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Ergonomics of the thermal environment — Medical supervision of individuals exposed to extreme hot or cold environments

Ergonomie des ambiances thermiques — Surveillance médicale des personnes exposées à la chaleur ou au froid extrêmes

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Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 3.

Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

Attention is drawn to the possibility that some of the elements of this International Standard may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights.

International Standard ISO 12894 was prepared by Technical Committee ISO/TC 159, *Ergomomics*, Subcommittee SC 5, *Ergonomics of the physical environment*.

Annexes A to F of this International Standard are for information only.

Introduction

This International Standard is one of a group of standards which specify methods for measuring and evaluating hot, moderate and cold thermal environments. International Standards or Technical Reports, which describe the evaluation of hot and cold thermal environments, give advice on the acceptability of these environments for human exposure, taking account of the activity level and the effects of clothing worn. That advice is given on the basis that the individuals concerned are healthy, that is, without any medical factor which might predispose them to ill effects from the thermal environment. Furthermore, biological variability prevents the accurate prediction of the response of any particular individual to climatic extremes. For these reasons, it is necessary to provide appropriate medical supervision for individuals who are to be exposed to extreme thermal environments. This International Standard describes a method to determine the degree of medical supervision relevant to different types of exposure, in order to limit the risk of any individual suffering from ill health.

Ergonomics of the thermal environment — Medical supervision of individuals exposed to extreme hot or cold environments

1 Scope

This International Standard provides advice to those concerned with the safety of human exposures to extreme hot or cold thermal environments. Extreme thermal environments are those which result in a high rate of heat gain or loss by the body. A precise definition of such environments cannot easily be given, as the change in body heat storage depends on clothing and activity as well as the parameters of the climatic environment. As a guide, the boundaries of extreme environments might be considered to be as follows: for hot environments, a wet bulb globe temperature of 25 °C; for cold environments an air temperature of 0 °C or below.

Extreme environments can only be tolerated for limited periods of time before a risk of ill health results. Control measures are necessary to ensure the safety of those so exposed, one of which is the provision of appropriate medical supervision prior to and during exposures.

This International Standard is intended to assist those with responsibility for such exposures to reach decisions about the appropriate level of medical supervision in different situations. This International Standard should be read and used in the context of other relevant guidance and legislation.

This guidance is applicable to laboratory and occupational exposures to extreme environments. In either case an assessment should be made of the expected thermal stress on the individual, but the detailed arrangements for medical supervision will differ. Control of occupational exposures must also satisfy national health and safety legislation.

The laboratory or climatic chamber studies for which this International Standard will be relevant include those in which people may be exposed to high or low ambient conditions or local heating or cooling. Studies may, for example, investigate physiological or psychophysical responses to the environment or the benefit of clothing or other protective equipment. Scientific investigations and demonstrations for teaching purposes are included in the scope. In some countries, such studies are subject to specific legislation and, in all cases, experimental exposures should be conducted in the context of accepted ethical criteria as detailed in relevant national and international statements (see informative annex A and the bibliography).

Extremes of environment may be only one component of the total physiological stress imposed in a study. In such cases, appropriate advice must also be obtained with regard to any medical supervision required prior to exposure to the other stressors involved, for example whole body vibration.

In some cases, ergonomic investigations are conducted in the field, for example, to document the physiological stress of particular occupations. If the overall stress of the task is increased as a result of the proposed study, this International Standard will be relevant.

This International Standard does not apply to the use of hypo or hyper thermia in the course of medical investigation or treatment.

2 Normative references

The following normative documents contain provisions which, through reference in this text, constitute provisions of this International Standard. For dated references, subsequent amendments to, or revisions of, any of these publications do not apply. However, parties to agreements based on this International Standard are encouraged to

investigate the possibility of applying the most recent editions of the normative documents indicated below. For undated references, the latest edition of the normative document referred to applies. Members of ISO and IEC maintain registers of currently valid International Standards.

ISO 9886, *Evaluation of thermal strain by physiological measurements.*

ISO 13731, *Ergonomics of the thermal environment — Vocabulary and symbols.*

3 Terms and definitions

For the purposes of this International Standard, the following terms and definitions apply.

3.1
independent medical officer
qualified medical practitioner identified in a study protocol as responsible for the arrangements for medical fitness assessment and health monitoring in support of a study to which this International Standard applies and who is not the principal investigator

3.2
experimenter
the member of the investigation team who is in overall control of a particular experimental session

3.3
medical fitness assessment
procedure by which the state of past and present health of an individual is reviewed to identify any possible medical predisposition to harm from exposure to extreme thermal environments

3.4
health monitoring
process in which the acute effects on the individual resulting from exposure to an extreme thermal environment are observed and interpreted by someone with appropriate training, utilizing physiological monitoring and clinical observation

NOTE The purpose is to detect any indications that an individual may no longer be adequately tolerating the exposure conditions, and therefore to prevent any serious ill health arising, if necessary by removal of the individual from the exposure.

3.5
occupational physician
qualified medical practitioner who has received appropriate training and who is responsible for the supervision of the health at work of employees in one or more enterprise

3.6
principal investigator
where more than one person is responsible for the design of a study a principal investigator should be nominated and he or she will normally be responsible for obtaining ethical approval for a study and for ensuring that adequate arrangements are made for medical supervision of the experimental subjects

NOTE In the case of multicentre studies with a centrally agreed protocol, the person organizing the study, i.e. the promoter, may be responsible for seeking ethical approval.

4 Principles of medical supervision of individuals

4.1 General

The use of the relevant International Standards, given in clause 2, for the assessment of the thermal environment, will allow exposures to be controlled in such a way that the risk of illness arising is minimized. Where body core temperature is maintained in the band 36,0 °C to 38,0 °C then serious general health effects, resulting from

changes in body heat storage, are unlikely, although not entirely unknown. Core temperature is defined in ISO 13731 and described in ISO 9886. In this International Standard, where reference is made to values of core temperature, it is intended that these will have been obtained from valid measurement sites, such as those described in ISO 9886.

If core temperature departs from the range previously specified, there is a progressively increasing risk of acute ill health, specifically heat stroke (heat hyperpyrexia) or profound hypothermia, either of which can be life threatening. Disorders resulting from changes in body heat storage are not, however, the only types of ill health that can arise in extreme thermal environments. For example, in the cold, asthmatic attacks may occur, (particularly in association with exercise), angina may be precipitated, and rhinitis, coughs and nose bleeds have all been reported. Also peripheral cooling can result in frostbite. In the heat, blood flow redistribution can result in episodes of low blood pressure and the risk of collapse before significant heat gain has occurred.

The main illnesses which can arise from changes in body heat storage in hot or cold environments are summarized in informative annex B. This also gives information on the other health effects which can occur in hot and cold conditions.

ISO 9886 and ISO 13731 apply only to healthy subjects in whom the normal physiological control of body temperature is unimpaired. Also, they are unable to take account of the variability of responses between different individuals, although some large differences, such as those between acclimatized and unaclimatized individuals, are considered. For these reasons, it will be important, in the circumstances described below, to include a system of medical supervision of the exposed individuals in risk management. Such supervision may entail both medical fitness assessment prior to exposure and health monitoring during exposure.

4.2 Ergonomic investigations

4.2.1 Introduction

Ergonomic investigations may be conducted in the laboratory or in the field. In either case, the protection of the individuals participating in the studies must be a major consideration.

4.2.2 Laboratory studies

4.2.2.1 General

Studies should be conducted according to accepted ethical guidelines, for example, as contained in the “Helsinki Declaration” (see [8] in the bibliography). The study protocol should be approved by a local research ethics committee. The Principal Investigator and each Experimenter should be aware of their duties towards the subjects both in the design and conduct of the investigations. They should ensure that only individuals who have given their consent participate in the studies and that subjects are free to withdraw from participation during the course of an investigation if they so wish. The application of these principles is described in annex A.

The protocol should describe any arrangements for medical fitness assessment or health monitoring and identify an independent medical officer responsible for the implementation of these arrangements. The medical officer may advise on any likely risks to the subjects and on the level of fitness assessment and monitoring appropriate to the intended study. The medical officer may delegate specific duties to appropriately qualified individuals, for example, health monitoring during exposures may best be done by experienced laboratory staff with appropriate training in first aid and basic resuscitation techniques. The medical officer will act as the final arbiter in questions of fitness of particular individuals to participate in a study.

The medical officer should have practical experience of observing the effects of thermal stress on people, as well as a sound theoretical knowledge of these effects. This may be obtained by cooperation with a research team, or in the course of formal training in applied physiology or related disciplines.

4.2.2.2 Medical fitness assessment

Medical fitness assessment should take place prior to exposure to extreme hot or cold environments. This should take account of the intended exposure conditions and is centred on the individual. It is intended to determine

whether there are any reasons to consider that the person may be susceptible to ill effects from the planned environmental exposure.

Assessment may be by questionnaire and medical examination and advice is given in informative annexes C and D on when these options may be appropriate. If physiological measurement is to be used during exposure, either to support health monitoring or to collect information, then simple initial health checks may also be required, see informative annex E.

A questionnaire should always be completed and the option for a medical examination should be followed in every case where there is any doubt about the fitness of an individual. Examination allows an assessment of the psychological suitability of an individual which cannot be judged from responses to a questionnaire.

Where assessment is by questionnaire and this does not reveal any medical factor which may predispose an individual to ill effects, he or she may be accepted as a subject. Where results suggest a possible predisposition, an individual should only be accepted on the advice of a medical officer who may ask to examine the individual or to obtain an opinion from a relevant specialist.

4.2.2.3 Health monitoring

Assessment of the anticipated physiological strain, coupled with appropriate medical fitness assessment will, in most situations, provide adequate safeguards against the risk of illness occurring from exposure to hot or cold conditions. In the more extreme conditions, to which this International Standard applies, and particularly in exposures to heat, the onset of ill health and the occurrence of symptoms may be rapid and some form of health monitoring is likely to be required to detect these changes and allow an early intervention. An example might be where the prediction of physiological strain is not practicable due to the type of clothing to be worn.

The level of health monitoring required will depend on the detailed circumstances of exposure. The minimum possible is the observation of the subjects by someone with experience of the effects of heat or cold on the body. In many cases, the measurement of physiological parameters will form part of the experimental protocol and the data collected will be used in the results of the study. If not already required for this reason, monitoring of core and skin temperatures, heart rate and, in some cases, blood pressure is likely to be required as these factors may be limiting. Upper limits for withdrawal of subjects from exposure should be decided as part of the experimental protocol.

In most cases, it will be adequate for the monitoring to be done by a trained non-medical person and to have access to the opinion of a medical officer but, in more severe conditions, it will be prudent for the medical officer, or another appropriately trained person (such as an emergency medical technician or paramedic), to be available to attend promptly to a casualty if required. Whether or not a medical officer is available to assist in monitoring and treatment, it will be necessary to have arrangements in place for the rapid removal of a casualty to a hospital with emergency facilities. More detailed advice on the appropriate level of monitoring is given in informative annexes C and D.

During any prolonged series of experiments in which behavioural changes could occur in the subjects, there should be arrangements in place to allow the experimenter and the independent medical officer to obtain the advice of a psychologist.

4.2.3 Field investigations

Ergonomic investigations made in the field should conform to the same ethical guidelines provided for laboratory-based studies. Where volunteers who are not normally employed in the work task act as subjects, the requirements for medical fitness assessment and health monitoring are as described in 4.2.2.2 and 4.2.2.3.

Where workers regularly employed in the task under investigation are the subject of study, the requirements for medical supervision should be agreed with the occupational physician responsible for the health of the workers. The requirements will be based on those described in 4.3, taking account of the effect of the study on normal work practices and of the views of workers and their representatives.

4.2.4 Practical implementation of medical supervision

Advice on the practical requirements of medical supervision in the laboratory, or during field studies with volunteers not normally exposed to the conditions, can be found in informative annex E.

4.3 Occupational exposure

4.3.1 General

Medical supervision of workers who may be exposed to very hot or cold conditions at work should form part of their normal occupational health care and should take account of national health and safety legislation. Work environments are generally less predictable than those used in laboratory investigations and some jobs may require high rates of energy expenditure and the use of protective clothing. In these circumstances, endogenous heat production contributes significantly to the resulting heat strain.

A risk assessment should be undertaken for all occupational exposures to extreme thermal environments. This should allow an evaluation of the likely physiological strain of the task to be made, before the work actually begins. Also, it should allow the available means of reducing this physiological strain to be identified. Work tasks should not be designed in a way which permits unacceptable physiological strain to occur, for example, no work should be planned in which the risk assessment shows that there is a significant potential for general hypothermia to occur. However, where outdoor work takes place, it will not always be possible to entirely eliminate such risks, for example, during fishing, forestry or agriculture in cold temperate or sub-arctic climates, or during construction work in tropical latitudes.

Work which carries a risk of heat strain must be carefully controlled. Heat strain may however be expected to occur in some emergency situations, such as rescue work in mines. The level of fitness assessment and health monitoring should be matched to the circumstances of exposure and general guidance is given in annex F.

4.3.2 Medical fitness assessment

This will be determined by the occupational physician responsible for the workforce in the context of relevant national legislation and guidance. All the components of the job should be taken into account and this may include the need to respond to emergency situations. Direct health monitoring will often be impractical in work tasks, therefore adequate fitness assessment with proper control of exposure will form the basis for the prevention of ill health from exposure to heat or cold at work.

4.3.3 Health monitoring

After appropriate medical fitness assessments have been completed, health monitoring may still be required in some occupational situations where exposure is extreme. Further advice is contained in informative annex F. Information on any acute ill health which occurs during exposures should be reported back to the occupational physician with responsibility for the workers.

Annex A
(informative)

General principles underlying ergonomic investigations in which volunteer subjects may experience discomfort

A.1 General principles

In this annex the general principles relating to the ethics of experimentation on human subjects are described. Reference should also be made to relevant national codes or regulations or other international guidance. (See the bibliography).

Within the field of ergonomics, it is of legitimate interest to study the boundaries of environmental conditions which individuals can safely tolerate and also the effects of such environmental conditions on the performance of mental and physical tasks. Such studies are usually best conducted in the laboratory, in which exposure can be carefully controlled and responses closely monitored. These studies are often conducted with volunteers with no previous experience of the environmental stresses to be studied, or the measurement techniques to be used. Such studies are considered to be ethically acceptable if they comply with certain general principles.

There must be a genuine expectation of increased scientific knowledge on completion of the study. In the case of teaching demonstrations using standard procedures, the benefit is in the increased knowledge and experience of the students concerned. The level of benefit in terms of increased knowledge should outweigh the discomfort experienced by the subjects. Thus it will not normally be acceptable to submit volunteers to great discomfort, unless the information to be obtained is considered to be of high practical or theoretical value.

The study must be planned using current knowledge of the problem being investigated and the methodology proposed must be suitable to obtain the required information. This should not be extended to obtain information which may be only “of interest”, in other words, all the data collected should be directly relevant to the object of the experiment.

No serious risk to the health or personal safety of the subjects should be foreseeable. Although studies should be designed so as to minimize such risks, individuals will vary in their tolerance to the environmental conditions and the resulting discomfort. They should be free to withdraw from the study if they so wish, at any time and without the need to give any explanation.

The investigator must have access to adequate facilities to conduct the experiment successfully and to provide for the welfare of the subjects. This will include suitable changing rooms and areas where instrumentation can be applied in privacy as well as areas for subjects to rest and recover after an experiment.

The protocol for the investigation should be submitted to a research ethics committee for approval, and due account taken of any comments made by the committee. The protocol should include an assessment of the severity of the environmental exposure on the subjects, information on any potential risks to health, and details of the arrangements proposed for fitness assessment and health monitoring of the subjects, where this is appropriate. The protocol should also include information about the arrangements which have been made for financial compensation of a subject in the event that any injury or harm to health occurs. It is recommended that laboratories have appropriate insurance to cover this eventuality.

Volunteer subjects should give their written consent to participate in the study. Consent is only valid if it is both true and informed. For consent to be true, there should be no factor which might unfairly influence the decision of the individual to participate, either in the relationship between the investigator and the potential subject, or in the remuneration which may be offered. A suggested form of written consent is given in A.2. Particular care should be taken to ensure that no pressure to participate is exerted on individuals in a subordinate position to the investigator, such as students or junior members of staff.

