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ANNEX II

ESSENTIAL HEALTH AND SAFETY REQUIREMENTS

- 3. ADDITIONAL REQUIREMENTS SPECIFIC TO PARTICULAR RISKS
- 3.1. Protection against mechanical impact
- 3.1.1. Impact caused by falling or ejected objects and collisions of parts of the body with an obstacle

PPE intended to protect against this type of risk must be sufficiently shock-absorbent to prevent injury resulting, in particular, from the crushing or penetration of the protected part, at least up to an impact-energy level above which the excessive dimensions or mass of the means of shockabsorption would preclude effective use of the PPE for the foreseeable period of wear.

- 3.1.2. Falls
- 3.1.2.1. Prevention of falls due to slipping

The outsoles of protective footwear intended to prevent slipping must be designed and manufactured or equipped with additional means so as to ensure adequate grip, having regard to the nature or state of the surface.

3.1.2.2. Prevention of falls from a height

PPE intended to prevent falls from a height or their effects must incorporate a body harness and a connexion system which can be connected to a reliable external anchorage point. It must be designed and manufactured so that, under the foreseeable conditions of use, the vertical drop of the user is minimised to prevent collision with obstacles while the braking force does not attain the threshold value at which physical injury or the opening or breakage of any PPE component which might cause the user to fall can be expected to occur.

Such PPE must also ensure that, after braking, the user is maintained in a correct position in which he may await help if necessary.

The manufacturer's instructions must specify, in particular, all relevant information relating to:

- the characteristics required for the reliable external anchorage point and the necessary (a) minimum clearance below the user;
- the proper way of putting on the body harness and of attaching the connexion system (b) to the reliable external anchorage point.
- 3.1.3. Mechanical vibration

PPE designed to prevent the effects of mechanical vibrations must be capable of ensuring adequate attenuation of harmful vibration components for the part of the body at risk.

3.2. Protection against static compression of a part of the body

PPE designed to protect a part of the body against static compressive stress must be sufficiently capable of attenuating its effects so as to prevent serious injury or chronic complaints.

3.3. Protection against mechanical injuries

PPE constituent materials and other components designed to protect all or a part of the body against superficial injuries, such as abrasion, perforation, cuts or bites, must be chosen or Changes to legislation: There are outstanding changes not yet made to Regulation (EU) 2016/425 of the European Parliament and of the Council. Any changes that have already been made to the legislation appear in the content and are referenced with annotations. (See end of Document for details) View outstanding changes

designed and incorporated so as to ensure that those types of PPE provide sufficient resistance to abrasion, perforation and gashing (see also point 3.1) under the foreseeable conditions of use.

3.4. Protection in liquids

3.4.1. Prevention of drowning

PPE designed to prevent drowning must be capable of returning to the surface as quickly as possible, without danger to health, a user who may be exhausted or unconscious after falling into a liquid medium, and of keeping the user afloat in a position which permits breathing while awaiting help.

PPE may be wholly or partially inherently buoyant or may be inflated by gas which can be manually or automatically released, or inflated orally.

Under the foreseeable conditions of use:

- (a) PPE must, without prejudice to its satisfactory operation, be capable of withstanding the effects of impact with the liquid medium and the environmental factors inherent in that medium;
- (b) inflatable PPE must be capable of inflating rapidly and fully.

Where particular foreseeable conditions of use so require, certain types of PPE must also satisfy one or more of the following additional requirements:

- (a) they must have all the inflation devices referred to in the second subparagraph, and/ or a light or sound-signalling device;
- (b) they must have a device for hitching and attaching the body so that the user may be lifted out of the liquid medium;
- (c) they must be suitable for prolonged use throughout the period of activity exposing the user, possibly dressed, to the risk of falling into the liquid medium or requiring the user's immersion in it.

3.4.2. Buoyancy aids

Clothing intended to ensure an effective degree of buoyancy, depending on its foreseeable use, shall be safe when worn and afford positive support in the liquid medium. In foreseeable conditions of use, this PPE must not restrict the user's freedom of movement but must enable the user, in particular, to swim or take action to escape from danger or to rescue other persons.

3.5. Protection against the harmful effects of noise

PPE intended to prevent the harmful effects of noise must be capable of attenuating the latter so that the exposure of the user does not exceed the limit values laid down [F1 in the Control of Noise at Work Regulations 2005 (S.I. 2005/1643) and the Control of Noise at Work Regulations (Northern Ireland) 2006 (S.R. 2006 No.1)].

Textual Amendments

F1 Words in Annex 2 para. 3.5 substituted (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, Sch. 35 para. 3(45)(c); 2020 c. 1, Sch. 5 para. 1(1)

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Each item of PPE must bear labelling indicating the noise attenuation level provided by the PPE. Should that not be possible, the labelling must be fixed to the packaging.

3.6. Protection against heat and/or fire

PPE designed to protect all or a part of the body against the effects of heat and/or fire must possess thermal insulation capacity and mechanical strength appropriate to the foreseeable conditions of use.

3.6.1. PPE constituent materials and other components

Constituent materials and other components intended for protection against radiant and convective heat must possess an appropriate coefficient of transmission of incident heat flux and be sufficiently incombustible to preclude any risk of spontaneous ignition under the foreseeable conditions of use.

Where the external surface of those materials and components must be reflective, the reflective power must be appropriate to the intensity of the heat flux due to radiation in the infrared range.

Materials and other components of equipment intended for brief use in high-temperature environments and of PPE which may be splashed by hot products such as molten material must also possess sufficient thermal capacity to retain most of the stored heat until after the user has left the danger area and removed the PPE.

PPE materials and other components which may be splashed by hot products must also possess sufficient mechanical-impact absorbency (see point 3.1).

PPE materials and other components which may accidentally come into contact with flame and those used in the manufacture of industrial or fire-fighting equipment must also possess a degree of non-flammability and thermal or arc heat protection corresponding to the risk class associated with the foreseeable conditions of use. They must not melt when exposed to flames nor contribute to flame propagation.

3.6.2. Complete PPE ready for use

Under the foreseeable conditions of use:

- the quantity of heat transmitted by PPE to the user must be sufficiently low to prevent the heat accumulated during wear in the part of the body at risk from attaining, under any circumstances, the pain or health impairment threshold;
- (b) PPE must, if necessary, prevent liquid or steam penetration and must not cause burns resulting from contact between its protective integument and the user.

If PPE incorporates refrigeration devices for the absorption of incident heat by means of liquid evaporation or solid sublimation, the design of such devices must be such that any volatile substances released are discharged beyond the outer protective integument and not towards the user.

If PPE incorporates a breathing device, that device must adequately fulfil the protective function assigned to it under the foreseeable conditions of use.

The manufacturer's instructions accompanying PPE intended for brief use in high-temperature environments must, in particular, provide all relevant data for the determination of the maximum permissible user exposure to the heat transmitted by the equipment when used in accordance with its intended purpose.

3.7. Protection against cold

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PPE designed to protect all or a part of the body against the effects of cold must possess thermal insulating capacity and mechanical strength appropriate to the foreseeable conditions of use for which it is intended.

3.7.1. PPE constituent materials and other components

Constituent materials and other components suitable for protection against cold must possess a coefficient of transmission of incident thermal flux as low as required under the foreseeable conditions of use. Flexible materials and other components of PPE intended for use in a low-temperature environment must retain the degree of flexibility required for the necessary gestures and postures.

PPE materials and other components which may be splashed by cold products must also possess sufficient mechanical-impact absorbency (see point 3.1).

3.7.2. Complete PPE ready for use

Under the foreseeable conditions of use, the following requirements apply:

- (a) the flux transmitted by PPE to the user must be sufficiently low to prevent the cold accumulated during wear at any point on the part of the body being protected, including the tips of fingers and toes in the case of hands or feet, from attaining, under any circumstances, the pain or health impairment threshold;
- (b) PPE must as far as possible prevent the penetration of such liquids as rain water and must not cause injuries resulting from contact between its cold protective integument and the user.

If PPE incorporates a breathing device, that device must adequately fulfil the protective function assigned to it under the foreseeable conditions of use.

The manufacturer's instructions accompanying PPE intended for brief use in low-temperature environments must provide all relevant data concerning the maximum permissible user exposure to the cold transmitted by the equipment.

3.8. Protection against electric shock

3.8.1. Insulating equipment

PPE designed to protect all or part of the body against the effects of electric current must be sufficiently insulated against the voltages to which the user is likely to be exposed under the most unfavourable foreseeable conditions.

To this end, the constituent materials and other components of those types of PPE must be chosen or designed and incorporated so as to ensure that the leakage current measured through the protective integument under test conditions at voltages correlated with those likely to be encountered in situ is minimised and, in any event, below a maximum conventional permissible value which correlates with the tolerance threshold.

Together with their packaging, PPE types intended exclusively for use during work or activities in electrical installations which are or may be under tension must bear markings indicating, in particular, their protection class or corresponding operating voltage, their serial number and their date of manufacture. A space must also be provided outside the protective integument of such PPE for the subsequent inscription of the date of entry into service and those of the periodic tests or inspections to be conducted.

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The manufacturer's instructions must indicate, in particular, the exclusive use for which those PPE types are intended and the nature and frequency of the dielectric tests to which they are to be subjected during their useful life.

3.8.2. Conductive equipment

Conductive PPE intended for live working at high voltages shall be designed and manufactured in such a way as to ensure that there is no difference of potential between the user and the installations on which he is intervening.

3.9. Radiation protection

3.9.1. Non-ionising radiation

PPE designed to prevent acute or chronic eye damage from sources of non-ionising radiation must be capable of absorbing or reflecting the majority of the energy radiated in the harmful wavelengths without unduly affecting the transmission of the innocuous part of the visible spectrum, the perception of contrasts and the ability to distinguish colours where required by the foreseeable conditions of use.

To that end, eye protective equipment must be designed and manufactured so as to possess, for each harmful wavelength, a spectral transmission factor such that the radiant-energy illumination density capable of reaching the user's eye through the filter is minimised and under no circumstances exceeds the maximum permissible exposure value. PPE designed to protect the skin against non-ionising radiation must be capable of absorbing or reflecting the majority of the energy radiated in the harmful wavelengths.

Furthermore, the glasses must not deteriorate or lose their properties as a result of the effects of radiation emitted under the foreseeable conditions of use and all marketed specimens must bear the protection-factor number corresponding to the spectral distribution curve of their transmission factor.

Glasses suitable for radiation sources of the same type must be classified in the ascending order of their protection factors and the manufacturer's instructions must indicate, in particular, how to select the appropriate PPE taking into account the relevant conditions of use such as the distance from the source and the spectral distribution of the energy radiated at that distance.

The relevant protection factor number must be marked on all specimens of filtering eye protective equipment by the manufacturer.

3.9.2. Ionising radiation

3.9.2.1. Protection against external radioactive contamination

PPE constituent materials and other components designed to protect all or a part of the body against radioactive dust, gases, liquids or mixtures thereof must be chosen or designed and incorporated so as to ensure that this equipment effectively prevents the penetration of the contaminants under the foreseeable conditions of use.

Depending on the nature or condition of these contaminants, the necessary leak-tightness can be provided by the impermeability of the protective integument and/or by any other appropriate means, such as ventilation and pressurisation systems designed to prevent the back-scattering of these contaminants.

Any decontamination measures to which PPE is subject must not prejudice its possible reuse during the foreseeable useful life of those types of equipment.

3.9.2.2. Protection against external irradiation

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PPE intended to provide complete user protection against external irradiation or, failing this, adequate attenuation thereof, must be designed to counter only weak electron (e.g. beta) or weak photon (e.g. X, gamma) radiation.

The constituent materials and other components of these types of PPE must be chosen or designed and incorporated so as to provide the degree of user protection required by the foreseeable conditions of use without leading to an increase in exposure time as a result of the impedance of user gestures, posture or movement (see point 1.3.2).

PPE must bear a mark indicating the type and equivalent thickness of the constituent material(s) suitable for the foreseeable conditions of use.

3.10. Protection against substances and mixtures which are hazardous to health and against harmful biological agents

3.10.1. Respiratory protection

PPE intended for the protection of the respiratory system must make it possible to supply the user with breathable air when exposed to a polluted atmosphere and/or an atmosphere having an inadequate oxygen concentration.

The breathable air supplied to the user by PPE must be obtained by appropriate means, for example after filtration of the polluted air through PPE or by supply from an external unpolluted source.

The constituent materials and other components of those types of PPE must be chosen or designed and incorporated so as to ensure appropriate user respiration and respiratory hygiene for the period of wear concerned under the foreseeable conditions of use.

The leak-tightness of the facepiece and the pressure drop on inspiration and, in the case of the filtering devices, purification capacity must keep contaminant penetration from a polluted atmosphere low enough not to be prejudicial to the health or hygiene of the user.

The PPE must bear details of the specific characteristics of the equipment which, in conjunction with the instructions, enable a trained and qualified user to employ the PPE correctly.

In the case of filtering equipment, the manufacturer's instructions must also indicate the time limit for the storage of new filters kept in their original packaging.

3.10.2. Protection against cutaneous and ocular contact

PPE intended to prevent the surface contact of all or part of the body with substances and mixtures which are hazardous to health or with harmful biological agents must be capable of preventing the penetration or permeation of such substances and mixtures and agents through the protective integument under the foreseeable conditions of use for which the PPE is intended.

To this end, the constituent materials and other components of those types of PPE must be chosen or designed and incorporated so as to ensure, as far as possible, complete leak-tightness, which will allow where necessary prolonged daily use or, failing this, limited leak-tightness necessitating a restriction of the period of wear.

Where, by virtue of their nature and the foreseeable conditions of their use, certain substances and mixtures which are hazardous to health or harmful biological agents possess high penetrative power which limits the duration of the protection provided by the PPE in question, the latter must be subjected to standard tests with a view to their classification on the basis of their performance. PPE which is considered to be in conformity with the test specifications must bear a marking indicating, in particular, the names or, in the absence of the names, the

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codes of the substances used in the tests and the corresponding standard period of protection. The manufacturer's instructions must also contain, in particular, an explanation of the codes (if necessary), a detailed description of the standard tests and all appropriate information for the determination of the maximum permissible period of wear under the different foreseeable conditions of use.

3.11. Diving equipment

The breathing equipment must make it possible to supply the user with a breathable gaseous mixture, under foreseeable conditions of use and taking account in particular of the maximum depth of immersion.

Where the foreseeable conditions of use so require, the diving equipment must comprise the following:

- (a) a suit which protects the user against cold (see point 3.7) and/or pressure resulting from the depth of immersion (see point 3.2);
- (b) an alarm designed to give the user prompt warning of an approaching failure in the supply of breathable gaseous mixture (see point 2.8);
- (c) a lifesaving device enabling the user to return to the surface (see point 3.4.1).

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Changes and effects yet to be applied to the whole legislation item and associated provisions

- Art. 3(2) words substituted by S.I. 2019/696 Sch. 35 para. 3(4)(a) (This amendment not applied to legislation.gov.uk. Sch. 35 para. 3(4)(a) substituted immediately before IP completion day by S.I. 2020/1460, reg. 1(4), Sch. 3 para. 24(4))
- Art. 3(3) words substituted by S.I. 2019/696 Sch. 35 para. 3(4)(a) (This amendment not applied to legislation.gov.uk. Sch. 35 para. 3(4)(a) substituted immediately before IP completion day by S.I. 2020/1460, reg. 1(4), Sch. 3 para. 24(4))
- Art. 3(5) substituted by S.I. 2019/696 Sch. 35 para. 3(4)(b) (This amendment not applied to legislation.gov.uk. Sch. 35 para. 3(4)(b) omitted immediately before IP completion day by virtue of S.I. 2020/1460, reg. 1(4), Sch. 3 para. 3)
- Art. 3(5) words substituted in earlier amending provision S.I. 2019/696, Sch. 35 para. 3(4)(b) by S.I. 2020/852 reg. 4(2)Sch. 1 para. 1(u)(ii) (This amendment not applied to legislation.gov.uk. Sch. 1 para. 1(u)(ii) omitted immediately before it comes into force by virtue of S.I. 2020/1460, regs. 1(3), Sch. 4 para. 1(3))
- Art. 24(2A) inserted by S.I. 2024/504 reg. 17(b)