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REDLINE VERSION

INTERNATIONAL STANDARD

colour inside

GROUP SAFETY PUBLICATION

Safety requirements for electrical equipment for measurement, control, and laboratory use –
Part 2-020: Particular requirements for laboratory centrifuges

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IEC 61010-2-020:2016-05 RLV(en)

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

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SAFETY REQUIREMENTS FOR ELECTRICAL EQUIPMENT FOR MEASUREMENT, CONTROL, AND LABORATORY USE –

Part 2-020: Particular requirements for LABORATORY CENTRIFUGES

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International Standard IEC 61010-2-020 has been prepared by IEC technical committee 66: Safety of measuring, control and laboratory equipment.

This third edition cancels and replaces the second edition published in 2006. It constitutes a technical revision and includes the following significant changes from the second edition:

a) This Part 2 is established on the basis of the third edition (2010) of IEC 61010-1.The changes listed in its foreword affect this Part 2, too.

b) The language has been updated to reflect current terminology for LABORATORY CENTRIFUGES used in the industry today.

It has the status of a group safety publication in accordance with IEC Guide 104.

The text of this standard is based on the following documents:

CDV	Report on voting
66/542/CDV	66/565A/RVC

Full information on the voting for the approval of this standard can be found in the report on voting indicated in the above table.

This publication has been drafted in accordance with the ISO/IEC Directives, Part 2.

This Part 2-020 is intended to be used in conjunction with IEC 61010-1. It was established on the basis of the third edition (2010).

This Part 2-020 supplements or modifies the corresponding clauses in IEC 61010-1 so as to convert that publication into the IEC standard: *Safety requirements for LABORATORY CENTRIFUGES*.

Where a particular subclause of Part 1 is not mentioned in this Part 2, that subclause applies as far as is reasonable. Where this part states "addition", "modification" or "replacement", the relevant requirement, test specification or note in Part 1 should be adapted accordingly.

In this standard:

1) the following print types are used:
   - requirements: in roman type;
   - NOTES: in small roman type;
   - *conformity and tests: in italic type;*
   - terms used throughout this standard which have been defined in Clause 3: SMALL ROMAN CAPITALS.
2) subclauses, tables or figures which are additional to those in Part 1 are numbered starting from 101; additional annexes are lettered AA, BB, etc.

A list of all parts of the IEC 61010 series, under the general title: *Safety requirements for electrical equipment for measurement, control, and laboratory use*, may be found on the IEC website.

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The committee has decided that the contents of this publication will remain unchanged until the stability date indicated on the IEC website under "http://webstore.iec.ch" in the data related to the specific publication. At this date, the publication will be

- reconfirmed,
- withdrawn,
- replaced by a revised edition, or
- amended.

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SAFETY REQUIREMENTS FOR ELECTRICAL EQUIPMENT FOR MEASUREMENT, CONTROL, AND LABORATORY USE –

Part 2-020: Particular requirements for laboratory centrifuges

1 Scope and object

This clause of Part 1 is applicable except as follows:

1.1.1 Scope

Replacement:

This Part 2 is applicable to electrically powered LABORATORY CENTRIFUGES.

This group safety publication is primarily intended to be used as a product safety standard for the products mentioned in the scope, but shall also be used by technical committees in the preparation of its publications for products similar to those mentioned in the scope of this standard, in accordance with the principles laid down in IEC Guide 104 and ISO/IEC Guide 51.

NOTE If all or part of the equipment falls within the scope of one or more other Part 2 standards of IEC 61010 as well as within the scope of this standard, it will also need to meet the requirements of those other Part 2 standards.

1.1.2 Equipment excluded from scope

Addition:

Add the following new item:

aa) IEC 60034 (Rotating electrical machinery);

1.2 Object

1.2.1 Aspects included in scope

Addition:

Add the following ~~five~~ new items:

aa) contact with moving parts (see 7.3);

bb) LABORATORY CENTRIFUGE movement during any DISRUPTION (see 7.3.101);

cc) high energy chemical reaction after ROTOR DISRUPTION (see 7.7.2.2 l));

dd) ineffectiveness of BIOSEALS (see 13.101)

1.2.2 Aspects excluded from scope

Addition:

Add the following ~~two~~ new items:

aa) additional precautions which may need to be observed when centrifuging materials which are flammable or explosive (see 5.4.101);

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bb) additional precautions which may need to be observed when centrifuging materials that could react chemically with sufficient vigour to cause a HAZARD (see 5.4.101).

1.4 Environmental conditions

1.4.1 Normal environmental conditions

~~*Modification*~~ *Replacement:*

~~*Modify*~~ *Replace item c) by the following:*

c) temperature 2 °C to 40 °C;

1.4.2 Extended environmental conditions

~~*Modification*~~ *Replacement:*

~~*Modify*~~ *Replace item c) by the following:*

c) ambient temperatures below 2 °C or above 40 °C;

2 Normative references

This clause of Part 1 is applicable except as follows:

Addition:

ISO 3864 (all parts), *Graphical symbols – Safety colours and safety signs*

3 Terms and definitions

This clause of Part 1 is applicable except as follows:

3.1 Equipment and states of equipment

Addition~~s~~:

Add the following ~~three~~ new terms and definitions:

3.1.101
LABORATORY CENTRIFUGE
apparatus intended for laboratory use that applies a centrifuging effect to sample materials

3.1.102
CENTRIFUGE-ROTOR COMBINATION
LABORATORY CENTRIFUGE and ROTOR ASSEMBLY that are intended to operate together and which have to be evaluated together

3.1.103
DISRUPTION
event in which the ROTOR ASSEMBLY, or part of it, fails or becomes detached during rotation

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3.2 Parts and accessories

Additions:

Add the following ~~eight~~ new terms and definitions:

3.2.101
CHAMBER
enclosed space within a LABORATORY CENTRIFUGE in which the ROTOR ASSEMBLY rotates

3.2.102
ROTOR
primary component of a LABORATORY CENTRIFUGE which holds the material to be subjected to centrifugal force and which is rotated by the DRIVE SYSTEM

3.2.103
BUCKET
sub-assembly of a ROTOR designed to support one or more containers

3.2.104
PROTECTIVE CASING
casing which completely surrounds the ROTOR ASSEMBLY and which includes the LID and its securing devices

3.2.105
LID
access cover of the CHAMBER

3.2.106
ROTOR ASSEMBLY
ROTOR carrying a combination of ROTOR accessories specified by the manufacturer

Note 1 to entry: In the context of a ROTOR ASSEMBLY, ROTOR accessories include all components used with or in the CENTRIFUGE ROTOR for the purpose of holding samples, including adaptors, tubes and bottles.

3.2.107
DRIVE SYSTEM
all components of the CENTRIFUGE associated with the provision of torque to, or the rotational support of, the ROTOR ASSEMBLY

3.2.108
BIOSEAL
device or mechanism additional to, or integral with, a ROTOR or BUCKET and a closure assembly, and which is designed to prevent the escape of contents, for example micro-biological material, during centrifuging

3.5 Safety terms

Additions:

Add the following ~~two~~ new terms and definitions:

3.5.101
CLEARANCE ENVELOPE
space around a LABORATORY CENTRIFUGE which is needed for safety

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3.5.102
MCA
MAXIMUM CREDIBLE ACCIDENT
planned event chosen to represent worst-case conditions for a test that will evaluate the inherent mechanical safety of a CENTRIFUGE-ROTOR COMBINATION (see 7.7 and Annex BB)

4 Tests

This clause of Part 1 is applicable~~, except as follows~~.

~~**4.3.1 Environmental conditions**~~

~~*Addition:*~~

~~*Add the following new note:*~~

~~NOTE Consideration should be given to operating refrigerated centrifuges at the maximum humidity specified in 1.4.1 d) and 1.4.2 d) because of condensation concerns (see 11.101).~~

5 Marking and documentation

This clause of Part 1 is applicable except as follows.

5.1.2 Identification

~~*Modification*~~ *Replacement:*

~~*Modify*~~ *Replace item b) by the following:*

b) serial number or other means to identify the production batch of the equipment.

Addition:

Add the following new subclause:

5.1.101 ROTORS and accessories

All OPERATOR-replaceable ROTORS and ROTOR ASSEMBLIES, including ROTOR ACCESSORIES, shall be marked with the manufacturer's or supplier's name or registered trade mark, and identification code (such as id code, serial number or batch number).

If components are too small, or are not suitable for such marking, the required information shall be marked on the original packaging, as well as being stated in the documentation.

NOTE ~~1~~ Packaging can be the outer box, an insert, etc.

~~NOTE 2 Each ROTOR should be marked with a serial number or with other means to identify uniquely the production batch.~~

~~NOTE 3 Where~~ If the manufacturer specifies that an individual part, for example a BUCKET, is to be fitted only to a specific ROTOR or in specific ROTOR positions for balance or some other reason, each BUCKET and ROTOR position should be identified by marking with corresponding numbers or letters.

~~NOTE 4 ROTOR accessories designed to be used together as a set, for example in terms of weight, should be marked with an identification of that same set.~~

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5.4.2 Equipment ratings

Addition:

Add the following ~~three~~ new items:

aa) a list of all ROTORS and ROTOR accessories specified for use with a LABORATORY CENTRIFUGE, together with their RATED rotational frequencies;

bb) any restrictions by the manufacturer warning against the use of particular materials to be centrifuged;

cc) density and volume limits for ROTOR ASSEMBLY loading and, if applicable, derating instructions.

5.4.3 Equipment installation

Addition:

Add, after item a), the following ~~five~~ sub-items:

i) floor or bench area required for the CLEARANCE ENVELOPE for the intended use (see 7.4.101);

~~NOTE Subclause 7.3.101 limits the permitted movement of a LABORATORY CENTRIFUGE to 300 mm, in the event of a DISRUPTION. The manufacturer's instructions should therefore include a requirement for the user to mark this boundary around the CENTRIFUGE, or that laboratory management procedures should require that no person or any hazardous materials be within such a boundary while the LABORATORY CENTRIFUGE is operating.~~

ii) total weight of the CENTRIFUGE;

iii) instructions for site preparation;

iv) methods for levelling of the CENTRIFUGE;

v) means for securing to the mounting surface.

5.4.4 Equipment operation

Addition:

Add the following ~~five~~ new items:

aa) loading and balancing procedures;

bb) ROTOR changing procedure;

cc) any specific requirement for an OPERATOR to be present at stated phases of the centrifuging procedure;

dd) necessary safeguards for personnel. ~~Examples of~~ Instructions shall include at least the following:

- not to lean on a LABORATORY CENTRIFUGE;
- not to stay within the CLEARANCE ENVELOPE longer than necessary for operational reasons;
- not to deposit any potentially hazardous materials within the CLEARANCE ENVELOPE;
- methods for safe operation during open LID procedures (see 7.3.102.2);

ee) instructions for use of BIOSEALS and other biocontainment components, including the proper closure techniques. These instructions shall ~~make clear to the OPERATOR~~ indicate that BIOSEALS and related components are intended to be part of biocontainment systems, ~~such~~ as ~~are~~ specified in international and national biosafety guidelines~~, and cannot~~. They are not to be relied on as the only means of safeguarding workers and the environment when handling pathogenic micro-organisms.

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5.4.5 Equipment maintenance

Addition:

~~*Renumber the note to the first paragraph as Note 1 and*~~ *Add the following new* ~~*second*~~ *paragraph* ~~*and Note 2*~~*:*

Where applicable, the instructions shall specify:

aa) inspection of any means of fixing the equipment to the mounting surface and the condition of the mounting surface itself;

bb) safeguards for the OPERATOR during cleaning;

cc) inspection of the PROTECTIVE CASING;

dd) inspection of the ROTOR ASSEMBLY, and safety considerations;

ee) checking the continuity of the PROTECTIVE BONDING;

ff) frequency of inspection, routine maintenance and the method of replacement of BIOSEALS and other biocontainment components.

~~NOTE 2 These instructions should make clear to the OPERATOR that regular maintenance of BIOSEALS and other biocontainment components as specified in the instructions is especially important to ensure safety in day to day use.~~

Addition:

Add the following ~~*three*~~ *new subclauses:*

5.4.101 Hazardous substances

The instructions for use shall state the precautions to be observed when the materials to be used with a LABORATORY CENTRIFUGE are known to be toxic, radioactive, or contaminated with pathogenic micro-organisms.

NOTE ~~1~~ This information is relevant to the safety of both OPERATORS and service personnel.

The use within the LABORATORY CENTRIFUGE of the following materials shall be prohibited in the instructions for use:

a) flammable or explosive materials;

b) materials which could react chemically with sufficient vigour to cause a HAZARD.

~~NOTE 2 CENTRIFUGES may be specifically designed to be safe when handling such materials, but such centrifuges are not within the scope of this standard.~~

Conformity is checked by inspection.

5.4.102 Cleaning and decontamination

Documentation shall include:

a) a statement that, if hazardous material is spilt on or inside the equipment, the user has responsibility for carrying out appropriate decontamination;

b) manufacturer's recommendations for cleaning and, where necessary, ~~decontamination~~ decontaminating, together with the recognized generic names of recommended materials for cleaning and decontaminating:

c) the following statement:

"Before using any cleaning or decontamination methods except those recommended by the manufacturer, users should check with the manufacturer that the proposed method will not damage the equipment"

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d) the following statement:

Cleaning and decontamination may be necessary as a safeguard before LABORATORY CENTRIFUGES, ROTORS, and any accessories are maintained, repaired, or transferred. Manufacturers may provide a format for users to document that such treatment has been carried out

NOTE Be advised, there are national guidelines and the internationally recognized "Laboratory Biosafety Manual", published in 1993 by the Wor5ld Health Organization in Geneva, which gives information on decontaminants, their use, dilutions, properties, and potential applications.

Conformity is checked by inspection.

5.4.103 Effects of chemicals and environmental influences

To ensure continued safe use of a LABORATORY CENTRIFUGE the documentation shall identify damage which could result from, for example:

a) the effect of chemicals;

b) environmental influences, including natural ultra-violet radiation likely to be encountered;

c) corrosion, and other weakening of construction materials that are part of the PROTECTIVE CASING or other ~~safety~~ protective components.

~~NOTE Assessment may be based on existing data, for example that supplied by a materials supplier. The manufacturer may have to arrange for additional tests with regard to the intended use of the LABORATORY CENTRIFUGE.~~

Conformity is checked by inspection of the documentation and the relevant data and/or additional testing (if needed).

6 Protection against electric shock

This clause of Part 1 is applicable.

7 Protection against mechanical HAZARDS

This clause of Part 1 is applicable except as follows.

7.1 General

Addition:

~~*Renumber the existing note as Note 1 and*~~ *Add the following new note* ~~*2:*~~

NOTE ~~2~~ 101 A DISRUPTION, resulting in damage to a part of the PROTECTIVE CASING, for example a LID-locking mechanism, is considered to be a SINGLE FAULT CONDITION.

7.3 Moving parts

Addition:

Add the following ~~*four*~~ *new subclauses.*

7.3.101 LID

7.3.101.1 Requirements

The LID shall be locked closed when the ROTOR drive is energized, and shall remain locked until the circumferential velocity of the ROTOR ASSEMBLY is not more than 2 m/s (see Annex BB).

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In the event of a power failure, the LID-locking mechanism shall not release, and subsequent release shall require the use of a TOOL.

The LID shall be held closed with sufficient strength to withstand the results of testing according to 7.7.3. Fragments produced by any DISRUPTION shall be contained as specified in item a) of 7.7.

To evaluate which of the following points are appropriate for the CENTRIFUGE-ROTOR COMBINATION under consideration, information shall be recorded showing the tests conducted by the manufacturer or by a test facility:

a) mechanical abuse;
b) mislatching;
c) misalignment;
d) corrosion;
e) material degradation;
f) material defects;
g) vibration;
h) cleaning and decontamination;
i) environmental influences;
j) other considerations appropriate for the design.

Conformity is checked by visual inspection; by the review of recorded information, by the tests carried out under 7.7.3, and by any further tests considered appropriate for safety.

7.3.101.2 Exception

For LABORATORY CENTRIFUGES that satisfy all the following limitations, a device which merely interrupts motor power may be used instead of an interlock mechanism (see Annex BB):

a) the LABORATORY CENTRIFUGE incorporates a device which holds the LID closed;
b) the device which interrupts motor power does not permit the drive motor to be energized unless the LID is closed;
c) the rotational frequency of the ROTOR ASSEMBLY does not exceed 3 600 rpm;
d) the energy at maximum rotational frequency for the highest energy ROTOR ASSEMBLY when fully loaded does not exceed 1 kJ;
e) the maximum centrifugal force does not exceed 2 000 *g*;
f) the largest ROTOR ASSEMBLY diameter does not exceed 250 mm;
g) a switch is provided for disconnecting motor power, independent of the LID position;
h) the ROTOR ASSEMBLY is visible when the LID is closed, to permit observation of any rotation;
i) all ROTOR ASSEMBLIES used conform to 7.3 of Part 1;
j) if access is possible at a circumferential velocity of the ROTOR ASSEMBLY of more than 2 m/s, a warning label in accordance with ISO 3864 is provided on or near the access point, indicating that the LID should not be opened until rotation has stopped. Where there is insufficient space for such a label, symbol 14 of Table 1 is considered to be an acceptable marking.

Conformity is checked by visual inspection and by the review of data to confirm that all the above limitations are met.

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7.3.102 ROTOR ASSEMBLIES

7.3.102.1 General

If a HAZARD could result from contact with moving parts of the ROTOR ASSEMBLY or DRIVE SYSTEM in NORMAL CONDITION or SINGLE FAULT CONDITION, suitable protective means shall be provided to prevent OPERATOR access, except as permitted by 7.3.101.2 and 7.3.102.2.

There shall be no holes or other openings in the top of the CHAMBER which permit the penetration of a 4 mm diameter pin.

Conformity is checked by inspection and by using the test fingers shown in Figures B.1 and B.2, and by checking openings in the top with a 4 mm diameter pin, in *NORMAL CONDITION* and *SINGLE FAULT CONDITION.*

The jointed test finger shown in Figure B.2 is applied in every possible position without applying any force. If it is possible to touch a part by applying a force, the rigid test finger shown in Figure B.1 is applied with a force of 10 N. The force is exerted against all outer surfaces, including the bottom, by the tip of the test finger so as to avoid wedge or lever action. The finger shall not touch any moving part that could cause a *HAZARD.*

7.3.102.2 ROTOR ASSEMBLIES requiring access during rotation

If the manufacturer supplies ROTOR ASSEMBLIES requiring OPERATOR interaction (e.g. zonal or continuous-flow ROTOR ASSEMBLIES), LABORATORY CENTRIFUGES are permitted to have an override control which allows the motor to be energized while the access LID is open, provided that:

a) the override control allows the motor to be energized only by use of a device (which can be a code or code-card) that makes it possible to override a ~~safety~~ protective system and functions by means that cannot be performed using other tools, or when a special guard plate allows only limited access to the rotor assembly;

b) means are provided to cancel the override function automatically when use of the rotor assembly requiring OPERATOR interaction is ended;

c) maximum speed while the LID is open is limited to 5 000 rpm.

Conformity is checked by inspection

7.4 Stability

Addition:

Add a new third paragraph as follows:

No displacement of the LABORATORY CENTRIFUGE from its installed position shall be visible during NORMAL USE.

Addition:

Add the following new subclause:

7.4.101 LABORATORY CENTRIFUGE movement during malfunction

After installation according to the manufacturer's instructions, movement of a LABORATORY CENTRIFUGE as a result of ROTOR ASSEMBLY imbalance, ROTOR ASSEMBLY DISRUPTION, or drive failure (seizure), shall not present a HAZARD.

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Movement shall be limited either by design, or by fastening to the mounting surface, or a combination of both, so that no part of the LABORATORY CENTRIFUGE moves outside a CLEARANCE ENVELOPE extending 300 mm, or less if stated by the manufacturer, in any direction from the outermost parts of the LABORATORY CENTRIFUGE in its original position (for rationale see Clause BB.6).

Conformity is checked by testing to confirm that the 300 mm limit, or any lower limit stated by the manufacturer, is not exceeded in *NORMAL USE* and after inducing the worst-case situation according to 7.7.2.2 for:

a) imbalance;

~~NOTE 1~~ *Use of an imbalance sensor is acceptable as a means for limiting movement, ~~due to this cause, but unless the sensor is a HIGH INTEGRITY type, its possible failure should be considered when determining the worst-case condition~~ but its possible failure should be considered when determining the worst-case condition unless examination of the equipment and design demonstrates conclusively that the sensor will not fail.*

b) disruption of the ROTOR ASSEMBLY;

c) DRIVE SYSTEM failure;

d) seizure of the DRIVE SYSTEM.

NOTE ~~2~~ The failure mode which will produce the greatest movement ~~may~~ can be different from the failure mode of the MCA determined for testing the PROTECTIVE CASING according to 7.7.3. See Annex CC for additional guidance in determining the worst case rotor.

For these tests, the *LABORATORY CENTRIFUGE* is mounted on, or fixed to, a horizontal smooth concrete test surface of dimensions appropriate for the size of *LABORATORY CENTRIFUGE* being tested, and as specified in the manufacturer's instructions.

7.7 Expelled parts

Replacement:

Replace the title and text by the following new title and ~~five new subclauses~~ text.

7.7 Protection against expelled parts or projected parts

7.7.1 General

LABORATORY CENTRIFUGES shall be designed for safe operation in NORMAL USE and SINGLE FAULT CONDITION, when used with ROTOR ASSEMBLIES specified by the manufacturer.

In the event of a DISRUPTION:

a) no parts or fragments of the ROTOR ASSEMBLY exceeding ~~1,5~~ 5 mm in any dimension shall completely penetrate the PROTECTIVE CASING. Smaller material (except for aerosols and liquids) shall remain within a ~~CLEARANCE ENVELOPE~~ trajectory extending ~~300 mm~~ 1 m in any direction from the outermost parts of the LABORATORY CENTRIFUGE. (See rationale in Annex BB.6).

b) no part of the LABORATORY CENTRIFUGE shall become detached or expelled in such a way as to present a HAZARD to personnel or the environment. In the case of parts detached or expelled from the centrifuge (not part of the ROTOR ASSEMBLY) this is to be evaluated in accordance with Clause 17.

c) the fastenings of the access LID shall not be loosened, and there shall be no distortion which could create an unimpeded path between any point on the ROTOR ASSEMBLY and any point outside the LABORATORY CENTRIFUGE.

Conformity of every CENTRIFUGE-ROTOR COMBINATION specified by the manufacturer is checked by testing as specified in 7.7.3, under MCA conditions, or by causing DISRUPTION by partially

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cutting the ROTOR, or by overloading the ROTOR ASSEMBLY, or by other appropriate means. If more than one worst-case ROTOR ASSEMBLY selection exists, each can be tested with a new PROTECTIVE CASING.

After the tests, the criteria of a) to c) above shall be met, and visible cracks shall be examined to determine whether or not the PROTECTIVE CASING would have contained the ROTOR parts irrespective of their trajectory. A questionable result shall require the test to be repeated once only, and a further questionable result is considered to be a failure. ~~The voltage tests of 6.8 (without humidity pre-conditioning) are performed, and~~ The equipment is checked to ensure that parts which are HAZARDOUS LIVE have not become ACCESSIBLE and that ACCESSIBLE conductive parts do not exceed the values of 6.3.2. In the event that the test causes the operation of an overcurrent protection device, if the device can not be reset without operating again, the unit is considered to have failed safe. (See rationale Annex BB6.2).

NOTE 1 Consideration should be given to the presence of temporary gaps in containment during the MCA test in determining questionable results.

Alternatively, the safety of a CENTRIFUGE-ROTOR COMBINATION can be established by analytical evaluation based on comparison with one of more of the CENTRIFUGE-ROTOR COMBINATIONS already tested, to confirm that the PROTECTIVE CASING would have passed the relevant test of 7.7.3.

NOTE 2 CENTRIFUGE-ROTOR COMBINATIONS designed such that satisfactory evaluation by comparison with another CENTRIFUGE-ROTOR COMBINATION already tested cannot be made are tested as specified in 7.7.3.

7.7.2 Considerations for MCA tests

7.7.2.1 Information to be recorded

Recorded information shall include:

a) corrosion effects to be expected;
b) material fatigue behaviour;
c) material degradation considerations, including effects of inspection, maintenance, and component replacement schedules;
d) temperature limitation considerations;
e) material defect considerations;
f) improper BUCKET installation considerations;
g) relevant environmental considerations;
h) relevant maximum loading considerations;
i) electrical circuit diagram and functional descriptions;
j) material specifications and technical data;
k) pre-treatment methods to induce ROTOR ASSEMBLY failure;
l) traceability of all measuring instruments used during tests;
m) any other relevant information.

Conformity is checked by inspection of documentation relating to the above items.

7.7.2.2 Considerations for worst-case conditions

All combinations of the following that are possible shall be considered:

a) ROTOR selection: the worst-case specified ROTOR ASSEMBLY or ROTOR ASSEMBLIES; (for calculating the kinetic energy of rotors, refer to annex CC)
b) rotational frequency control setting: the maximum that an OPERATOR can select;

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c) supply voltage: 10 % above the maximum RATED voltage marked on the equipment;

d) ROTOR ASSEMBLY load: the maximum specified load, partial load, and no load, including state and density of load (e.g. liquid, solid);

e) ROTOR accessories, worst case loading of specified accessories used with or in the ROTOR for the purpose of holding samples, including adaptors, tubes, and bottles;

f) ROTOR ASSEMBLY imbalance: the most severe condition;

g) altitude factors: the effect of reduced atmospheric pressure and density at increased altitude on ROTOR DRIVE SYSTEMS which rely on windage to limit maximum rotational frequency (see 1.4.1 b) and 1.4.2 b)).

NOTE 1 The windage limitation can be determined by conducting a rotational frequency test in a cabinet or room in which the pressure is controlled to 80 kPa or less, or alternatively the rotational frequency n_2, which would be reached at 2 000 m altitude, can be determined from:

$$n_2 = n_1 \times \sqrt[3]{R}$$

where

n_1 is the maximum rotational frequency at standard atmospheric pressure at sea-level (101 kPa);

n_2 is the corresponding maximum rotational frequency at an atmospheric pressure equivalent to 2 000 m;

R = 1,27 (the ratio of the density of air at sea-level, to that at 2 000 m).

h) friction between the LABORATORY CENTRIFUGE or LABORATORY CENTRIFUGE feet and the surface on which the LABORATORY CENTRIFUGE is placed;

i) ambient temperature: the effect on components of working at any temperature in the permitted range from 2 °C to 40 °C;

j) a combination of ROTOR ASSEMBLY and drive unit causing an instability of the dynamic behaviour;

k) installation as specified by the manufacturer;

l) the possibility of high energy chemical reaction after DISRUPTION

NOTE 2 In LABORATORY CENTRIFUGES which develop energies of the order of 275 kJ and above, and which are refrigerated under vacuum, it is possible for a DISRUPTION to cause a chemical explosion if parts of the ROTOR ASSEMBLY are made of reactive material, such as aluminium and titanium. An explosion can occur due to interaction at high energies of the ROTOR ASSEMBLY fragments with refrigerants and water.

In such cases, the worst-case conditions can be achieved by the following combination of means:

i) disabling rotational frequency controls and limiting devices so that the highest rotational frequency is reached;

ii) selecting whichever ROTOR of reactive material has the highest rotational energy, and pretreating it so as to cause a DISRUPTION. The pre-treatment shall maximize the surface area of the resulting fragments;

iii) adjusting the refrigeration system to have the maximum amount of refrigerant in the evaporator which cools the CHAMBER;

iv) loading the ROTOR ASSEMBLY with water to 80 % of its nominal capacity;

v) running the LABORATORY CENTRIFUGE in worst-case conditions of all other unspecified factors until a DISRUPTION occurs.

NOTE 3 Test personnel should be aware that extraordinary energy release ~~may~~ can result from the tests where a high-energy chemical reaction is possible after DISRUPTION. A remote bunker facility is recommended.

Conformity is checked by inspection of documentation relating to the above items.

7.7.2.3 SINGLE FAULT CONDITIONS to be considered

The following SINGLE FAULT CONDITIONS shall be considered:

a) rotational frequency control condition: whichever SINGLE FAULT CONDITION that results in the highest rotational frequency;

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b) rotational frequency limiting system whichever SINGLE FAULT CONDITION permits the highest rotational frequency;

c) MAINS power interruption: intermittent or permanent loss of MAINS power, if either presents a hazardous condition;

d) drive seizure: the sudden application of the rotational energy to the frame and case of a LABORATORY CENTRIFUGE;

e) any component failure;

f) non-quantitative SINGLE FAULT CONDITIONS:

   i) corrosion effects, for example corrosion at the bottom of a BUCKET or cavity, stress corrosion cracking of alloys, corrosion of welds in the PROTECTIVE CASING, environmental crazing of polymers, etc.;

   ii) material fatigue behaviour, which may affect the mode of failure;

   iii) material defects;

   iv) improper installation of a BUCKET or any other component that is fitted in a swinging BUCKET system (e.g. the omission of a BUCKET), incorrect mounting of a BUCKET at its pivot points, use of an incorrect BUCKET, and overloading a BUCKET;

   v) temperature effects, such as expected extremes during transportation, high ROTOR ASSEMBLY temperatures during operation, and any necessary treatment specified by the manufacturer.

~~NOTE Failure of HIGH INTEGRITY components need not be considered.~~

Conformity is checked by inspection of documentation relating to the above items.

7.7.3 Testing the PROTECTIVE CASING

For each worst-case ROTOR ASSEMBLY selection in each MCA, determined according to 7.7.2.1 to 7.7.2.3, testing as necessary shall be carried out to prove the adequacy of the PROTECTIVE CASING, and to show that it would have contained the ROTOR parts irrespective of their trajectory. No parts or fragments shall be expelled from the PROTECTIVE CASING during the tests, other than those permitted by 7.7.1 a).

~~*NOTE 1*~~ *Each test may be carried out with a new PROTECTIVE CASING.*

~~*NOTE 2*~~ *The ROTOR ASSEMBLY under test may first be appropriately weakened to induce it to fail during the test of the PROTECTIVE CASING in accordance with the MCA failure mode.*

~~*NOTE 3*~~ *One of the more difficult fragments of a ROTOR ASSEMBLY to contain in a DISRUPTION is an approximate half ROTOR. Experience over the years has shown that many designs of ROTOR can disrupt to give such a size of fragment. This should be taken into account when determining an MCA, as well as other ROTOR failure modes.*

Test data shall be recorded, including the following:

a) description of the LABORATORY CENTRIFUGE and ROTOR ASSEMBLY – model, ROTOR type, accessories and loading;

b) MCA conditions, with justification;

c) ROTOR ASSEMBLY failure inducement method with justification;

d) date and time of the test;

e) environmental conditions during the test;

f) photographs of the LABORATORY CENTRIFUGE and relevant parts before and after the test, with video-recording of the DISRUPTION;

g) rotational frequency at the time of ROTOR ASSEMBLY failure, and hence the energy involved;

h) type of ROTOR ASSEMBLY failure;

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i) description of any damage caused to the PROTECTIVE CASING;

j) details of any movement of the LABORATORY CENTRIFUGE;

k) details of the escape of any debris.

8 Mechanical resistance to shock and impact

This clause of Part 1 is applicable.

9 Protection against the spread of fire

This clause of Part 1 is applicable.

10 Equipment temperature limits and resistance to heat

This clause of Part 1 is applicable.

11 Protection against HAZARDS from fluids

This clause of Part 1 is applicable except as follows.

11.2 Cleaning

Replacement:

Replace the second paragraph by the following ~~new paragraph~~:

Conformity is checked by cleaning the equipment 20 times if a cleaning process is specified and decontaminating the equipment once if a decontamination process is specified, in accordance with the manufacturer's instructions. If a manufacturer specifies only certain cleaning procedures, only these shall be applied. If no restriction is given in the instructions for use, a steam sterilization test at one of the time-temperature conditions of Table 101 (see 11.2.101) shall be repeated 20 times.

If, immediately after this treatment, there are any signs of wetting of parts likely to cause a HAZARD, the equipment shall pass the voltage test of 6.8 (without humidity preconditioning) and ACCESSIBLE parts shall not exceed the limits of 6.3.1.

Addition:

Add the following new subclause:

11.2.101 Steam sterilization

If a manufacturer claims that an item can be decontaminated by steam sterilization, it shall be capable of withstanding steam sterilization under at least one of the time-temperature conditions given in Table 101.

~~NOTE 1 Manufacturers should be aware of the internationally recognized "Laboratory Biosafety Manual", published in 1993 by the World Health Organization in Geneva, which gives information on decontaminants, their use, dilutions, properties, and potential applications. There are also national guidelines which cover these areas.~~

~~NOTE 2 Cleaning and decontamination may be necessary as a safeguard before LABORATORY CENTRIFUGES, ROTORS, and any accessories are maintained, repaired, or transferred. Manufacturers should provide a format for users to certify that such treatment has been carried out.~~

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Table 101 – Time-temperature conditions

Absolute pressure	Corresponding steam temperature		Minimum hold time
kPa	Nominal °C	Range °C	min
325	136,0	134 to 138	3
250	127,5	126 to 129	10
215	122,5	121 to 124	15
175	116,5	115 to 118	30
NOTE "Minimum hold time" means the time the contaminant is at steam temperature.			

Conformity is checked by test.

11.3 Spillage

Modification:

Insert "or onto" *after* "into" *in the first line.*

Addition:

Add the following new subclause:

11.101 Refrigerated and water-cooled LABORATORY CENTRIFUGES

Refrigerated and water-cooled LABORATORY CENTRIFUGES shall not become hazardous while operated in elevated humidity and temperature conditions.

Conformity is checked by operating the LABORATORY CENTRIFUGE in an environmental cabinet which has been set at the maximum RATED humidity and temperature of the LABORATORY CENTRIFUGE. The equipment is operated in the standby mode, at the lowest settable CABINET temperature, for a period of 7 h.

Immediately after treatment, the equipment shall pass the voltage test of 6.8 (without further humidity preconditioning), and ACCESSIBLE parts shall not exceed the limits of 6.3.1.

12 Protection against radiation, including laser sources, and against sonic and ultrasonic pressure

This clause of Part 1 is applicable.

13 Protection against liberated gases and substances, explosion and implosion

This clause of Part 1 is applicable, except as follows.

Replacement:

Replace the title by the following new title:

13 Protection against liberated gases, explosion and implosion and escape of microbiological materials

Addition:

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Add the following new subclause:

13.101 Microbiological materials

BIOSEALS in ROTORS and BUCKETS which are RATED by the manufacturer as being fit to contain microbiological specimens during centrifuging shall prevent the escape of biological materials, when operated and maintained in accordance with the manufacturer's instructions (see Annex AA).

Conformity is checked by testing the *BIOSEAL* as specified in Annex AA.

NOTE Additional test methods are under consideration for types of BIOSEAL for which the test of Annex AA is not applicable, and to cover much smaller micro-organisms (see also Annex BB, 13.101).

14 Components

This clause of Part 1 is applicable.

15 Protection by interlocks

This clause of Part 1 is applicable.

16 ~~Test and measurement equipment~~ Hazards resulting from application

This clause of Part 1 is ~~not~~ applicable.

17 Risk assessment

This clause of Part 1 is applicable.

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Annexes

The annexes of Part 1 are applicable except as follows.

Annex ~~H~~ L

Index of defined terms

Additional defined terms:

Addition:

Add the following ~~two~~ new annexes:

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Annex AA
(normative)

Dynamic microbiological test method for BIOSEALS

AA.1 ~~Introduction~~ General

This test method is based upon exposing the BIOSEAL of a BUCKET or ROTOR to a concentrated suspension of bacterial spores while the LABORATORY CENTRIFUGE is operating and testing to show that no spores escape. This test is designed to challenge the BIOSEAL design as a whole during a foreseeable event likely to occur when operated in accordance with the manufacturer's instructions (see 5.4) and with good laboratory practices associated with handling bio-hazardous materials.

AA.2 Equipment and method

AA.2.1 CENTRIFUGE

The BUCKET or ROTOR is used as part of a ROTOR ASSEMBLY in conjunction with the type of LABORATORY CENTRIFUGE that is recommended by its manufacturer. BUCKETS, ROTORS and LABORATORY CENTRIFUGES are used in accordance with their manufacturer's instructions. Tests shall be carried out in CENTRIFUGES capable of reaching the maximum speed for the ROTOR as stated by the manufacturer. If possible, the LABORATORY CENTRIFUGE is operated from outside the test cabinet or test room during the tests.

AA.2.2 Test cabinet or test room

The cabinet is essentially airtight and of appropriate size for the LABORATORY CENTRIFUGE under test. It is fitted with high efficiency particulate air (HEPA) filters on both the inlet and outlet and a means of introducing the LABORATORY CENTRIFUGE and ROTOR ASSEMBLY to be tested. It is also provided with an electrical supply and facilities for operating the LABORATORY CENTRIFUGE from outside the test cabinet. The cabinet is fitted with an extractor fan capable of extracting air at a rate of approximately 2,8 m^3/min. If the CENTRIFUGE used is a floor standing model, then the cabinet or test room may have to be accessed by test personnel wearing full, clean room clothing including gloves and overshoes.

AA.2.3 Test suspension

An aqueous suspension of spores of the test organism, Bacillus subtilis var. niger (also referred to as B. atrophaeus Nakamura or B. globigii), containing $\geq 1 \times 10^{10}$ spores/ml.

AA.2.4 Test plates

Sterile agar plates with appropriate medium for the growth of the test organism. The batch of agar plates shall be shown to be capable of recovering low concentrations of the test micro-organism by plating out 0,1 ml of a 100 spore/ml to 1 000 spore/ml suspension on two plates with an accuracy of ±30 %.

AA.2.5 Sampling equipment

For all LABORATORY CENTRIFUGES, sampling equipment consists of sterile cotton swabs, moistened with sterile water, for sampling surfaces.

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AA.2.6 Fumigation equipment

Equipment shall be suitable for appropriate fumigation of the test cabinet and its contents after each individual test, to kill the spores remaining from the test suspension. The effectiveness of the fumigation is verified by ensuring that there is no background contamination of the ROTOR or cabinet before testing. Care shall be taken to ensure that the fumigant is fully dispersed before testing is undertaken. The ventilation system of the test cabinet is inactivated and a measure of the fumigant concentration is taken after a period equal to the relevant test period. If the concentration of the fumigant is appreciable (in the case of formaldehyde > 2 ppm) then the test is delayed, and ventilation is continued, until the level drops.

NOTE Fumigants are toxic by inhalation and care should be taken to avoid any exposure of personnel and also in the subsequent disposal of the vapour.

AA.2.7 Assessment of samples

All cultures are made on the surface of test plates. Swabs are rubbed over the surface of the test plates, which are incubated aerobically at 37 °C for between 18 h and 24 h. *Bacillus subtilis* var. *niger* colonies are recognized by their orange colour and are recorded as colony-forming units.

AA.3 Test procedure

AA.3.1 Checking of test suspension

Immediately before each test, appropriate dilutions of the test suspension are plated onto test plates.

AA.3.2 Test method

AA.3.2.1 Number of tests

Three separate tests, in which the BIOSEAL of the BUCKET or ROTOR is tested, are performed on each BUCKET or ROTOR. Control samples are taken before the test, as defined in AA.3.2.4.

AA.3.2.2 Fixed-angle ROTOR test method

Appropriate containers for the ROTOR under test are filled with the test suspension and placed, without capping or sealing, into every place in the ROTOR. All the ROTOR positions are filled to their RATED capacity, in accordance with the manufacturer's instructions.

Additional test suspension is pipetted carefully into the middle of the ROTOR, to simulate a 'spill'. If possible, without overflowing the ROTOR, the volume of this 'spill' should be equivalent to or greater than the volume of one container for containers of volumes up to 5ml, or for ROTORS holding containers of larger volume it should be either 5 ml or 10 % of the volume of one of the containers, whichever is greater. A note ~~must~~ shall be made if less than the full volume of test suspension is used to simulate the 'spill'.

If canisters are used as the primary mode of protection in angle head ROTORS, then the BUCKET seal test method of AA.3.2.3 is used.

AA.3.2.3 BUCKET seal method

A different test method is required for sealed BUCKETS and canisters. The BUCKETS are filled with the test suspension to their rated capacity. After closing the cap, the BUCKET is slowly inverted twice to place the test suspension on the inside of the BUCKET seal.

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~~NOTE~~ Since BUCKETS and ROTORS come in many designs, the above test methods may not be appropriate for all designs. In these instances, other methods may have to be devised to achieve the same effect, such as challenging the BIOSEAL when used in accordance with the manufacturer's instructions.

AA.3.2.4 Control samples

Surface samples are taken before each test to measure any background contamination with the test micro-organism. Initially, surface samples are taken from inside the "O"-ring of the BIOSEAL. After the test suspension is introduced into the BUCKET or ROTOR, surface samples are taken over the complete exterior of the BIOSEAL of the BUCKET or ROTOR and at multiple points around the inside of the CHAMBER at the height the BIOSEALS of the BUCKETS or ROTOR would be while the LABORATORY CENTRIFUGE is running; and, when a sealed BUCKET is being tested, the surface of the ROTOR. In the case of sealed BUCKETS or canisters, additional swab samples of the seal are taken after the BUCKET has been inverted. Swab samples are also taken in areas of potential contamination.

AA.3.2.5 Centrifugation

After taking the control samples (see AA.3.2.4), the LABORATORY CENTRIFUGE is accelerated to the maximum speed for the ROTOR ASSEMBLY under test, maintained at that speed for 5 min, then decelerated to rest.

After the LABORATORY CENTRIFUGE has come to rest, the LID is opened and test swab samples are taken from the surfaces from which the control samples were taken (see AA.3.2.4).

AA.3.2.6 Decontamination

After each test, the test cabinet and contents are decontaminated by fumigation and the cabinet is thoroughly aired by means of the extractor fan.

The BUCKET or ROTOR under test is decontaminated according to the method recommended by the manufacturer.

AA.4 Pass and fail criteria

Each ROTOR or BUCKET is subjected to three separate and valid tests. A pass requires each of the individual tests carried out to be passed, and failure of any single valid test results in overall failure.

The test is only valid if either the maximum volume of additional test suspension, as described in AA.3.2.2, was added, or if a sample from immediately inside the BIOSEAL shows $> 1 \times 10^3$ colony-forming units more than the control sample from this location.

For the three separate tests, the numbers of colony-forming units recovered by swabbing after centrifugation (apart from immediately inside the BIOSEAL of the BUCKET or ROTOR) shall not exceed the numbers recovered from the control samples collected before a test by more than 1 colony-forming unit (this is to allow for sampling error at very low numbers). If more than five colonies are detected in any of the control samples then the test is void and shall be repeated.

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Annex BB
(informative)

General guidance and rationale for particular subclauses

BB.1 Subclause 1.4 Environmental conditions

The lower limit of the ambient temperature at which equipment conforming to Part 1 should be safe to operate is +5 °C. For the purpose of LABORATORY CENTRIFUGES, the limit is lowered to +2 °C in this standard, since many LABORATORY CENTRIFUGES are used in cold-rooms. The nominal temperature at which such cold-rooms are maintained is +4 °C, but tolerances in the temperature control system inevitably mean that lower temperatures are experienced at times (but should never be as low as 0 °C). Therefore, the lower ~~figure~~ temperature of +2 °C has been chosen.

BB.2 Subclause 3.5.102 mca (MAXIMUM CREDIBLE ACCIDENT)

Safety requirements which state specific construction parameters for LABORATORY CENTRIFUGES could limit innovation by the design engineer. This approach can unnecessarily increase the cost to the user without assurance that the construction methods will provide the necessary safety for the OPERATOR. This standard provides basic design considerations for safe design and proof of safety by mechanical testing.

The concept used is testing to an MCA. Choosing an MCA utilizes all information from the instrument, ROTOR, component designs and development tests. Although a single MCA is not considered statistically significant from the point of view of a number of tests, nevertheless it is very unlikely that such an event will even happen during NORMAL USE.

BB.3 Subclause 5.4.102 relation to Table 101

While it is optional for a manufacturer to claim that an item can be decontaminated by steam sterilization, if such a claim is made, it is essential that such sterilization should be under realistic conditions to achieve decontamination.

Table 101 is included to provide an indication of the time-temperature conditions which are generally found suitable by microbiologists for autoclave decontamination of items which have been contaminated with hazardous biological agents. It should be noted, however, that it is the responsibility of the user to ensure that the time-temperature conditions chosen for use are appropriate to inactivate the particular biological agent(s) which may have contaminated the BUCKETS and/or ROTOR. (This is particularly important for any work with prions, which are not readily inactivated by either heat or chemical means.)

BB.4 Subclause 7.3.101.1 LID (first paragraph)

One of the purposes of this standard is to specify the protection needed to prevent an OPERATOR being injured by moving parts of a CENTRIFUGE. For practical reasons, neither limitation of the rotational frequency, nor limitation of the rotational energy of the ROTOR ASSEMBLY, can be used to provide such protection.

If the intention is to permit the OPERATOR to gain access to the ROTOR ASSEMBLY before rotation has completely stopped – such as is held to be necessary for some centrifuging work – a potential HAZARD exists. The HAZARD is significant if an OPERATOR attempts to slow down the ROTOR ASSEMBLY by hand while the rotational frequency is such that the hand cannot easily follow the movement of the ROTOR ASSEMBLY. Once the rotational frequency is low

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enough for the hand to follow the rotation, even if it was inserted "against" the direction of rotation, no injury should be caused. It has been shown that the circumferential velocity limit of 2 m/s which is specified, easily allows an OPERATOR to follow the rotation by hand.

BB.5 Subclause 7.3.101.2 Exception

Certain LABORATORY CENTRIFUGES are permitted to have an access LID with a power-interrupt system instead of an interlock mechanism that is dependent on rotational frequency.

A carefully restricted definition of these exempted LABORATORY CENTRIFUGES has been achieved by specifying restricted maximum values for rotational frequency, centrifugal force, ROTOR ASSEMBLY energy and ROTOR diameter. LABORATORY CENTRIFUGES that fall within these restricted limits are widely used throughout the world, with hundreds of thousands in service and tens of thousands sold each year.

The reason for permitting less stringent requirements for such LABORATORY CENTRIFUGES is that significant extra complexity would be involved in providing a LID interlock mechanism without providing additional reduction of HAZARD.

The working group experts have been unable to trace any accidents with such LABORATORY CENTRIFUGES that may be attributed to the lack of an interlock mechanism. They are of the opinion that, if the device which holds the LID closed is released while the ROTOR ASSEMBLY is at speed and the LID is opened slightly, any potential HAZARD to the OPERATOR, due to opening the LID, is immediately reduced by:

a) an increase in sound level that warns the OPERATOR of exposure of the ROTOR ASSEMBLY;

b) an air flow which tends to deflect dangling objects such as a tie or hair away from the ROTOR ASSEMBLY;

c) the immediate and rapidly progressive reduction in energy due to the power-interrupt. Access to the ROTOR ASSEMBLY, by hand or other object, first requires the time to release and open the LID and then to reach in to the ROTOR ASSEMBLY.

BB.6 Subclause 7.4.101 LABORATORY CENTRIFUGE movement during malfunction

It is specified that the whole of a LABORATORY CENTRIFUGE shall remain inside a CLEARANCE ENVELOPE extending 300 mm from the outermost surface of the CENTRIFUGE. That dimension was selected after extensive examination of DISRUPTION data under MCA conditions. A requirement to have no movement at all during malfunction was considered, but was rejected because:

a) it could be attained by rigidly securing the LABORATORY CENTRIFUGE to a foundation with a mass many times the mass of the LABORATORY CENTRIFUGE. Present practice is that LABORATORY CENTRIFUGES are not rigidly fastened, so successful enforcement of a provision for fastening would be unlikely;

b) a requirement for rigid fastening would be a restriction of present practice. Bench-top LABORATORY CENTRIFUGES are frequently moved by an OPERATOR without involving service or maintenance staff. Most LABORATORY CENTRIFUGES may be moved for cleaning or relocated without elaborate work;

c) rigid fastening of a LABORATORY CENTRIFUGE would necessitate permanent changes to the mounting surface, and there is reluctance to make such permanent changes to laboratory benches and floors;

d) a review of accident data available to the working group did not provide any evidence of injury due to LABORATORY CENTRIFUGE movement.

The potential HAZARD of a LABORATORY CENTRIFUGE moving out of control and impacting personnel, as unlikely as that may be, has been considered. This risk has been reduced to an

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acceptable level of injury by limiting the permitted motion in the event of an MCA that produces LABORATORY CENTRIFUGE motion. Setting that maximum movement at 300 mm is based on the following considerations:

– the 300 mm CLEARANCE ENVELOPE limit of movement is established from MCA testing and therefore is unlikely to be reached in NORMAL USE;

– the potential for injury is limited by the amount of energy available when movement is restricted to 300 mm and the probability of persons being within the CLEARANCE ENVELOPE during the event;

– aisles and passageways are normally wider than 600 mm. The HAZARD of kinetic energy transfer from a moving LABORATORY CENTRIFUGE to a person is therefore limited to the absorption of energy when a person is squeezed into the remaining 300 mm wide space.

It is recognized that many LABORATORY CENTRIFUGES, particularly bench-top models, will not be mounted on a concrete surface in NORMAL USE. The concrete test surface has been specified in order that test results obtained from different test locations may be expected to be consistent.

BB.6.1 Sub-clause 7.7.1 a) Protection against expelled parts or projected parts

LABORATORY CENTRIFUGES shall be designed for safe operation in NORMAL USE and SINGLE FAULT CONDITION, when used with ROTOR ASSEMBLIES specified by the manufacturer. The protective casing shall restrain the user from unintended access to the potentially hazardous moving parts inside the centrifuge and protect the user from any escaping hazard. Because of the need for ventilation, even under NORMAL CONDITIONS, the protective casing is not hermetically sealed. The function of the casing is to reduce the potential mechanical hazard of escaping parts to a safe limit.

The definition of safe limit is not obvious. Based on comprehensive research of injury biomechanics, a normalized energy value (energy per projected area) was found to be the best predictor for ocular injury after a direct hit by a projectile. Using this predictor, a level for a 50% injury risk of corneal abrasion after a direct hit was determined. This level is also used to limit the hazards of projectile toys in EN 71-1:2011-07.

As a general, simple evaluation method, a specified maximal size of 5 mm for parts or fragments, and a maximal distance of 1 m from the centrifuge, make it very unlikely that this value of normalized energy would be exceeded.

BB.6.2 Sub-clause 7.7.1 Conformity statement – paragraph 2

The MCA test is a catastrophic test, as such, at the end of this test the unit is not considered able to be put back into service. The dielectric voltage withstand test establishes whether a functioning unit is still providing adequate isolation for the user from hazardous voltages (refer to 6.7.1 – The nature of insulation). As the unit cannot be used beyond the MCA test, establishing whether the accessible parts still comply with the permissible limits of clause 6.3.2 ensures that the user is still protected if they touch the unit. If the MCA test causes the overcurrent protection device to operate and this device can not be reset, this implies that hazardous voltages cannot be applied to the unit and it is therefore considered to have failed safe.

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BB.7 Subclause 13.101

The use of BUCKETS and ROTORS with BIOSEALS is advocated by international [1][1)] and some national (such as [2] [3]) guidelines for work on microbiological material that require protection for workers and the environment. Accordingly, such equipment is in routine use in diagnostic microbiology laboratories, as well as other microbiological containment laboratories. The

1) Numbers in square brackets refer to Clause BB.8.

dynamic test, originally devised by Harper [4], has been adapted for more recent designs of LABORATORY CENTRIFUGE and ROTOR and is suitable for evaluation of BIOSEALS or parts of LABORATORY CENTRIFUGES, including those that have CHAMBERS that are sealed and evacuated.

The provision of BUCKETS and ROTORS with BIOSEALS is optional, but manufacturers who wish to make performance claims should be prepared to demonstrate that the BIOSEALS prevent escape of droplets and aerosols under dynamic test conditions that simulate the intended use. The choice of spores of Bacillus subtilis var. niger as the test agent is based upon long experience in the field of testing microbiological safety cabinets and similar equipment, which has shown them to be effective, and have also established that they neither infect those carrying out the tests nor have any adverse consequence for the environment. The spores are robust and do not significantly lose viability upon desiccation when a suspension is aerosolized, and even if leaked into an evacuated CHAMBER, and colonies of Bacillus subtilis var. niger have a characteristic colour which enables them to be distinguished from any contaminating organism. Although there is no single size of micro-organism to be contained by the BIOSEALS, and thus the spores will not correspond precisely to such a size, in practice leakage is found to occur in significant volumes and the ability to detect a single spore, once it has been grown into a colony on a test plate, gives the sensitivity for this to be an appropriate assay.

The requirement to provide specific instructions for the use of BIOSEALS and related components is based on the mandatory need for additional equipment and laboratory procedures to safeguard OPERATORS. These instructions to the OPERATOR are necessary to make clear that BIOSEALS alone are not adequate to provide complete protection, particularly as the seal can be compromised by wear or damage, for example to an "O"-ring.

BB.8 Reference documents

[1] WORLD HEALTH ORGANIZATION. *Laboratory Biosafety Manual*, 2nd Edition. Geneva, 1993.

[2] CENTERS FOR DISEASE CONTROL AND PREVENTION AND NATIONAL INSTITUTES OF HEALTH. *Biosafety in Microbiological and Biomedical Laboratories*, 4th Edition. Washington, 1999.

[3] ADVISORY COMMITTEE ON DANGEROUS PATHOGENS. *Categorisation of biological agents according to hazard and categories of containment*, 4th Edition. London, 1995.

[4] HARPER, G.J. Evaluation of sealed containers for use in centrifuges by a dynamic microbiological test method. *J. Clin. Pathol*. 1984, 37, pp. 1134–1139.

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Annex CC
(informative)

General guidance for an empirical method to determine the kinetic energy of a ROTOR

Subclause 7.7.2.2 a) Determination of the kinetic energy

1) The rotor shall be loaded to the maximum and then it must be weighed.
   - fully loaded with samples as per maximum operated conditions
   - sample tubes / bottles will be loaded with test fluid.
2) Fasten the rotor with its axis of rotation to a rod. (Ensure that the rotor and the rod cannot be twisted against each other.)
3) Fasten a piece of fishing line with a tensile strength double the weight of the total assembly to ensure that there is no stretch to the rod and to the ceiling as per Figure 101. Ensure that the distances $s1$ and $s2$ are identical (approximately 50 mm each) and that the distance with regard to the ceiling is as long as possible (approximately 1 m to 1,5 m).
   - The vertical access shall be confirmed to be vertical.
4) Now, rotate the rotor through a small angle (approximate to but not greater than 30°) and release the rotor allowing it to rotate clockwise and anti-clockwise across a marked datum point. Ensure that the rotor does not wobble. Determine the time for one cycle with the aid of stopwatch. (One cycle corresponds to one rotation to and fro). We recommend measuring 10 cycles and then dividing the value by 10 in order to keep the error as small as possible.

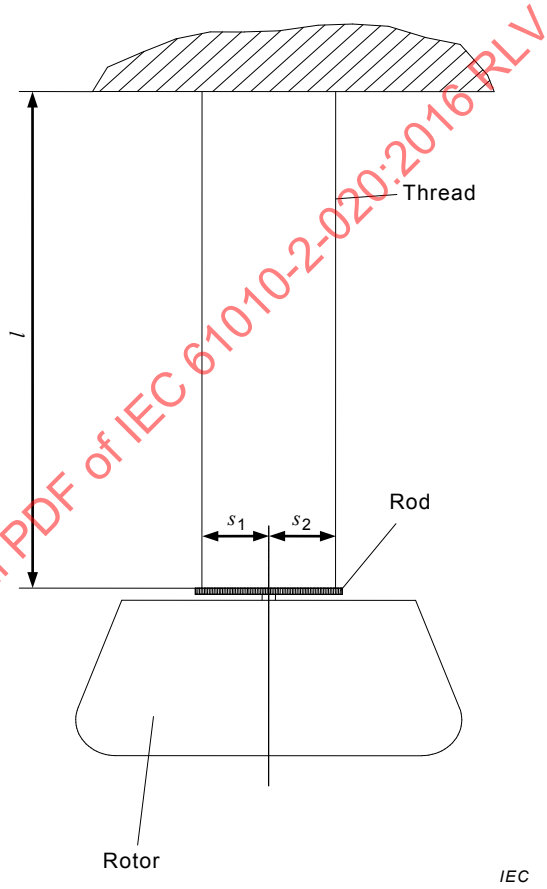

Figure 101 – Rotor test setup

5) The mass moment of inertia can be calculated with the aid of the following formula:

$$J_p = m \times g \times \frac{s1 \times s2 \times T^2}{l \times 4 \times \pi^2}$$

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6) Then, the kinetic energy can be calculated as follows:

$$E_{kin} = \frac{1}{2} \times J_p \times \omega^2 \quad \omega = 2 \times \pi \times n$$

where

m is the mass in [kg]

g is 9,81 m/s^2

$s1$=$s2$ is the thread distance with regard to the axis of rotation of the rotor in [m]

T is the cycle time in [s]

l is the thread length in [m]

J_P is the mass moment of inertia in [kgm^2]

ω is the angular velocity in [1 / s^2]

n is the speed in 1/s

E_{kin} is the kinetic energy in [Nm].

NOTE 1 Glycerine has a density of 1,26 and so the sample container is filled with glycerine until the rated load of the sample container is achieved.

NOTE 2 Examples of cords that could satisfy the requirements of the fishing line referenced above are those defined in the following standards:

- BS 4881:1993, *Polypropelene film cord, lines and twines*
- ISO 1873-1:1995, *Plastics – Polypropylene moulding and extrusion materials – Part 1: Designation systems and basic for specifications*
- ISO 1873-2:2007, *Plastics – Polypropylene moulding and extrusion materials – Part 2: Preparation of test specimens and determination of properties*
- EN ISO 1346:2004, *Fibre ropes – Polypropylene split film, monofilament and multifilament and polypropylene high tenacity multifilament – 3-, 4- and 8-strand ropes*
- EN 12423:1999, *Polypropylene twines*

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Bibliography

Addition:

Add the following publication:

IEC 60034 (all parts), *Rotating electrical machines*

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IEC 61010-2-020

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PUBLICATION GROUPÉE DE SÉCURITÉ

Safety requirements for electrical equipment for measurement, control, and laboratory use –
Part 2-020: Particular requirements for laboratory centrifuges

Exigences de sécurité pour appareils électriques de mesurage, de régulation et de laboratoire –
Partie 2-020: Exigences particulières pour centrifugeuses de laboratoire

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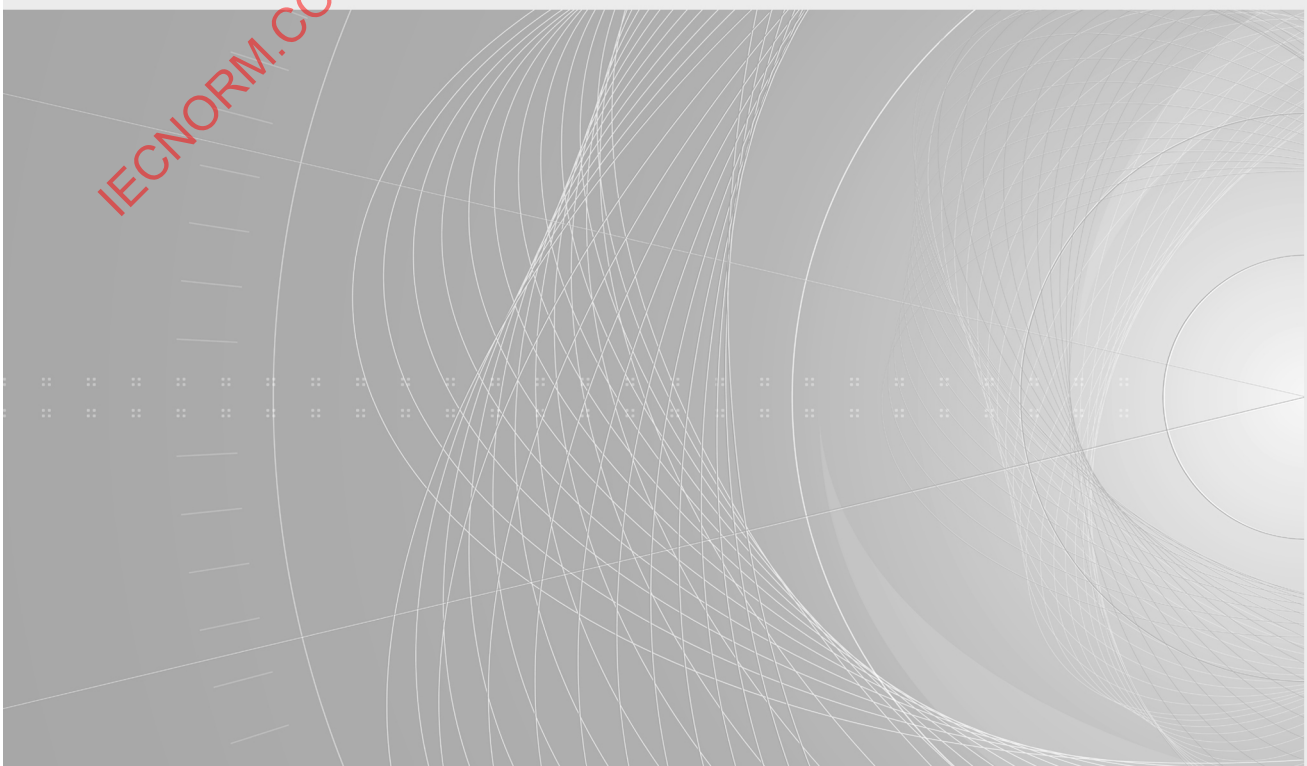

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

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SAFETY REQUIREMENTS FOR ELECTRICAL EQUIPMENT FOR MEASUREMENT, CONTROL, AND LABORATORY USE –

Part 2-020: Particular requirements for LABORATORY CENTRIFUGES

FOREWORD

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International Standard IEC 61010-2-020 has been prepared by IEC technical committee 66: Safety of measuring, control and laboratory equipment.

This third edition cancels and replaces the second edition published in 2006. It constitutes a technical revision and includes the following significant changes from the second edition:

a) This Part 2 is established on the basis of the third edition (2010) of IEC 61010-1.The changes listed in its foreword affect this Part 2, too.
b) The language has been updated to reflect current terminology for LABORATORY CENTRIFUGES used in the industry today.

It has the status of a group safety publication in accordance with IEC Guide 104.

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The text of this standard is based on the following documents:

CDV	Report on voting
66/542/CDV	66/565A/RVC

Full information on the voting for the approval of this standard can be found in the report on voting indicated in the above table.

This publication has been drafted in accordance with the ISO/IEC Directives, Part 2.

This Part 2-020 is intended to be used in conjunction with IEC 61010-1. It was established on the basis of the third edition (2010).

This Part 2-020 supplements or modifies the corresponding clauses in IEC 61010-1 so as to convert that publication into the IEC standard: *Safety requirements for LABORATORY CENTRIFUGES*.

Where a particular subclause of Part 1 is not mentioned in this Part 2, that subclause applies as far as is reasonable. Where this part states "addition", "modification" or "replacement", the relevant requirement, test specification or note in Part 1 should be adapted accordingly.

In this standard:

1) the following print types are used:
   - requirements: in roman type;
   - NOTES: in small roman type;
   - *conformity and tests: in italic type;*
   - terms used throughout this standard which have been defined in Clause 3: SMALL ROMAN CAPITALS.
2) subclauses, tables or figures which are additional to those in Part 1 are numbered starting from 101; additional annexes are lettered AA, BB, etc.

A list of all parts of the IEC 61010 series, under the general title: *Safety requirements for electrical equipment for measurement, control, and laboratory use*, may be found on the IEC website.

The committee has decided that the contents of this publication will remain unchanged until the stability date indicated on the IEC website under "http://webstore.iec.ch" in the data related to the specific publication. At this date, the publication will be

- reconfirmed,
- withdrawn,
- replaced by a revised edition, or
- amended.

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SAFETY REQUIREMENTS FOR ELECTRICAL EQUIPMENT FOR MEASUREMENT, CONTROL, AND LABORATORY USE –

Part 2-020: Particular requirements for laboratory centrifuges

1 Scope and object

This clause of Part 1 is applicable except as follows:

1.1.1 Scope

Replacement:

This Part 2 is applicable to electrically powered LABORATORY CENTRIFUGES.

This group safety publication is primarily intended to be used as a product safety standard for the products mentioned in the scope, but shall also be used by technical committees in the preparation of its publications for products similar to those mentioned in the scope of this standard, in accordance with the principles laid down in IEC Guide 104 and ISO/IEC Guide 51.

NOTE If all or part of the equipment falls within the scope of one or more other Part 2 standards of IEC 61010 as well as within the scope of this standard, it will also need to meet the requirements of those other Part 2 standards.

1.1.2 Equipment excluded from scope

Addition:

Add the following new item:

aa) IEC 60034 (Rotating electrical machinery);

1.2 Object

1.2.1 Aspects included in scope

Addition:

Add the following new items:

aa) contact with moving parts (see 7.3);

bb) LABORATORY CENTRIFUGE movement during any DISRUPTION (see 7.3.101);

cc) high energy chemical reaction after ROTOR DISRUPTION (see 7.7.2.2 l));

dd) ineffectiveness of BIOSEALS (see 13.101)

1.2.2 Aspects excluded from scope

Addition:

Add the following new items:

aa) additional precautions which may need to be observed when centrifuging materials which are flammable or explosive (see 5.4.101);

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bb) additional precautions which may need to be observed when centrifuging materials that could react chemically with sufficient vigour to cause a HAZARD (see 5.4.101).

1.4 Environmental conditions

1.4.1 Normal environmental conditions

Replacement:

Replace item c) by the following:

c) temperature 2 °C to 40 °C;

1.4.2 Extended environmental conditions

Replacement:

Replace item c) by the following:

c) ambient temperatures below 2 °C or above 40 °C;

2 Normative references

This clause of Part 1 is applicable except as follows:

Addition:

ISO 3864 (all parts), *Graphical symbols – Safety colours and safety signs*

3 Terms and definitions

This clause of Part 1 is applicable except as follows:

3.1 Equipment and states of equipment

Addition:

Add the following new terms and definitions:

3.1.101
LABORATORY CENTRIFUGE
apparatus intended for laboratory use that applies a centrifuging effect to sample materials

3.1.102
CENTRIFUGE-ROTOR COMBINATION
LABORATORY CENTRIFUGE and ROTOR ASSEMBLY that are intended to operate together and which have to be evaluated together

3.1.103
DISRUPTION
event in which the ROTOR ASSEMBLY, or part of it, fails or becomes detached during rotation

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3.2 Parts and accessories

Addition:

Add the following new terms and definitions:

3.2.101
CHAMBER
enclosed space within a LABORATORY CENTRIFUGE in which the ROTOR ASSEMBLY rotates

3.2.102
ROTOR
primary component of a LABORATORY CENTRIFUGE which holds the material to be subjected to centrifugal force and which is rotated by the DRIVE SYSTEM

3.2.103
BUCKET
sub-assembly of a ROTOR designed to support one or more containers

3.2.104
PROTECTIVE CASING
casing which completely surrounds the ROTOR ASSEMBLY and which includes the LID and its securing devices

3.2.105
LID
access cover of the CHAMBER

3.2.106
ROTOR ASSEMBLY
ROTOR carrying a combination of ROTOR accessories specified by the manufacturer

Note 1 to entry: In the context of a ROTOR ASSEMBLY, ROTOR accessories include all components used with or in the CENTRIFUGE ROTOR for the purpose of holding samples, including adaptors, tubes and bottles.

3.2.107
DRIVE SYSTEM
all components of the CENTRIFUGE associated with the provision of torque to, or the rotational support of, the ROTOR ASSEMBLY

3.2.108
BIOSEAL
device or mechanism additional to, or integral with, a ROTOR or BUCKET and a closure assembly, and which is designed to prevent the escape of contents, for example micro-biological material, during centrifuging

3.5 Safety terms

Addition:

Add the following new terms and definitions:

3.5.101
CLEARANCE ENVELOPE
space around a LABORATORY CENTRIFUGE which is needed for safety

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3.5.102
MCA
MAXIMUM CREDIBLE ACCIDENT
planned event chosen to represent worst-case conditions for a test that will evaluate the inherent mechanical safety of a CENTRIFUGE-ROTOR COMBINATION (see 7.7 and Annex BB)

4 Tests

This clause of Part 1 is applicable.

5 Marking and documentation

This clause of Part 1 is applicable except as follows.

5.1.2 Identification

Replacement:

Replace item b) by the following:

b) serial number or other means to identify the production batch of the equipment.

Addition:

Add the following new subclause:

5.1.101 ROTORS and accessories

All OPERATOR-replaceable ROTORS and ROTOR ASSEMBLIES, including ROTOR ACCESSORIES, shall be marked with the manufacturer's or supplier's name or registered trade mark, and identification code.(such as id code, serial number or batch number)

If components are too small, or are not suitable for such marking, the required information shall be marked on the original packaging, as well as being stated in the documentation.

NOTE Packaging can be the outer box, an insert, etc.

If the manufacturer specifies that an individual part, for example a BUCKET, is to be fitted only to a specific ROTOR or in specific ROTOR positions for balance or some other reason, each BUCKET and ROTOR position should be identified by marking with corresponding numbers or letters.

Conformity is checked by inspection.

5.4.2 Equipment ratings

Addition:

Add the following new items:

aa) a list of all ROTORS and ROTOR accessories specified for use with a LABORATORY CENTRIFUGE, together with their RATED rotational frequencies;

bb) any restrictions by the manufacturer warning against the use of particular materials to be centrifuged;

cc) density and volume limits for ROTOR ASSEMBLY loading and, if applicable, derating instructions.

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5.4.3 Equipment installation

Addition:

Add, after item a), the following sub-items:

i) floor or bench area required for the CLEARANCE ENVELOPE for the intended use (see 7.4.101);

ii) total weight of the CENTRIFUGE;

iii) instructions for site preparation;

iv) methods for levelling of the CENTRIFUGE;

v) means for securing to the mounting surface.

5.4.4 Equipment operation

Addition:

Add the following new items:

aa) loading and balancing procedures;

bb) ROTOR changing procedure;

cc) any specific requirement for an OPERATOR to be present at stated phases of the centrifuging procedure;

dd) necessary safeguards for personnel. Instructions shall include at least the following:

- not to lean on a LABORATORY CENTRIFUGE;
- not to stay within the CLEARANCE ENVELOPE longer than necessary for operational reasons;
- not to deposit any potentially hazardous materials within the CLEARANCE ENVELOPE;
- methods for safe operation during open LID procedures (see 7.3.102.2);

ee) instructions for use of BIOSEALS and other biocontainment components, including the proper closure techniques. These instructions shall indicate that BIOSEALS and related components are intended to be part of biocontainment systems, as specified in international and national biosafety guidelines. They are not to be relied on as the only means of safeguarding workers and the environment when handling pathogenic micro-organisms.

5.4.5 Equipment maintenance

Addition:

Add the following new paragraph:

Where applicable, the instructions shall specify:

aa) inspection of any means of fixing the equipment to the mounting surface and the condition of the mounting surface itself;

bb) safeguards for the OPERATOR during cleaning;

cc) inspection of the PROTECTIVE CASING;

dd) inspection of the ROTOR ASSEMBLY, and safety considerations;

ee) checking the continuity of the PROTECTIVE BONDING;

ff) frequency of inspection, routine maintenance and the method of replacement of BIOSEALS and other biocontainment components.

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Addition:

Add the following new subclauses:

5.4.101 Hazardous substances

The instructions for use shall state the precautions to be observed when the materials to be used with a LABORATORY CENTRIFUGE are known to be toxic, radioactive, or contaminated with pathogenic micro-organisms.

NOTE This information is relevant to the safety of both OPERATORS and service personnel.

The use within the LABORATORY CENTRIFUGE of the following materials shall be prohibited in the instructions for use:

a) flammable or explosive materials;

b) materials which could react chemically with sufficient vigour to cause a HAZARD.

Conformity is checked by inspection.

5.4.102 Cleaning and decontamination

Documentation shall include:

a) a statement that, if hazardous material is spilt on or inside the equipment, the user has responsibility for carrying out appropriate decontamination;

b) manufacturer's recommendations for cleaning and, where necessary, decontaminating, together with the recognized generic names of recommended materials for cleaning and decontaminating:

c) the following statement:

"Before using any cleaning or decontamination methods except those recommended by the manufacturer, users should check with the manufacturer that the proposed method will not damage the equipment”

d) the following statement:

Cleaning and decontamination may be necessary as a safeguard before LABORATORY CENTRIFUGES, ROTORS and any accessories are maintained, repaired, or transferred. Manufacturers may provide a format for users to document that such treatment has been carried out

NOTE Be advised, there are national guidelines and the internationally recognized "Laboratory Biosafety Manual", published in 1993 by the Wor5ld Health Organization in Geneva, which gives information on decontaminants, their use, dilutions, properties, and potential applications.

Conformity is checked by inspection.

5.4.103 Effects of chemicals and environmental influences

To ensure continued safe use of a LABORATORY CENTRIFUGE the documentation shall identify damage which could result from, for example:

a) the effect of chemicals;

b) environmental influences, including natural ultra-violet radiation likely to be encountered;

c) corrosion, and other weakening of construction materials that are part of the PROTECTIVE CASING or other protective components.

Conformity is checked by inspection of the documentation and the relevant data and/or additional testing (if needed).

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6 Protection against electric shock

This clause of Part 1 is applicable.

7 Protection against mechanical HAZARDS

This clause of Part 1 is applicable except as follows.

7.1 General

Addition:

Add the following new note:

NOTE 101 A DISRUPTION, resulting in damage to a part of the PROTECTIVE CASING, for example a LID-locking mechanism, is considered to be a SINGLE FAULT CONDITION.

7.3 Moving parts

Addition:

Add the following new subclauses.

7.3.101 LID

7.3.101.1 Requirements

The LID shall be locked closed when the ROTOR drive is energized, and shall remain locked until the circumferential velocity of the ROTOR ASSEMBLY is not more than 2 m/s (see Annex BB).

In the event of a power failure, the LID-locking mechanism shall not release, and subsequent release shall require the use of a TOOL.

The LID shall be held closed with sufficient strength to withstand the results of testing according to 7.7.3. Fragments produced by any DISRUPTION shall be contained as specified in item a) of 7.7.

To evaluate which of the following points are appropriate for the CENTRIFUGE-ROTOR COMBINATION under consideration, information shall be recorded showing the tests conducted by the manufacturer or by a test facility:

a) mechanical abuse;
b) mislatching;
c) misalignment;
d) corrosion;
e) material degradation;
f) material defects;
g) vibration;
h) cleaning and decontamination;
i) environmental influences;
j) other considerations appropriate for the design.

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Conformity is checked by visual inspection; by the review of recorded information, by the tests carried out under 7.7.3, and by any further tests considered appropriate for safety.

7.3.101.2 Exception

For LABORATORY CENTRIFUGES that satisfy all the following limitations, a device which merely interrupts motor power may be used instead of an interlock mechanism (see Annex BB):

a) the LABORATORY CENTRIFUGE incorporates a device which holds the LID closed;

b) the device which interrupts motor power does not permit the drive motor to be energized unless the LID is closed;

c) the rotational frequency of the ROTOR ASSEMBLY does not exceed 3 600 rpm;

d) the energy at maximum rotational frequency for the highest energy ROTOR ASSEMBLY when fully loaded does not exceed 1 kJ;

e) the maximum centrifugal force does not exceed 2 000 *g*;

f) the largest ROTOR ASSEMBLY diameter does not exceed 250 mm;

g) a switch is provided for disconnecting motor power, independent of the LID position;

h) the ROTOR ASSEMBLY is visible when the LID is closed, to permit observation of any rotation;

i) all ROTOR ASSEMBLIES used conform to 7.3 of Part 1;

j) if access is possible at a circumferential velocity of the ROTOR ASSEMBLY of more than 2 m/s, a warning label in accordance with ISO 3864 is provided on or near the access point, indicating that the LID should not be opened until rotation has stopped. Where there is insufficient space for such a label, symbol 14 of Table 1 is considered to be an acceptable marking.

Conformity is checked by visual inspection and by the review of data to confirm that all the above limitations are met.

7.3.102 ROTOR ASSEMBLIES

7.3.102.1 General

If a HAZARD could result from contact with moving parts of the ROTOR ASSEMBLY or DRIVE SYSTEM in NORMAL CONDITION or SINGLE FAULT CONDITION, suitable protective means shall be provided to prevent OPERATOR access, except as permitted by 7.3.101.2 and 7.3.102.2.

There shall be no holes or other openings in the top of the CHAMBER which permit the penetration of a 4 mm diameter pin.

Conformity is checked by inspection and by using the test fingers shown in Figures B.1 and B.2, and by checking openings in the top with a 4 mm diameter pin, in NORMAL CONDITION and SINGLE FAULT CONDITION.

The jointed test finger shown in Figure B.2 is applied in every possible position without applying any force. If it is possible to touch a part by applying a force, the rigid test finger shown in Figure B.1 is applied with a force of 10 N. The force is exerted against all outer surfaces, including the bottom, by the tip of the test finger so as to avoid wedge or lever action. The finger shall not touch any moving part that could cause a HAZARD.

7.3.102.2 ROTOR ASSEMBLIES requiring access during rotation

If the manufacturer supplies ROTOR ASSEMBLIES requiring OPERATOR interaction (e.g. zonal or continuous-flow ROTOR ASSEMBLIES), LABORATORY CENTRIFUGES are permitted to have an override control which allows the motor to be energized while the access LID is open, provided that:

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a) the override control allows the motor to be energized only by use of a device (which can be a code or code-card) that makes it possible to override a protective system and functions by means that cannot be performed using other tools, or when a special guard plate allows only limited access to the rotor assembly;

b) means are provided to cancel the override function automatically when use of the rotor assembly requiring OPERATOR interaction is ended;

c) maximum speed while the LID is open is limited to 5 000 rpm.

Conformity is checked by inspection

7.4 Stability

Addition:

Add a new third paragraph as follows:

No displacement of the LABORATORY CENTRIFUGE from its installed position shall be visible during NORMAL USE.

Addition:

Add the following new subclause:

7.4.101 LABORATORY CENTRIFUGE movement during malfunction

After installation according to the manufacturer's instructions, movement of a LABORATORY CENTRIFUGE as a result of ROTOR ASSEMBLY imbalance, ROTOR ASSEMBLY DISRUPTION, or drive failure (seizure), shall not present a HAZARD.

Movement shall be limited either by design, or by fastening to the mounting surface, or a combination of both, so that no part of the LABORATORY CENTRIFUGE moves outside a CLEARANCE ENVELOPE extending 300 mm, or less if stated by the manufacturer, in any direction from the outermost parts of the LABORATORY CENTRIFUGE in its original position (for rationale see Clause BB.6).

Conformity is checked by testing to confirm that the 300 mm limit, or any lower limit stated by the manufacturer, is not exceeded in NORMAL USE and after inducing the worst-case situation according to 7.7.2.2 for:

a) imbalance;

use of an imbalance sensor is acceptable as a means for limiting movement. , but its possible failure should be considered when determining the worst-case condition unless examination of the equipment and design demonstrates conclusively that the sensor will not fail.

b) disruption of the ROTOR ASSEMBLY;

c) DRIVE SYSTEM failure;

d) seizure of the DRIVE SYSTEM.

NOTE The failure mode which will produce the greatest movement can be different from the failure mode of the MCA determined for testing the PROTECTIVE CASING according to 7.7.3. See Annex CC for additional guidance in determining the worst case rotor.

For these tests, the LABORATORY CENTRIFUGE is mounted on, or fixed to, a horizontal smooth concrete test surface of dimensions appropriate for the size of LABORATORY CENTRIFUGE being tested, and as specified in the manufacturer's instructions.

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7.7 Expelled parts

Replacement:

Replace the title and text by the following new title and text.

7.7 Protection against expelled parts or projected parts

7.7.1 General

LABORATORY CENTRIFUGES shall be designed for safe operation in NORMAL USE and SINGLE FAULT CONDITION, when used with ROTOR ASSEMBLIES specified by the manufacturer.

In the event of a DISRUPTION:

a) no parts or fragments of the ROTOR ASSEMBLY exceeding 5 mm in any dimension shall completely penetrate the PROTECTIVE CASING. Smaller material (except for aerosols and liquids) shall remain within a trajectory extending 1 m in any direction from the outermost parts of the LABORATORY CENTRIFUGE; (See rationale in Annex BB.6)

b) no part of the LABORATORY CENTRIFUGE shall become detached or expelled in such a way as to present a HAZARD to personnel or the environment. In the case of parts detached or expelled from the centrifuge (not part of the ROTOR ASSEMBLY) this is to be evaluated in accordance with Clause 17.

c) the fastenings of the access LID shall not be loosened, and there shall be no distortion which could create an unimpeded path between any point on the ROTOR ASSEMBLY and any point outside the LABORATORY CENTRIFUGE.

Conformity of every CENTRIFUGE-ROTOR COMBINATION specified by the manufacturer is checked by testing as specified in 7.7.3, under MCA conditions, or by causing DISRUPTION by partially cutting the ROTOR, or by overloading the ROTOR ASSEMBLY, or by other appropriate means. If more than one worst-case ROTOR ASSEMBLY selection exists, each can be tested with a new PROTECTIVE CASING.

After the tests, the criteria of a) to c) above shall be met, and visible cracks shall be examined to determine whether or not the PROTECTIVE CASING would have contained the ROTOR parts irrespective of their trajectory. A questionable result shall require the test to be repeated once only, and a further questionable result is considered to be a failure. The equipment is checked to ensure that parts which are HAZARDOUS LIVE have not become ACCESSIBLE and that ACCESSIBLE conductive parts do not exceed the values of 6.3.2. In the event that the test causes the operation of an overcurrent protection device, if the device can not be reset without operating again, the unit is considered to have failed safe. (See rationale Annex BB6.2)

NOTE 1 Consideration should be given to the presence of temporary gaps in containment during the MCA test in determining questionable results.

Alternatively, the safety of a CENTRIFUGE-ROTOR COMBINATION can be established by analytical evaluation based on comparison with one of more of the CENTRIFUGE-ROTOR COMBINATIONS already tested, to confirm that the PROTECTIVE CASING would have passed the relevant test of 7.7.3.

NOTE 2 CENTRIFUGE-ROTOR COMBINATIONS designed such that satisfactory evaluation by comparison with another CENTRIFUGE-ROTOR COMBINATION already tested cannot be made are tested as specified in 7.7.3.

7.7.2 Considerations for MCA tests

7.7.2.1 Information to be recorded

Recorded information shall include:

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a) corrosion effects to be expected;

b) material fatigue behaviour;

c) material degradation considerations, including effects of inspection, maintenance, and component replacement schedules;

d) temperature limitation considerations;

e) material defect considerations;

f) improper BUCKET installation considerations;

g) relevant environmental considerations;

h) relevant maximum loading considerations;

i) electrical circuit diagram and functional descriptions;

j) material specifications and technical data;

k) pre-treatment methods to induce ROTOR ASSEMBLY failure;

l) traceability of all measuring instruments used during tests;

m) any other relevant information.

Conformity is checked by inspection of documentation relating to the above items.

7.7.2.2 Considerations for worst-case conditions

All combinations of the following that are possible shall be considered:

a) ROTOR selection: the worst-case specified ROTOR ASSEMBLY or ROTOR ASSEMBLIES; (for calculating the kinetic energy of rotors, refer to annex CC)

b) rotational frequency control setting: the maximum that an OPERATOR can select;

c) supply voltage: 10 % above the maximum RATED voltage marked on the equipment;

d) ROTOR ASSEMBLY load: the maximum specified load, partial load, and no load, including state and density of load (e.g. liquid, solid);

e) ROTOR accessories, worst case loading of specified accessories used with or in the ROTOR for the purpose of holding samples, including adaptors, tubes, and bottles;

f) ROTOR ASSEMBLY imbalance: the most severe condition;

g) altitude factors: the effect of reduced atmospheric pressure and density at increased altitude on ROTOR DRIVE SYSTEMS which rely on windage to limit maximum rotational frequency (see 1.4.1 b) and 1.4.2 b)).

NOTE 1 The windage limitation can be determined by conducting a rotational frequency test in a cabinet or room in which the pressure is controlled to 80 kPa or less, or alternatively the rotational frequency n_2, which would be reached at 2 000 m altitude, can be determined from:

$$n_2 = n_1 \times \sqrt[3]{R}$$

where

n_1 is the maximum rotational frequency at standard atmospheric pressure at sea-level (101 kPa);

n_2 is the corresponding maximum rotational frequency at an atmospheric pressure equivalent to 2 000 m;

R = 1,27 (the ratio of the density of air at sea-level, to that at 2 000 m).

h) friction between the LABORATORY CENTRIFUGE or LABORATORY CENTRIFUGE feet and the surface on which the LABORATORY CENTRIFUGE is placed;

i) ambient temperature: the effect on components of working at any temperature in the permitted range from 2 °C to 40 °C;

j) a combination of ROTOR ASSEMBLY and drive unit causing an instability of the dynamic behaviour;

k) installation as specified by the manufacturer;

l) the possibility of high energy chemical reaction after DISRUPTION

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NOTE 2 In LABORATORY CENTRIFUGES which develop energies of the order of 275 kJ and above, and which are refrigerated under vacuum, it is possible for a DISRUPTION to cause a chemical explosion if parts of the ROTOR ASSEMBLY are made of reactive material, such as aluminium and titanium. An explosion can occur due to interaction at high energies of the ROTOR ASSEMBLY fragments with refrigerants and water.

In such cases, the worst-case conditions can be achieved by the following combination of means:

i) disabling rotational frequency controls and limiting devices so that the highest rotational frequency is reached;

ii) selecting whichever ROTOR of reactive material has the highest rotational energy, and pretreating it so as to cause a DISRUPTION. The pre-treatment shall maximize the surface area of the resulting fragments;

iii) adjusting the refrigeration system to have the maximum amount of refrigerant in the evaporator which cools the CHAMBER;

iv) loading the ROTOR ASSEMBLY with water to 80 % of its nominal capacity;

v) running the LABORATORY CENTRIFUGE in worst-case conditions of all other unspecified factors until a DISRUPTION occurs.

NOTE 3 Test personnel should be aware that extraordinary energy release can result from the tests where a high-energy chemical reaction is possible after DISRUPTION. A remote bunker facility is recommended.

Conformity is checked by inspection of documentation relating to the above items.

7.7.2.3 SINGLE FAULT CONDITIONS to be considered

The following SINGLE FAULT CONDITIONS shall be considered:

a) rotational frequency control condition: whichever SINGLE FAULT CONDITION that results in the highest rotational frequency;

b) rotational frequency limiting system whichever SINGLE FAULT CONDITION permits the highest rotational frequency;

c) MAINS power interruption: intermittent or permanent loss of MAINS power, if either presents a hazardous condition;

d) drive seizure: the sudden application of the rotational energy to the frame and case of a LABORATORY CENTRIFUGE;

e) any component failure;

f) non-quantitative SINGLE FAULT CONDITIONS:

   i) corrosion effects, for example corrosion at the bottom of a BUCKET or cavity, stress corrosion cracking of alloys, corrosion of welds in the PROTECTIVE CASING, environmental crazing of polymers, etc.;

   ii) material fatigue behaviour, which may affect the mode of failure;

   iii) material defects;

   iv) improper installation of a BUCKET or any other component that is fitted in a swinging BUCKET system (e.g. the omission of a BUCKET), incorrect mounting of a BUCKET at its pivot points, use of an incorrect BUCKET, and overloading a BUCKET;

   v) temperature effects, such as expected extremes during transportation, high ROTOR ASSEMBLY temperatures during operation, and any necessary treatment specified by the manufacturer.

Conformity is checked by inspection of documentation relating to the above items.

7.7.3 Testing the PROTECTIVE CASING

For each worst-case ROTOR ASSEMBLY selection in each MCA, determined according to 7.7.2.1 to 7.7.2.3, testing as necessary shall be carried out to prove the adequacy of the PROTECTIVE CASING, and to show that it would have contained the ROTOR parts irrespective of their

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trajectory. No parts or fragments shall be expelled from the PROTECTIVE CASING during the tests, other than those permitted by 7.7.1 a).

Each test may be carried out with a new PROTECTIVE CASING.

The ROTOR ASSEMBLY under test may first be appropriately weakened to induce it to fail during the test of the PROTECTIVE CASING in accordance with the MCA failure mode.

One of the more difficult fragments of a ROTOR ASSEMBLY to contain in a DISRUPTION is an approximate half ROTOR. Experience over the years has shown that many designs of ROTOR can disrupt to give such a size of fragment. This should be taken into account when determining an MCA, as well as other ROTOR failure modes.

Test data shall be recorded, including the following:

a) description of the LABORATORY CENTRIFUGE and ROTOR ASSEMBLY – model, ROTOR type, accessories and loading;

b) MCA conditions, with justification;

c) ROTOR ASSEMBLY failure inducement method with justification;

d) date and time of the test;

e) environmental conditions during the test;

f) photographs of the LABORATORY CENTRIFUGE and relevant parts before and after the test, with video-recording of the DISRUPTION;

g) rotational frequency at the time of ROTOR ASSEMBLY failure, and hence the energy involved;

h) type of ROTOR ASSEMBLY failure;

i) description of any damage caused to the PROTECTIVE CASING;

j) details of any movement of the LABORATORY CENTRIFUGE;

k) details of the escape of any debris.

8 Mechanical resistance to shock and impact

This clause of Part 1 is applicable.

9 Protection against the spread of fire

This clause of Part 1 is applicable.

10 Equipment temperature limits and resistance to heat

This clause of Part 1 is applicable.

11 Protection against HAZARDS from fluids

This clause of Part 1 is applicable except as follows.

11.2 Cleaning

Replacement:

Replace the second paragraph by the following:

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Conformity is checked by cleaning the equipment 20 times if a cleaning process is specified and decontaminating the equipment once if a decontamination process is specified, in accordance with the manufacturer's instructions. If a manufacturer specifies only certain cleaning procedures, only these shall be applied. If no restriction is given in the instructions for use, a steam sterilization test at one of the time-temperature conditions of Table 101 (see 11.2.101) shall be repeated 20 times.

If, immediately after this treatment, there are any signs of wetting of parts likely to cause a HAZARD, the equipment shall pass the voltage test of 6.8 (without humidity preconditioning) and ACCESSIBLE parts shall not exceed the limits of 6.3.1.

Addition:

Add the following new subclause:

11.2.101 Steam sterilization

If a manufacturer claims that an item can be decontaminated by steam sterilization, it shall be capable of withstanding steam sterilization under at least one of the time-temperature conditions given in Table 101.

Table 101 – Time-temperature conditions

Absolute pressure	Corresponding steam temperature		Minimum hold time
kPa	Nominal °C	Range °C	min
325	136,0	134 to 138	3
250	127,5	126 to 129	10
215	122,5	121 to 124	15
175	116,5	115 to 118	30
NOTE "Minimum hold time" means the time the contaminant is at steam temperature.			

Conformity is checked by test.

11.3 Spillage

Modification:

Insert "or onto" *after* "into" *in the first line.*

Addition:

Add the following new subclause:

11.101 Refrigerated and water-cooled LABORATORY CENTRIFUGES

Refrigerated and water-cooled LABORATORY CENTRIFUGES shall not become hazardous while operated in elevated humidity and temperature conditions.

Conformity is checked by operating the LABORATORY CENTRIFUGE in an environmental cabinet which has been set at the maximum RATED humidity and temperature of the LABORATORY CENTRIFUGE. The equipment is operated in the standby mode, at the lowest settable CABINET temperature, for a period of 7 h.

Immediately after treatment, the equipment shall pass the voltage test of 6.8 (without further humidity preconditioning), and ACCESSIBLE parts shall not exceed the limits of 6.3.1.

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12 Protection against radiation, including laser sources, and against sonic and ultrasonic pressure

This clause of Part 1 is applicable.

13 Protection against liberated gases and substances, explosion and implosion

This clause of Part 1 is applicable, except as follows.

Replacement:

Replace the title by the following new title:

13 Protection against liberated gases, explosion and implosion and escape of microbiological materials

Addition:

Add the following new subclause:

13.101 Microbiological materials

BIOSEALS in ROTORS and BUCKETS which are RATED by the manufacturer as being fit to contain microbiological specimens during centrifuging shall prevent the escape of biological materials, when operated and maintained in accordance with the manufacturer's instructions (see Annex AA).

Conformity is checked by testing the BIOSEAL as specified in Annex AA.

NOTE Additional test methods are under consideration for types of BIOSEAL for which the test of Annex AA is not applicable, and to cover much smaller micro-organisms (see also Annex BB, 13.101).

14 Components

This clause of Part 1 is applicable.

15 Protection by interlocks

This clause of Part 1 is applicable.

16 Hazards resulting from application

This clause of Part 1 is applicable.

17 Risk assessment

This clause of Part 1 is applicable.

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Annexes

The annexes of Part 1 are applicable except as follows.

Annex L

Index of defined terms

Additional defined terms:

Addition:

Add the following new annexes:

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Annex AA
(normative)

Dynamic microbiological test method for BIOSEALS

AA.1 General

This test method is based upon exposing the BIOSEAL of a BUCKET or ROTOR to a concentrated suspension of bacterial spores while the LABORATORY CENTRIFUGE is operating and testing to show that no spores escape. This test is designed to challenge the BIOSEAL design as a whole during a foreseeable event likely to occur when operated in accordance with the manufacturer's instructions (see 5.4) and with good laboratory practices associated with handling bio-hazardous materials.

AA.2 Equipment and method

AA.2.1 CENTRIFUGE

The BUCKET or ROTOR is used as part of a ROTOR ASSEMBLY in conjunction with the type of LABORATORY CENTRIFUGE that is recommended by its manufacturer. BUCKETS, ROTORS and LABORATORY CENTRIFUGES are used in accordance with their manufacturer's instructions. Tests shall be carried out in CENTRIFUGES capable of reaching the maximum speed for the ROTOR as stated by the manufacturer. If possible, the LABORATORY CENTRIFUGE is operated from outside the test cabinet or test room during the tests.

AA.2.2 Test cabinet or test room

The cabinet is essentially airtight and of appropriate size for the LABORATORY CENTRIFUGE under test. It is fitted with high efficiency particulate air (HEPA) filters on both the inlet and outlet and a means of introducing the LABORATORY CENTRIFUGE and ROTOR ASSEMBLY to be tested. It is also provided with an electrical supply and facilities for operating the LABORATORY CENTRIFUGE from outside the test cabinet. The cabinet is fitted with an extractor fan capable of extracting air at a rate of approximately 2,8 m^3/min. If the CENTRIFUGE used is a floor standing model, then the cabinet or test room may have to be accessed by test personnel wearing full, clean room clothing including gloves and overshoes.

AA.2.3 Test suspension

An aqueous suspension of spores of the test organism, Bacillus subtilis var. niger (also referred to as B. atrophaeus Nakamura or B. globigii), containing $\geq 1 \times 10^{10}$ spores/ml.

AA.2.4 Test plates

Sterile agar plates with appropriate medium for the growth of the test organism. The batch of agar plates shall be shown to be capable of recovering low concentrations of the test micro-organism by plating out 0,1 ml of a 100 spore/ml to 1 000 spore/ml suspension on two plates with an accuracy of ±30 %.

AA.2.5 Sampling equipment

For all LABORATORY CENTRIFUGES, sampling equipment consists of sterile cotton swabs, moistened with sterile water, for sampling surfaces.

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AA.2.6 Fumigation equipment

Equipment shall be suitable for appropriate fumigation of the test cabinet and its contents after each individual test, to kill the spores remaining from the test suspension. The effectiveness of the fumigation is verified by ensuring that there is no background contamination of the ROTOR or cabinet before testing. Care shall be taken to ensure that the fumigant is fully dispersed before testing is undertaken. The ventilation system of the test cabinet is inactivated and a measure of the fumigant concentration is taken after a period equal to the relevant test period. If the concentration of the fumigant is appreciable (in the case of formaldehyde > 2 ppm) then the test is delayed, and ventilation is continued, until the level drops.

NOTE Fumigants are toxic by inhalation and care should be taken to avoid any exposure of personnel and also in the subsequent disposal of the vapour.

AA.2.7 Assessment of samples

All cultures are made on the surface of test plates. Swabs are rubbed over the surface of the test plates, which are incubated aerobically at 37 °C for between 18 h and 24 h. *Bacillus subtilis* var. *niger* colonies are recognized by their orange colour and are recorded as colony-forming units.

AA.3 Test procedure

AA.3.1 Checking of test suspension

Immediately before each test, appropriate dilutions of the test suspension are plated onto test plates.

AA.3.2 Test method

AA.3.2.1 Number of tests

Three separate tests, in which the BIOSEAL of the BUCKET or ROTOR is tested, are performed on each BUCKET or ROTOR. Control samples are taken before the test, as defined in AA.3.2.4.

AA.3.2.2 Fixed-angle ROTOR test method

Appropriate containers for the ROTOR under test are filled with the test suspension and placed, without capping or sealing, into every place in the ROTOR. All the ROTOR positions are filled to their RATED capacity, in accordance with the manufacturer's instructions.

Additional test suspension is pipetted carefully into the middle of the ROTOR, to simulate a 'spill'. If possible, without overflowing the ROTOR, the volume of this 'spill' should be equivalent to or greater than the volume of one container for containers of volumes up to 5ml, or for ROTORS holding containers of larger volume it should be either 5 ml or 10 % of the volume of one of the containers, whichever is greater. A note shall be made if less than the full volume of test suspension is used to simulate the 'spill'.

If canisters are used as the primary mode of protection in angle head ROTORS, then the BUCKET seal test method of AA.3.2.3 is used.

AA.3.2.3 BUCKET seal method

A different test method is required for sealed BUCKETS and canisters. The BUCKETS are filled with the test suspension to their rated capacity. After closing the cap, the BUCKET is slowly inverted twice to place the test suspension on the inside of the BUCKET seal.

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Since BUCKETS and ROTORS come in many designs, the above test methods may not be appropriate for all designs. In these instances, other methods may have to be devised to achieve the same effect, such as challenging the BIOSEAL when used in accordance with the manufacturer's instructions.

AA.3.2.4 Control samples

Surface samples are taken before each test to measure any background contamination with the test micro-organism. Initially, surface samples are taken from inside the "O"-ring of the BIOSEAL. After the test suspension is introduced into the BUCKET or ROTOR, surface samples are taken over the complete exterior of the BIOSEAL of the BUCKET or ROTOR and at multiple points around the inside of the CHAMBER at the height the BIOSEALS of the BUCKETS or ROTOR would be while the LABORATORY CENTRIFUGE is running; and, when a sealed BUCKET is being tested, the surface of the ROTOR. In the case of sealed BUCKETS or canisters, additional swab samples of the seal are taken after the BUCKET has been inverted. Swab samples are also taken in areas of potential contamination.

AA.3.2.5 Centrifugation

After taking the control samples (see AA.3.2.4), the LABORATORY CENTRIFUGE is accelerated to the maximum speed for the ROTOR ASSEMBLY under test, maintained at that speed for 5 min, then decelerated to rest.

After the LABORATORY CENTRIFUGE has come to rest, the LID is opened and test swab samples are taken from the surfaces from which the control samples were taken (see AA.3.2.4).

AA.3.2.6 Decontamination

After each test, the test cabinet and contents are decontaminated by fumigation and the cabinet is thoroughly aired by means of the extractor fan.

The BUCKET or ROTOR under test is decontaminated according to the method recommended by the manufacturer.

AA.4 Pass and fail criteria

Each ROTOR or BUCKET is subjected to three separate and valid tests. A pass requires each of the individual tests carried out to be passed, and failure of any single valid test results in overall failure.

The test is only valid if either the maximum volume of additional test suspension, as described in AA.3.2.2, was added, or if a sample from immediately inside the BIOSEAL shows $> 1 \times 10^3$ colony-forming units more than the control sample from this location.

For the three separate tests, the numbers of colony-forming units recovered by swabbing after centrifugation (apart from immediately inside the BIOSEAL of the BUCKET or ROTOR) shall not exceed the numbers recovered from the control samples collected before a test by more than 1 colony-forming unit (this is to allow for sampling error at very low numbers). If more than five colonies are detected in any of the control samples then the test is void and shall be repeated.

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Annex BB
(informative)

General guidance and rationale for particular subclauses

BB.1 Subclause 1.4 Environmental conditions

The lower limit of the ambient temperature at which equipment conforming to Part 1 should be safe to operate is +5 °C. For the purpose of LABORATORY CENTRIFUGES, the limit is lowered to +2 °C in this standard, since many LABORATORY CENTRIFUGES are used in cold-rooms. The nominal temperature at which such cold-rooms are maintained is +4 °C, but tolerances in the temperature control system inevitably mean that lower temperatures are experienced at times (but should never be as low as 0 °C). Therefore, the lower temperature of +2 °C has been chosen.

BB.2 Subclause 3.5.102 mca (MAXIMUM CREDIBLE ACCIDENT)

Safety requirements which state specific construction parameters for LABORATORY CENTRIFUGES could limit innovation by the design engineer. This approach can unnecessarily increase the cost to the user without assurance that the construction methods will provide the necessary safety for the OPERATOR. This standard provides basic design considerations for safe design and proof of safety by mechanical testing.

The concept used is testing to an MCA. Choosing an MCA utilizes all information from the instrument, ROTOR, component designs and development tests. Although a single MCA is not considered statistically significant from the point of view of a number of tests, nevertheless it is very unlikely that such an event will ever happen during NORMAL USE.

BB.3 Subclause 5.4.102 relation to Table 101

While it is optional for a manufacturer to claim that an item can be decontaminated by steam sterilization, if such a claim is made, it is essential that such sterilization should be under realistic conditions to achieve decontamination.

Table 101 is included to provide an indication of the time-temperature conditions which are generally found suitable by microbiologists for autoclave decontamination of items which have been contaminated with hazardous biological agents. It should be noted, however, that it is the responsibility of the user to ensure that the time-temperature conditions chosen for use are appropriate to inactivate the particular biological agent(s) which may have contaminated the BUCKETS and/or ROTOR. (This is particularly important for any work with prions, which are not readily inactivated by either heat or chemical means.)

BB.4 Subclause 7.3.101.1 LID (first paragraph)

One of the purposes of this standard is to specify the protection needed to prevent an OPERATOR being injured by moving parts of a CENTRIFUGE. For practical reasons, neither limitation of the rotational frequency, nor limitation of the rotational energy of the ROTOR ASSEMBLY, can be used to provide such protection.

If the intention is to permit the OPERATOR to gain access to the ROTOR ASSEMBLY before rotation has completely stopped – such as is held to be necessary for some centrifuging work – a potential HAZARD exists. The HAZARD is significant if an OPERATOR attempts to slow down the ROTOR ASSEMBLY by hand while the rotational frequency is such that the hand cannot easily follow the movement of the ROTOR ASSEMBLY. Once the rotational frequency is low

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enough for the hand to follow the rotation, even if it was inserted "against" the direction of rotation, no injury should be caused. It has been shown that the circumferential velocity limit of 2 m/s which is specified, easily allows an OPERATOR to follow the rotation by hand.

BB.5 Subclause 7.3.101.2 Exception

Certain LABORATORY CENTRIFUGES are permitted to have an access LID with a power-interrupt system instead of an interlock mechanism that is dependent on rotational frequency.

A carefully restricted definition of these exempted LABORATORY CENTRIFUGES has been achieved by specifying restricted maximum values for rotational frequency, centrifugal force, ROTOR ASSEMBLY energy and ROTOR diameter. LABORATORY CENTRIFUGES that fall within these restricted limits are widely used throughout the world, with hundreds of thousands in service and tens of thousands sold each year.

The reason for permitting less stringent requirements for such LABORATORY CENTRIFUGES is that significant extra complexity would be involved in providing a LID interlock mechanism without providing additional reduction of HAZARD.

The working group experts have been unable to trace any accidents with such LABORATORY CENTRIFUGES that may be attributed to the lack of an interlock mechanism. They are of the opinion that, if the device which holds the LID closed is released while the ROTOR ASSEMBLY is at speed and the LID is opened slightly, any potential HAZARD to the OPERATOR, due to opening the LID, is immediately reduced by:

a) an increase in sound level that warns the OPERATOR of exposure of the ROTOR ASSEMBLY;

b) an air flow which tends to deflect dangling objects such as a tie or hair away from the ROTOR ASSEMBLY;

c) the immediate and rapidly progressive reduction in energy due to the power-interrupt. Access to the ROTOR ASSEMBLY, by hand or other object, first requires the time to release and open the LID and then to reach in to the ROTOR ASSEMBLY.

BB.6 Subclause 7.4.101 LABORATORY CENTRIFUGE movement during malfunction

It is specified that the whole of a LABORATORY CENTRIFUGE shall remain inside a CLEARANCE ENVELOPE extending 300 mm from the outermost surface of the CENTRIFUGE. That dimension was selected after extensive examination of DISRUPTION data under MCA conditions. A requirement to have no movement at all during malfunction was considered, but was rejected because:

a) it could be attained by rigidly securing the LABORATORY CENTRIFUGE to a foundation with a mass many times the mass of the LABORATORY CENTRIFUGE. Present practice is that LABORATORY CENTRIFUGES are not rigidly fastened, so successful enforcement of a provision for fastening would be unlikely;

b) a requirement for rigid fastening would be a restriction of present practice. Bench-top LABORATORY CENTRIFUGES are frequently moved by an OPERATOR without involving service or maintenance staff. Most LABORATORY CENTRIFUGES may be moved for cleaning or relocated without elaborate work;

c) rigid fastening of a LABORATORY CENTRIFUGE would necessitate permanent changes to the mounting surface, and there is reluctance to make such permanent changes to laboratory benches and floors;

d) a review of accident data available to the working group did not provide any evidence of injury due to LABORATORY CENTRIFUGE movement.

The potential HAZARD of a LABORATORY CENTRIFUGE moving out of control and impacting personnel, as unlikely as that may be, has been considered. This risk has been reduced to an

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acceptable level of injury by limiting the permitted motion in the event of an MCA that produces LABORATORY CENTRIFUGE motion. Setting that maximum movement at 300 mm is based on the following considerations:

– the 300 mm CLEARANCE ENVELOPE limit of movement is established from MCA testing and therefore is unlikely to be reached in NORMAL USE;
– the potential for injury is limited by the amount of energy available when movement is restricted to 300 mm and the probability of persons being within the CLEARANCE ENVELOPE during the event;
– aisles and passageways are normally wider than 600 mm. The HAZARD of kinetic energy transfer from a moving LABORATORY CENTRIFUGE to a person is therefore limited to the absorption of energy when a person is squeezed into the remaining 300 mm wide space.

It is recognized that many LABORATORY CENTRIFUGES, particularly bench-top models, will not be mounted on a concrete surface in NORMAL USE. The concrete test surface has been specified in order that test results obtained from different test locations may be expected to be consistent.

BB.6.1 Sub-clause 7.7.1 a) Protection against expelled parts or projected parts

LABORATORY CENTRIFUGES shall be designed for safe operation in NORMAL USE and SINGLE FAULT CONDITION, when used with ROTOR ASSEMBLIES specified by the manufacturer. The protective casing shall restrain the user from unintended access to the potentially hazardous moving parts inside the centrifuge and protect the user from any escaping hazard. Because of the need for ventilation, even under NORMAL CONDITIONS, the protective casing is not hermetically sealed. The function of the casing is to reduce the potential mechanical hazard of escaping parts to a safe limit.

The definition of safe limit is not obvious. Based on comprehensive research of injury biomechanics, a normalized energy value (energy per projected area) was found to be the best predictor for ocular injury after a direct hit by a projectile. Using this predictor, a level for a 50% injury risk of corneal abrasion after a direct hit was determined. This level is also used to limit the hazards of projectile toys in EN 71-1:2011-07.

As a general, simple evaluation method, a specified maximal size of 5 mm for parts or fragments, and a maximal distance of 1 m from the centrifuge, make it very unlikely that this value of normalized energy would be exceeded.

BB.6.2 Sub-clause 7.7.1 Conformity statement – paragraph 2

The MCA test is a catastrophic test, as such, at the end of this test the unit is not considered able to be put back into service. The dielectric voltage withstand test establishes whether a functioning unit is still providing adequate isolation for the user from hazardous voltages (refer to 6.7.1 – The nature of insulation). As the unit cannot be used beyond the MCA test, establishing whether the accessible parts still comply with the permissible limits of clause 6.3.2 ensures that the user is still protected if they touch the unit. If the MCA test causes the overcurrent protection device to operate and this device can not be reset, this implies that hazardous voltages cannot be applied to the unit and it is therefore considered to have failed safe.

BB.7 Subclause 13.101

The use of BUCKETS and ROTORS with BIOSEALS is advocated by international [1][1)] and some national (such as [2] [3]) guidelines for work on microbiological material that require protection for workers and the environment. Accordingly, such equipment is in routine use in diagnostic microbiology laboratories, as well as other microbiological containment laboratories. The

1) Numbers in square brackets refer to Clause BB.8.

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dynamic test, originally devised by Harper [4], has been adapted for more recent designs of LABORATORY CENTRIFUGE and ROTOR and is suitable for evaluation of BIOSEALS or parts of LABORATORY CENTRIFUGES, including those that have CHAMBERS that are sealed and evacuated.

The provision of BUCKETS and ROTORS with BIOSEALS is optional, but manufacturers who wish to make performance claims should be prepared to demonstrate that the BIOSEALS prevent escape of droplets and aerosols under dynamic test conditions that simulate the intended use. The choice of spores of Bacillus subtilis var. niger as the test agent is based upon long experience in the field of testing microbiological safety cabinets and similar equipment, which has shown them to be effective, and have also established that they neither infect those carrying out the tests nor have any adverse consequence for the environment. The spores are robust and do not significantly lose viability upon desiccation when a suspension is aerosolized, and even if leaked into an evacuated CHAMBER, and colonies of Bacillus subtilis var. niger have a characteristic colour which enables them to be distinguished from any contaminating organism. Although there is no single size of micro-organism to be contained by the BIOSEALS, and thus the spores will not correspond precisely to such a size, in practice leakage is found to occur in significant volumes and the ability to detect a single spore, once it has been grown into a colony on a test plate, gives the sensitivity for this to be an appropriate assay.

The requirement to provide specific instructions for the use of BIOSEALS and related components is based on the mandatory need for additional equipment and laboratory procedures to safeguard OPERATORS. These instructions to the OPERATOR are necessary to make clear that BIOSEALS alone are not adequate to provide complete protection, particularly as the seal can be compromised by wear or damage, for example to an "O"-ring.

BB.8 Reference documents

[1] WORLD HEALTH ORGANIZATION. *Laboratory Biosafety Manual*, 2nd Edition. Geneva, 1993.

[2] CENTERS FOR DISEASE CONTROL AND PREVENTION AND NATIONAL INSTITUTES OF HEALTH. *Biosafety in Microbiological and Biomedical Laboratories*, 4th Edition. Washington, 1999.

[3] ADVISORY COMMITTEE ON DANGEROUS PATHOGENS. *Categorisation of biological agents according to hazard and categories of containment*, 4th Edition. London, 1995.

[4] HARPER, G.J. Evaluation of sealed containers for use in centrifuges by a dynamic microbiological test method. *J. Clin. Pathol*. 1984, 37, pp. 1134–1139.

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Annex CC
(informative)

General guidance for an empirical method to determine the kinetic energy of a ROTOR

Subclause 7.7.2.2 a) Determination of the kinetic energy

1) The rotor shall be loaded to the maximum and then it must be weighed.
   - fully loaded with samples as per maximum operated conditions
   - sample tubes / bottles will be loaded with test fluid.
2) Fasten the rotor with its axis of rotation to a rod. (Ensure that the rotor and the rod cannot be twisted against each other.)
3) Fasten a piece of fishing line with a tensile strength double the weight of the total assembly to ensure that there is no stretch to the rod and to the ceiling as per Figure 101. Ensure that the distances $s1$ and $s2$ are identical (approximately 50 mm each) and that the distance with regard to the ceiling is as long as possible (approximately 1 m to 1,5 m).
   - The vertical access shall be confirmed to be vertical.
4) Now, rotate the rotor through a small angle (approximate to but not greater than 30°) and release the rotor allowing it to rotate clockwise and anti-clockwise across a marked datum point. Ensure that the rotor does not wobble. Determine the time for one cycle with the aid of stopwatch. (One cycle corresponds to one rotation to and fro). We recommend measuring 10 cycles and then dividing the value by 10 in order to keep the error as small as possible.

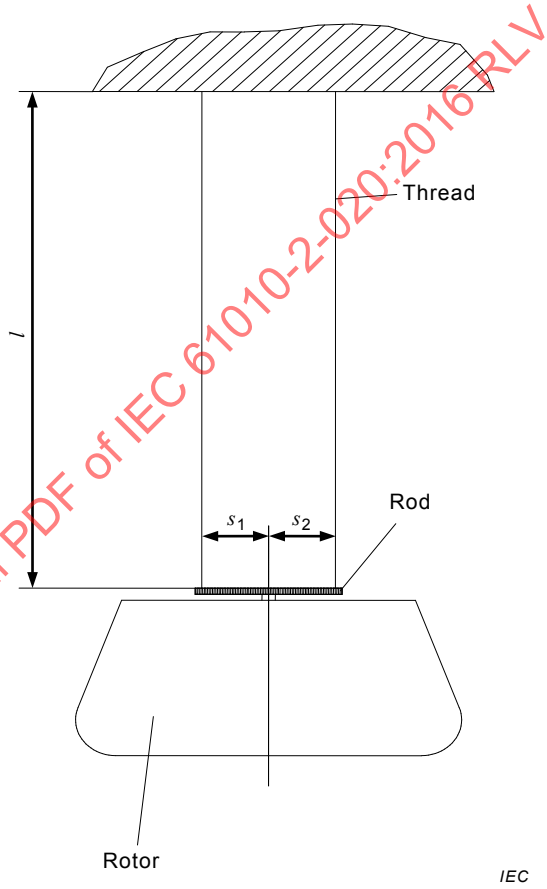

Figure 101 – Rotor test setup

5) The mass moment of inertia can be calculated with the aid of the following formula:

$$J_p = m \times g \times \frac{s1 \times s2 \times T^2}{l \times 4 \times \pi^2}$$

6) Then, the kinetic energy can be calculated as follows:

$$E_{kin} = \frac{1}{2} \times J_p \times \omega^2 \quad \omega = 2 \times \pi \times n$$

where

m is the mass in [kg]

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g is 9,81 m/s^2

$s1=s2$ is the thread distance with regard to the axis of rotation of the rotor in [m]

T is the cycle time in [s]

l is the thread length in [m]

J_P is the mass moment of inertia in [kgm^2]

ω is the angular velocity in [1 / s^2]

n is the speed in 1/s

E_{kin} is the kinetic energy in [Nm].

NOTE 1 Glycerine has a density of 1,26 and so the sample container is filled with glycerine until the rated load of the sample container is achieved.

NOTE 2 Examples of cords that could satisfy the requirements of the fishing line referenced above are those defined in the following standards:

- BS 4881:1993, *Polypropelene film cord, lines and twines*
- ISO 1873-1:1995, *Plastics – Polypropylene moulding and extrusion materials – Part 1: Designation systems and basic for specifications*
- ISO 1873-2:2007, *Plastics – Polypropylene moulding and extrusion materials – Part 2: Preparation of test specimens and determination of properties*
- EN ISO 1346:2004, *Fibre ropes – Polypropylene split film, monofilament and multifilament and polypropylene high tenacity multifilament – 3-, 4- and 8-strand ropes*
- EN 12423:1999, *Polypropylene twines*

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Bibliography

Addition:

Add the following publication:

IEC 60034 (all parts), *Rotating electrical machines*

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COMMISSION ÉLECTROTECHNIQUE INTERNATIONALE

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EXIGENCES DE SÉCURITÉ POUR APPAREILS ÉLECTRIQUES DE MESURAGE, DE RÉGULATION ET DE LABORATOIRE –

Partie 2-020: Exigences particulières pour CENTRIFUGEUSES DE LABORATOIRE

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La Norme internationale IEC 61010-2-020 a été établie par le comité d'études 66 de l'IEC: Sécurité des appareils de mesure, de commande et de laboratoire.

Cette troisième édition annule et remplace la deuxième édition parue en 2006. Cette édition constitue une révision technique et inclut les modifications majeures suivantes par rapport à la deuxième édition:

a) La présente Partie 2 est établie sur la base de la troisième édition (2010) de l'IEC 61010-1. Les modifications énumérées dans son Avant-propos affectent également la présente Partie 2.
b) Le langage a été mis à jour pour refléter la terminologie des CENTRIFUGEUSES DE LABORATOIRE utilisée actuellement dans l'industrie.

Elle a le statut d'une publication groupée de sécurité conformément au Guide IEC 104.

Le texte de cette norme est issu des documents suivants:

CDV	Rapport de vote
66/542/CDV	66/565A/RVC

Le rapport de vote indiqué dans le tableau ci-dessus donne toute information sur le vote ayant abouti à l'approbation de cette norme.

Cette publication a été rédigée selon les Directives ISO/IEC, Partie 2.

La présente Partie 2-020 doit être utilisée conjointement avec l'IEC 61010-1. Elle a été établie sur la base de la troisième édition (2010).

Cette Partie 2-020 complète ou modifie les articles correspondants de l'IEC 61010-1 de façon à la transformer en norme IEC: *Exigences de sécurité pour CENTRIFUGEUSES DE LABORATOIRE.*

Lorsqu'un paragraphe particulier de la Partie 1 n'est pas mentionné dans cette Partie 2, ce paragraphe s'applique pour autant que cela soit raisonnable. Lorsque cette partie spécifie "addition", "modification", ou "remplacement", il convient d'adapter en conséquence l'exigence correspondante, la spécification d'essai correspondante ou la note correspondante de la Partie 1.

Dans la présente Norme:

1) les caractères d'imprimerie suivants sont utilisés:
   - exigences: caractères romains;
   - NOTES: petits caractères romains,
   - *conformité et essais: caractères italiques;*
   - termes définis à l'Article 3 et utilisés dans toute la présente norme: PETITES MAJUSCULES EN CARACTERES ROMAINS.
2) les paragraphes, tableaux ou figures complémentaires à ceux de la Partie 1 sont numérotés à partir de 101; les annexes supplémentaires sont désignées AA, BB, etc.

Une liste de toutes les parties de la série IEC 61010, publiées sous le titre général: *Exigences de sécurité pour appareils électriques de mesurage, de régulation et de laboratoire*, peut être consultée sur le site web de l'IEC.

Le comité a décidé que le contenu de cette publication ne sera pas modifié avant la date de stabilité indiquée sur le site web de l'IEC sous "http://webstore.iec.ch" dans les données relatives à la publication recherchée. À cette date, la publication sera

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- supprimée,
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- amendée.

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EXIGENCES DE SÉCURITÉ POUR APPAREILS ÉLECTRIQUES DE MESURAGE, DE RÉGULATION ET DE LABORATOIRE –

Partie 2-020: Exigences particulières pour centrifugeuses de laboratoire

1 Domaine d'application et objet

L'article de la Partie 1 s'applique avec les exceptions suivantes:

1.1.1 Domaine d'application

Remplacement:

La présente Partie 2 s'applique aux CENTRIFUGEUSES DE LABORATOIRE alimentées en énergie électrique.

Cette publication groupée de sécurité est principalement destinée à être utilisée comme une norme de sécurité de produit pour les produits mentionnés dans le domaine d'application. Elle doit également être utilisée par les comités d'études pour l'élaboration de leurs publications relatives à des produits semblables à ceux mentionnés dans le domaine d'application de la présente norme, conformément aux principes établis dans le Guide IEC 104 et le Guide ISO/IEC 51.

NOTE Si une ou toutes les parties de l'appareil relèvent du domaine d'application d'une ou plusieurs autres Parties 2 de l'IEC 61010, ainsi que du domaine d'application de la présente Norme, il est également nécessaire que l'appareil satisfasse à l'ensemble des exigences de ces parties 2.

1.1.2 Appareils exclus du domaine d'application

Addition:

Ajouter le nouveau point suivant:

aa) IEC 60034 (Machines électriques tournantes).

1.2 Objet

1.2.1 Aspects inclus dans le domaine d'application

Addition:

Ajouter les nouveaux points suivants:

aa) contact avec des parties mobiles (voir 7.3);

bb) déplacement de la CENTRIFUGEUSE DE LABORATOIRE pendant une PERTURBATION (voir 7.3.101);

cc) réaction chimique à énergie élevée après une PERTURBATION DE ROTOR (voir 7.7.2.2 l);

dd) inefficacité du JOINT BIOLOGIQUE (voir 13.101).

1.2.2 Aspects exclus du domaine d'application

Addition:

Ajouter les nouveaux points suivants:

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aa) les précautions additionnelles qu'il peut être nécessaire d'observer lors de la centrifugation des matériaux qui sont inflammables ou explosifs (voir 5.4.101);

bb) les précautions additionnelles qu'il peut être nécessaire d'observer lors de la centrifugation des matériaux pouvant réagir chimiquement avec une force suffisante pour provoquer un DANGER (voir 5.4.101).

1.4 Conditions d'environnement

1.4.1 Conditions d'environnement normales

Remplacement:

Remplacer le point c) par le suivant:

c) température de 2 °C à 40 °C;

1.4.2 Conditions d'environnement étendues

Remplacer:

Remplacer le point c) par le suivant:

c) températures ambiantes inférieures à 2 °C ou supérieures à 40 °C;

2 Références normatives

L'article de la Partie 1 s'applique avec l'exception suivante:

Addition:

ISO 3864 (toutes les parties), *Symboles graphiques – Couleurs de sécurité et signaux de sécurité*

3 Termes et définitions

L'article de la Partie 1 s'applique avec les exceptions suivantes:

3.1 Appareils et états des appareils

Addition:

Ajouter les nouveaux termes et définitions suivants:

3.1.101
CENTRIFUGEUSE DE LABORATOIRE
appareil prévu pour l'utilisation en laboratoire qui applique un effet de centrifugation aux matériaux d'échantillons

3.1.102
COMBINAISON CENTRIFUGEUSE-ROTOR
CENTRIFUGEUSE DE LABORATOIRE et ENSEMBLE-ROTOR, destinés à fonctionner ensemble, et qui doivent être évalués ensemble

3.1.103
PERTURBATION
évènement au cours duquel l'ENSEMBLE-ROTOR, ou une partie de ce dernier, se casse ou se détache pendant la rotation

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3.2 Parties et accessoires

Addition:

Ajouter les nouveaux termes et définitions suivants:

3.2.101
CHAMBRE
espace fermé contenu dans une CENTRIFUGEUSE DE LABORATOIRE dans lequel l'ENSEMBLE-ROTOR tourne

3.2.102
ROTOR
composant primaire d'une CENTRIFUGEUSE DE LABORATOIRE qui retient le matériau à soumettre à la force centrifuge et qui est mis en rotation par le SYSTEME D'ENTRAINEMENT

3.2.103
GODET
accessoire du ROTOR conçu pour maintenir un ou plusieurs conteneurs

3.2.104
CARTER DE PROTECTION
carter qui entoure complètement l'ENSEMBLE-ROTOR et qui comprend le COUVERCLE et ses moyens de fixation

3.2.105
COUVERCLE
composant mobile qui permet d'accéder à la CHAMBRE

3.2.106
ENSEMBLE-ROTOR
ROTOR équipé d'un ensemble d'accessoires du ROTOR spécifiés par le constructeur

Note 1 à l'article: Dans le contexte d'un ENSEMBLE-ROTOR, les accessoires du rotor incluent tous les composants utilisés avec ou dans le ROTOR de CENTRIFUGEUSE afin de tenir des échantillons, y compris des adaptateurs, des tubes et des bouteilles.

3.2.107
SYSTEME D'ENTRAINEMENT
tous les composants de la CENTRIFUGEUSE associés à l'application d'un couple à ou au support de rotation de l'ENSEMBLE-ROTOR

3.2.108
JOINT BIOLOGIQUE
dispositif ou mécanisme complémentaire à un ROTOR ou à un GODET et un ensemble de fermeture, ou qui en fait partie intégrante, et qui est conçu pour empêcher la fuite du contenu, par exemple de matières microbiologiques, pendant la centrifugation

3.5 Termes de sécurité

Addition:

Ajouter les nouveaux termes et définitions suivants:

3.5.101
ESPACE LIBRE
espace entourant une CENTRIFUGEUSE DE LABORATOIRE, nécessaire à la sécurité

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3.5.102
PIRE ACCIDENT ENVISAGEABLE
PAE
configuration choisie pour représenter le pire cas pour un essai, dont le but est d'évaluer la sécurité mécanique inhérente à une COMBINAISON CENTRIFUGEUSE-ROTOR (voir 7.7 et l'Annexe BB)

4 Essais

L'article de la Partie 1 s'applique.

5 Marquage et documentation

L'article de la Partie 1 s'applique avec les exceptions suivantes.

5.1.2 Identification

Remplacement:

Remplacer le point b) par le suivant:

b) numéro de série ou tout autre moyen permettant d'identifier le lot de production de l'appareil.

Addition:

Ajouter le nouveau paragraphe suivant:

5.1.101 ROTORS et accessoires

Tous les ROTORS et ENSEMBLES-ROTORS, y compris les ACCESSOIRES des ROTORS, qui peuvent être remplacés par un OPERATEUR, doivent être marqués du nom ou de la marque déposée du constructeur ou du fournisseur, et comporter le code d'identification (tel qu'un code id, un numéro de série ou un numéro de lot).

Si les composants sont trop petits ou ne sont pas appropriés pour porter ce genre de marquage, les informations exigées doivent être marquées sur l'emballage d'origine, et également mentionnées dans la documentation.

NOTE L'emballage peut être la boîte contenant l'appareil, les éléments ou la documentation qu'elle contient, etc.

Si le constructeur spécifie qu'une partie, par exemple un GODET, doit être montée uniquement sur certains types de ROTORS ou dans des positions particulières du ROTOR pour des raisons d'équilibre ou autres, il convient d'identifier chaque position respective du GODET et du ROTOR par un marquage contenant les chiffres ou les lettres correspondants.

La conformité est vérifiée par examen.

5.4.2 Caractéristiques assignées des appareils

Addition:

Ajouter les nouveaux points suivants:

aa) une liste de tous les ROTORS et accessoires de ROTORS indiqués pour être utilisés avec une CENTRIFUGEUSE DE LABORATOIRE, ainsi que leurs vitesses de rotation ASSIGNEES;

bb) toutes les restrictions définies par le constructeur, concernant l'interdiction de centrifuger certaines matières;

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cc) les limites de densité et de volume, de même que les instructions pour la réduction de charge de l'ENSEMBLE-ROTOR, le cas échéant.

5.4.3 Installation des appareils

Addition:

Ajouter, après le point a), les points suivants:

i) la superficie du plancher ou de l'établi nécessaire pour l'ESPACE LIBRE pour l'utilisation prévue (voir 7.4.101);

ii) le poids total de la CENTRIFUGEUSE;

iii) les instructions pour la préparation du site;

iv) les méthodes pour mise à niveau de la CENTRIFUGEUSE;

v) les moyens de fixation sur la surface de montage.

5.4.4 Fonctionnement de l'appareil

Addition:

Ajouter les nouveaux points suivants:

aa) les procédures de chargement et d'équilibrage;

bb) les procédures de changement de ROTOR;

cc) toute exigence spécifique pour qu'un OPÉRATEUR soit présent aux phases indiquées de la procédure de centrifugation;

dd) les moyens de sécurité nécessaires pour le personnel. Les instructions doivent indiquer au moins les informations suivantes:

– ne pas se pencher sur une CENTRIFUGEUSE DE LABORATOIRE;

– ne pas rester à l'intérieur de l'ESPACE LIBRE plus longtemps que nécessaire pour des raisons de service;

– ne pas déposer de matières potentiellement dangereuses à l'intérieur de l'ESPACE LIBRE;

– les méthodes pour le fonctionnement en toute sécurité pendant les procédures d'ouverture de COUVERCLE (voir 7.3.102.2);

ee) les instructions pour l'utilisation des JOINTS BIOLOGIQUES et autres composants de sécurité biologique, y compris les bonnes techniques de fermeture. Ces instructions doivent indiquer que les JOINTS BIOLOGIQUES et leurs composants sont destinés à faire partie des systèmes de sécurité biologique, comme cela est spécifié dans les lignes directrices de biosécurité nationales et internationales. Elles ne doivent pas être considérées comme les seuls moyens de protéger les travailleurs et l'environnement durant la manipulation de micro-organismes pathogènes.

5.4.5 Entretien de l'appareil et service

Addition:

Ajouter le nouvel alinéa suivant:

Lorsqu'elles sont applicables, les instructions doivent spécifier:

aa) l'examen des moyens de fixation de l'appareil à la surface de montage ainsi que l'état de la surface de montage elle-même;

bb) les mesures de protection de l'OPÉRATEUR pendant le nettoyage;

cc) l'examen du CARTER DE PROTECTION;

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dd) l'examen de l'ENSEMBLE-ROTOR et les aspects concernant la sécurité;

ee) l'examen de la continuité de la LIAISON DE PROTECTION;

ff) la fréquence d'examen, l'entretien périodique et la méthode de remplacement des JOINTS BIOLOGIQUES et autres composants de la sécurité biologique.

Addition:

Ajouter les nouveaux paragraphes suivants:

5.4.101 Substances dangereuses

Les instructions d'utilisation doivent indiquer les précautions à observer lorsque les matières à utiliser dans une CENTRIFUGEUSE DE LABORATOIRE sont réputées être toxiques, radioactives, ou lorsqu'elles sont contaminées par des micro-organismes pathogènes.

NOTE Cette information concerne à la fois la sécurité des OPERATEURS et celle du personnel de service.

L'utilisation des matières suivantes dans la CENTRIFUGEUSE DE LABORATOIRE doit être interdite dans les instructions d'utilisation:

a) les matières inflammables ou explosives;

b) les matières qui peuvent réagir chimiquement avec une force suffisante pour causer un DANGER.

La conformité est vérifiée par examen.

5.4.102 Nettoyage et décontamination

La documentation doit indiquer:

a) que l'utilisateur a la responsabilité d'effectuer la décontamination appropriée si la matière dangereuse s'est répandue sur ou à l'intérieur de l'appareil;

b) les recommandations du constructeur pour le nettoyage, et si nécessaire, la décontamination, avec les noms génériques reconnus des matériaux recommandés pour le nettoyage et la décontamination.

c) la déclaration suivante:

"Il convient que les utilisateurs n'utilisent pas de méthodes de nettoyage ou de décontamination différentes de celles recommandées par le constructeur, sans au préalable vérifier auprès du constructeur que les méthodes proposées ne risquent pas d'endommager l'appareil"

d) la déclaration suivante:

Le nettoyage et la décontamination peuvent s'avérer nécessaires à titre préventif avant que les CENTRIFUGEUSES DE LABORATOIRE, les ROTORS et autres accessoires soient entretenus, réparés ou transférés. Les constructeurs peuvent fournir un format permettant aux utilisateurs de documenter la réalisation de ce traitement.

NOTE À noter que des lignes directrices nationales et le document "Laboratory Biosafety Manual" (Manuel de Sécurité Biologique pour Laboratoires) reconnu au niveau international, publié en 1993 par l'Organisation mondiale de la santé à Genève, donnent des informations sur les décontaminants, leur utilisation, leurs dilutions, leurs propriétés et les applications potentielles.

La conformité est vérifiée par examen.

5.4.103 Effets des produits chimiques et des influences environnementales

Pour utiliser en toute sécurité et régulièrement une CENTRIFUGEUSE DE LABORATOIRE, la documentation doit mentionner les dommages qui peuvent résulter, par exemple:

a) de l'effet des produits chimiques,

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b) des influences de l'environnement, y compris de l'action des rayons ultraviolets naturels susceptibles d'être rencontrés;

c) de la corrosion, et d'autres fragilisations des matériaux de construction entrant dans la composition du CARTER DE PROTECTION ou d'autres composants de protection.

La conformité est vérifiée par examen de la documentation et des données appropriées et/ou par des essais complémentaires (le cas échéant).

6 Protection contre les chocs électriques

L'article de la Partie 1 s'applique.

7 Protection contre les DANGERS mécaniques

L'article de la Partie 1 s'applique avec les exceptions suivantes.

7.1 Généralités

Addition:

Ajouter la nouvelle note suivante:

NOTE 101 Une PERTURBATION ayant pour résultat des dommages sur une partie du CARTER DE PROTECTION, par exemple un mécanisme de verrouillage du COUVERCLE, est considérée comme une CONDITION DE PREMIER DEFAUT.

7.3 Parties mobiles

Addition:

Ajouter les nouveaux paragraphes suivants.

7.3.101 COUVERCLE

7.3.101.1 Exigences

Le COUVERCLE doit être verrouillé en position fermée lorsque l'entraînement du ROTOR est alimenté et doit rester verrouillé jusqu'à ce que la vitesse circonférentielle de l'ENSEMBLE-ROTOR ne dépasse pas 2 m/s (voir Annexe BB).

Dans l'éventualité d'une panne d'alimentation, le mécanisme de verrouillage du COUVERCLE ne doit pas se débloquer et tout déverrouillage ultérieur doit nécessiter l'utilisation d'un OUTIL.

Le COUVERCLE doit être maintenu fermé avec une force suffisante pour résister aux résultats des essais selon 7.7.3. Les fragments produits par la PERTURBATION doivent être maintenus à l'intérieur comme spécifié au point a) de 7.7.

Pour évaluer lequel des points ci-dessous s'applique à la COMBINAISON CENTRIFUGEUSE-ROTOR à l'étude, le constructeur ou un autre organisme capable d'effectuer les essais doit enregistrer toute information montrant les essais effectués:

a) les contraintes mécaniques;

b) le mauvais verrouillage;

c) le défaut d'alignement;

d) la corrosion;

e) la dégradation des matériaux;

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f) les défauts des matériaux;

g) les vibrations;

h) le nettoyage et la décontamination;

i) les influences environnementales;

j) les autres considérations liées à la conception.

La conformité est vérifiée par un examen visuel, par l'examen de l'information enregistrée, par les essais effectués dans les conditions de 7.7.3, et par tout autre essai considéré comme étant approprié pour la sécurité.

7.3.101.2 Exception

Pour les CENTRIFUGEUSES de LABORATOIRE qui satisfont à toutes les limites suivantes, un dispositif qui interrompt simplement l'alimentation moteur peut être utilisé à la place d'un mécanisme de verrouillage (voir Annexe BB):

a) la CENTRIFUGEUSE DE LABORATOIRE incorpore un dispositif qui maintient le COUVERCLE fermé;

b) le dispositif qui interrompt l'alimentation moteur ne permet pas au mécanisme d'entraînement d'être alimenté tant que le COUVERCLE est fermé;

c) la vitesse de rotation de l'ENSEMBLE-ROTOR ne dépasse pas les 3 600 r/min;

d) l'énergie, à vitesse de rotation maximale, pour l'énergie la plus élevée de l'ENSEMBLE-ROTOR entièrement chargé, ne dépasse pas 1 kJ;

e) la force centrifuge maximale ne dépasse pas 2 000 *g*;

f) le diamètre maximal de l'ENSEMBLE-ROTOR ne dépasse pas 250 mm;

g) un interrupteur est mis en place, pour couper l'alimentation moteur, indépendamment de la position du COUVERCLE;

h) la vision de l'ENSEMBLE-ROTOR est possible, COUVERCLE fermé, pour permettre l'observation à chaque rotation;

i) tous les ENSEMBLES-ROTORS utilisés sont conformes au 7.3 de la Partie 1;

j) si l'accès est possible à une vitesse circonférentielle de l'ENSEMBLE-ROTOR supérieure à 2 m/s, une indication conforme à l'ISO 3864 figure sur ou à proximité du point d'accès, précisant qu'il convient de laisser le COUVERCLE fermé jusqu'à l'arrêt complet de la rotation. S'il n'y a pas assez de place pour faire figurer cet avertissement, le symbole 14 du Tableau 1 est considéré comme un marquage acceptable.

La conformité est vérifiée par un examen visuel et par l'examen des données pour confirmer que toutes les limites ci-dessus sont satisfaites.

7.3.102 ENSEMBLE-ROTOR

7.3.102.1 Généralités

Si un DANGER peut résulter du contact avec les parties mobiles de l'ENSEMBLE-ROTOR ou du SYSTEME D'ENTRAINEMENT en CONDITION NORMALE ou en CONDITION DE PREMIER DEFAUT, des moyens de protection appropriés doivent être fournis pour éviter l'accès à l'OPERATEUR, sauf comme permis par 7.3.101.2 et 7.3.102.2.

La partie supérieure de la CHAMBRE ne doit pas présenter de trous ou autres ouvertures permettant la pénétration d'une broche de 4 mm de diamètre.

La conformité est vérifiée par examen et en utilisant les doigts d'épreuve représentés aux Figures B.1 et B.2 et en vérifiant les ouvertures supérieures à l'aide d'une broche de 4 mm de diamètre, en CONDITION NORMALE ou en CONDITION DE PREMIER DEFAUT.

Le doigt d'épreuve articulé représenté à la Figure B.2 est appliqué dans toutes les positions

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possibles sans exercer de force. S'il peut être possible de toucher une partie en appliquant une force, le doigt d'épreuve rigide représenté à la Figure B.1 est utilisé avec une force de 10 N. Cette force est exercée contre toutes les surfaces extérieures, y compris la base, avec le bout du doigt d'épreuve en évitant toute action d'angle ou de levier. Le doigt d'épreuve ne doit pas toucher une partie mobile qui risque de provoquer un DANGER.

7.3.102.2 ENSEMBLES-ROTORS nécessitant un accès pendant la rotation

Si le constructeur fournit des ENSEMBLES-ROTORS nécessitant l'intervention de l'OPERATEUR (par exemple les ENSEMBLES ROTORS à compartiments ou à flux continu), alors les CENTRIFUGEUSES de LABORATOIRE peuvent comporter un dispositif de déblocage qui autorise la mise sous tension du moteur, avec COUVERCLE d'accès ouvert, sous les conditions suivantes:

a) la commande de déblocage permet la mise sous tension du moteur uniquement en utilisant un dispositif (qui peut être un code ou une carte code) qui établit la possibilité de débloquer le système et les fonctions de protection par des moyens qui ne peuvent pas être réalisés en utilisant d'autres outils, ou lorsqu'une plaque spéciale de protection ne permet qu'un accès limité à ce type d'ENSEMBLE-ROTOR;

b) des moyens sont mis en place pour annuler automatiquement la fonction de déblocage, dès que l'utilisation de l'ENSEMBLE-ROTOR nécessitant l'intervention d'un OPERATEUR est terminée;

c) la vitesse maximale lorsque le COUVERCLE est ouvert est limitée à 5 000 r/min.

La conformité est vérifiée par examen.

7.4 Stabilité

Addition:

Ajouter un nouveau troisième alinéa comme suit:

En UTILISATION NORMALE, aucun déplacement de la CENTRIFUGEUSE DE LABORATOIRE par rapport à sa position d'installation, ne doit être visible.

Addition:

Ajouter le nouveau paragraphe suivant:

7.4.101 Déplacement de la CENTRIFUGEUSE DE LABORATOIRE dans le cas d'un mauvais fonctionnement

Après installation selon les instructions du constructeur, un déplacement d'une CENTRIFUGEUSE DE LABORATOIRE résultant d'un déséquilibre de l'ENSEMBLE-ROTOR, d'une PERTURBATION de l'ENSEMBLE-ROTOR, ou d'une panne du SYSTEME D'ENTRAINEMENT (blocage ou grippage), ne doit présenter aucun DANGER.

Le déplacement doit être limité, soit par la conception, soit par la fixation à la surface de montage, ou encore par combinaison de ces deux procédés, de façon qu'aucune partie de la CENTRIFUGEUSE DE LABORATOIRE ne puisse se déplacer à l'extérieur d'un ESPACE LIBRE de 300 mm, ou moins si mentionné par le constructeur, dans toutes les directions par rapport aux parties extérieures de la CENTRIFUGEUSE DE LABORATOIRE dans sa position d'origine (voir les justifications en BB.6).

La conformité est vérifiée par l'essai pour confirmer que la limite de 300 mm, ou toute limite inférieure indiquée par le constructeur, n'est pas dépassée en UTILISATION NORMALE et dans la situation correspondant au pire des cas, selon 7.7.2.2, en cas de

a) déséquilibre;

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L'utilisation d'un capteur de déséquilibre est autorisée en tant que dispositif pour limiter le déplacement. Il convient cependant d'envisager le fait qu'il peut tomber en panne, dans l'hypothèse de la détermination de la condition du cas le plus défavorable, à moins que l'examen de l'appareil et de la conception démontre de façon concluante que le capteur ne tombera pas en panne.

b) PERTURBATION de l'ENSEMBLE-ROTOR;

c) panne du SYSTEME D'ENTRAINEMENT;

d) blocage ou grippage du SYSTEME D'ENTRAINEMENT.

NOTE Le cas de panne qui produit le déplacement le plus important peut être différent de celui du PAE déterminé pour soumettre à l'essai le CARTER DE PROTECTION selon 7.7.3. Voir l'Annexe CC pour des lignes directrices supplémentaires permettant de déterminer le cas de ROTOR le plus défavorable.

Pour ces essais, la CENTRIFUGEUSE DE LABORATOIRE est montée sur, ou fixée à une surface d'essai en béton lisse horizontale, de dimensions correspondant à la taille de la CENTRIFUGEUSE DE LABORATOIRE soumise à l'essai, et conforme aux spécifications indiquées dans les instructions du constructeur.

7.7 Parties éjectées

Remplacement:

Remplacer le titre et le texte par le nouveau titre et texte suivants:

7.7 Protection contre les éjections d'objets ou les projections d'objets

7.7.1 Généralités

Les CENTRIFUGEUSES DE LABORATOIRE doivent être conçues pour un fonctionnement en toute sécurité en UTILISATION NORMALE et en CONDITION DE PREMIER DEFAUT, lorsqu'elles sont utilisées avec des ENSEMBLES ROTORS spécifiés par le constructeur.

En cas de PERTURBATION:

a) aucune partie ou fragment de l'ENSEMBLE-ROTOR dépassant 5 mm dans une dimension quelconque ne doit pénétrer complètement le CARTER DE PROTECTION. Un matériau plus petit (excepté pour les aérosols et les liquides) doit demeurer dans une trajectoire dépassant 1 m dans toutes les directions par rapport aux parties extérieures de la CENTRIFUGEUSE DE LABORATOIRE; (Voir les justifications en Annexe BB.6)

b) aucune partie de la CENTRIFUGEUSE DE LABORATOIRE ne doit se détacher ou être éjectée de telle sorte qu'elle présente un DANGER pour le personnel ou l'environnement. Dans le cas de parties détachées ou éjectées de la centrifugeuse (ne faisant pas partie de l'ENSEMBLE-ROTOR), cette évaluation est à réaliser selon l'Article 17.

c) les armatures du COUVERCLE d'accès ne doivent pas se relâcher, et il ne doit y avoir aucune déformation pouvant créer un chemin de passage linéaire libre entre une partie de l'ENSEMBLE-ROTOR et un point extérieur à la CENTRIFUGEUSE DE LABORATOIRE.

La conformité de chaque COMBINAISON CENTRIFUGEUSE-ROTOR indiquée par le constructeur est vérifiée par essai comme indiqué dans 7.7.3, selon les conditions de PAE ou en provoquant une PERTURBATION par découpage partiel du ROTOR, ou en surchargeant l'ENSEMBLE-ROTOR, ou par tout autre moyen approprié. S'il existe plus d'un choix des pires cas d'ENSEMBLE-ROTOR, chacun peut être soumis à l'essai avec un nouveau CARTER DE PROTECTION.

Après les essais, les critères de a) à c) ci-dessus doivent être satisfaits, et les fissures visibles doivent être examinées pour déterminer si le CARTER DE PROTECTION aurait contenu les parties du rotor quelle que soit leur trajectoire. En cas de résultats douteux, l'essai doit être répété une seule fois, un autre résultat douteux est considéré comme une panne. L'appareil est vérifié pour s'assurer que les parties qui sont ACTIVES DANGEREUSES ne sont pas devenues ACCESSIBLES et que les parties conductrices ACCESSIBLES ne dépassent pas les

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valeurs de 6.3.2. Dans le cas où l'essai provoque le fonctionnement d'un dispositif de protection contre les surintensités, si le dispositif ne peut être réinitialisé sans fonctionner à nouveau, l'unité est considérée comme de sécurité intrinsèque. (Voir les justifications en Annexe BB6.2).

NOTE 1 Lors des essais des PAE, pour la détermination des résultats douteux, il convient d'accorder une attention particulière à la présence de lacunes temporaires de la capacité du CARTER DE PROTECTION à contenir les parties.

En variante, la sécurité d'une COMBINAISON CENTRIFUGEUSE-ROTOR peut être établie par une évaluation analytique basée sur la comparaison avec une ou plusieurs COMBINAISONS CENTRIFUGEUSE-ROTOR ayant déjà été soumises à l'essai, pour confirmer que le CARTER DE PROTECTION aurait satisfait à l'essai approprié de 7.7.3.

NOTE 2 Les COMBINAISONS de CENTRIFUGEUSE-ROTOR dont la conception est telle que l'évaluation satisfaisante par comparaison avec d'autres COMBINAISONS DE CENTRIFUGEUSE-ROTOR déjà soumises à l'essai ne peut pas être faite, sont examinées comme spécifié en 7.7.3.

7.7.2 Considérations concernant les essais des PAE

7.7.2.1 Informations à consigner

Les informations consignées doivent comprendre:

a) les effets corrosifs prévisibles;

b) le comportement des matériaux à la fatigue;

c) les considérations concernant la dégradation du matériau, y compris les conséquences des opérations d'examen, d'entretien, des remplacements périodiques de certains composants;

d) les considérations concernant les limites de température;

e) les considérations concernant les défauts du matériau;

f) les considérations concernant le montage inapproprié des GODETS;

g) les considérations appropriées concernant l'environnement;

h) les considérations appropriées concernant la charge maximale;

i) le schéma du circuit électrique et les descriptions fonctionnelles;

j) les spécifications du matériau et les données techniques;

k) les méthodes de prétraitement pour provoquer des pannes de l'ENSEMBLE-ROTOR;

l) les enregistrements de tous les instruments de mesure utilisés pendant les essais;

m) toute autre information appropriée.

La conformité est vérifiée par examen de la documentation relative aux points ci-dessus.

7.7.2.2 Considérations concernant les conditions du cas le plus défavorable

Toutes les combinaisons possibles parmi les cas suivants doivent être envisagées:

a) le choix du ROTOR: le cas le plus défavorable du ou des ENSEMBLES-ROTORS spécifiés; (se reporter à l'Annexe CC pour le calcul de l'énergie cinétique des rotors)

b) le réglage de la commande de vitesse de rotation: la vitesse de rotation maximale qu'un OPERATEUR peut sélectionner;

c) la tension d'alimentation: 10 % supérieure à la tension maximale ASSIGNEE marquée sur l'appareil;

d) la charge de l'ENSEMBLE-ROTOR: la charge maximale spécifiée, une charge partielle et à vide, y compris l'état et la densité de la charge (par exemple, liquide, solide);

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e) les accessoires de ROTOR, le pire cas de chargement des accessoires spécifiés utilisés avec ou dans le ROTOR afin de tenir des échantillons, y compris des adaptateurs, des tubes, et des bouteilles;

f) le déséquilibre de l'ENSEMBLE-ROTOR: la condition la plus sévère;

g) les facteurs d'altitude: les conséquences résultant de la réduction de la pression atmosphérique et de la densité lorsque l'altitude augmente sur les SYSTEMES D'ENTRAINEMENT DU ROTOR qui dépendent de la ventilation de l'air pour limiter la vitesse de rotation maximale (voir 1.4.1 b) et 1.4.2 b)).

NOTE 1 La limitation de la vitesse de rotation par la ventilation de l'air peut être déterminée en effectuant un essai de vitesse de rotation dans une enceinte ou dans une salle dans laquelle la pression est maintenue sous contrôle à 80 kPa ou moins, ou en calculant la vitesse de rotation n_2, qui peut être atteinte à 2 000 m d'altitude, à l'aide de la formule:

$$n_2 = n_1 \times \sqrt[3]{R}$$

où

n_1 est la vitesse de rotation maximale à pression atmosphérique normale au niveau de la mer (101 kPa);

n_2 est la vitesse de rotation maximale correspondant à une pression atmosphérique équivalente à 2 000 m;

R = 1,27 (rapport de la densité de l'air au niveau de la mer, sur celle à 2 000 m).

h) le frottement entre la CENTRIFUGEUSE DE LABORATOIRE ou les pieds de la CENTRIFUGEUSE et la surface sur laquelle la CENTRIFUGEUSE DE LABORATOIRE est placée;

i) la température ambiante: les conséquences sur les composants d'un fonctionnement à toutes les températures de la plage autorisée, de 2 °C à 40 °C;

j) une combinaison d'ENSEMBLE-ROTOR et de SYSTEME D'ENTRAINEMENT causant une instabilité au niveau du comportement dynamique;

k) l'installation selon les spécifications du constructeur;

l) la possibilité de réaction chimique d'énergie élevée après PERTURBATION.

NOTE 2 Dans certaines CENTRIFUGEUSES DE LABORATOIRE qui développent des énergies de l'ordre de 275 kJ et plus, et possédant des systèmes de réfrigération et d'évacuation de chaleur, il est possible qu'une PERTURBATION cause une explosion chimique lorsque des parties de l'ENSEMBLE-ROTOR sont constituées de matériaux réactifs, tels que l'aluminium ou le titane. Une explosion peut survenir du fait d'une interaction, aux énergies élevées, de fragments de l'ENSEMBLE-ROTOR avec des fluides frigorigènes et de l'eau.

Dans de tels cas, les conditions du cas le plus défavorable peuvent être réalisées par la combinaison des moyens suivants:

i) la mise hors service des systèmes de commande et de limitation de vitesse de rotation afin d'atteindre la vitesse de rotation maximale;

ii) le choix du ROTOR en matériau réactif, ayant la plus haute énergie de rotation possible, et en le prétraitant de manière à provoquer une PERTURBATION. Le prétraitement doit optimiser la zone de surface des fragments résultants;

iii) le réglage du système de réfrigération pour obtenir la plus grande quantité de fluide frigorigène dans l'évaporateur qui refroidit la CHAMBRE;

iv) le chargement de l'ENSEMBLE-ROTOR avec de l'eau, à 80 % de sa capacité nominale;

v) le fonctionnement de la CENTRIFUGEUSE DE LABORATOIRE dans les conditions les plus défavorables pour tous les autres facteurs non définis, jusqu'à obtenir une PERTURBATION.

NOTE 3 Il convient d'informer le personnel effectuant les essais que des libérations importantes d'énergie peuvent résulter des essais au cours desquels une réaction chimique à haute énergie est possible après la PERTURBATION. Un abri à distance est recommandé.

La conformité est vérifiée par examen de la documentation relative aux points ci-dessus.

7.7.2.3 CONDITIONS DE PREMIER DEFAUT à prendre en compte

Les CONDITIONS DE PREMIER DEFAUT suivantes doivent être prises en compte:

a) condition de régulation de la vitesse de rotation: la CONDITION DE PREMIER DEFAUT qui provoque la vitesse de rotation maximale;

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