INTERNATIONAL STANDARD

ISO 18385

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Minimizing the risk of human DNA contamination in products used to collect, store and analyze biological material for forensic purposes — Requirements

Réduire au maximum le risque de contamination de l'ADN dans les produits utilisés pour recueillir et analyser du matériel biologique en criminalistique — Exigences

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Foreword

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The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

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For an explanation on the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the WTO principles in the Technical Barriers to Trade (TBT) see the following URL: Foreword - Supplementary information

The committee responsible for this document is ISO/TC 272, *Forensic sciences*.

Introduction

This International Standard was produced with the aim to create global standards for manufacturers of forensic products used in human DNA analysis. Inadvertent contamination by manufacturers of consumables and reagents, when combined with the improved sensitivity of DNA testing methods, increasingly interferes with forensic analysis.

Minimizing the risk of human DNA contamination in products used to collect, store and analyze biological material for forensic purposes — Requirements

WARNING — This International Standard calls for the use of procedures that may be a health hazard or cause injury if adequate precautions are not taken.

1 Scope

This International Standard specifies requirements for the production of products used in the collection, storage, and analysis of biological material for forensic DNA purposes, but not those consumables and reagents used in post-amplification analysis.

The consumables and reagents covered by this International Standard include those used for evidence collection (sampling kits), such as swabs, containers, and packaging, and also products used in the analysis of DNA samples, such as tubes and other plasticware, disposable laboratory coats, gloves, and other consumables.

This International Standard applies to the production of consumables and reagents which do not require cleaning for continued use. This International Standard does not cover technical product specifications (i.e. product design).

This International Standard excludes microbiological testing.

This International Standard specifies a requirement for manufacturers to minimize the risk of occurrence of detectable human nuclear DNA contamination in products used by the global forensic community.

An overview of the International Standard is provided in Figure 1.

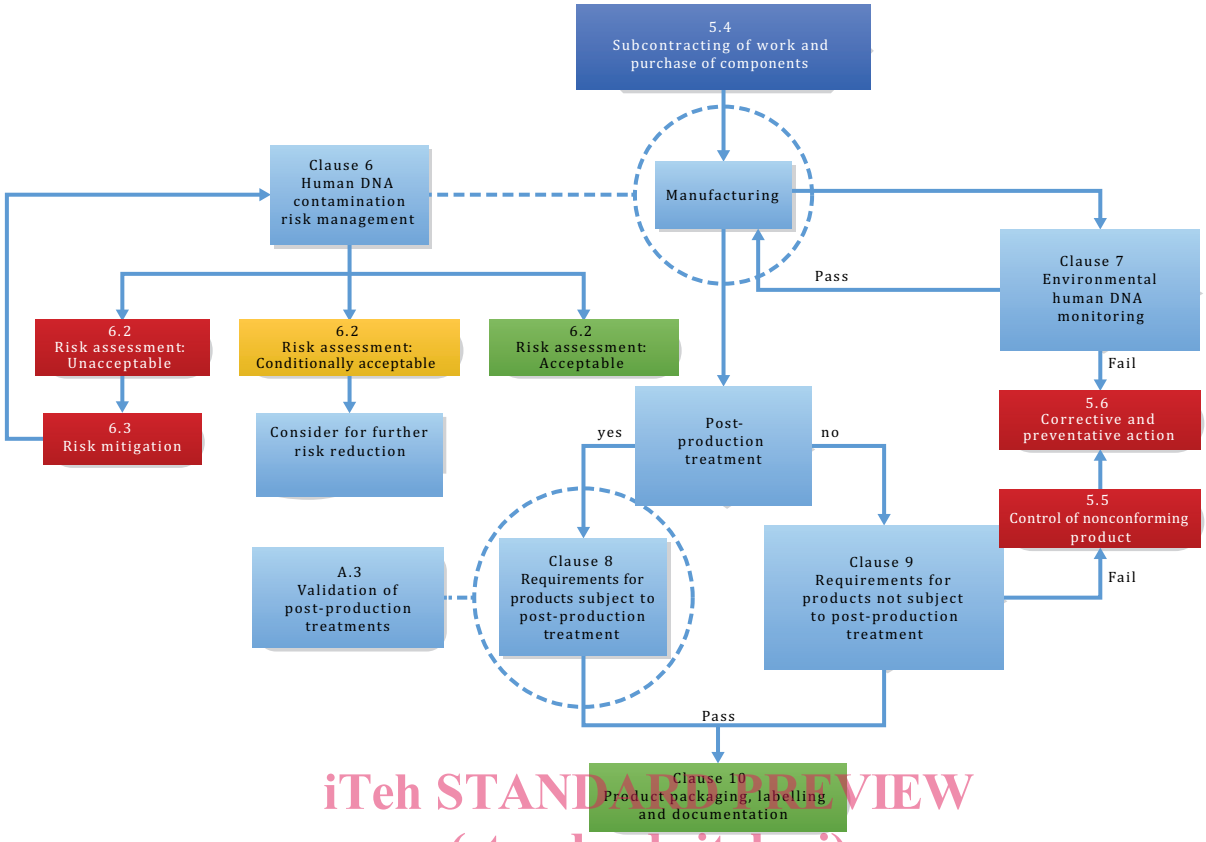

Figure 1 — Overview of the processes covered by this International Standard

2 Terms and definitions

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

2.1
allele
one of a number of alternatives at a specific location on an individual's DNA

2.2
amplification
process of copying segments of the DNA sequence exponentially

Note 1 to entry: This is also called Polymerase Chain Reaction (PCR).

2.3
amplification negative control
sample with no DNA material used to verify that the *amplification* (2.2) is free of *contamination* (2.7)

2.4
amplification positive control
sample with known DNA material used to verify that the *amplification* (2.2) works

2.5
analytical threshold
relative fluorescence unit value at which a laboratory has determined to call a peak an *allele* (2.1)

2.6
batch release test
test performed by or on behalf of the *manufacturer* (2.15) on a batch of components, which has to be satisfactorily completed before the batch can be released

[SOURCE: ISO/TS 21003-7:2008, 3.1.9]

2.7
contamination
introduction of detectable nuclear DNA or human cellular material during the manufacturing or assembly processes that would compromise the forensic human DNA analysis

2.8
contamination detection limit
value at or above which human DNA is deemed to be 'detected' and below which the compound is deemed to be 'not detected'

2.9
DNA reduction factor
ratio of the DNA quantity of an untreated cell-spiked sample to the DNA quantity of an identical cell-spiked sample that has undergone appropriate post-production treatment

2.10
eluate
solution resulting from the DNA extraction process

2.11
extraction negative control
sample with no cellular or DNA material used to verify that the DNA extraction is free of *contamination* (2.7)

2.12
extraction positive control
sample with known cellular or DNA material used to verify that a DNA extraction works

2.13
ISO 18385 forensic DNA grade
label given to products that have been produced in accordance with this International Standard

2.14
kit
set of consumables and/or chemicals (or reagents), and instructions for use, packaged together and intended for use as specified by the *manufacturer* (2.15)

2.15
manufacturer
organization that produces and/or packages the product

2.16
manufacturing environment
area, room, or space identified for the production and/or packaging of products used to collect and analyze biological materials

2.17
out-of-specification
test results that do not comply with the product specification

2.18
person reference sample
biological material taken from a known source with the purpose of creating a DNA profile for comparison

2.19
post-production treatment
contamination (2.7) reduction treatment conducted after *primary packaging* (2.20) to ensure that any human DNA contaminants above the *contamination detection limit* (2.8) are physically destroyed or not accessible to DNA *amplification* (2.2)

2.20
primary packaging
packaging designed to come into direct contact with the product

[SOURCE: ISO 21067:2007, 2.2.2]

2.21
primary transport container
product designed to transport the sample

EXAMPLE Envelopes, evidence bags, specimen jars, swab boxes, and collection devices with integrated transport mechanisms.

2.22
product
consumables and reagents which do not require cleaning for continued use and are used to collect, store, and analyze biological material for forensic purposes, but not used in post-amplification analysis

2.23
production
process or method for the manufacture of products

2.24
sample
portion of biological material or collected item, on which the test or analysis is carried out

2.25
validation
confirmation, through the provision of objective evidence, that the requirements for a specific intended use or application have been fulfilled

Note 1 to entry: The term “validated” is used to designate the corresponding status.

Note 2 to entry: The use conditions for validation can be real or simulated.

[SOURCE: ISO 9000:2015, 3.8.13]

2.26
verification
confirmation, through the provision of objective evidence, that specified requirements have been fulfilled

Note 1 to entry: The term “verified” is used to designate the corresponding status.

Note 2 to entry: Confirmation can comprise activities such as

— performing alternative calculations,

— comparing a new design specification with a similar proven design specification,

— undertaking tests and demonstrations, and

— reviewing documents prior to issue.

[SOURCE: ISO 9000:2015, 3.8.12]

3 Abbreviated terms

bp	Base pair
DNA	Deoxyribonucleic acid
EO	Ethylene oxide
HEPA	High efficiency particulate air
PCR	Polymerase chain reaction
QA	Quality assurance
qPCR	Quantitative PCR
STR	Short tandem repeat

4 Types of products

4.1 General

For the purposes of this International Standard, the products used in the collection, storage, and analysis of biological material for forensic DNA purposes are as outlined below. These products include, but are not limited to, the examples listed in 4.2, 4.3, and 4.4.

4.2 Products that come into direct contact with biological stains or material potentially containing human DNA

These products are considered to be high risk because the contaminating biological material or DNA is likely to be transferred. As a result, they should undergo post-production treatment provided it does not damage the product.

These products include, but are not limited to, the following examples:

a) gloves;

b) paper substrates onto which samples are deposited from persons;

c) plate seals/covers/strips;

d) plates;

e) primary transport container;

f) sampling kits;

g) spin baskets;

h) swabs;

i) tapes for sample recovery;

j) tips;

k) tubes.