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Organisation internationale de normalisation
International Organization for Standardization
Международная Организация по Стандартизации

Our ref. TMB / NWIP

TO THE ISO MEMBER BODIES

Date 2012-06-04

New work item proposal – *Minimizing the risk of contamination in products used to collect and analyse biological material for forensic DNA purposes.*

Dear Sir or Madam,

Please find attached a new work item proposal submitted by SA (Australia) on *Minimizing the risk of contamination in products used to collect and analyse biological material for forensic DNA purposes*. It should be noted that, if the NWIP is approved, the work is proposed to be carried out in a Project Committee.

You are kindly invited to complete the ballot form (Form 05) which could be downloaded at www.iso.org/forms and send it, preferably in Word format, to the Secretariat of the ISO Technical Management Board at *tmb@iso.org* before **4 September 2012.**

Yours faithfully,

Sophie Clivio
Secretary to the Technical Management Board

Encl: NWIP (Form 04)
Draft IS

NEW WORK ITEM PROPOSAL	
Date of presentation	Reference number (to be given by the Secretariat)
Proposer Damian Fisher, Standards Australia	**ISO/TC** **/ SC** N
Secretariat Australia	

A proposal for a new work item within the scope of an existing committee shall be submitted to the secretariat of that committee with a copy to the Central Secretariat and, in the case of a subcommittee, a copy to the secretariat of the parent technical committee. Proposals not within the scope of an existing committee shall be submitted to the secretariat of the ISO Technical Management Board.

The proposer of a new work item may be a member body of ISO, the secretariat itself, another technical committee or subcommittee, or organization in liaison, the Technical Management Board or one of the advisory groups, or the Secretary-General.

The proposal will be circulated to the P-members of the technical committee or subcommittee for voting, and to the O-members for information.

See overleaf for guidance on when to use this form.

IMPORTANT NOTE: Proposals without adequate justification risk rejection or referral to originator.
Guidelines for proposing and justifying a new work item are given overleaf.

Proposal (to be completed by the proposer)

Title of proposal (in the case of an amendment, revision or a new part of an existing document, show the reference number and current title)

English title	Minimizing the risk of contamination in products used to collect and analyse biological material for forensic DNA purposes
French title (if available)	Minimiser le risque de contamination dans les produits utilisés pour recueillir et analyser du matériel biologique à des fins d'analyse génétique (ADN)

Scope of proposed project

To develop an ISO Standard via the track 1 process. This could be undertaken by a new Sub-Committee of ISO/TC 194 - Biological evaluation of medical devices or a new PC or TC.

The proposed new International Standard is aimed at setting particular criteria around which the consumables used in forensic DNA collection and analysis should be manufactured.

This Standard specifies provisions for the production of products used in forensic DNA collection and analysis. Products covered by the scope of this Standard include consumables used for evidence collection (including those used in DNA kits), such as swabs, containers and packaging, and also products used in the analysis of DNA samples, such as tubes and other plastic ware, disposable laboratory coats, gloves, masks and other consumables. This Standard does not cover technical product specifications

Inclusions: Single-use items used for collection and analysis of biological material, such as swabs, tubes, chemicals and reagents and personal protection equipment.

Exclusions: Instruments used for the analysis of biological material, items used in the process post DNA amplification, items used in other non DNA forensic disciplines and multiple use items.

Concerns known patented items (see ISO/IEC Directives Part 1 for important guidance)

☐ Yes ☒ No If "Yes", provide full information as annex

Envisaged publication type (indicate one of the following, if possible)

☒ International Standard ☐ Technical Specification ☐ Publicly Available Specification ☐ Technical Report

Purpose and justification (attach a separate page as annex, if necessary)

The proposed Standard will provide guidance to manufacturers in procedures that will assist in minimizing human DNA contamination. Inclusions: Single-use items used for collection and analysis of biological material, such as swabs, tubes, chemicals and reagents and personal protective equipment.

This is a significant issue as contamination events in the manufacturing process have resulted in non case related DNA profiles obtained during case work analysis hampering police investigations and leading to flawed justice outcomes. This has occurred both in Australia and internationally (see Gill et al. 2009 for publication on this issue).

Following Australian stakeholders discussions with German and United Kingdom counterparts, it was determined that due to the international applicability of the proposed Standard, its development should be progressed as an ISO International Standard. It is expected that the Standard will be used by all manufacturers of forensic products worldwide largely at the policy request of forensic laboratories and policing agencies. Police agencies are particularly interested in the applications of this proposed Standard and strongly support its development.

A factor that could hinder the success of the successful establishment of the Standard is meeting any international legal requirements surrounding the use of DNA relating material between countries. This could effect the global application of the Standard and would need to be thoroughly addressed in the development of the Standard. Another issue that may be encountered is the ability of the manufacturers to meet the specifications of the Standard, however it is anticipated these aspects may be addressed during the development phase of the project so that the final Standard is of the required level, whilst also of a reasonable level for manufacturers to comply with.

The technology around the manufacturer of consumables and products used in the collection and analysis of DNA material is reasonably stable and the requirements are understood. Any changes to the sampling or analysis processes in the DNA collection or analysis should be easily contained within the manufacturing processes and no major changes to specifications contained within the Standard would be required. A majority of the requirements for DNA collection, such as the DNA collection kits are envisaged to be stable for the short to medium term. As a result of the development of the proposed Standard some aspects of the manufacturing process will benefit from advances such as improved decontamination procedures and quality assurance analysis to reduce the levels of viable human DNA. Whilst the Standard would not be the basis for the future development of any technology the Standard is critical for the advancement of forensic DNA analysis and ensuring the quality of results produced for the justice sector.

The development of this Standard is considered urgent as numerous examples, some of which have been published, have been demonstrated where consumables associated with DNA collection and analysis have been contaminated during the manufacturing process with human DNA. It is anticipated a Standard will be available for release by 31 December 2014.

There are numerous benefits to be gained from the development and implementation of this proposed Standard. Consistent and accepted Standards around the quality of forensic evidence within the forensic community will benefit all users of the judicial system including members of the public as well as legal and forensic practitioners. Compliance to an accepted platform of protocols by manufacturers of forensic biology products ensures that forensic scientists can be confident of the results they are producing. This has a direct bearing on the collection of forensic samples, forensic examinations, analyses, interpretations and opinion evidence in the courts and reduces the risk of flawed justice outcomes.

Target date for availability (date by which publication is considered to be necessary) ISO Standard 31 Decmber 2014

Proposed development track ☒ 1 (24 months) ☐ 2 (36 months - default) ☐ 3 (48 months)

Relevant documents to be considered

Gill et al. 2010 Manufacturer contamination of disposable plastic-ware and other reagents.
Schmidt et al. 1995 Evidence of contamination in PCR laboratory disposables and the Australian Standard AS 5483 - Minimizing the risk of contamination in products used to collect and analyse biological material for forensic DNA purposes.

Relationship of project to activities of other international bodies

Nil known

Liaison organizations	**Need for coordination with:**
International Commitment has been obtained from the following groups: Bundeskiminalamt, Germany UK Forensic Science Regulator University of Granada, Spain USA ASCLD Board of Directors Asian Forensic Science Network	☐ IEC ☐ CEN ☐ Other (please specify)

Preparatory work (at a minimum an outline should be included with the proposal)

☒ A draft is attached ☐ An outline is attached. It is possible to supply a draft by

The proposer or the proposer's organization is prepared to undertake the preparatory work required ☒ Yes ☐ No

Proposed Project Leader (name and address)	**Name and signature of the Proposer** (include contact information)
Dr Linzi Wilson-Wilde, General Manager National Institute of Forensic Science, Australia New Zealand Policing Advisory Agency, L6, T3, WTC, 637 Flinders Street, Docklands, VIC Australia 3008	Damian Fisher, Senior National Sector Manager, Standards Australia, Level 10, 20 Bridge Street, Sydney, NSW, 2000, Australia damian.fisher@standards.org.au

Comments of the TC or SC Secretariat

Supplementary information relating to the proposal

☒ This proposal relates to a new ISO document;

☐ This proposal relates to the amendment/revision of an existing ISO document;

☐ This proposal relates to the adoption as an active project of an item currently registered as a Preliminary Work Item;

☐ This proposal relates to the re-establishment of a cancelled project as an active project.

Other:

Voting information

The ballot associated with this proposal comprises a vote on:

☒ Adoption of the proposal as a new project

☐ Adoption of the associated draft as a committee draft (CD)

☐ Adoption of the associated draft for submission for the enquiry vote (DIS or equivalent)

Other:

Annex(es) are included with this proposal (give details)

☒ Preliminary draft based on AS 5483

Date of circulation	Closing date for voting	Signature of the TC or SC Secretary

Use this form to propose:

a) a new ISO document (including a new part to an existing document), or the amendment/revision of an existing ISO document;

b) the establishment as an active project of a preliminary work item, or the re-establishment of a cancelled project;

c) the change in the type of an existing document, e.g. conversion of a Technical Specification into an International Standard.

This form is not intended for use to propose an action following a systematic review - use ISO Form 21 for that purpose.

Proposals for correction (i.e. proposals for a Technical Corrigendum) should be submitted in writing directly to the secretariat concerned.

Guidelines on the completion of a proposal for a new work item

(see also the ISO/IEC Directives Part 1)

a) Title: Indicate the subject of the proposed new work item.

b) Scope: Give a clear indication of the coverage of the proposed new work item. Indicate, for example, if this is a proposal for a new document, or a proposed change (amendment/revision). It is often helpful to indicate what is not covered (exclusions).

c) Envisaged publication type: Details of the types of ISO deliverable available are given in the ISO/IEC Directives, Part 1 and/or the associated ISO Supplement.

d) Purpose and justification: Give details based on a critical study of the following elements wherever practicable. *Wherever possible reference should be made to information contained in the related TC Business Plan*.

1) The specific aims and reason for the standardization activity, with particular emphasis on the aspects of standardization to be covered, the problems it is expected to solve or the difficulties it is intended to overcome.

2) The main interests that might benefit from or be affected by the activity, such as industry, consumers, trade, governments, distributors.

3) Feasibility of the activity: Are there factors that could hinder the successful establishment or global application of the standard?

4) Timeliness of the standard to be produced: Is the technology reasonably stabilized? If not, how much time is likely to be available before advances in technology may render the proposed standard outdated? Is the proposed standard required as a basis for the future development of the technology in question?

5) Urgency of the activity, considering the needs of other fields or organizations. Indicate target date and, when a series of standards is proposed, suggest priorities.

6) The benefits to be gained by the implementation of the proposed standard; alternatively, the loss or disadvantage(s) if no standard is established within a reasonable time. Data such as product volume or value of trade should be included and quantified.

7) If the standardization activity is, or is likely to be, the subject of regulations or to require the harmonization of existing regulations, this should be indicated.

If a series of new work items is proposed having a common purpose and justification, a common proposal may be drafted including all elements to be clarified and enumerating the titles and scopes of each individual item.

e) Relevant documents and their effects on global relevancy: List any known relevant documents (such as standards and regulations), regardless of their source. When the proposer considers that an existing well-established document may be acceptable as a standard (with or without amendment), indicate this with appropriate justification and attach a copy to the proposal.

f) Cooperation and liaison: List relevant organizations or bodies with which cooperation and liaison should exist.

ISO TC /SC N

Date: 2012-05-24

ISO/WD 101051

ISO TC /SC /WG

Secretariat: SA

Minimizing the risk of contamination in products used to collect and analyse biological material for forensic DNA purposes

Élément introductif — Élément central — Élément complémentaire

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Document type: International Standard
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Document stage: (20) Preparatory
Document language: E

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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 101051 was prepared by Technical Committee ISO/TC , *Forensic Analysis*, Subcommittee SC , .

This second/third/... edition cancels and replaces the first/second/... edition (), [clause(s) / subclause(s) / table(s) / figure(s) / annex(es)] of which [has / have] been technically revised.

Introduction

This Standard was prepared by the Standards Australia Committee CH-041, Forensic Analysis. This Standard is the result of a consensus among the representatives of the Committee to produce it as an Australian Standard.

The objective of this Standard is to provide provisions for the production of products used in forensic analysis in order to minimize contamination with human DNA during the production process.

The Standard may be used in conjunction with other Standards that detail quality assurance methods, such as ISO 9001.

Minimizing the risk of contamination in products used to collect and analyse biological material for forensic DNA purposes

1 Scope

This Standard specifies provisions for the production of products used in forensic DNA collection and analysis. Products covered by the scope of this Standard include consumables used for evidence collection (including those used in DNA kits), such as swabs, containers and packaging, and also products used in the analysis of DNA samples, such as tubes and other plastic ware, disposable laboratory coats, gloves, masks and other consumables.

This Standard does not cover technical product specifications.

WARNING — THIS STANDARD CALLS FOR THE USE OF PROCEDURES THAT MAY BE A HEALTH HAZARD OR CAUSE INJURY IF ADEQUATE PRECAUTIONS ARE NOT TAKEN.

The quality guidelines for human DNA testing specified in this Standard are applicable to all other biological testing of products used to collect and analyse biological material for forensic purposes, excluding microbiological testing.

This Standard applies to the production specifications for single-use material only and excludes items used in the DNA analysis process post-PCR.

2 Referenced and related documents

2.1 Referenced documents

The following documents are referred to in this Standard:

ISO 9001, *Quality management systems—Requirements*

ISO/IEC 17025, *General requirements for the competence of testing and calibration laboratories*

2.2 Related documents

Further information may be found in the following Standards:

AS 2030, *Gas cylinders (all parts)*

AS/NZS 2161, *Occupational protective gloves (all parts)*

AS/NZS 2243, *Safety in laboratories (all parts)*

AS/NZS 4501, *Occupational protective clothing*

AS/NZS 4501.1, *Occupational protective clothing—Part 1: Guidelines on the selection, use, care and maintenance of protective clothing*

AS/NZS 4501.2, *Occupational protective clothing—Part 2: General requirements*

AS/NZS 14644, *Cleanrooms and associated controlled environments*

AS/NZS 14644.2, *Cleanrooms and associated controlled environments—Part 2: Specifications for testing and monitoring to prove continued compliance with ISO 14644-1 (ISO 14644-2:2000, MOD)*

AS/NZS 14644.3, *Cleanrooms and associated controlled environments—Part 3: Test methods (ISO 14644-3:2005, MOD)*

ISO 31000, *Risk management—Principles and guidelines*

ISO 14644, *Cleanrooms and associated controlled environments*

ISO 14644.1, *Cleanrooms and associated controlled environments—Part 1: Classification and air cleanliness*

ISO 14644.2, *Cleanrooms and associated controlled environments—Part 2: Specifications for testing and monitoring to prove continued compliance with ISO 14644-1 (ISO 14644-2:2000, MOD)*

ISO 14644.4, *Cleanrooms and associated controlled environments—Part 4: Design, construction and start-up*

ISO 14644.5, *Cleanrooms and associated controlled environments——Part 5: Operations*

ISO 14644.6, *Cleanrooms and associated controlled environments—Part 6: Vocabulary*

ISO 14644.7, *Cleanrooms and associated controlled environments—Part 7: Separative devices (clean air hoods, gloveboxes, isolators and mini-environments)*

ISO 14644.8, *Cleanrooms and associated controlled environments—Part 8: Classification of airborne molecular contamination*

ISO 13485, *Medical devices—Quality management systems—Requirements for regulatory purposes*

ISO 3696, *Water for analytical laboratory use—Specification and test methods*

ISO 10993, *Biological evaluation of medical devices*

ISO 10993-7. *Biological evaluation of medical devices—Part 7: Ethylene oxide sterilization residuals*

ISO 11135, *Sterilization of health products–ethylene oxide*

ISO 11135-1, *Sterilization of health–ethylene oxide—Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices*

UNODC*, Guidelines on Representative Drug Sampling, ISBN 978-92-1-148241-6*

3 Definitions and abbreviations

3.1 Definitions

For the purposes of this document, the following definitions apply:

3.1.1
Accreditation
Formal recognition by an independent recognized body that has assessed the technical competency of an organization to meet the requirements of a predetermined standard.

3.1.2
Allele
An alternate of two or more possible DNA sequences at a particular location on an individual's genome.

3.1.3
Amplification
The process of copying sections of the DNA sequence exponentially, commonly called PCR.

3.1.4
Critical environment
An environment in which products may be handled individually and risk of contamination is high. Examples include the environment within which forensic reference person kits are put together from individual products, and where those products are not individually sealed.

3.1.5
Human DNA contamination detection limit
Value at or above which DNA is deemed to be 'detected' and below which the compound is deemed to be 'not detected'. The value should be set so that human DNA fragments are of a sufficient size and/or quantity that they do not interfere with current forensic DNA analysis methods.

3.1.6
Environment
An area, room or space identified for the production and/or packaging of products used to collect and analyse biological material. See also critical environment, manufacturing environment and sensitive environment.

3.1.7
Forensic DNA Grade
Products that have been produced in accordance with this Standard and from which human DNA is minimized and present at a level or concentration lower than the limit of detection using current methods in forensic laboratories.

3.1.8
Genome
The entirety of an individual's DNA sequence containing the hereditary information.

3.1.9
Gross human DNA contamination
Contamination of visible biological material.

3.1.10
Manufacturing environment
An environment in which products for use in forensic DNA analysis are mass produced using mainly automated procedures, where there is minimal human interaction with the products and the DNA contamination risk is low.

3.1.11
Production
The process or method for the manufacture of products.

3.1.12
Post Production Treatment
A treatment conducted after the last stage of production to ensure that any human DNA contaminants above the human DNA contamination detection limit are physically destroyed. Post-production treatments include, but are not limited to, radiation techniques such as ultraviolet (UV), gamma irradiation (GR) and electron beam processing (EB) and chemical techniques such as ethylene oxide (EO).

3.1.13
Products
Single use consumables and reagents used in the forensic DNA analysis process, including those consumables and reagents used in collection, extraction and amplification, but not those consumables and reagents used in the analysis of amplified DNA.

3.1.14
Sample
A portion taken from a collected item, on which the test or analysis is carried out.

3.1.15
Sensitive environment
An environment in which products for use in forensic DNA analysis are subject to some human handling, mainly of bulk quantities, and the DNA contamination risk is medium. An example is the environment where products are grouped and packaged into boxes.

3.1.16
Validation
The process of documenting evidence to demonstrate that a product, method or system consistently performs as expected.

3.2 Abbreviations

bp	Base pair
DNA	Deoxyribonucleic acid
EB	Electron beam processing
EO	Ethylene oxide
GR	Gamma irradiation
HEPA	High efficiency particulate air
PCR	Polymerase chain reaction
pg	Picogram
QA	Quality assurance
qPCR	Quantitative PCR
STR	Short tandem repeat
UV	Ultraviolet

4 Types of products

4.1 General

For the purposes of this Standard, the products used in the collection and analysis of DNA are as outlined below. These products include, but are not limited to, the following examples.

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

These products are generally not damaged by post-production treatment(s) used to minimize human DNA contamination. These products include the following examples:

a) Swabs.

b) Tape.

c) Envelopes.

d) Petri dishes.

e) Specimen jars.

f) Evidence bags.

g) Tweezers.

h) Scalpel blades.

i) Nail clippers.

j) Tooth picks.

k) Scissors.

l) Pipettes/droppers.

m) Tubes.

n) Tips.

o) Plates.

p) Vials.

q) Plate seals/covers.

r) Blotting paper.

s) Spin baskets.

4.3 Chemicals, reagents and solvents and some disposables involved in the analysis of human DNA:

These products include the following examples:

a) PCR amplification kits.

b) DNA microconcentrators.

c) DNA extraction kits.

4.4 Products used in areas where human DNA is collected or analysed

These products are designed not to come into direct contact with biological stains or material potentially containing human DNA. They include the following:

a) Products used to protect surfaces such as disposable bench coverings.

b) Masks.

c) Gloves.

d) Lab coats.

e) Scene suits.

f) Shoe covers.

g) Hair nets.

h) Facial hair covers.

i) Sleeve protectors.

4.5 Products used in the collection of human DNA

Products used for the collection of person reference samples only:

a) Swabs used to collect samples from persons.

b) Lancets.

c) Paper substrates onto which samples are deposited from persons.

5 Quality systems

5.1 General

Quality systems shall comply with ISO 9001.

5.2 Documentation

Approved designated personnel shall establish and maintain documented procedures for the production of products, creating and monitoring the environments where products are produced, defining post production treatment and testing and, where required, remedial actions. The documents shall be version controlled and have specific effective dates.

Records of the products produced shall include details that allow traceability to their source materials and include batch number that identify the date and time that an item was produced and the environment that it was produced in.

Documents and records required by this Standard shall be maintained for a minimum of seven years.

5.3 Authorization

The responsibilities and authority for implementing, performing and monitoring the procedures and provisions described in this Standard shall be specified and documented.

5.4 Subcontracting of work and purchase of components

If any of the requirements outlined in this Standard are subcontracted, the responsibility to identify a subcontractor that adheres to this Standard shall remain with the organization that subcontracts the work.

The manufacturer shall retain responsibility for all components of their products.

6 Environment provisions

6.1 General

This Clause (6) sets out provisions pertaining to the environments in which products are produced. It applies to all products listed in Clause 4.

The environment shall include any area where products are produced and shall be identified, defined and documented as a manufacturing environment, a sensitive environment or a critical environment.

A manufacturing process may employ multiple types of environment.

6.2 Manufacturing environments

6.2.1 Equipment

All equipment associated with the production of the products in the manufacturing environment shall be identified and documented.

To minimize the risk of contamination, the production processes in the manufacturing environment should be automated where possible.

6.2.2 Personnel

Access to the manufacturing environment shall be restricted. All authorised personnel entering the manufacturing environment shall be provided with appropriate training regarding DNA contamination risk reduction techniques. All training shall be documented.

A voluntary reference sample may be collected from personnel who enter the manufacturing environment. If a sample is provided, a relevant DNA profile shall be generated and recorded for quality assurance purposes.

Personnel entering the manufacturing environment shall wash their hands, or use hand sanitizer, immediately prior to entering.

Personnel entering the manufacturing environment shall at all times wear the following coverings:

a) Gown.

b) Hairnet.

If facial hair is present, a facial hair covering (i.e. for beards and/or moustaches), shall be worn.

6.2.3 Maintenance

A regular cleaning schedule shall be established and conducted, targeting surfaces and areas of potential biological contamination. The cleaning schedule conducted shall be documented and compliance records maintained.

A procedure for decontamination of surfaces and areas contaminated with biological material shall be devised, documented, implemented and compliance records maintained. All necessary decontamination equipment should be retained within close proximity to the manufacturing environment.

6.3 Sensitive environments

The provisions set out in Clauses 6.1 to 6.2 shall apply, along with the following.

The purpose, operations to be carried out in, and any constraints of the sensitive environment shall be documented.

Personnel entering the sensitive environment shall wear the following coverings:

a) Mask.

b) Gloves.

6.4 Critical environments

The provisions set out in Clauses 6.1 to 6.3 shall apply, along with the following.

The critical environment shall be a contained area with no provision for normal passage and include the following features:

a) Unidirectional workflow.

b) Positive air pressure.

c) HEPA filters over air inlets.

A register shall be kept to record the entry and exit of all personnel, including the date and time of entry and exit.

The design of the critical environment should include an anteroom or vestibule for the storage and donning of personnel coverings. Used personal coverings should be regularly removed from the anteroom/vestibule and cleaned or disposed of.

7 Quality assurance and monitoring of sensitive and critical environments

7.1 General

7.1.1 Quality Assurance Plan

This Clause (7) specifies provisions for periodic testing of sensitive and critical environments, described in Clause 6.3 and 6.4 to establish that the environment is free from gross human DNA contamination.

Quality assurance and monitoring of the environment shall be performed according to a validated and documented plan, developed in response to validation studies.

The plan should take into account the frequency of product batch production, other products produced in the same environment, the risk of contamination and the quality control history.

The plan should include locations tested, number of samples per location tested, test method (and detection limits), replicate testing, acceptance limits, reproducibility of results, and maximum time intervals between testing (see Annex A).

7.1.2 Tests

All tests methods should follow ISO/IEC 17025.

The results of tests should be recorded and at minimum include the following:

a) Name and address of manufacturer.

b) Date testing performed.

c) Test sample locations.

d) Testing equipment and methods.

e) Analytical controls.

f) Testing results (including compliant/non–compliant).

Analytical controls shall be clearly specified and their interpretation recorded.

7.1.3 Focus

The areas and items monitored should include, but not be limited to, equipment used in the production process and work surfaces that come into contact with the manufactured products.

An assessment of the risk of contamination in the environment shall be conducted. Testing shall be conducted according to the results of the risk assessment.

Testing should also be conducted following any clean-up procedure pursuant to any known human DNA contamination events, or if there is any modification to the equipment, system or processes within the critical environment that has the potential to affect the integrity of the environment.

7.2 Pass/fail parameters

The pass/fail parameters shall be determined and documented. A procedure regarding measures that shall be taken with batches of products produced in an environment that has failed the QA monitoring (i.e. DNA contamination is detected), shall be developed and documented.

If the pass parameter is not met, a confirmatory test should be conducted as soon as practically possible. If it is confirmed that DNA contamination has been detected, a risk assessment shall be conducted on the risk of further contamination and the effect of the contamination on the end products. All manufacturing shall be halted until the environment is decontaminated.

All tests shall be documented and the records retained to identify any systemic failures.

8 Post-production treatment of products

8.1 General

The manufacturer shall perform a post-production treatment on products unless validation results demonstrate that such treatment is unnecessary.

8.2 Where post-production treatment is undertaken

Manufacturers shall validate and document methods for post-production treatment.

Validation of post-production treatments shall demonstrate that the treatment is effective at physically destroying human DNA contamination above the specified detection limit, does not introduce interference or negatively impact on the performance of products, and that products are safe for human contact.

NOTE For validation of post production treatments, see Annex A.

The post–production treatment shall not adversely affect the manufactured products.

Sterilization of consumables by EO shall be performed according to ISO 10993 and ISO 10993-7 to ensure appropriate dissipation rates of EO are adhered to.

8.3 Where post-production treatment is not undertaken

Manufacturers shall validate and document the use of contamination minimization measures that ensure the final products have contamination below the human DNA contamination detection limit.

Validation shall include documented assessment of:

a) the nature of all raw materials and the likelihood that they may contain detectable DNA.

b) every stage of manufacture including the level of manual human involvement and the potential for such involvement to introduce contaminant DNA.

c) the nature of the product to determine if DNA contamination would be evenly or sporadically dispersed should contamination occur.

d) The effect of human DNA contamination on the forensic DNA analysis methods.

Validation of the production method shall include testing of the end product for the presence of detectable DNA. Where DNA is likely to be sporadic or heterogeneously distributed, a large sample size will be required to provide a statistically significant result.

9 Monitoring of contamination minimization measures

9.1 General

An ongoing verification process shall be designed and documented to demonstrate effective contamination minimization measures.

9.2 Where post-production treatment is undertaken

Manufacturers shall monitor and record compliance with the documented post-production treatment process, as a minimum, on a six monthly basis.

A verification process shall be conducted and include periodic testing of the efficacy of the post-production treatment through the use of DNA spiked samples. The frequency of testing shall be based on a documented risk assessment.

9.3 Where no post production treatment is undertaken

Manufactures will monitor and record compliance with the documented method of production including use of all contamination minimization measures, as a minimum, on a six monthly basis.

Verification of the continued success of all contamination prevention measures shall be undertaken by periodic DNA testing of the product. The frequency of testing and sample size shall be based on a documented risk assessment that includes the factors outlined in Clause 8.3.

9.4 Test methods

The test method used shall be validated and be sensitive enough to demonstrate conformity to this Standard.

The test method shall comply with Clauses 5.3 to 5.9 of ISO/IEC 17025.

The performance monitoring of products shall be carried out on completion of the final processing event prior to release, whether it is an individual item, a component to be assembled into a kit elsewhere or the final assembled kit.

9.5 Results and reporting

Where testing indicates that post-production treatments do not meet requirements as specified in Clause (9), a confirmatory test should be performed and if the same result is obtained, the affected batch (or batches) shall not be labelled ‘Forensic DNA Grade’.

A report shall be provided upon request and shall include the following information for the end user:

a) A lot or batch number.

b) A basic description of the item referred to.

c) A description of the quality tests conducted, limit of detection for the characteristic tested for, and the results of the quality tests.

d) Details of relevant certification or accreditation held by the manufacturer and/or testing facility.

e) Date of manufacture.

Documented procedures shall be established, maintained and applied to log corrective action notifications from consumers if products are found by consumers not to meet the requirements of this Standard. A corrective and preventative action file should be opened to investigate the cause of the failure and the required corrective action(s) taken.

10 Product packaging and labelling

Products shall be packaged in a manner that maintains their integrity.

Manufacturers shall clearly label products as ‘Forensic DNA Grade’ when produced according to the requirements specified in this Standard.

Manufacturers shall clearly label products where a post-production treatment has been applied.

Labelling shall be as follows:

a) ‘Forensic DNA Grade EO’ when EO treatment has been applied.

b) ‘Forensic DNA Grade UV’ when UV treatment has been applied.

c) ‘Forensic DNA Grade GR’ when GR treatment has been applied.

d) ‘Forensic DNA Grade EB’ when EB treatment has been applied.

If another post-production treatment is applied, an appropriate label shall be used.

Annex A
(informative)

Compliance testing

Compliance testing targets methods of detecting human DNA fragments that are of sufficient size and/or quantity to interfere with current forensic DNA analysis methods.

Current methods usually analyse human STR DNA fragments typically larger than 70bp. Commercially available PCR STR DNA analysis kits are generally used by forensic laboratories, Some laboratories analyse human DNA using mitochondrial DNA (mtDNA) analysis methods. Exact details of the methods may be obtained from the relevant forensic laboratories.

Real-time qPCR, using primers that are known to detect human DNA, can be used for testing. This method uses commercially available equipment and DNA analysis kits. The analysis of samples by STR, mtDNA or qPCR is also available from commercial suppliers such as paternity testing laboratories.

The sampling of a defined surface size (such as 10 cm x 10 cm, per 5 m^2) using swabs is preferable. Also, analysis of 100% of the swab tip, and with the extracted DNA solution concentrated to a volume not to exceed 50 µl will provide a result that would indicate the presence of DNA above the specified detection limit.

Analysis controls include positive and negative extraction and amplification controls.

The details of the type of controls, the conditions in which the controls were used, and the interpretation of the obtained results are usually recorded and kept.

Validation of post-production treatments will include a quantitative assessment of quantifying extracted human DNA from treated versus untreated samples, where samples have been spiked with a known quantity of human biological or DNA material, such as 50ng equivalent of white blood cells.