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## **EAST AFRICAN STANDARD**

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**Automatic milking installations — Requirements and testing**

**EAST AFRICAN COMMUNITY**

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## Foreword

Development of the East African Standards has been necessitated by the need for harmonizing requirements governing quality of products and services in East Africa. It is envisaged that through harmonized standardization, trade barriers which are encountered when goods and services are exchanged within the Community will be removed.

In order to meet the above objectives, the EAC Partner States have enacted an East African Standardization, Quality Assurance, Metrology and Test Act, 2006 (EAC SQMT Act, 2006) to make provisions for ensuring standardization, quality assurance, metrology and testing of products produced or originating in a third country and traded in the Community in order to facilitate industrial development and trade as well as helping to protect the health and safety of society and the environment in the Community.

East African Standards are formulated in accordance with the procedures established by the East African Standards Committee. The East African Standards Committee is established under the provisions of Article 4 of the EAC SQMT Act, 2006. The Committee is composed of representatives of the National Standards Bodies in Partner States, together with the representatives from the private sectors and consumer organizations. Draft East African Standards are circulated to stakeholders through the National Standards Bodies in the Partner States. The comments received are discussed and incorporated before finalization of standards, in accordance with the procedures of the Community.

Article 15(1) of the EAC SQMT Act, 2006 provides that "Within six months of the declaration of an East African Standard, the Partner States shall adopt, without deviation from the approved text of the standard, the East African Standard as a national standard and withdraw any existing national standard with similar scope and purpose".

East African Standards are subject to review, to keep pace with technological advances. Users of the East African Standards are therefore expected to ensure that they always have the latest versions of the standards they are implementing.

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## Introduction

In the preparation of this East African Standard, the following sources were consulted extensively:

ISO 20966:2007, *Automatic milking installations — Requirements and testing*

Codex Alimentarius website: [http://www.codexalimentarius.net/mrls/pestdes/jsp/pest\\_q-e.jsp](http://www.codexalimentarius.net/mrls/pestdes/jsp/pest_q-e.jsp)

USDA Foreign Agricultural Service website: <http://www.mrlatabase.com>

USDA Agricultural Marketing Service website: <http://www.ams.usda.gov/AMSV1.0/Standards>

USDA Plant Inspectorate Service website: [http://www.aphis.usda.gov/import\\_export/plants](http://www.aphis.usda.gov/import_export/plants)

European Union: [http://ec.europa.eu/sanco\\_pesticides/public](http://ec.europa.eu/sanco_pesticides/public)

Assistance derived from these sources is hereby acknowledged.

Draft for comments only — Not to be cited as East African Standard

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**Automatic milking installations —  
Requirements and testing**

*Installations de traite automatique — Exigences et essais*

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## Foreword

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

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

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

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

ISO 20966 was prepared by Technical Committee ISO/TC 23, *Tractors and machinery for agriculture and forestry*.

# Automatic milking installations — Requirements and testing

**WARNING** — Some of the tests specified in this International Standard involve procedures which could lead to a hazardous situation. The attention of any person performing tests in accordance with this International Standard is drawn to the need to be appropriately trained in the type of work to be carried out. It is left to the responsibility of the user to check all national regulatory conditions and health and safety requirements applicable for the relevant country.

## 1 Scope

This International Standard specifies requirements for the construction of automatic milking installations (AMI), including specific safety and hygiene aspects and minimum performance requirements and testing, in addition to those described in ISO 5707 and ISO 6690.

It does not contain requirements for the design of the building in which the milking installation is installed.

## 2 Normative references

The following referenced documents are indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 3600, *Tractors, machinery for agriculture and forestry, powered lawn and garden equipment — Operator's manuals — Content and presentation*

ISO 3918, *Milking machine installations — Vocabulary*

ISO 4413, *Hydraulic fluid power — General rules relating to systems*

ISO 4414, *Pneumatic fluid power — General rules relating to systems*

ISO 5707, *Milking machine installations — Construction and performance*

ISO/TR 11688-1, *Acoustics — Recommended practice for the design of low-noise machinery and equipment — Part 1: Planning*

ISO/TR 11688-2, *Acoustics — Recommended practice for the design of low-noise machinery and equipment — Part 2: Introduction to the physics of low-noise design*

ISO 12100-1:2003, *Safety of machinery — Basic concepts, general principles for design — Part 1: Basic terminology, methodology*

ISO 12100-2:2003, *Safety of machinery — Basic concepts, general principles for design — Part 2: Technical principles*

ISO 13852:1996, *Safety of machinery — Safety distances to prevent danger zones being reached by the upper limbs*

ISO 14159, *Safety of machinery — Hygiene requirements for the design of machinery*



IEC 60204-1:2005, *Safety of machinery — Electrical equipment of machines — Part 1: General requirements*

IEC 60227-1, *Polyvinyl chloride insulated cables of rated voltages up to and including 450/750 V — Part 1: General requirements*

IEC 60245-1, *Rubber insulated cables — Rated voltages up to and including 450/750 V — Part 1: General requirements*

IEC 60529:2001, *Degrees of protection provided by enclosures (IP code)*

IEC 60825-1:2001, *Safety of laser products — Part 1: Equipment classification, requirements and user's guide*

IEC 60947-4-1, *Low-voltage switchgear and control gear — Part 4-1: Contactors and motor starters — Electromechanical contactors and motor starters*

IEC 60947-5-1, *Low-voltage switchgear and control gear — Part 5-1: Control circuit devices and switching elements — Electromechanical control circuit devices*

IEC 61800-1, *Adjustable speed electrical power drive systems — Part 1: General requirements — Rating specifications for low-voltage adjustable speed d. c. power drive systems*

EN 1088, *Safety of machinery — Interlocking devices associated with guards — Principles for design and selection*

EN 13732, *Food processing machinery — Bulk milk coolers on farms — Requirements for construction, performance, suitability for use, safety and hygiene*

### 3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 3918 and the following apply.

#### 3.1

##### **control system**

assembly of hardware and software components to start, operate and stop the AMI

### 4 Safety and hygiene requirements

The safety requirements given in Annex A apply.

The hygiene requirements given in ISO 14159 apply.

### 5 Functional requirements

#### 5.1 General

The milking machine shall fulfil the requirements specified in ISO 5707.

It shall be possible to operate the AMI both for milking and testing purposes.

## 5.2 Preparation before milking

### 5.2.1 Cleaning of teats

There shall be provision to clean the teats and the parts of the udder in contact with the liners without injuring the animal.

The result of the cleaning operation is checked by inspection of the teat and udder areas after operation.

NOTE Annex B presents an example of a method of evaluating the inspection of cleaning of teats and udders, although the ultimate result of cleaning is the milk quality in the bulk milk tank.

### 5.2.2 Foremilking

There shall be provisions for separation of the foremilk from the milk intended for human consumption.

Information shall be provided about the procedures regarding separation of foremilk, and how to inspect the performance.

The performance of the foremilk separation shall be verified during operation.

## 5.3 Milking

### 5.3.1 Accidental teatcup detachment

The system shall have provisions to detect accidental teatcup detachment so that the AMU can initiate corrective action to attempt to achieve a successful milking.

### 5.3.2 Milk yield measurement

The milk yield for each milking shall be measured. The accuracy of milk yield measuring systems shall be stated in the user's manual.

### 5.3.3 Detection of abnormal milk

Where an automatic milking unit has provisions to detect abnormal milk from an individual animal and prevent its milk from being mixed with milk intended for human consumption, the abnormal milk detection method together with recommended limit values shall be described in the user's manual.

NOTE Annex C presents an example of a method of evaluating detection systems for milk deemed as abnormal due to blood or changes in homogeneity with possible limits of blood levels.

### 5.3.4 Teatcup removal

There shall be provisions to limit the total machine-on time. Methods, procedures and limits shall be stated in the user's manual.

## 5.4 Post-milking teat applications

It is recommended that there be means to apply disinfectant and/or skin conditioner to the teats after milking.

## 5.5 Milk transport

### 5.5.1 Diversion of milk

The AMI shall have provisions to divert milk identified as abnormal, undesirable or withheld milk before it reaches the storage tank.

NOTE The decision to divert undesirable and withheld milk is always taken before milking. The decision to divert abnormal milk can be taken at any time during foremilk, milking or after milking of the animal. Diverted milk can be transported to a holding tank or a safe means of disposal.

### 5.5.2 Delivery lines

Milk shall be prevented from entering the bulk milk tank during cleaning of the bulk milk tank.

Milk shall be prevented from entering the bulk milk tank during milk collection if required by local, regional or national regulations.

## 5.6 Milk cooling and storage

### 5.6.1 General

A bulk milk tank shall have provision to inform the automatic milking machine (AMM) if milk can be received or not.

Cleaning solution shall be prevented from entering the bulk milk tank whilst milk is present in the tank.

### 5.6.2 Refrigerated bulk milk tank

A refrigerated bulk milk tank shall comply, where appropriate, with EN 13732.

NOTE 1 EN 13732 was developed for batch milking excluding continuous milking such as with an AMM.

The cooling system shall have sufficient capacity to cool milk received in an empty bulk milk tank from high-producing animals milked simultaneously in the available milking units.

The cooling system shall be designed so that the milk does not freeze, even at low milk flow from a single animal into an empty tank.

NOTE 2 Milk temperatures and cooling times are usually stated by local, regional or national requirements.

### 5.6.3 Tank for temporary storage

If milk is intended to be stored in a temporary tank (buffer tank) longer than 1 h, such as during milk collection and cleaning of the bulk milk tank, the cooling time specified by local, regional or national requirements applies (see 5.6.2, Note 2).

## 6 Cleaning

There shall be provisions to initiate automatic cleaning, rinsing or sanitizing of milk contact surfaces for:

- a) teatcups, between milking of each animal, including surfaces that can come in contact with the animal teat;
- b) all surfaces that have come into contact with milk detected as abnormal, undesirable or withheld milk, before milking an animal for milk intended for human consumption;

- c) surfaces that have been in contact with unrefrigerated milk after a specified time without milking;
- d) system cleaning after a specified interval.

NOTE Cleaning intervals are specified by international, national or local regulations.

## 7 Instructions for use

In addition to the instructions for milking machines, at least the following shall be emphasized in the user's manual:

- a) procedures to be followed in the event of alarms raised;
- b) use of system check functions;
- c) entering animal details, events and action points into the AMI management and monitoring system;
- d) use of the AMI management system, and any sensors, to produce alarms and action lists required by the user as a basis for management of the animals.

## 8 Management

### 8.1 Alarms and notifications

When the safety of a human or animal is at risk, an alarm shall be transmitted immediately to the human supervisor. When the system detects an error but the safety of humans and animals is not at risk, a notification shall be directed to the human supervisor at an appropriate time.

### 8.2 Retrieval of information

The user shall have provision to access at least the following time-stamped information for a specified number of days:

- a) data for each milking, including animal identity, duration, yield, whether milking was successful or not on all teats, unintended detachment, re-attachment of teatcups during milking, reason for diversion of milk;
- b) data for each non-milking visit to the milking machine, including animal identity;
- c) data for each system cleaning, including duration and action done, such as rinsing or sanitation;
- d) data and reason for each alarm;
- e) identification of each bottle or vial used during automatic milk sampling.

NOTE 1 If any of the above information is intended for export to other parties, a suitable format for data transfer can be that specified in ISO 11787<sup>[2]</sup>, ISO 11788-1<sup>[3]</sup> and ISO 11788-2<sup>[4]</sup>.

NOTE 2 Other information of interest can be:

- milk quality parameters such as conductivity, somatic cell count, fat content, protein content, urea content;
- system cleaning parameters such as detergent type and dosage, temperature of the cleaning fluid;
- milk cooling parameters such as a log of milk tank temperatures.

## 9 Monitoring

### 9.1 Animals

The system shall maintain a current record of the following:

- a) time since last milking for each animal;

NOTE For practical reasons the time can be measured from when the animal leaves the milking place.

- b) animals due for milking;
- c) animals that are overdue for milking (a preset time has elapsed since permission to be milked was granted);
- d) animals with unsuccessful milking;
- e) animal identity where the system has detected abnormal milk;
- f) animal identity and time of each milking where the milk has been diverted.

### 9.2 Disinfection

Means shall be provided to monitor the cleaning solution temperature and to ensure that intended cleaning and disinfecting has been carried out.

### 9.3 Stored milk

Means shall be provided to monitor the temperature of the milk in the bulk milk tank and to ensure that intended cleaning and disinfecting of milk storage vessels has been carried out.

## Annex A (normative)

### Safety requirements with respect to humans and animals

#### A.1 Scope

This annex defines safety requirements for AMI falling within the scope of this International Standard. It also stipulates requirements on the electrical equipment of the installations.

#### A.2 Safety requirements and measurements

##### A.2.1 General

**A.2.1.1** All known, relevant and significant hazards related to the intended use of AMI have been addressed. When, through machine evolution or technological development, new and previously unknown hazards are discovered, the general principles of risk reduction as outlined in Clause 5 of ISO 12100-1:2003 shall be applied to the hazard(s).

**A.2.1.2** Unless otherwise specified in this International Standard, the safety distances shall comply with the requirements given in Tables 1, 3, 4 and 6 of ISO 13852:1996.

##### A.2.2 Controls

###### A.2.2.1 Safety and reliability of control systems

The control systems shall be designed and constructed to comply with the following standards.

- a) Electrical components shall comply with:
  - 1) IEC 60947-5-1 (section 3) for control switches with positive opening operation used as mechanically actuated position detectors for interlocking guards and for relays used in auxiliary circuits;
  - 2) IEC 60947-4-1 for electromechanical actuators and motor starters used in main circuits;
  - 3) IEC 60245-1 for rubber insulated cables;
  - 4) IEC 60227-1 for polyvinyl chloride cables, if this cable is additionally protected against mechanical damage by positioning (e.g. inside frames).
- b) Mechanical components shall comply with 3.5 of ISO 12100-2:2003.
- c) Mechanically actuated position detectors for guards actuated in the positive mode shall comply with EN 1088.
- d) Pneumatic and hydraulic components and systems shall comply with ISO 4414 and ISO 4413 respectively.
- e) Electrical principles used shall comply with IEC 60204-1.
- f) Adjustable speed electrical power drive systems shall comply with IEC 61800-1.

### A.2.2.2 Starting and operating

**A.2.2.2.1** If hazards arising through movements of the machine and also from moving parts of the machine cannot be avoided during intended use, unauthorized or untrained persons shall be kept out of the hazardous area. A warning sign shall be shown on the AMI and shall be explained in the user's manual.

**A.2.2.2.2** If hazards from moving machine parts cannot be avoided while operating the machine manually, e.g. attaching the teatcups first time (apprenticeship), one of the following means shall be provided:

- a) an enabling control device fulfilling 3.23.2 of ISO 12100-1:2003 or
- b) devices for limiting of velocity and power of the moving parts so that all motion initiated from the pendant shall not exceed 250 mm/s as measured at the mechanical interface.

NOTE What constitutes an acceptable speed will also depend on the forces exerted and the layout of the installation.

### A.2.2.3 Normal stopping

The AMI shall comply with 9.2.2 of IEC 60204-1:2005.

### A.2.2.4 Emergency stop

The AMI shall comply with 9.2.5.4 of IEC 60204-1:2005.

The emergency stop controls shall be located out of reach of the animals.

### A.2.3 Protection against non-mechanical hazards — Noise reduction at the design stage

When designing machinery, the information and technical measures to control noise at source given in ISO/TR 11688-1 and ISO/TR 11688-2 shall be taken into account.

### A.2.4 Electricity

The AMI shall comply with IEC 60204-1 unless otherwise stated in this annex.

The AMI shall comply in particular, with Clause 6 of IEC 60204-1:2005 for the prevention of electric shock and Clause 7 of IEC 60204-1:2005 for protection against short circuits and for protection against overloading.

The degree of protection for electrical components of the low voltage area, installed where animals are expected to be present, shall be at least IP 55 in accordance with IEC 60529:2001.

### A.2.5 Pneumatic

The AMI shall comply with ISO 4414.

### A.2.6 Hydraulic

The AMI shall comply with ISO 4413.

### A.2.7 Heat

The temperature of hot water applied to the animal shall not exceed 45 °C to avoid injuries.

### A.2.8 Laser

The laser shall be class 2M in accordance with IEC 60825-1:2001.

### A.3 Provisions in case of faults

Provision shall be made to give a notification to the operating personnel in case of faults such as:

- repeated unsuccessful attempts to attach the teatcup;
- loss of power;
- control fault.

It shall be possible to manually open the exits for the animals and remove all equipment under the animal so that the animal can exit.

### A.4 Accesses and exits for the animals

The closing force of power-driven doors and gates shall be limited so that injuries caused by pinching of parts of the animal's or human's body shall be minimized.

### A.5 Information for use

#### A.5.1 User's manual

The user's manual shall include safety instructions for normal operation and servicing of the machine, including the use of personal protective equipment as appropriate, and shall correspond to ISO 3600. In particular, it shall point out that unauthorized or untrained persons shall be kept out of the hazardous area (see A.2.2.2.1).

#### A.5.2 Warning signs

A warning sign shall be shown on the AMI where hazards arising from movements of the machine can occur (see A.2.2.2.1).



## Annex B (informative)

### Example of a method of evaluating cleaning of teats and udders

**B.1** The cleanliness of teats and parts of the udder that come in contact with the liner can be scored by trained personnel, according to reference [5], as:

- 1) completely clean (< 1 % of the teat surface visibly contaminated);
- 2) slightly soiled (1 % to 10 % of the teat surface visibly contaminated);
- 3) partially soiled (11 % to 25 % of the teat surface visibly contaminated);
- 4) heavily soiled (> 25 % of the teat surface visibly contaminated).

**B.2** The test should be performed on three herds, as described in B.3 to B.6, during normal operation of the automatic milking machine.

**B.3** In each herd, one randomly selected front teat and one rear teat are scored from each of a number of animals until at least 50 teats have scored either 2 or 3 before the automatic teat cleaning.

**B.4** Animals with one or more teats with score 4 before cleaning are excluded from the test. A maximum of 50 % of the teats given score 1 before the automatic cleaning can be included.

**B.5** At least 75 % of the teats shall have a score of 1 after the automatic cleaning, and out of the animals with at least one teat given a score of 2 or 3 before cleaning, at least 50 % of the teats should have a score of 1 after cleaning.

**B.6** Where visual scoring of teats is not possible immediately after the automatic cleaning, milk composite samples shall be collected during milking of the animals fulfilling B.3 and B.4. The sampler normally used for milk yield recording can be used for this purpose. Sampling into clean vials shall be started immediately after machine cleaning. Milk samples shall be stored cold until bacteriological analysis. Milk samples shall be analysed for coliform count according to IDF Standard 73 B [6]. At least 75 % of the milk samples shall test negative for coliforms < 10 cfu/ml. Less than 5 % of the samples may have more than 100 cfu/ml.

## Annex C (informative)

### Example of methods of evaluating detection systems for milk deemed as abnormal due to the presence of blood or to changes in homogeneity

#### C.1 General

The most common abnormalities in milk are blood content and changes in homogeneity. This annex attempts to describe the complex matter of detecting these milk defects. It describes one method of evaluating detection systems for blood in milk and one for changes in homogeneity. Guidance on interpretation of test results is also included, although no internationally accepted limits exist.

This is the first attempt to deal with this question. The matter is to be further evaluated based on experience, research and developments.

#### C.2 Test of detection system for blood in milk

##### C.2.1 General

Milk from 10 animals is used as a basis for development of four samples of 1 kg from each animal, homogeneously mixed with 0  $\mu\text{mol}$ , 3  $\mu\text{mol}$ , 6  $\mu\text{mol}$  and 120  $\mu\text{mol}$  haemoglobin, equivalent to (0, 50, 100 and 2 000) mg haemoglobin. The AMM is set to milk an artificial udder fed with one sample per quarter from one cow at a time for a quarter detection system. For detection systems measuring composite milk, one sample mixed with blood is milked together with three samples without blood. Sensitivity of the detection system is calculated from the samples with 120  $\mu\text{mol}$  haemoglobin/l as the number of positively detected samples divided by 10 samples and multiplied by 100 %. The remaining samples with 0  $\mu\text{mol}$ , 3  $\mu\text{mol}$  and 6  $\mu\text{mol}$  haemoglobin are used to calculate the specificity as the number of negatively detected samples divided by 30 samples and multiplied by 100 %.

NOTE 1 Alternatively, blood can be injected at a steady rate into one of the short milk tubes during milking of 30 animals (40 for a detection system measuring composite milk) to reach the four planned concentrations of haemoglobin.

NOTE 2 According to Rasmussen and Bjerring<sup>[7]</sup> the 120  $\mu\text{mol/l}$  threshold is scored as visually red with a sensitivity of > 80 % by a representative group of people when scoring the coloured milk on a black surface. This level is equivalent to a mixture of 980 ml milk and 20 ml of bovine blood, containing 6 mmol haemoglobin per litre of blood. The 3  $\mu\text{mol/l}$  and 6  $\mu\text{mol/l}$  thresholds are scored as visually white with a sensitivity of > 80 % by a representative group of people when compared with milk without haemoglobin. These levels are equivalent to having 0,05 % and 0,1 % blood with 6 mmol/l haemoglobin in the milk. See also Table C.1.

NOTE 3 The molecular weight of the single-unit haemoglobin molecule used in this annex is 16 000.

**Table C.1 — Specificity and sensitivity for the detection of blood in milk**

Purpose of the sample	Number <i>n</i>	Haemoglobin in milk		Blood in milk %	Limit Milkings and %	Human eye
		$\mu\text{mol}$	mg/kg			
Specificity	10	0	0	0	Max 2/200 normal milk is diverted > 99 %	> 80 %: "white"
	10	3	50	0,05		
	10	6	100	0,1		
Sensitivity	10	120	2000	2	> 16/20 > 69 %	> 80 %: "blood"

## C.2.2 Test of detection system for changes in homogeneity

### C.2.2.1 General

The expected cell counts of the CMT-scores (California Mastitis Test, Schalm *et al.*<sup>[8]</sup>) are in cells/ml:

- 1) < 150 000;
- 2) 150 000 to 300 000;
- 3) 300 000 to 800 000;
- 4) 800 000 to 3 000 000;
- 5) > 3 000 000.

### C.2.2.2 Detection at the quarter level

Foremilk samples (about 10 ml of milk) of all milking quarters of at least 50 animals are taken immediately before cleaning of teats. Sampling shall be performed in at least three herds for at least 36 h in each herd. The foremilk sampled is poured through a filter with a pore size of 0,1 mm × 0,1 mm.

Samples from quarters with visible clots larger than 2 mm on the filter and CMT score > 3 are abnormal. At least 20 samples shall test abnormal. Milk from quarters where foremilk samples from two consecutive milkings do not show any clots on the filter and have a CMT score < 4 are denoted normal samples. At least 800 samples shall test normal. All other samples are discarded from the analysis.

The sensitivity of the detection system on quarter level,  $SE_q$ , in percent, is calculated using Equation C.1:

$$SE_q = \frac{a}{b} \times 100 \quad (C.1)$$

where

- $a$  is the number of quarters correctly indicated as abnormal by the detection system;
- $b$  is the number of quarters with abnormal milk according to the reference method.

The specificity of the detection system on quarter level,  $SP_q$ , in percent, is calculated using Equation C.2:

$$SP_q = \frac{c}{d} \times 100 \quad (C.2)$$

where

- $c$  is the number of quarters correctly indicated as normal by the detection system;
- $d$  is the number of quarters with normal milk according to the reference method.

### C.2.3 Detection at the animal level

For detection systems based on measurements in composite milk, foremilk samples are taken of at least 200 animal milkings of > 50 animals. Sampling shall be performed in at least three herds for at least 36 h in each herd. The foremilk sampled is poured through a filter with a pore size of 0,1 mm × 0,1 mm.

Cow composite milk where foremilk from one or more quarters with visible clots larger than 2 mm on the filter and CMT score > 3 is denoted as abnormal. Cow composite milk where foremilk from all quarters for at least two consecutive milkings does not show any clots on the filter and a CMT score < 4 is denoted normal. At least 800 samples shall test normal. All other samples are discarded from the analysis.

The sensitivity of the detection system on animal level,  $SE_u$ , in percent is calculated using Equation C.3:

$$SE_u = \frac{e}{f} \times 100 \quad (\text{C.3})$$

where

$e$  is the number of animals correctly indicated as abnormal by the detection system;

$f$  is the number of animals with abnormal milk according to the reference method.

The specificity of the detection system on animal level,  $SP_u$ , in percent, is calculated using Equation C.4:

$$SP_u = \frac{g}{h} \times 100 \quad (\text{C.4})$$

where

$g$  is the number of animals correctly indicated as normal by the detection system;

$h$  is the number of animals with normal milk according to the reference method.

NOTE Finding of clots in the foremilk on the filter means that the quarter and animal suffer from clinical mastitis.

### C.3 Guideline for interpretation of results

The sensitivity of devices for detecting abnormal milk should be > 70 %. At least 16 out of 20 milkings with abnormal milk should be detected, which will ensure a minimum sensitivity of 69 % for an 80 % confidence interval.

The specificity of devices for detecting abnormal milk should be > 99 %, which means that a maximum 2 out of 200 animal milkings with normal milk are automatically diverted.

The confidence interval for an expected specificity of 99 % is 98 % to 100 % for 200 milkings with normal milk. A minimum 199 out of 200 milkings with normal milk should be indicated as normal milk by the detection system.

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