaker, see remarks).

Relative disqualifying criteria

- Unipolarity

Remarks

Employees of this group with pacemakers may be fit for high safety duties when they are not totally PM-dependent. That means they have a genuine heart rhythm that is sufficient to guarantee physical and cognitive competence in case of PM malfunctioning. Electromagnetic influence must be excluded by comparing the existing electromagnetic field in the workplace with the safety limits of the device.

The distance between the pacemaker and electric devices (for example communication equipment) must be at least 40 cm.

Group B

The distance between the pacemaker and electric devices (for example communication equipment) must be at least 40 cm.

ICD

Group A

Implantable cardioverters (ICD) are incompatible with high safety duties.

Group B

The distance between the ICD and electric devices (for example communication equipment) must be at least 40 cm.

3.10. Other cardiac disorders

Group A

Strong disqualifying criteria

- Brugada syndrome
- Long QT syndrome
- Pulmonary arterial hypertension
- Arrhythmogenic right ventricular cardiomyopathy (ARVC)

3.11. Cardiac drugs

Anticoagulants are allowed when the INR is regularly measured and is within the therapeutic range. The employee should monitor the INR by himself after he has been adequately trained in self-measurement.

Anti-arrhythmic drugs are allowed after careful cardiological assessment.

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Annex A

SCORE

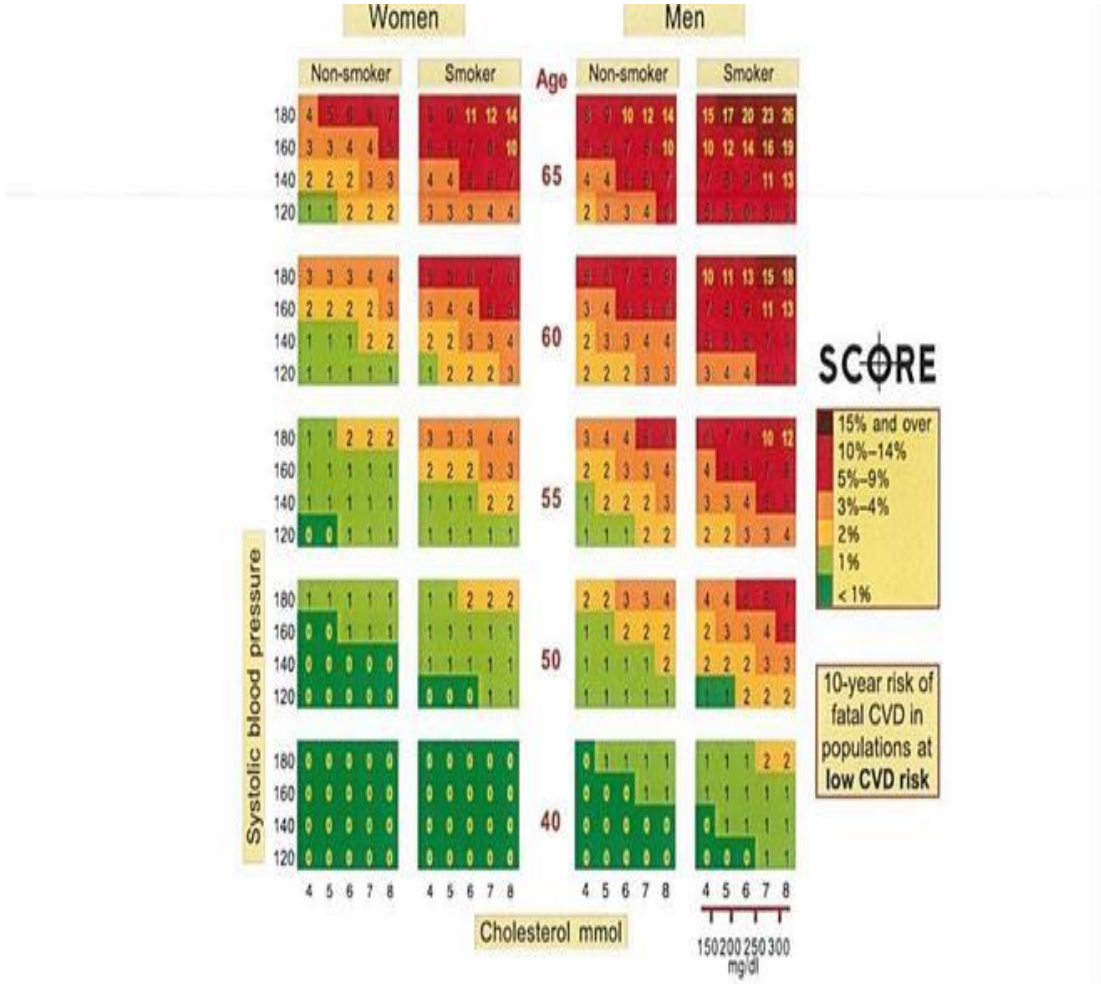

Fig. 2 Ten-year risk of fatal cardiovascular disease in populations at low cardiovascular disease risk. Chart based on total cholesterol.

Annex B

NYHA classification

The New York Heart Association (NYHA) Functional Classification places patients in one of four categories based on how much they are limited during physical activity; the limitations/symptoms are in regards to normal breathing and varying degrees in shortness of breath and or angina pain.

NYHA Class	Symptoms
I	Cardiac disease, but no symptoms and no limitation in ordinary physical activity, e.g. shortness of breath when walking, climbing stairs etc.
II	Mild symptoms (mild shortness of breath and/or angina) and minor limitation during ordinary activity.
III	Marked limitation in activity due to symptoms, even during less-thanordinary activity, e.g. walking short distances (20–100 m). Comfortable only at rest.
IV	Severe limitations. Experiences symptoms even while *at rest*. Mostly bedbound patients.

Annex C

Hypertension

The cut off points for hypertension depends on the method of measurement.

Definitions of hypertension by office and out-of-office blood pressure levels.

Method of measurement	Systolic BP (mmHg)		Diastolic BP (mmHg)
Office	≥140	and/or	≥90
Ambulatory BP			
Mean of day time (or awake) BP	≥135	and/or	≥85
Mean of night time (or asleep) BP	≥120	and/or	≥70
Mean of 24 -h	≥130	and/or	≥80
Home BP (selfmeasurement)	≥135	and/or	≥85

Annex D

CHA_2DS_2VASc score

The CHA_2DS_2VASc score is a clinical prediction rule for estimating the risk of stroke in patients with non-rheumatic atrial fibrillation (AF).

It consists of:

*Stroke risk stratification with the **CHA_2DS_2VASc score***

CHA_2DS_2VASc score	**Score**
Congestive heart failure/left ventricular dysfunction	1
Hypertension	1
Age ≥ 75 years	2
Diabetes mellitus	1
Stroke/TIA/systemic embolism	2
Vascular disease (prior MI, PAD or aortic plaque)	1
Age 65-74 years	1
Sex category (female gender)	1

The maximum score can be 9 and oral anticoagulation should be considered for a CHA_2DS_2VASc score ≥ 1 and is recommended ≥ 2

HAS-BLED score

The HAS-BLED score is a bleeding risk stratification score for patients with an indication for oral anticoagulation.

*Bleeding risk stratification with the **HAS-BLED score***

HAS-BLED score	**Score**
Hypertension i.e. uncontrolled blood pressure	1
Abnormal renal/liver function	1 or 2
Stroke	1
Bleeding tendency or predisposition	1
Labile INRs (if on vit. K antagonists)	1
Age (e.g. > 65 year, frail condition)	1
Drugs (e.g. concomitant aspirin or NSAIDs) or alcohol excess/abuse	1

A HAS-BLED score ≥ 3 is considered as high risk for bleeding.

4. DIABETES MELLITUS

General remarks

In case he can be declared fit for safety duties, the employee with diabetes mellitus must be well informed and well controlled according to (inter)national guidelines. He must have the capacity to respond and act adequately if symptoms occur. Regular care should include periodic evaluations by a physician experienced with diabetes mellitus.

The employee should receive instructions to stop performing safety tasks at the first signs of any impending incapacity. For example, the train driver should stop the train immediately at the first manifestation of symptoms.

Whilst employees with diabetes could be physically fit for their duty, they may have an acute or chronic impairment of their cognitive functioning due to the disease or its treatment. This causes a diminished capacity to judge and handle safety critical work. Individual risk assessment is based on the type of diabetes, the kind of treatment, the control of the disease, the education and personal responsibility on the part of the employee. The main risks concerning operational safety are the risks of sudden or severe hypoglycemia, lack of awareness of hypoglycemia or prolonged hyperglycemia.

- Hypoglycemia is defined as an event during which typical symptoms of hypoglycemia are accompanied by a plasma glucose concentration of ≤ 3.9 mmol/l (70 mg/dl) [1].
- Severe hypoglycemia is defined as requiring the assistance of another individual (third party assistance) [1].
- Lack of awareness of hypoglycemia is defined as loss of the warning symptoms that previously allowed the patient to recognize developing hypoglycemia and take corrective action[1].
- During prolonged hyperglycemia, with a threshold at 15 mmol/l (270 mg/dl), cognitive functioning declines significantly in a multi-tasking environment. For example, significantly more mistakes are made during this prolonged hyperglycemia and slower responses were found during basic oral arithmetic tasks[2,3,4,5,6].
- Most diabetic patient treatment goals include a target range for HbA1c values. A diabetic person with good glucose control has a HbA1c level that is close to or within the reference range. The recommended HbA1c value depends on local guidelines and varies between below 48 mmol/mol (6.5%) and 53 mmol/mol (7.0%). With values below 53 mmol/mol (7%) the health benefits of reduced HbA1c become smaller and the intensive glycemic control required to reach this level can lead to an increased rate of dangerous hypoglycemic episodes.

For an adequate assessment of the fitness of employees with diabetes , actual information is required of the type of diabetes (type 1 or type 2), level of physical fitness, the kind and severity of hypoglycemic symptoms, hyperglycemia and lack of awareness of hypoglycemia, the diabetes journal (self-monitoring of blood sugar), actual laboratory results (glycemia, HbA1c, kidney function and albumin in urine), the presence or absence of possible limiting complications, co-morbidity, cardiovascular risk assessment and medication use.

When an employee with diabetes is declared fit for safety duties, a periodic review should be conducted. This includes at least an oral history or questionnaire, analysis of the diabetes journal and actual laboratory results. The frequency of reviewing depends on the type of diabetes, treatment and complications.

The vast majority of cases of diabetes fall into two broad etiopathogenetic categories[7]. Since type 1 and type 2 diabetes are different in a number of ways affecting the safety risk, the assessment will be differentiated accordingly.

4.1. Diabetes Mellitus type 1

In type 1 diabetes the cause is an absolute deficiency of insulin secretion[7].

Due to the relative high risk of accidents and incidents in literature with type 1 diabetes combined with the possibly diminished hypoglycemia awareness and the high chances of severe and unexpected hypoglycemia, patients with type 1 diabetes are only acceptable in high safety duties[8] in highly exceptional cases. Indeed, some countries do not allow it. These selected cases must be monitored intensively by a physician experienced in diabetes. Future technical solutions (a fully automated artificial pancreas) that have been proven safe and fail proof, which are treatments for diabetes type 1 can be of assistance and positive in the evaluation of fit/unfit for duty. These highly exceptional cases must strictly meet all the conditions mentioned.

Group A

Strong disqualifying criteria

- Newly diagnosed or unstable type 1 diabetes until control is achieved
- Lack of awareness of hypoglycemia
- Frequent (> 2/week), sudden (unexpected) and/or severe hypo- glycaemia

Conditions

- Must be free from any complications
- Must have a very good awareness of hypoglycemia
- Must have regular self-monitoring
- Must have an annual medical review by a relevant specialist
- Must have excellent disease insight

Group B

Strong disqualifying criteria

- Newly diagnosed or unstable type 1 diabetes until control is achieved
- Lack of awareness of hypoglycemia
- Frequent (more than 2/week), sudden (unexpected) and/or severe hypoglycaemia

Relative disqualifying criteria

- Complications of diabetes (see relevant chapters)
- Prolonged hyperglycemia (>15 mmol/l, > 270 mg/dl)
- Longstanding intensive insulin therapy

Remarks

Conditions for performing safety duties are an adequate understanding and awareness of the disease, regular self-control and periodic evaluations.

4.2. Diabetes Mellitus type 2

In type 2 diabetes, the cause is a combination of resistance to insulin action and an inadequate compensatory insulin secretory response[7]. The risk of hypoglycemia depends on the kind of therapy[9, 10,11,12].

The risk of hypoglycemia is absent with dietary treatment, insulin sensitizers such as biguanide (for example metformin), alpha-glucosidase inhibitors (for example acarbose), thiazolidinediones (for example pioglitazone), dipeptidyl peptidase IV (DPP-IV) inhibitors[13] and glucagon like peptide-1 (GLP-1) agonists[14]. These therapies therefore form no risk for performing safety duties.

The risk of hypoglycemia with sulphonylureas is relatively low and less than 1% of patients will experience a severe hypoglycemia, the event rate is 0,03/patient year.

Since type 2 diabetes is a progressive disease, the addition of insulin will become increasingly prevalent during treatment. The risk of hypoglycemia with once daily basal insulin in type 2 diabetes is relatively low and 2-4% of patients will experience a severe hypoglycemia, event rate is 0.1-0.2/patient year. After longstanding (more than 5 years) insulin therapy, risks in type 2 diabetes may become similar to risks in type 1 diabetes. There are individual differences[15].

The use of an insulin pump will increase the flexibility of diabetes management and reduces the risk of hypoglycemia in particular in combination with real-time continuous glucose monitoring[16].

Group A

Strong disqualifying criteria

- Newly diagnosed or unstable type 2 diabetes, irrespective of treatment, until control is achieved
- Lack of awareness of hypoglycemia
- Frequent (more than 2/week), sudden (unexpected) and/or severe hypoglycemia

Relative disqualifying criteria

- Complications of diabetes (see relevant chapters)
- Prolonged hyperglycemia (>15 mmol/l; >270 mg/dl)

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- Insulin secretagogues (for example sulfonylureas or meglitinides)
- Longstanding intensive insulin therapy

Remarks

Conditions for performing safety duties are an adequate understanding and awareness of the disease, regular self-monitoring and periodic evaluations.

Group B

Strong disqualifying criteria

- Newly diagnosed or unstable type 2 diabetes until control is achieved
- Lack of awareness of hypoglycemia
- Frequent (more than 2/week), sudden (unexpected) and/or severe hypoglycemia

Relative disqualifying criteria

- Complications of diabetes (see relevant chapters)
- Prolonged hyperglycemia (>15 mmol/l; >270 mg/dl)
- Longstanding intensive insulin therapy

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5. DISORDERS OF THE CENTRAL NERVOUS SYSTEM

General remarks

Neurological diseases can lead to disturbances of consciousness, coordination, muscular strength, physical ability, mobility and cognitive functioning (memory, reasoning, concentration, behavior, etc.), all of which can cause impairment of safe functioning.

It is possible, after careful assessment and in cooperation with a certified railway occupational physician and a neurologist, to make exceptions.

Specific attention is required for all neurological diseases which can result in the following disqualifying symptoms: Increased risk of sudden impairment

- Impairment of cognitive function
- Impairment of sensory function
- Significant impairment of musculoskeletal function
- Any other impairment that could constitute a threat to safe railway operations

Personal Responsibility

The employee with a neurological disease must, if declared fit for safety duties, have a good understanding of the disease and capacity to act adequately in case of the appearance of symptoms. He should receive instructions to stop his safety critical tasks at the first signs of an impending disturbance of functioning.

The employee should be assessed on his insight and capability to act adequately. Extra attention is needed for neurological diseases with possible cognitive disturbance.

(Neuro)psychological assessment

Psychological tests regarding aptitudes for various rail safety workers have been specifically developed for use in recruitment and other situations. Rail safety workers who have had brain-injuries or diseases affecting mental processes should be (neuro)psychologically assessed to help gauge their recovery and suitability for work.

5.1 Epileptic seizures

Epileptic seizures constitute a serious danger to rail safety. A seizure can lead to acute loss of consciousness and to cognitive or physical impediment. Epilepsy is defined as having had two or more epileptic seizures, less than 5 years apart. If within a 24-hour period more than one epileptic seizure occurs, these are treated as “a single event” for the purpose of applying these regulations. A provoked epileptic seizure is defined

as a seizure which has a recognizable causative factor that is avoidable and should not be called epilepsy.

Epilepsy

Group A

Strong disqualifying criteria

- Confirmed diagnosis

Remarks

Fitness to resume high safety duties may be reconsidered after 10 years free of seizures with or without the aid of anti-epileptic drugs and if a recent (not older than 6 months) EEG shows no epileptiform activity[1,2,3,10]. The anti-epileptic drug may not be categorized DRUID[4] category III[1] and must not cause side effects in the employee. The employee should show no cognitive impairment at the mandatory (neuro)psychological assessment[11,12].

Group B

Strong disqualifying criteria

- Confirmed diagnosis in combination with cognitive impairment at neuropsychological assessment
- Anti-epileptic medication DRUID category III

First or Single seizures

A first or single seizure can be provoked or unprovoked. There is always some uncertainty whether a first seizure will be followed by a second, after which the diagnosis epilepsy can be made.

Provoked seizures

Group A

Strong disqualifying criteria

- EEG shows epileptiform activity

[1] DRUID (DRiving Under the Influence of Drugs, alcohol and medicines) is an international project that has categorized medicinal drugs in four categories. Cat III medication is likely to produce severe effects on fitness to drive or presumed to be potentially dangerous.

- The provoking factor is likely to occur while working and is not successfully avoidable or treated
- Anti-epileptic medication DRUID category III

Remarks

If the EEG shows no epileptiform activity, anti-epileptic medication could be unnecessary, so discussion with the prescribing neurologist could be helpful to withdraw medication.

The employee can be declared fit after one year with or without anti-epileptic medication, no epileptiform activity on the EEG and no repeated seizure[1,2,3,10]. Changing or withdrawing any anti-epileptic drug should lead to a temporary stop to high safety duties for at least six months. If the employee stays six months seizure-free after the completed change or withdrawal and the EEG after these six months shows no epileptiform activity he may resume high safety duties.

Unprovoked seizures (no triggering factor found)

Group A

Strong disqualifying criteria

- EEG shows epileptiform activity
- Anti-epileptic medication DRUID category III

Remarks

If the EEG shows no epileptiform activity, anti-epileptic medication could be unnecessary, so discussion with the prescribing neurologist could be helpful to withdraw medication.

The employee can be declared fit after two years with or without anti-epileptic medication, no epileptiform activity on the EEG and no repeated seizure[6].

Changing or withdrawing any anti-epileptic drug should lead to a temporary stop to high safety duties for at least six months. If the employee stays six months seizure-free after the completed change or withdrawal and the EEG after these six months shows no epileptiform activity he may resume high safety duties.

5.2 Head Injuries and Intracranial Operations

Group A

Strong disqualifying criteria

- Any persisting signs of brain damage that inhibit the required functional ability
- Cognitive impairment at (neuro)psychological assessment

- More than one “provoked” epileptic seizure following a head injury or intracranial operation

Remarks

If an employee has no or no more than one provoked seizure following an operation or head injury he may resume high safety duties one year after complete recovery if neurological assessment shows no EEG-abnormalities and the employee shows no cognitive impairment at (neuro)psychological assessment.

If within a 24-hour period more than one epileptic seizure occurs, these are treated as “a single event” for the purpose of applying these guidelines.

In cases of mild concussion with no residual symptoms employees may resume normal duty after complete recovery.

Group B

Strong disqualifying criteria

- Persisting signs of brain damage that inhibit the required functional ability
- Cognitive impairment at neuropsychological assessment

Remarks

If an employee has no or no more than one provoked seizure following an operation or head injury, he may resume safety duties six months after complete recovery, if neurological assessment shows no EEG-abnormalities and the employee shows no cognitive impairment at neuropsychological assessment.

In cases of mild concussion with no residual symptoms employees may resume normal duty after complete recovery.

5.3 Multiple sclerosis

Group A

Strong disqualifying criteria

- Any symptoms that prevent safe and normal execution of work
- Disease is clearly progressive
- Cognitive impairment at neuropsychological assessment
- Inadequate visual fields and/or colour vision following retrobulbar neuritis

Group B

Strong disqualifying criteria

- Any symptoms that prevent safe and normal execution of work

- Disease is clearly progressive
- Cognitive impairment at the neuropsychological assessment

Remarks

If the MS is clearly in remission and the physical capabilities are sufficient for execution of work and there is no cognitive impairment at the neuropsychological assessment the employee could be found fit but should be reviewed at least once a year. There must be a good understanding of the disease and the individual responsibility should be emphasized.

5.4 Ménière's disease and other causes of recurrent vertigo

Group A

Strong disqualifying criteria

- Confirmed diagnosis of Ménière's disease
- Recurrent attacks of vertigo

Remarks

If the employee has been free from attacks for at least six months and the disease is no longer active according to the report of a neurologist or ENT specialist the employee may be found fit for high safety duties providing the appropriate hearing standard is met. The employee should be reviewed at least once a year.

Note that the medication used for this disease can also influence the psychological fitness.

5.5 Parkinson's disease

Group A and B

Strong disqualifying criteria

- Any symptoms that could prevent safe and normal execution of work
- Disease is clearly progressive
- Cognitive impairment at neuropsychological assessment

Remarks

Where the disease is in its early stages and symptoms are well controlled by therapy and do not hinder the required functional ability, the employee can be found fit, but should be reviewed at least once a year.

5.6 Cerebrovascular diseases (TIA/stroke)

A TIA or stroke leads to immediate unfitness for safety duties.

In the first months after a TIA or stroke, there is a high risk of recurrence. After 3-6 months this risk changes towards an increased risk for coronary heart disease[8,9,13,14].

When the employee has recovered, the fitness for safety duties may be reconsidered, taking into account reports from the neurologist and cardiologist, considering remaining symptoms and with specific attention to the cardiovascular risk profile. A neuropsychological examination is mandatory to exclude cognitive impairments[6,8].

In the case of a TIA and especially after a stroke, three aspects have to be judged:

1) the (remaining) neurological and functional damage
2) the risk of recurrence
3) the cardiovascular risk (origin of the CVA and for the assessment of future risks)

TIA

Group A

Strong disqualifying criteria

- The first four weeks after a TIA
- Any symptoms that could prevent safe and normal execution of work Remarks

After four weeks the employee can resume high safety duties provided there are no neurological / physical disqualifying symptoms and the cardiovascular risk factors are well treated and the employee shows good compliance with medication[1,2,5,6,8]. There should be no cognitive impairment at the neuropsychological assessment.

The assessment has to take into account the level of control of cardiovascular risks (see Table 1 in the cardiovascular diseases section).

Note: Although the ESC target values for patients with established coronary heart disease and diabetes mellitus are recommended for preventing recurrence of new cardiac events, it may be not optimal for safety duties because of the higher risk of hypoglycemia. See chapter on diabetes mellitus for the optimal recommended values of fasting glycaemia and HbA1c.

Group B

Strong disqualifying criteria

- The first two weeks after a TIA
- Any symptoms that could prevent safe and normal execution of work

Relative disqualifying criteria

- Inadequately treated cardiovascular risk factors

Remarks

After 2 weeks the employee can resume safety duties provided there are no neurological / physical disqualifying symptoms and the cardiovascular risk factors are well treated and the employee shows good compliance with medication[1,2,5,6,8]. There should be no cognitive impairment at the neuropsychological assessment.

Stroke

Group A

Strong disqualifying criteria

- The first three months after a stroke
- Any symptoms that could prevent safe and normal execution of work Inadequately treated cardiovascular risk factors

Remarks

After three months the employee could resume high safety duties provided there are no disqualifying criteria mentioned below.

Strong disqualifying criteria after three months

- Neurological / physical disqualifying symptoms
- Poor compliance with medication
- Cognitive impairment

Relative disqualifying criteria

- Inadequately treated cardiovascular risk factors

Group B

Strong disqualifying criteria

- Any symptoms that could prevent safe and normal execution of work
- The first month following a stroke

Relative disqualifying criteria

- Inadequately treated cardiovascular risk factors

5.7. Cerebral aneurysms and other vascular anomalies

The employee with a cerebral aneurysm or comparable vascular anomaly is unfit, unless the aneurysm is found incidentally and has a diameter < 5mm as demonstrated by neurological imaging exams. Rupture risk is significantly higher when the aneurysm is located in the posterior circulation or is symptomatic[15].

If surgery (e.g. coiling) has taken place and there were no neurological symptoms postoperatively, the employee may be found fit for high safety duties after six months.

If after surgery, the employee shows neurological symptoms he can be found fit after five years without physical and/or mental disorders. The employee should show no cognitive impairment at neuropsychological assessment. For postoperative epileptic seizures see relevant chapter.

Group A

Strong disqualifying criteria

- Aneurysm with a diameter > 5 mm
- Symptomatic aneurysms
- Aneurysms in the posterior circulation

Relative disqualifying criteria

- Inadequately treated cardiovascular risk factors

Remarks

Special attention is required for hypertension (see relevant chapter).

When found fit a neurological imaging examination is recommended every two years.

Group B

Strong disqualifying criteria:

- Any symptoms that could prevent safe and normal execution of work

Remarks

Special attention is required to reduce hypertension (see relevant chapter). When found fit, a neurological imaging examination is recommended every two years.

5.8 Other neurological disorders

Group A

Strong disqualifying criteria

- Myasthenia gravis
- Alzheimer
- Dementia

Group B

Strong disqualifying criteria

- Alzheimer
- Dementia

Remarks

Other neurological disorders must be assessed individually taking into account symptoms to disorders of the central nervous system as mentioned in the introduction of this chapter. If assessed as fit for high safety duties, regular reviews are necessary.

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6. SYNCOPE

Syncope is a transient loss of consciousness (T-LOC) due to reversible global cerebral hypo-perfusion, characterized by a rapid onset, short duration and spontaneous complete recovery. Syncopes can be classified as neutrally-mediated (reflex-syncope), secondary to orthostatic hypotension or secondary to cardiac causes.

Most syncopes can be attributed to vasovagal episodes which can usually be diagnosed by a careful history and do not warrant further investigation, provided there was a prodrome that allowed the individual to safely avoid danger and the syncope did not occur while in a sitting position. If other causes have been diagnosed and treated, return to work can be allowed one month after successful treatment provided there are no other disqualifying criteria, mentioned in relevant chapters.

History-taking should include: earlier syncopes, possible triggers, medication, alcohol, drugs, prodromal symptoms, sleep disorders, cardiac (e.g. arrhythmias) or other diseases (e.g. diabetes mellitus). Physical examination should include orthostatic blood pressure measurements and auscultation of heart and lungs, and tests should include ECG and blood glucose[1,2,3,4].

Group A

Strong disqualifying criteria

- Cardiovascular disorders such as (tachy-)arrhythmias that cannot be controlled by treatment (see chapter cardiovascular disorders)
- One year after the last of a series of recurrent syncopes
- One year after one unexplained syncope
- Three months after a vasovagal syncope in a sitting position

Remarks

One month after a well diagnosed and satisfactorily treated cause the employee may be found fit for high safety duties.

One week after a well diagnosed situational syncope with a trigger that can be avoided the employee may be found fit for high safety duties. When there is doubt, this period should be prolonged.

Depending on the cause and always in case of unexplained syncopes a (neuro)psychological assessment is recommended.

Group B

Strong disqualifying criteria

Depending on the job circumstances the employee can resume work immediately, if there is no impact on railway safety. If there is, the criteria for group A should be applied.

Remarks

After a well diagnosed and satisfactorily treated cause the employee may be found fit for safety duties. After a well diagnosed situational syncope with a trigger that can be avoided the employee may be found fit for safety duties.

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7. SLEEP DISORDERS

7.1 Obstructive Sleep Apnoea

Group A and B

Strong disqualifying criteria

- Excessive daytime sleepiness (EDS)
- AHI > 30

Relative disqualifying criteria

- AHI between 15 and 30
- ESS > 16

Remarks

Factors that are predictive for OSA include a history of disruptive snoring, witnessed apnoeas or history of frequent reported snoring/gasping during sleep, a history of hypertension and an Adjusted Neck Circumference (ANC) of greater than 48 cm. The ANC is neck circumference (in cm) + 4 (if hypertension) + 3 (if reports of frequent snoring) + 3 (if reports of frequent choking/ gasping/ apnoeas at night)[13]. Excessive daytime sleepiness can be estimated via a medical history and the use of the Epworth Sleepiness Scale (ESS), scores of 16 or more are indicative of severe sleepiness. The gold standard for the diagnosis OSA is polysomnography, which provides detailed information on sleep stage, air flow and oxygen saturation[1-6] and gives a measure of the apnoea-hypopnoea index (AHI). A way to screen employees with safety duties is the use of portable pulse oximeters, on indication followed by polysomnography[11,12] and appropriate therapy.

When an employee is successfully treated leading to no more daytime sleepiness and an AHI < 15 he can be found fit for high safety duties if the (neuro) psychological assessment shows no cognitive impairment[7-10]. When treated with CPAP he should be annually reviewed. The review should include a report of compliance and results of his CPAP treatment.

Because of the increased cardiovascular risk in patients with OSA the employee should be encouraged to have a BMI < 30 kg/m^2 and blood pressure <140/90 mmHg. In case of hypertension see the relevant chapter.

7.2 Narcolepsy

Group A

Strong disqualifying criteria

- Confirmed diagnosis

Group B

Strong disqualifying criteria

- Excessive daytime sleepiness
- ESS > 16
- Narcolepsy with Cataplexy

Remarks

After six months of absence of symptoms the employee can be declared fit provided that he has been clinically assessed by a sleep physician, there are normal findings in polysomnography and the Multiple Sleep Latency Test (MSLT) and there is no history of cataplexy[1,2,3,5,6]. The employee must be compliant with taking his medication and there should be no cognitive impairment at a (neuro)psychological assessment[9,10]. The employee should be reviewed at least once a year.

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8. VISION AND HEARING CRITERIA

These criteria are from the UIMC minimum interoperability medical fitness standards for railway staff in 2001. They are in part superseded by legal regulations like the European Train Driver Directive, Technical Specifications for Interoperability (TSI) and national regulations. Please check there for applicable standards.

8.1 Vision at periodic assessment

8.1.1 Group A

- Distance vision combined 1.2, aided or unaided
- Minimum of 0.5 for the worse eye
- If lenses are necessary, they must be worn
- Maximum corrective lenses: hypermetropia + 5 / myopia — 8
- Departures are allowed in exceptional cases and after having sought the opinion of an eye specialist. The occupational doctor makes the decision.
- Intermediate and near vision: sufficient, aided or unaided
- Contact lenses are allowed
- Normal colour vision: using the Ishihara standard completed by another test, if needed
- Visual field: complete
- Fusion: present
- Binocular vision: present
- Contrast sensitivity: sufficient
- Ability to withstand blinding
- Absence of progressive eye disease
- Coloured and photochromatic lenses are not allowed. Sun glasses are allowed.
- Eye implants, keratotomies and keratectomies are allowed only when being reassessed once a year or on demand of the occupational physician.

Provision applying compulsorily to all persons wearing glasses and contact lenses: they must have a spare pair handy at any time.

8.1.2 Group B

- Distance vision combined 0.8, aided or unaided
- Minimum of 0.3 for the worse eye
- If lenses are necessary, they must be worn
- Maximum corrective lenses: hypermetropia + S / myopia – 8
- Departures are allowed in exceptional cases and after having sought the opinion of an eye specialist. The occupational doctor makes the decision
- Intermediate and near vision: sufficient, aided or unaided
- Contact lenses are allowed
- Normal colour vision: using the Ishihara standard completed by another test, if needed
- Visual field: complete
- Fusion: present
- Binocular vision: present
- Contrast sensitivity: sufficient
- Absence of progressive eye disease
- Eye implants, keratotomies and keratectomies are allowed only when being reassessed once a year or on demand of the occupational physician.

Provision applying compulsorily to all persons wearing glasses and contact lenses: they must have a spare pair handy at any time.

8.2 ENT at periodic assessment

Sufficient hearing confirmed with tone audiogram, that is: Hearing good enough to keep a phone conversation going and be able to hear alert tones and radio messages.

8.2.1 The following values given for information might be taken as guidelines for ***group A:***

- The hearing loss must not be higher than 40 dB at 0,5 and 1 kHz
- The hearing loss must not be higher than 45 dB at 2 kHz for the ear with the worse air conduction of sound
- If there is any doubt, a test in actual practice shall be given in presence of the occupational physician.
- No anomaly of the vestibular system
- No chronic speech disorder (if messages have to be exchanged loudly and clearly)
- No hearing aids

8.2.2 The following values given for information might be taken as guidelines for ***group B:***

- The hearing loss must not be higher than 40 dB at 0,5 and 1 kHz
- The hearing loss must not be higher than 45 dB at 2 kHz for the worse
- ear (air conduction of sound) with one ear being aided if needed

9. PSYCHIATRIC DISORDERS

Psychiatric disorders encompass a range of cognitive, emotional and behavioral disorders such as schizophrenia, depression, dementia, anxiety disorders, attention deficit hyperactivity disorder, autism, developmental delay and personality disorders.

Substance abuse disorders are addressed in following section 10: Alcohol, drugs and other psychotropic substances.

Fitness to perform safety critical work can be influenced by factors such as intellectual capacity, alertness, perception, learning, memory, attention, concentration, emotion, reaction time, auditory and visual functions, decision-making ability, information processing, executive function and personality. A medical condition that interferes with any of these factors to a significant degree may impair the ability to perform safety critical work.

9.1. Assessment of psychiatric disorders

Most psychiatric disorders are usually associated with relevant disturbances of behavior, cognitive ability, reality perception and health insight, and therefore will commonly affect performance of safety critical work. Patients with psychiatric disorders frequently struggle with adherence to medical treatment due to concerns about side effects, dependency, costs, time, as well as stigma and implications for their careers. Patients with psychiatric disorders may also experience hypersomnia due to sleep disturbance or medication side effects.

Group A and B

Strong disqualifying disorders

- Schizophrenia
- Dementia
- Bipolar affective disorder
- Acute episode of major depression
- Post-traumatic stress disorder
- Cognitive impairment
- Psychotic disorders
- Psycho-organic syndromes

Staff with acute episodes of these psychiatric disorders are not fit to perform safety critical work because cognitive function and reality perception are regularly impaired. After recovery, the risk of relapse, chronic symptoms and residual personality changes need to be seriously considered. After more than one relapse, including

relapse associated with poor compliance, patients with these disorders would usually be declared permanently unfit.

Psychiatric disorders, particularly if accompanied by paranoid beliefs or lack of insight, may lead to noncompliance with requests to attend medical reviews or take prescribed medication, and may lead to difficulty obtaining a full picture of the workers condition and functioning. In cases where an examining doctor is not satisfied that they have a complete picture of the worker's condition, the worker should be classed unfit for duty until adequate information can be obtained.

A diagnosis of a severe psychiatric condition does not automatically disqualify an individual from safety critical work, however a comprehensive multidisciplinary review of fitness and risk assessment must be undertaken. The risk assessment should include risk of relapse, and risk of harm in the case of a relapse. A person suffering an acute psychosis or mania may pose a significant safety risk and should be classed as unfit for the duties of groups A and B.

In case of brief psychotic disorders, any trigger or underlying disease should be carefully diagnosed. If a return to safety critical work is considered, fit for duty subject to at least annual review may be determined, considering the nature of the work and information provided by a psychiatrist as to whether the

following criteria are met:

- the condition is well controlled for at least 6 months
- The person has demonstrated meaningful engagement with treatment over a substantial period (for a psychotic condition or mania this time period must be at least 2 years for group A and 1 year for group B)
- the person has insight into the potential effects of their condition on their work
- there are no adverse medication effects that may impair capacity for safe working
- the impact of comorbidities has been considered (e.g. substance abuse)
- a neuropsychological assessment shows no cognitive impairment
- the individual has created a relapse prevention plan outlining warning signs, things that can help keep them well, and what to do if they start to become unwell. This plan is shared with supervisor and appropriate colleagues

Group A and B

<u>Relative disqualifying disorders</u>

- Mild depression
- Anxiety disorder
- Adult attention deficit hyperactivity disorder (ADHD)

- Developmental disorder
- Autism

Workers with these disorders can be fit to perform safety critical work if the following criteria are met:

- symptoms are mild or not relevant for work
- or symptoms are well under control by adequate and successful therapy (if necessary, including prescription of medication).

To assess the impact of these psychiatric disorders on fitness to perform safety critical work, the focus should be on assessing the severity, the significance of likely functional effects, the level of insight that the worker has into their condition and their capacity to reliably remove themselves from work and seek additional treatment when they become unwell, the frequency and duration of exacerbations and adherence to the treatment. Work performance reports may be a useful source of information regarding overall safe working skills. Reports of critical incidents, such as suicides on railways, should also be considered.

If a worker's cognitive ability is in doubt a neuropsychological assessment can be requested which should demonstrate no cognitive impairment.

In ADHD, the hyperactivity usually gets milder in adults, but attention deficits and lower vigilance remain. Therefore, candidates and workers with ADHD are unfit for safety critical work requesting high vigilance under low stimulation, like lookouts and train drivers of cargo or long-distance trains. To assess the fitness for safety critical work, the standard traffic psychological tests are not sufficient. They must be completed by an individual assessment of the ADHD specialist and a traffic psychologist.

All medication should be trialed and reviewed for a period of 3 months before returning to safety critical work, including: how medication may help to control or overcome aspects of the condition that may impact on working safely; and whether medication side effects may affect the ability to work safely by causing sedation, impairing reaction time or motor skills, causing blurred vision, hypotension or dizziness, or impacting on the ability to sustain shift work, particularly night shift work. Additionally, night shift work may make such conditions more difficult to manage.

9.2 Potential impacts of psychiatric disorders

The table below summarizes some potential impacts of various psychiatric disorders on safety critical work.

Condition	Potential impairment/effects on safety critical work
Schizophrenia	Reduced ability to sustain concentration or attention Reduced cognitive and perceptual processing speeds, including reaction time Reduced ability to perform in complex situations such as when there are multiple distractions Abnormalities of perceptions such as hallucinations, which are distracting and pre-occupying Delusional beliefs that interfere with working, for example, persecutory beliefs may include being followed and result in erratic working
Bipolar affective disorder	Depression and suicidal ideation Mania or hypomania, with impaired judgement about working safely, skill and associated recklessness Delusional beliefs that may directly affect work Grandiose beliefs that may result in extreme risk taking Reduced memory, reaction time or vigilance
Depression	Disturbance of attention, vigilance information processing and judgement, including reduced ability to anticipate situations Psychomotor retardation with reduced memory and reaction times Sleep disturbance and fatigue Suicidal ideation that may result in reckless conduct
Anxiety disorders	Pre-occupation or distraction Reduced vigilance Reduced reaction time Decreased working memory Panic attacks, difficulty in arriving promptly at a decision Obsessional behaviors, including obsessional slowness, that impairs the ability to work efficiently and safely
Post-traumatic stress disorder	Avoidance of certain situations related to traumatic experience Increased startle response Poor sleep and nightmares Recurrent intrusive memories (There may be overlap with depression and substance misuse)
Adult attention deficit hyperactivity disorder	Difficulty sustaining attention, making decisions, planning, organizing and prioritizing.
Developmental disorders and autism	Impairment may include communication, cognition, executive functioning, memory, attention and emotional control.

9.3 Psychoactive Medicines

The prescription of psychiatric drugs is an important part of effective treatment for most psychiatric disorders. Taken correctly, the benefits usually clearly outweigh the side effects, but fitness for driving and safety related work will only be improved by medicines under specific conditions:

- use of medication by the patient according to the prescription
- patient refrains from alcohol and other medicines besides those prescribed by the attending physician
- at the beginning of a treatment or when medication or dose is changed the patient is temporary unfit for safety related duties.

Compared to prescription medicine for other disorders, the nature of some psychiatric disorders lets more people struggle to adhere to the medication prescribed. Positive attitudes toward their prescribed medications and good insight improves patient compliance and thereby the effectiveness of the pharmacological therapy. Low or uncertain compliance is a risk for cognitive impairment and relapse.

As with other disorders, the employee with a psychiatric disorder must have a good disease understanding and capacity to act adequately in case of recurrent symptoms occurring to be declared fit for safety duties. The worker should receive instructions to stop performing safety tasks at the first signs of an impending incapacity.

<u>Tranquilizer, anxiolytics, sleep medication</u>

Benzodiazepines show a significant (1.5 – 5-fold) increased risk of traffic accidents. If they are used or necessary for the treatment of a psychiatric disorder, the employee is not fit for duty. For the same reason they are also not suitable for the treatment of sleep disorders or anxiety in safety critical staff, especially benzodiazepines with half-life >10 hours. Long-term treatment with benzodiazepines may result in permanent cognitive impairment and benzodiazepines with a very short half-life, such as alprazolam, can be easily habit-forming.

Zopiclone and zolpidem have similar side effects as benzodiazepines, they may be associated with potentially dangerous complex sleep-related behaviors. Caution is needed with other central nervous system depressant drugs. These medications are also not suitable for safety critical staff.

Antihistamines of the first generation can cause serious drowsiness, especially if taken as over-the-counter sleeping medication. They should not be taken by staff in safety critical functions or driving vehicles. Antihistamines of the third generation (e.g. levocetirizine) show no relevant side effects on driving.

<u>Antidepressants</u>

SSRIs (selective serotonin reuptake inhibitors) are the most often prescribed type of antidepressant. In general, they have no negative effects on cognitive functions.

Most patients with depression perform better on medication with SSRIs than without medication.

SNRIs (serotonin and norepinephrine reuptake inhibitors) are widely used in the treatment of depression, anxiety disorders and some personality disorders. In tests venlafaxine did not show negative effects on driving ability.

Tricyclic antidepressants (TCAs): depending on the dose the risk of driving accidents is 2-6fold. Therefore, employees taking TCAs are usually not fit for driving and safety relevant work.

MAOIs (monoamine oxidase inhibitors) were the first antidepressants but are not often used anymore. They are mainly used as second line medications for severe depression or Parkinson'Disease. MAO inhibitors can cause a wide variety of side effects including orthostatic hypotension, dizziness, drowsiness, insomnia, and nausea.

Mirtazapine is often used in depression complicated by anxiety or trouble sleeping. Due to its common side effects sleepiness and dizziness it is not suited for safety relevant work. Bupropion is used on its own or as an add-on medication to SSRI antidepressants. Also, it is used to help people stop smoking. Side effects include insomnia, nausea, dizziness and headaches.

Saint John's wort is herbal medicine available without prescription used for mild to moderate depression. It is generally well tolerated without major side effects on driving but can interfere with the effects of many prescription medicines.

Even if SSRIs and SNRIs are beneficial for the cognitive abilities of most patients, immediately after beginning of treatment, and permanently in a small subgroup of patients with depression, the cognitive functions may be impaired. Therefore, caution is required before declaring a safety critical worker fit for duty.

If a worker's cognitive ability is in doubt a neuropsychological assessment can be requested which should demonstrate no cognitive impairment.

Mood stabilizer and anticonvulsants

In relation to long-term therapy with mood stabilizer and anticonvulsants such as lithium, lamotrigine and carbamazepine, there exists only limited data on driving safety. Most authors accept limited private driving but do not recommend professional driving. A careful psychiatric and neuropsychological assessment which should demonstrate no cognitive impairment is necessary.

Stimulants

Methylphenidate and lisdexamfetamine are central nervous system stimulants for the treatment of attention deficit hyperactivity disorder (ADHD) in youths and adults. In general, they improve the capacity of driving in adults with ADHD. Side effects are usually mild and generally well tolerated. However, it has to be considered that ADHD is a heterogeneous disorder characterized by the core symptoms of hyperactivity,

impulsivity and inattention, which all can be risks for high security functions. For the fitness assessment see the paragraph “Relative disqualifying disorders” above.

In an EU-wide study (DRUID Project) no negative influence of stimulants (e.g. amphetamines) in regular dose on fitness to drive could be established when used as appropriate treatment of ADHD.

Annex: Screening of anxiety/depression

a) with the WHO-Five Well-Being-Index (WHO-5)

A short and easy-to-use measure of current mental wellbeing is the WHO-5 questionnaire. It has adequate validity in screening for depression and is suitable for all ages 9 and above. It is free of charge, available in many languages and does not require permission to use (https://www.psykiatri-regionh.dk/who-5/who-5-questionnaires/Pages/default.aspx).

Psychiatric Research Unit
WHO Collaborating Centre in Mental Health

WHO (Five) Well-Being Index (1998 version)

Please indicate for each of the five statements which is closest to how you have been feeling over the last two weeks. Notice that higher numbers mean better well-being.

Example: If you have felt cheerful and in good spirits more than half of the time during the last two weeks, put a tick in the box with the number 3 in the upper right corner.

	Over the last two weeks	All of the time	Most of the time	More than half of the time	Less than half of the time	Some of the time	At no time
1	**I have felt cheerful and in good spirits**	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1	☐ 0
2	**I have felt calm and relaxed**	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1	☐ 0
3	**I have felt active and vigorous**	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1	☐ 0
4	**I woke up feeling fresh and rested**	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1	☐ 0
5	**My daily life has been filled with things that interest me**	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1	☐ 0

b) with the US/Australian K10 Questionnaire

Box 1 The K10 Questionnaire

The Kessler Psychological Distress Scale (K10) was developed in 1992 for use in population surveys. It has been widely used in the United States as well as in Australia, where it has been included in the Australian Survey of Mental Health and Wellbeing (1997) and Australian National Health Surveys.

Research has revealed a strong association between high scores on the K10 and the Composite International Diagnostic Interview (CIDI) diagnosis of anxiety and affective disorders. There is a lesser but significant association between the K10 and other mental disorder categories, and with the presence of any current mental disorder (Andrews & Slade 2001).

Sensitivity and specificity data analysis also supports the K10 as an appropriate screening instrument to identify likely cases of anxiety and depression in the community, and to monitor treatment outcomes.

The K10 questionnaire was adopted in the Australian National Standard for Health Assessment of Rail Safety Workers in 2004 and has been part of the standard since that time. The Australian standard outlines the rationale for the cut-off scores.

The K10 is a screening tool thus examining doctors should apply clinical judgement when interpreting the score and the action required. It is based on 10 questions about negative emotional states experienced during the 4-week period leading up to the assessment. The maximum total score is 50.

The examining health professional evaluates the responses to the questionnaire in conjunction with supporting information provided by the rail organisation, such as absenteeism and accident history, which may provide indications of a mental health problem. The examining health professional should form a clinical impression of the patient and consider if this is consistent with the score on the K10. It may also be necessary to obtain further information from the workers treating doctor.

High scores may be the result of acute distress brought on by domestic or work stress, or may be due to endogenous causes. Interventions appropriate to the particular situation will therefore need to be identified.

Scores below 19 indicate that the worker is likely to be well but should be considered in the context of the overall clinical impression of the patient.

Scores of 19-24 indicate that the worker is likely to have a mild disorder (specificity greater than 90%). The examining doctor should explore possible reasons including domestic or work stress, and provide brief counselling as required. The examining doctor should identify sources of support or guidance that may be helpful to the worker, including work-based employee assistance programs, community support services or the worker's general practitioner. The examining doctor may assess the worker as fit for duty subject to review to flag the issue for attention at subsequent assessments.

K10 scores of 25-29 indicate the worker is likely to suffer from a moderate mental disorder (specificity greater than 98%). The examining health professional should explore possible reasons and consider the supporting information and clinical picture. Workers in this zone should be managed by a combination of brief counselling, referral to the worker's general practitioner and continued monitoring. The examining doctor may assess the worker as fit for duty subject to review or temporarily unfit if there are immediate concerns.

K10 scores of equal to or greater than 30 indicate that the worker is likely to have a severe mental disorder (specificity greater than 99%). They should be assessed as temporarily unfit for duty pending further assessment and referred to their treating doctor.

K10 Questionnaire

Please tick the answer that is correct for you:	All of the time (Score 5)	Most of the time (Score 4)	Some of the time (Score 3)	A little of the time (Score 2)	None of the time (Score 1)
1. In the past 4 weeks, about how often did you feel tired out for no good reason?	☐	☐	☐	☐	☐
2. In the past 4 weeks, about how often did you feel nervous?	☐	☐	☐	☐	☐
3. In the past 4 weeks, about how often did you feel so nervous that nothing could calm you down?	☐	☐	☐	☐	☐
4. In the past 4 weeks, about how often did you feel hopeless?	☐	☐	☐	☐	☐
5. In the past 4 weeks, about how often did you feel restless or fidgety?	☐	☐	☐	☐	☐
6. In the past 4 weeks, about how often did you feel so restless you could not sit still?	☐	☐	☐	☐	☐
7. In the past 4 weeks, about how often did you feel depressed?	☐	☐	☐	☐	☐
8. In the past 4 weeks, about how often did you feel that everything was an effort?	☐	☐	☐	☐	☐
9. In the past 4 weeks, about how often did you feel so sad that nothing could cheer you up?	☐	☐	☐	☐	☐
10. In the past 4 weeks, about how often did you feel worthless?	☐	☐	☐	☐	☐

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10. ALCOHOL, DRUGS AND PSYCHOTROPIC SUBSTANCES

General Remarks

The reliability of judgement and performance of railway workers undertaking safety-critical tasks must not be influenced by physical, mental and/or behavioral disturbances.

Railway workers may not perform safety-critical tasks under the influence of psychotropic substances such as alcohol, illicit drugs and psychotropic medication. It is recommended to make no differences in the judgment between risk groups A and B.

It is the responsibility of the railway company to define and implement policies to manage the safety risks related to the use of alcohol, drugs and/or psychoactive substances. Railway workers must respect and have to follow these policies.

Addiction criteria are defined in the DSM (Diagnostic and Statistical Manual of Mental Disorders).

10.1. Alcohol

Because of its consequences on mental and/or physical function, it is not allowed to be under influence of alcohol on duty.

For that reason, alcohol consumption at work and enough time before the beginning of the work is forbidden.

Negative effects at low levels of alcoholaemia cannot be excluded because of individual susceptibility. It is recommended to respect an alcoholaemia of 0.0 g/l.

If a railway worker is in doubt before commencing a shift, self-testing with a breath-alcohol analyzer may be permitted subject to local regulations and company policies. For that reason, it is recommended that the employer or the occupational health unit provides breath alcohol analyzers for use by workers if regulations and policies permit.

Strong disqualifying criteria

- Alcohol-use disorders: regular abusive consumption and dependence (DSM)

Relative disqualifying criteria

- Unhealthy use: problem drinking (binge drinking) and risky use

Remarks

Alcohol consumption can be estimated via a medical history, an examination, the use of validated scales (*Fast Alcohol Consumption Evaluation*[1]*, Alcohol Use Disorders Identification Tes*t [2] ,……) and biological tests (mean corpuscular erythrocyte volume MCV, gamma-glutamyl transferase GGT, transaminases SGOT and SGPT, carbohydrate-deficient transferrin CDT and/or ethyl glucuronide EtG).

Particular attention is required for “risky consumers” and “binge-drinking”.

In case of chronic alcoholism, specific medical follow-up must be organized, and it is recommended that psychological aptitude be assessed. Follow-up requires regular medical assessment and laboratory testing for at least a year. Alcohol relapse is more frequent during the first six months. For this reason, safety-critical workers require a validated abstinence of at least 6 months before they may be permitted to resume safety critical tasks. It is recommended to assess abstinence with ethyl glucuronide EtG (blood, urine or hair) or phosphatidyl-ethanol PEth (blood) measurements which is a direct marker for alcohol intake, when assessing workers fitness to resume safety-critical tasks. Measurement of EtG in hair is a sensitive and specific marker of high and repeated doses of alcohol consumption. PEth can be used to check abstinence and a moderate alcohol consumption.

Direct markers	Type of supports	Detection time of abstinence
EtG	blood	≈ 10 hours
	urine	≈ 3 days
	hair	≈ months until years
PEth	blood	≈ 2-3 weeks

[1] Hodgson R Alwyn T John B Thom B Smith A. The FAST alcohol screening test. Alcohol Alcohol 2002;37:61–66.
[2] Thomas F. Babor. John C. Higgins-Biddle. John B. Saunders. Maristela G. Monteiro. World Health Organization. AUDIT. The Alcohol Use Disorders Identification Test. Guidelines for Use in Primary Care. Second Edition. WHO/MSD/MSB/01.6a

Direct markers	Blood results (mg/L)	Type of consumption
PEth	<20	abstinence
	20-40	low (3 glasses a week)
	41-100	moderate (1 glass a day or 4 glasses once or twice a week)
	101-210	high (2-3 glasses a day or 8 glasses once)
	>210	excessive

10.2. Drugs

Because of the consequences on mental and/or physical function and on behavior, it is not allowed to be under influence of drugs on duty.

For that reason, drug use is forbidden as it may lead to a momentary incapacity for working in safety-critical tasks.

It is recommended to systematically screen the following substances in urine:

Test	***Calibrator***	***Cut-off (EWDTS)****
Amphetamine (AMP)	*d-Amphetamine*	*500 ng/mL*
Cocaine (COC)	*Benzoylecgonine*	*150 ng/mL*
Cannabis (THC)	*11-nor-Δ9-THC-9 COOH*	*50 ng/mL*
Methamphetamine (MET)	*d-Methamphetamine*	*500 ng/mL*
Morphine (MOP)	*Morphine*	*300 ng/mL*

In specific cases, it is possible to test:

Test	***Calibrator***	***Cut-off (EWDTS)****
Benzodiazepine	*Oxazepam*	*100 ng/mL*
Methadone	*Methadone*	*250 ng/mL*
Buprenorphine	*Buprenorphine*	*5 ng/mL*

* European Guidelines for Workplace Drug Testing in Urine, 2015-11-01 Version 2.0

The test in the urine by immunoassay is the standard screening test. In case of a positive test it is possible to confirm the results by gas chromatography and mass spectrometry.

The saliva testing by immunoassay or a blood test could be used to check a recent use of drugs. In case of a positive test it is also possible to confirm the results by gas

chromatography and mass spectrometry. The cut-offs of the blood levels are the following: 1,5 μg/l for THC and 15 μg/l for morphine, cocaine and amphetamine.

THC-COOH in blood is recommended to make the difference between sporadic and regular cannabis consumption. Indeed, a very high concentration of THC-COOH (> 40 μg/ml in whole blood or 64 μg/l in plasma) indicates regular and significant cannabis consumption.

By indication, it is recommended to test other drugs (ecstasy, MDMA, MDEA…). Kits are available for other drugs (urine, saliva).

Strong disqualifying criteria

- Any use of drugs
- Any use of psychotropic drugs not in accordance with a doctor's prescription

Relative disqualifying criteria

- Occasional cannabis consumption*
- Use of psychotropic drugs in accordance with a doctor's prescription

* Fitness to undertake safety-critical tasks will be recovered if the worker abstains from any use of drugs and this is confirmed by regular random testing.

Remarks

Drug use can be estimated via a medical history, an examination, the use of validated scales (Cannabis Abuse Screening Test[1]) and biological tests (urine, blood, hair).

Drug addiction requires a medical assessment. It is strongly recommended to perform a psychological evaluation to assist in determining fitness for safety-critical tasks.

In any case, the medical follow-up must be organized, involving regular medical assessment and laboratory testing for at least 12 months. Reevaluation of the fitness to undertake safety critical tasks can be determined after a validated abstinence of

[1] Legleye S, Karila L, Beck F, Reynaud M. (2007). Validation of the CAST, a general population Cannabis Abuse Screening Test. Journal of Substance Use, 12(4): 233 - 242.

at least 12 months, based on individual evaluation. Hair testing may also be used to assess abstinence from drug use.

In relation to the use of cannabis, a sporadic and a regular (usual) consumption can be differentiated by testing THC-COOH in blood. This differentiation may assist to determine fitness for duty. In case of sporadic use of cannabis, abstinence should be confirmed by regular random urine testing.

Consumption of cannabidiol (legal in different countries) is forbidden because of potential psychoactive effects.

10.3. Psychotropic substances

Any use (prescribed, over-the-counter or misuse) of psychotropic medication/ substances that has the potential to influence vigilance, cognitive function and/or physical function, or which has been identified as being contraindicated by national authorities for motor driving, must be carefully evaluated including, if necessary, a (neuro)psychological assessment. Pharmaceutical guidelines may be helpful to assess fitness.

Railway workers have two responsibilities: they are firstly responsible to inform the prescribing physician about their safety-critical tasks. If the physician prescribes any psychotropic medication, the workers are secondly responsible to inform the railway physician to evaluate their fitness to perform safety-critical tasks.

The evaluation of the fitness must also consider the psychiatric disorders. For more details, see chapter 9.

ANNEXES

DSM-5 Criteria for Substance Use Disorder

A *mild* substance use disorder is diagnosed if 3 of the following criteria are met. People meeting 4 or 5 criteria are classified as having *moderate* substance use disorder, and *severe* substance use disorder is diagnosed in cases where 6 or more of the criteria are met.

1. Taking the substance in larger amounts or for longer than you meant to
2. Wanting to cut down or stop using the substance but not managing to
3. Spending a lot of time getting, using, or recovering from use of the substance
4. Cravings and urges to use the substance
5. Not managing to do what you should at work, home, or school because of substance use
6. Continuing to use, even when it causes problems in relationships
7. Giving up important social, occupational, or recreational activities because of substance use
8. Using the substance again and again, even when it puts you in danger
9. Continuing to use, even when you know you have a physical or psychological problem that could have been caused or made worse by the substance
10. Needing more of the substance to get the effect that you want (tolerance)
11. Development of withdrawal symptoms, which can be relieved by taking more of the substance

Source: American Psychiatric Association, 2013.

The FACE Questionnaire and its Scoring

1	How often do you have a drink containing alcohol? Never = 0 Once a month or less = 1 2 to 4 times a month = 2 2 to 3 times a week = 3 4 times and over per week = 4	score :
2	How many drinks containing alcohol do you have on a typical day when you are drinking ? 1 or 2 = 0 3 or 4 = 1 5 or 6 = 2 7 to 9 = 3 10 or more = 4	score :
3	Have your friends and relatives worried or complained about your drinking ? No = 0 Yes = 4	score :
4	Do you sometimes take a drink first thing in the morning? No = 0 Yes = 4	score:
5	Are there times when you drink and afterwards you can't remember what you said or did ? No = 0 Yes = 4	score: Total score:

Interpretation

Scores for men	Scores for women
< 5 low risk	< 4 low risk
5 to 8 heavy drinking	4 to 8 heavy drinking
> 8 abuse or dependence	> 8 abuse or dependence

The Alcohol Use Disorders Identification Test: Self-Report Version

PATIENT: Because alcohol use can affect your health and can interfere with certain medications and treatments, it is important that we ask some questions about your use of alcohol. Your answers will remain confidential so please be honest.
Place an X in one box that best describes your answer to each question.

Questions	0	1	2	3	4	
1. How often do you have a drink containing alcohol?	Never	Monthly or less	2-4 times a month	2-3 times a week	4 or more times a week	
2. How many drinks containing alcohol do you have on a typical day when you are drinking?	1 or 2	3 or 4	5 or 6	7 to 9	10 or more	
3. How often do you have six or more drinks on one occasion?	Never	Less than monthly	Monthly	Weekly	Daily or almost daily	
4. How often during the last year have you found that you were not able to stop drinking once you had started?	Never	Less than monthly	Monthly	Weekly	Daily or almost daily	
5. How often during the last year have you failed to do what was normally expected of you because of drinking?	Never	Less than monthly	Monthly	Weekly	Daily or almost daily	
6. How often during the last year have you needed a first drink in the morning to get yourself going after a heavy drinking session?	Never	Less than monthly	Monthly	Weekly	Daily or almost daily	
7. How often during the last year have you had a feeling of guilt or remorse after drinking?	Never	Less than monthly	Monthly	Weekly	Daily or almost daily	
8. How often during the last year have you been unable to remember what happened the night before because of your drinking?	Never	Less than monthly	Monthly	Weekly	Daily or almost daily	
9. Have you or someone else been injured because of your drinking?	No		Yes, but not in the last year		Yes, during the last year	
10. Has a relative, friend, doctor, or other health care worker been concerned about your drinking or suggested you cut down?	No		Yes, but not in the last year		Yes, during the last year	
					Total	

Interpretation
Scores
< 6 for women or < 7 for men : low risk
6-12 for women or 7-12 for men : hazardous or harmful alcohol consumption
≥ 13 : alcohol dependence likely

Cannabis Abuse Screening Test (CAST)

In the last 12 months …

1. Have you ever smoked cannabis before midday?

- never (0) – rarely (0) – from time to time (0) – fairly often (1) – very often (1)

2. Have you ever smoked cannabis when you were alone?

- never (0) – rarely (0) – from time to time (0) – fairly often (1) – very often (1)

3. Have you ever had memory problems when you smoked cannabis?

- never (0) – rarely (0) – from time to time (0) – fairly often (1) – very often (1)

4. Have friends or members of your family ever told you that you ought to reduce your cannabis use?

- never (0) – rarely (0) – from time to time (0) – fairly often (1) – very often (1)

5. Have you ever tried to reduce or stop your cannabis use without succeeding?

- never (0) – rarely (0) – from time to time (0) – fairly often (1) – very often (1)

6. Have you ever had problems because of your use of cannabis (argument, fight, accident, bad result at school, etc.) Precise : /_____/?

- never (0) – rarely (0) – from time to time (0) – fairly often (1) – very often (1)

Interpretation
Scores
≤ 1 : low risk
2 : moderate risk
≥ 3 : high risk

GLOSSARY

AHI	Apnoea-Hypopnea Index
ANC	Adjusted Neck Circumference
AV-block	Atrioventricular block
BMI	Body Mass Index
BNP	Brain Natriuretic Peptide
BP	Blood Pressure
CABG	Coronary Artery Bypass Graft
CPAP	Continuous Positive Airway Pressure, device to treat OSA
CVA	Cerebro vascular accident (stroke)
DRUID	Driving Under the Influence of Drugs, alcohol and medicines
DSM-5	Diagnostic and Statistical Manual of Mental Disorders, Version 5
EDS	Excessive Daytime Sleepiness
EEG	Electroencephalogram
ENT	Ear, Nose, Throat (specialist)
ESC	European Society of Cardiology
ESS	Epworth Sleepiness Scale
ICD	Implantable Cardioverter Defibrillator
INR	International Normalized Ratio
LBBB	Left bundle branch block
LDL	Low-density Lipoprotein
MET	Metabolic Equivalent of Task, 1 MET = 3.5 ml $O_2 \cdot kg^{-1} \cdot min^{-1}$
MI	Myocardial infarction
MS	Multiple Sclerosis
MSLT	Multiple Sleep Latency Test
N-STEMI	Non-ST-segment Elevation Myocardial Infarction
OSA	Obstructive Sleep Apnoea
PAD	Peripheral Artery Disease
PCI	Percutaneous Coronary Intervention
PTA	Percutaneous Transluminal Angioplasty
SCD	Sudden Cardiac Death
STEMI	ST- Segment Elevation Myocardial Infarction
TIA	Transient Ischemic Attack
T-LOC	Transient Loss of Consciousness
WPW	Wolff–Parkinson–White-syndrome

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