PAS 377:2012

Specification for consumables used in the collection, preservation and processing of material for forensic analysis

Requirements for product, manufacturing and forensic kit assembly

Forensic Science Regulator
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Foreword

This Publicly Available Specification (PAS) was commissioned by the Forensic Science Regulator and its development facilitated by BSI Standards Limited and published under licence from The British Standards Institution. It came into effect on 30 June 2012.

Acknowledgement is given to Dr Kevin Sullivan, as the technical author, and the following organizations that were involved in the development of this PAS as members of the steering group:

- Association of Forensic Science Providers
- Forensic Science Regulation Unit, Home Office
- GAMBICA
- Human Identity Trade Association
- Sterile Barrier Association
- Co-opted member

Acknowledgement is also given to the members of a wider review panel who were consulted in the development of this PAS.

The PAS process enables a specification to be rapidly developed in order to fulfil an immediate need in industry. A PAS may be considered for further development as a British Standard, or constitute part of the UK input into the development of a European or International Standard.

This PAS is not to be regarded as a British Standard. It will be withdrawn upon publication of its content in, or as, a British Standard.

Information about this document

Assessed capability. Users of this PAS are advised to consider the desirability of quality system assessment and registration against the appropriate standard in the BS EN ISO 9000 series by an accredited third-party certification body.

Test laboratory accreditation. Users of this PAS are advised to consider the desirability of selecting test laboratories that are accredited to BS EN ISO/IEC 17025 by a national or international accreditation body.

Use of this document

It has been assumed in the preparation of this PAS that the execution of its provisions will be entrusted to appropriately qualified and experienced people, for whose use it has been produced.

Presentational conventions

The provisions of this PAS are presented in roman (i.e. upright) type. Its requirements are expressed in sentences in which the principal auxiliary verb is "shall".

Commentary, explanation and general informative material is presented in italic type, and does not constitute a normative element.

Contractual and legal considerations

This publication does not purport to include all the necessary provisions of a contract. Users are responsible for its correct application.

Compliance with a PAS cannot confer immunity from legal obligations.

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Introduction

Forensic science is the application of a broad spectrum of sciences to answer questions of interest to the legal system. This includes the investigation and prosecution of crime by the police and assistance to the courts in determining guilt or innocence of those accused of having committed a crime.

In general terms, the forensic science process includes the following steps:

a) location and recovery of evidential material;

b) preservation and transportation to a laboratory;

c) analysis and interpretation of the results within a laboratory.

Depending on the forensic science process being undertaken, the analysis and interpretation includes comparison against controls or reference samples.

These steps typically utilize forensic kits and other consumables, depending on the type of evidence being recovered and analysed. This includes:

1) swabs, gauze and tapes for recovery of evidential material;

2) vessels to physically contain evidential material during transport to the laboratory;

3) glass vials, plastic tubes, microtitre plates, disposable purification columns and analytical reagents used in the laboratory analytical processes.

It is crucial that the consumables and forensic kits do not compromise the integrity of the samples collected or adversely affect the analytical process in any way: To do so could potentially diminish the value and reliability of the forensic evidence. This in turn would increase the risk of an investigation being misled, poor judicial outcomes being made in the courts, or could even result in a miscarriage of justice.

The aim of PAS 377 is to provide a high level specification that can be adopted by the manufacturers of consumables and assemblers of forensic kits. Evidence of compliance with PAS 377 can assist end users of consumables and forensic kits with their procurement decisions and provide assurance to other stakeholders in the Criminal Justice System by promoting confidence in the forensic science process.

In addition, PAS 377 specifies further requirements for consumables used in the forensic DNA analysis process.

NOTE 1 *PAS 377 translates an agreed position statement by European Network of Forensic Science Institutes (ENFSI), Scientific Working Group on DNA Analysis Methods (SWGDAM) and Biology Specialist Advisory Group (BSAG) of the Senior Managers of Australian and New Zealand Forensic Laboratories (SMANZFL) on manufacturer contamination of disposable plastic-ware and other reagents [1] into a specification for consumables and forensic kits specifically with regard to DNA anti-contamination measures. This position statement is in response to problems reported in high profile criminal investigations caused by the sporadic contamination of consumables with human DNA during manufacturing/ assembly processes [2]. These were caused by the use of consumables that had not been manufactured to meet the specific needs of forensic science and resulted in spurious links being made between unrelated crimes, which misled investigations and caused large-scale wastage of police resources. A contributing factor has been a common misconception that "sterile" is the same as "DNA free" [3].*

NOTE 2 *Forensic kits and consumables that meet the requirements of PAS 377 are intended for use by end users in conjunction with* The Forensic Science Regulator codes of practice and conduct *[4].*

NOTE 3 *PAS 377 is intended to assist assemblers in producing forensic kits that meet the Faculty of Forensic and Legal Medicine's document,* Recommendations for the collection of forensic specimens from complainants and suspects *[5].*

NOTE 4 *PAS 377 is intended to apply to all consumables and forensic kits, regardless of where they are produced, i.e. including those that are assembled by end users, such as sticky tapes intended for DNA collection being assembled within police or forensic science laboratories.*

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1 Scope

This PAS specifies requirements for:

a) consumables used in the collection, preservation and processing of material for forensic analysis;

b) the manufacture of these consumables; and

c) the assembly of forensic kits.

This PAS specifies further requirements for consumables used in DNA testing in Annex A, which are additional to those given in Clause **3** to Clause **6**.

This PAS is not intended to cover technical product specifications for consumables, although it could be used to assist in developing a technical product specification.

2 Terms and definitions

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

2.1 anti-contamination measure

action(s) taken to reduce contamination and/or its impact, including contamination avoidance, reduction and detection

2.2 assembler

organization that produces forensic kits

NOTE *The manufacturer (see **2.13**) might also be the assembler.*

2.3 consumable

single-use commodity used in the collection, preservation and processing of material for forensic analysis and is bought and used up recurrently

NOTE *Consumables used in forensic analysis include vessels, tamper evident containers, swabs, packaging that comes into direct contact with the material for forensic analysis, etc. and can be made from various materials, such as plastic, glass or a metal. A consumable can be used for collecting the material (e.g. a disposable glove), preserving the material (e.g. an airtight container for volatile liquid preservation), for processing the material (e.g. an analytical reagent, scalpel blade or disposable scissors), for the safe handling of materials (e.g. a knife tube) or for a combination of these purposes (e.g. a swab).*

2.4 container

item in which evidential material is physically held during transportation or storage

2.5 contamination

undesirable introduction during the manufacturing or assembling processes of the analyte that is the subject of the specific forensic analysis

NOTE *For example, the introduction of human DNA from manufacturing personnel into consumables used for DNA analysis, or ethanol into consumables used to collect blood for alcohol in blood measurement.*

2.6 DNA contamination

unintended presence of DNA

NOTE *The DNA contamination can be sporadic, i.e. unevenly distributed, or uniform, i.e. evenly dispersed.*

2.7 DNA dosage reduction

physical or chemical treatment that reduces the amount of amplifiable DNA present

2.8 end user

organization or individual who procures a consumable or forensic kit for use

NOTE *An end user could be, for example, a police force or a forensic science provider.*

2.9 forensic kit (kit)

set of consumables and accessories

NOTE 1 *Kits used to recover, preserve and transport material to a laboratory for analysis include, for example, DNA recovery kits, and forensic medical examination kits. Kits used to test recovered material include, for example, presumptive drug testing kits.*

NOTE 2 *Accessories can include instruction sheets, labels, etc. that do not come into direct contact with the material and are not subject to the same requirements as consumables outlined in this PAS.*

2.10 forensic science

application of a broad spectrum of sciences to answer questions of interest to the legal system

NOTE *This also includes coroners cases and identification of remains from mass disasters where there may not necessarily be legal implications.*

2.11 interference

unintended impact on the detection or quality of analysis of the evidential material and interpretation of the analytical results

2.12 low template DNA analysis (LTDNA analysis)

generation of a full or partial DNA profile by PCR amplification and analysis of less than 200 pg of human genomic DNA

2.13 manufacturer

organization that manufactures consumables

NOTE 1 *The manufacturer might also be the assembler (see **2.2**).*

NOTE 2 *For definition of consumable, see **2.3**.*

2.14 normal handling

use of the consumable or kit for the recovery, preservation, transportation and processing of material for forensic analysis in accordance with the manufacturer's instructions

2.15 processing

performance of a series of mechanical or chemical operations on a sample of material in order to determine its characteristics

2.16 risk

effect of uncertainty on objectives

NOTE 1 *An effect is a deviation from the expected – positive and/or negative.*

NOTE 2 *Objectives can have different aspects (such as financial, health and safety, and environmental goals) and can apply at different levels (such as strategic, organization-wide, project, product and process).*

NOTE 3 *Risk is often characterized by reference to potential events and consequences, or a combination of these.*

NOTE 4 *Risk is often expressed in terms of a combination of the consequences of an event (including changes in circumstances) and the associated likelihood of occurrence.*

[BS ISO 31000:2009, **2.1**]

2.17 tamper-evident container

consumable used to hold material for forensic analysis and which once sealed cannot be readily reopened or its contents otherwise accessed or its identification compromised without attempts to do so being evident

3 Product requirements

3.1 General

Data to demonstrate that a consumable and kit meet the requirements specified in **3.2** to **3.7** shall be documented.

The limits of detection of the technique and technology used shall be documented [see also **5.2**c)].

NOTE *The manufacturer should ensure that the samples tested are typically representative of the batch. Guidance on sampling is given, for example, in BS 6002-1, which describes an acceptance sampling system of single sampling plans for inspection by variables.*

3.2 Contamination

3.2.1 General

The packaging shall be designed so that it minimizes the risk of extraneous contamination during normal handling and storage.

The consumable/kit shall not have detectable levels of the analyte for which it is intended to be used.

NOTE 1 *It is the responsibility of both manufacturer and assembler to ensure this.*

NOTE 2 *For consumables, it is required to demonstrate the absence of an analyte whereby the sensitivity of the analyte assay technique employed is, at least, equal to the sensitivity of the analyte profiling technique for which the consumables are subsequently used (see **3.2.2** to **3.2.9**).*

NOTE 3 A *consumable or kit used in casework (see **3.2.3**) requires that lower levels of background DNA are achieved than those used in DNA reference sample analysis (see **3.2.2**).*

3.2.2 Consumable used in DNA reference sample analysis

A consumable used in DNA reference sample analysis shall have no detectable human DNA, under the following conditions by either:

a) using the standard PCR and analysis conditions for the STR profiling kit used for determining as a minimum the following ten STR loci contained within the paper, *The evolution of DNA databases – Recommendations for new European loci* [6]: HUMTHO1, VWA, FGA, D8S1179, D18S51, D21S11, D2S1338, D3S1358, D16S539 and D19S433.

   For each batch of consumables, a sample shall be tested from which no individual sample shall have either more than 2 allelic peaks of greater than 50 relative fluorescence units (rfu) or the threshold value for calling a heterozygote allele peak by the analytical method used, as reproduced by replicate analysis; or

b) using a quantification test specific for human DNA, where the quantifiable DNA does not exceed 50 pg of DNA for the whole volume of extract.

   The test shall be demonstrated to have the sensitivity to detect at these levels.

The manufacture of a consumable used in DNA reference sample analysis shall conform to **A.1** and **A.3**.

3.2.3 Consumable used in DNA casework sample analysis

A consumable used in DNA casework sample analysis shall have no detectable human DNA under the following conditions by either using:

a) enhanced PCR and analysis conditions, such as increased cycle number and/or increased capillary injection [7] for the STR profiling kit used, for determining a minimum of ten STR loci contained within the paper, *The evolution of DNA databases – Recommendations for new European loci* [6]; or

b) an alternative multiplex STR kit demonstrated to have the equivalent sensitivity under the manufacturer's recommended conditions as obtained using the methods given in a).

For each batch of consumables, samples shall be tested from which no individual sample shall have either more than 1 allelic peak of greater than 50 relative fluorescent units (rfu) or the threshold value for calling a heterozygote allele peak by the analytical method used as reproduced by replicate analysis.

NOTE *The manufacturer should ensure that the samples tested are typically representative of the batch.*

The manufacture of consumables used in DNA casework sample analysis shall conform to all parts of Annex A.

3.2.4 Consumable used in gunshot residue analysis

A consumable used in gunshot residue analysis shall not have detectable primer residue particles as determined by scanning electron microscopy, and/or propellant residue as determined by mass spectrometry.

NOTE *A consumable used in gunshot residue analysis might only be for use in primer residue particles and others only for propellant residue. It is a requirement to provide information on a consumable's specific use [see **5.1**d)].*

3.2.5 Consumable used in the analysis of alcohol (ethanol) in blood or other body fluids

A consumable used in the analysis of alcohol (ethanol) in blood or other body fluids shall have a maximum concentration of alcohol of 0.1 mg/100 ml of body fluid, when calculated back to the concentration in the original body fluid.

3.2.6 Consumable used in the analysis of pharmaceutical or illicit drugs in biological matrices

A consumable used in the analysis of pharmaceutical or illicit drugs in biological matrices shall have a maximum drug/metabolite concentration in accordance with Table 1, when calculated back to the concentration in the original biological matrix.

NOTE *Such analysis is usually carried out using combined techniques, such as gas or liquid chromatography-mass spectrometry, after extraction of the target compounds from the matrix and a concentration step, or steps. Any contamination in or on the consumable could therefore also become concentrated. Table 1 shows a selection of drugs for which laboratories are required to be able to test in standard toxicology cases and the detection limits that they are required to achieve, expressed as ng of drug per ml of body fluid. It is required that any contamination present does not result in drug concentrations greater than those quoted in Table 1 when results are calculated back to the concentration in the original biological matrix. In some biological matrices, such as hair or oral fluid, detection limits and, therefore, the acceptable levels of contamination might be lower.*

3.2.7 Consumable used in the detection and analysis of accelerants

A consumable used in the detection and analysis of accelerants shall have no detectable flammable liquid and other volatile organic materials as determined by gas chromatography-mass spectrometry (GCMS) analysis.

3.2.8 Consumable used in the detection and analysis of particulates

A consumable used in the detection and analysis of particulates (e.g. fibre lifting tapes) and that comes into direct contact with the material shall have no detectable particulate matter including as a minimum glass, paint fragments, hairs and hair fragments including eyelash and eyebrow and fibres visible under low power microscopy.

3.2.9 Consumable used for the collection and transportation of exhibits

A consumable used for the collection and transportation of exhibits (e.g. paper sacks, tamper-evident bags) shall have no detectable particulate matter as specified in **3.2.8** visible by the naked eye.

3.3 Interference

3.3.1 General

It shall be demonstrated that the analyte is not compromised by any interferent (including the consumable itself) that could impact on the quality of analysis of the evidential material, and interpretation of the analytical results.

3.3.2 Consumable used in DNA analysis

A consumable used in DNA analysis shall have no detectable effect caused by:

a) polymerase chain reaction (PCR) inhibitors that affect the PCR amplification process;

   NOTE *Some integral components of collection/purification kits can inhibit PCR. However, these are reduced to a level that does not affect amplification, when used in accordance with the manufacturer's instructions.*

b) nucleases;

c) material that could interfere with detection and analysis of fluorescently labelled PCR product, such as fluorescent dyes; and

d) substances that cause unintentional alteration to DNA electrophoretic characteristics (e.g. high salt concentration).

3.3.3 Consumable used in gunshot residue analysis

A consumable used in gunshot residue analysis of primer residues shall have no detectable particulate debris including metallic particles.

A consumable used in gunshot residue analysis of propellant residue shall have no detectable organic chemical characteristic of propellant residue.

3.3.4 Consumable used in the analysis of alcohol (ethanol) in blood or other body fluids

A consumable used in the analysis of alcohol (ethanol) in blood or other body fluids shall have no detectable xylenes and other volatile substances that interfere with analysis of ethanol, determined by headspace gas chromatography (headspace GC).

Table 1 – Maximum drug/metabolite concentration in consumables

Drug/metabolite	Maximum permitted concentration ng/ml
Amphetamine, methamphetamine, MDMA, MDA	1
Cocaine, benzoylecgonine, methylecgonine, cocaethylene, ethylecgonine	1
THC-11-oic acid, THC, THC-OH and glucuronides	0.1
Morphine, morphine-3-glucuronide, morphine-6-glucuronide, diamorphine, 6-monoacetylmorphine, codeine (and glucuronide), dihydrocodeine (and glucuronide), pholcodine, methadone, EDDP (methadone metabolite)	1
Buprenorphine, norbuprenorphine	0.1
Diazepam, desmethyldiazepam, temazepam, oxazepam, chlordiazepoxide, alprazolam, phenazepam, flunitrazepam, lorazepam, midazolam, clonazepam, nitrazepam (and glucuronides), 7-aminoflunitrazepam, 7-aminonitrazepam, 7-aminoclonazepam	0.1
Ketamine, norketamine	1
Mephedrone, methylone, naphyrone, butylone, MDPV	1
BZP, TFMPP, m-CPP	1
Amitriptyline, nortriptyline, dothiepin/dosulepin, fluoxetine, paroxetine, venlafaxine, fluvoxamine, citalopram, sertraline, trazodone, mirtazepine (and normetabolites)	1
Zopiclone, aminochloropyridine, zolpidem, zaleplon	0.1
Quetiapine, olanzapine, chlorpromazine, clozapine	0.1
Paracetamol, aspirin	10
Tramadol (and metabolites), oxycodone, dextropropoxyphene, norpropoxypheneamide	1
Fentanyl	0.1
Phenytoin, carbamazepine, lamotrigine, valproate	2
Diphenhydramine, chlorphenamine, hydroxyzine, promethazine	2
Propranolol, atenolol	2
GHB/GBL	100
Amobarbital, butobarbital, phenobarbital, pentobarbital, secobarbital	2
Sildenafil, tadalafil, vardenafil	1
NOTE *These data have been sourced from the National Forensic Framework Agreement for consumables (a restricted access document) and a response to that Framework by the Forensic Science Service (FSS) in terms of acceptable concentrations of contaminants for compliance with the Framework requirements.*	

3.3.5 Consumable used in the analysis of pharmaceutical or illicit drugs in biological matrices

A consumable used in the analysis of pharmaceutical or illicit drugs in biological matrices shall not leach detectable levels of plasticizers (such as bungs in vials) that can interfere with gas chromatography-mass spectrometry (GCMS) and liquid chromatography-mass spectrometry (LCMS) analyses.

3.4 Traceability and evidential continuity

3.4.1 Traceability

The source, history and traceability of all materials shall be known, documented and controlled to ensure that the consumable meets the requirements of this PAS.

3.4.2 Evidential continuity

A consumable used as a container shall be designed such that it can be labelled.

***NOTE** This can be through an integrated adhesive (e.g. bar code) or tie-on label large enough to bear appropriate details relating to the origin of the sample that are handwritten or printed with an indelible medium.*

3.5 Integrity

3.5.1 A consumable used for the collection of material shall be able to withstand normal handling. For a consumable used in the collection of perishable materials that are frozen, the consumable shall have structural resilience to freeze-thaw cycles.

***NOTE 1** It might be necessary to freeze material (such as liquid blood) during transportation and storage to avoid degradation.*

***NOTE 2** Glass should be avoided where possible due to loss of integrity through breakage, and subsequent risks to safety of personnel through physical injuries and exposure to biohazards.*

3.5.2 Structural integrity of a consumable used as a container shall be designed to ensure that material is not lost or compromised through substances leaching into or out of the container.

***NOTE** This includes engineering aspects such as the fit of a screwed or push-on cap, and chemical resistance of the materials of construction to the sample contained within it.*

3.5.3 Where a kit includes a consumable used as a tamper-evident container, the tamper evident container shall have a seal or other mechanism that:

a) indicates that it has been sealed;

   ***NOTE** This may be, for example, by a change of colour or by the removal of an identifiable strip.*

b) after being sealed, indicates if it has been tampered with.

   NOTE This may be, for example, by a permanent change in appearance following the opening of the container.

3.6 Preservation of liquid materials for forensic analysis (kits)

3.6.1 A kit for body fluid collection and retention in liquid form shall include:

a) where preservatives are required, preservatives of appropriate concentration to be used to preserve the material immediately after collection and during transportation and storage of the material;

b) instructions on use of the kit including information on how samples are correctly and stably stored during collection and during transfer to the laboratory.

3.6.2 A kit for body fluid collection shall not compromise the preservation of the analyte during refrigerated storage.

***NOTE 1** A kit for body fluid collection used for testing alcohol in blood or urine should include sodium fluoride in sufficient quantity to provide a minimum of 1.5% w/v sodium fluoride in solution based on the effective volume when the container is full.*

***NOTE 2** A kit for body fluid collection used for blood sample collection should include an anti-coagulant, such as potassium oxalate, in sufficient quantity to provide a concentration of 1% w/v based on the effective volume when the container is full.*

3.7 Health and safety

3.7.1 Hazard warnings shall be provided for consumables together with instructions as to storage, normal handling and disposal of consumables, where these pose a potential health and safety risk.

3.7.2 A consumable shall not become physically compromised during storage, and normal handling.

***NOTE 1** Attention is drawn to the IATA Packing Instruction 650 [8], which applies to UN 3373 (i.e. biological substances transported for diagnostic or investigative purposes).*

***NOTE 2** Medical examination devices designed to assist in the recovery of evidence from human bodies should conform to BS EN ISO 13485.*

3.7.3 A consumable (including packaging) used for the transportation of sharp items shall be of appropriate design and of sufficient structural strength to minimize the risk of injury to personnel.

4 Manufacturing of the consumable and assembly of the kit

***NOTE** Clause **4** applies to the in-house manufacture/assembly of consumables/kits and any subcontracted manufacture/assembly of components of consumables/kits.*

4.1 Risk assessment

4.1.1 The manufacturer/assembler shall establish and document a product-specific risk assessment of the manufacturing/assembly processes, which shall be reviewed no less than once a year.

***NOTE** Personnel conducting the risk assessment should be suitably qualified, experienced and familiar with the manufacturing/assembly process being assessed.*

4.1.2 The risk assessment shall identify and evaluate any risks of contamination in the manufacturing/assembly process and the actions to mitigate and control these risks.

***NOTE 1** This is to ensure that risks to users, customers, employees, other equipment and the work environment are evaluated and mitigated.*

***NOTE 2** Risk analysis should draw from a variety of data sources (e.g. customer complaints and/or past experience with similar products, field data, risks identified during the development process) and may use a range of suitable assessment methodologies, for example, hazard analysis critical control points (HACCP) and failure modes and effects analysis (FMEA).*

4.1.3 The risk assessment shall be used to inform the definition of the manufacturing/assembly process(es) and equipment (see **4.2**).

4.1.4 The manufacturer/assembler shall maintain records which document and track the analysis and mitigation of identified risks.

4.2 Manufacturing/assembly process and equipment

***NOTE** Interaction of personnel with production lines should be minimized through use of automated processes.*

4.2.1 The manufacturer/assembler shall define and document:

a) the manufacturing/assembly processes and equipment to be employed to meet the requirements specified in Clause **3**;

b) the stages of the manufacturing/assembly process that pose a risk of contamination to a consumable/kit and the necessary actions to implement in order to mitigate those identified;

c) the acceptance criteria for tests used for validating the consumable/kit meets the requirements specified in Clause **3**.

4.2.2 The manufacturer/assembler shall define and document in accordance with the risk assessment:

a) the work environment conditions for each workspace; and

b) documented procedures to clean, monitor and control (see **4.3**) these work environment conditions to avoid contamination.

4.2.3 Access to a workspace where it has been identified that there is a risk for the occurrence of contamination (see **4.1**) and access during manufacture of each batch of consumable/kit shall be controlled and recorded.

***NOTE** This includes controlling and recording access of personnel working on a regular basis in the production line as well as any individual, who accesses the workspace on occasion (e.g. an engineer). This data can be used when dealing with a contamination incident [see **4.3**f)].*

4.2.4 For each batch of consumables/kit, the personnel involved in its manufacture/assembly shall be recorded.

4.2.5 A workspace for which a risk of contamination has been identified (see **4.1**) shall have a production line and layout that enables a unidirectional flow of the consumable/kit. It shall have a positive air pressure and high-efficiency particulate air (HEPA) filters over air inlets.

4.3 Cleaning regime and environmental monitoring

A cleaning regime shall be specified for each workspace in accordance with the findings of the risk assessment (see **4.1**), including as a minimum:

a) frequency of cleaning;

***NOTE** Frequency can vary for work surfaces, floors, manufacturing/assembly equipment and cleaning equipment.*

b) use of disinfectants and cleaning agents;
c) use of cleaning equipment;
d) use of barrier clothing (see also **4.4**);
e) the cleaning procedures (work instructions);
f) the cleaning procedures to be taken in the event of contamination of the workspace and/or the consumable/kit;
g) the competencies and training required by personnel to undertake the cleaning (see also **4.5**).

NOTE *As part of the validation of a cleaning regime, the manufacturer/assembler may use decontaminants and decontamination procedures that have been proven by others, to be effective against the substances which would constitute contamination. The initial research data should be included as part of the manufacturer's/assembler's documentation.*

4.4 Barrier clothing

4.4.1 The barrier clothing to be employed shall be specified and its efficacy shall be demonstrated.

NOTE *Each workspace might have different barrier clothing requirements depending on the manufacturing/assembly activity being carried out and the level of automation of the process.*

4.4.2 Where barrier clothing is required, a segregated area shall be provided for personnel to change into/out of the required barrier clothing.

4.4.3 A cleaning regime shall be specified for the barrier clothing.

NOTE *For reusable barrier clothing, such as lab coats, there should be control measures in place to ensure that carry-over or build-up of contaminants due to previous use are prevented.*

4.4.4 Personnel shall be given training in the use of barrier clothing.

NOTE *For example, where gowns are specified for use in a defined workspace, personnel require training in gowning procedures.*

4.4.5 The use of barrier clothing and the implementation of the cleaning regime shall be recorded.

4.5 Personnel

4.5.1 The manufacturer/assembler shall identify and document the competencies and training required by personnel to undertake the cleaning regime and the manufacturing/assembly activities.

4.5.2 Personnel shall be trained on their role and duties in the cleaning regime and the manufacturing/assembly activities.

4.5.3 Personnel shall also be trained on the aspects of the risk assessment (see **4.1**) relevant to their role and duties including measures to be taken to avoid introduction of a potential contaminant or interferent to a batch of consumables/kits.

NOTE *Training provided depends on the consumable/kit being manufactured/assembled, the work environment and level of interaction of personnel with the production line. For example, in the case of consumables for gunshot analysis, awareness training should be provided that includes risks of contamination posed by recreational use of guns, fireworks, and other activities that might create primer type particles.*

4.5.4 Training received and other documentation to demonstrate that the specified competences have been achieved shall be recorded for all personnel.

4.6 Assembly of a kit

The organization shall establish and implement inspection or testing to verify that the individual consumables in the kit meet the requirements for performance as specified in Clause **3** and for manufacturing as specified in **4.2**.

NOTE *Testing can be carried out by either the assembler or the manufacturer. Where the manufacturer carries out the testing, the assembler is responsible for obtaining verification that it has been tested.*

5 Provision of information to the end user

5.1 General information

The manufacturer/assembler shall provide information with the consumable/kit, which includes but is not limited to the following:

a) batch number or other unique identifier (see **3.4.1**);

b) name of consumable/kit and product code;

c) expiry date and required storage conditions for consumables subject to deterioration over time or that require special storage conditions;

d) its intended use and specific uses for which it is not intended, or does not meet the specification.

NOTE *For example, a consumable that has been demonstrated as suitable for use in DNA reference sample analysis only, may not meet the requirements for a consumable used in DNA casework sample analysis.*

5.2 Further information

The manufacturer/assembler shall make available to end users by request the following information:

a) technical description of the consumable/kit (e.g. technical specification);

b) an outline of anti-contamination measures taken;

c) tests carried out, results and the limits of detection of the technique and technology used;

d) where applicable, the accreditation status of any third-party testing.

6 Quality management system

6.1 General requirements

The manufacturer/assembler shall establish, document and maintain a quality management system that demonstrates control of their personnel, processes and equipment.

NOTE Assessed capability. *Users of this PAS are advised to consider the desirability of quality system assessment and registration against the appropriate standard in the BS EN ISO 9000 series by an accredited third-party certification body.*

6.2 Documentation

6.2.1 The quality management system documentation shall include:

a) documented statements of a policy and objectives relevant to this PAS;

b) documents needed by the organization to ensure the effective planning, operation and control of its processes;

c) for each consumable or kit, a record either containing or identifying documents defining product specifications and quality management system requirements for the complete manufacturing or assembly process, including quality assurance and quality control measures deployed;

d) traceable evidence of conformity to requirements for each batch of consumables or each consumable within a kit by means of quality control testing;

NOTE *Testing can be carried out by the manufacturer, assembler or third party.*

e) evidence to support stated shelf life (expiry date) and storage instructions;

f) evidence of a continuous improvement ethos and openness to address quality issues;

g) documented supplier approval process and an approved suppliers list with the manufacturer's requirements and specifications for the supplies.

6.2.2 The documentation shall be reviewed at a minimum every 4 years.

NOTE *Some documents might need to be reviewed more frequently.*

6.3 Record retention

Records shall be maintained regarding the manufacture and testing of each batch of consumables for a period of time equivalent to or greater than the shelf life of the consumables.

NOTE *Records should be retained for a minimum of 7 years. Where a batch of consumables has a shelf life of more than 7 years, they should be retained for a period of time at a minimum equivalent to or greater than their shelf life. Ideally, all records, including DNA profiles (see* ***A.3****, Note 4), should be retained for 30 years so that they can be used in appeals and cold case reviews.*

6.4 Monitoring

The characteristics of the consumable/kit shall be monitored and measured to verify that consumable/kit requirements (see Clause **3**) have been met. Evidence of conformity with the acceptance criteria shall be maintained.

6.5 Non-conforming consumable or kit

There shall be a defined process for the control of non-conforming products. Where a non-conforming consumable or kit is identified, it shall be controlled to prevent its unintended use and the end users impacted shall be notified.

NOTE 1 *Non-conforming products include those that do not meet the requirements of Clause* ***3*** *and Clause* ***4****.*

NOTE 2 *Non-conforming products may be disposed of, quarantined and/or recalled.*

6.6 Continuous improvement

The manufacturer/assembler shall establish, document and maintain an improvement, corrective and preventative action process.

NOTE *The manufacturer/assembler should ensure continuous improvement in response to appropriate customer feedback including complaints and to instances of non-conformity and, in addition, be proactive in improving their processes, for example, through the assessment of risk, validation and product review.*

Annex A (normative)
Specific anti-contamination requirements for DNA consumables and kits

*This Annex specifies requirements for consumables used in DNA testing, which are additional to those given in Clause **3** to Clause **6**.*

***NOTE 1** Because forensic DNA testing typically analyses human DNA at extremely sensitive levels, this poses unique challenges to the manufacture of consumables free of contaminating DNA from manufacturing staff. Hence a multi-stage approach is applied. This entails firstly manufacturing consumables under conditions that minimize the potential to introduce human DNA contamination (see **A.1**). The second stage is to reduce any potential contamination to levels which are unlikely to interfere with subsequent analysis and interpretation of forensic samples (see **A.2**). This is applied to all consumables for casework samples apart from liquid consumables (see Note 3), and it also does not apply to consumables for reference samples. The last stage is to enable checks to be made against the DNA of manufacturing staff so that if any DNA still persists after the second stage, it can be identified as contamination by checking procedures (see **A.3**).*

***NOTE 2** Liquid consumables (see Note 3) are not readily amenable to procedures to reduce DNA dosage (see **A.2**). However, contamination in liquids is also more evenly spread, therefore quality control testing at the end of the first stage is a satisfactory minimum requirement.*

***NOTE 3** Uniform DNA contamination is where the DNA contaminant is evenly dispersed. This can be encountered in consumables that are liquids.*

Examples of liquid consumables include but not limited to:

a) wetting solutions used to moisten collection swabs;

b) buffers supplied with DNA extraction kits; and

c) PCR multimix solution used in the amplification of DNA as part of the DNA analysis process.

Anti-contamination measures are required at two stages to both minimize its occurrence and maximize the detection of contamination if it occurs:

*i) contamination avoidance during manufacturing and kit assembly and packaging (see **A.1**);*

*ii) provision of DNA profiles for contamination detection (see **A.3**).*

***NOTE 4** Sporadic DNA contamination is where the DNA contaminant is unevenly distributed. It can occur on or in solid (as opposed to liquid) consumables.*

Examples of solid consumables include but are not limited to:

a) swabs and tapes used to recover biological evidential material;

b) forensic medical examination kits;

c) tweezers, scissors and scalpel blades;

d) the containers in which samples are transported to the laboratory;

e) pipette tips, plastic tubes, microtitre plates and seals; and

f) purification columns used in the DNA analysis process.

During manufacture, personnel might sporadically contaminate individual items within a batch with their own DNA, for example, by shedding biological material, such as dandruff or other skin-flakes, or depositing DNA either in droplets of saliva or sweat, or by transferring DNA on to surfaces by touching them with hands on which DNA from sweat and saliva might have accumulated.

Sporadic contamination poses special challenges in quality assurance because:

1) testing of consumables and kit components for DNA contamination is destructive; and

2) testing a large number of samples within a batch could still fail to detect low-level sporadic contamination events within a manufactured or assembled batch of materials.

Anti-contamination measures are required at three stages to both minimize its occurrence and maximize the detection of contamination if it occurs:

*i) contamination avoidance during manufacturing and kit assembly and packaging (see **A.1**);*

*ii) DNA contamination dosage reduction (see **A.2**);*

*iii) provision of DNA profiles for contamination detection (see **A.3**).*

A.1 Contamination avoidance during manufacturing and kit assembly

NOTE Interaction of personnel with manufacturing lines should be minimized through use of automated processes.

A.1.1 Cleanroom class

For each workspace identified as a risk, there shall be positive airflow through HEPA filters, equivalent to ISO class 7 (see BS EN ISO 14644-1:2012) where open product is handled.

*NOTE 1 The risk assessment (see **4.1**) is used to identify additional requirements for ISO-classified work environments. For example, BS EN ISO Class 8 (see BS EN ISO 14644-1:2012) may be used for an assembly work environment.*

NOTE 2 BS EN ISO 14644 series covers the classification (i.e. ISO Class 1 to 9), specification and testing of cleanrooms. Cleanrooms are enclosed spaces where air quality is managed to reduce dust, microbes, and other airborne contaminants to minimal levels.

A.1.2 Cleaning regime and environmental monitoring

NOTE 1 Use of techniques that destroy DNA (e.g. ultraviolet light, specialist detergents) should be applied and should not introduce interferents or compromise the structural integrity of the consumable/ kit and/or the work environment.

*NOTE 2 Sensitivity of the analytical technique for assessing the cleaning should be of an equivalent level of detection as those specified in **3.2.2**.*

A.1.3 Barrier clothing

For all work environments identified as a risk, barrier clothing shall include as a minimum gloves, gowns, masks and coverings for hair and feet.

A.1.4 Personnel

Personnel shall be trained on their role and duties in the cleaning regime and the manufacturing/assembly activities in clean rooms.

All personnel with access to the work environments, regardless of job function, shall submit a DNA sample to the organization in accordance with **A.3**.

A.2 DNA contamination dosage reduction of a consumable used in DNA casework (not including liquid consumable)

Following consumable manufacture or kit assembly, any DNA contamination which might have occurred during these processes shall be reduced by the following.

a) Consumables that in use come into physical contact with the evidential sample shall be subject to physical or chemical treatment that reduces the amount of contaminating DNA, to the levels specified in **3.2.3**.

   *NOTE 1 This assurance can be provided by pre- and post-treatment assessment of control DNA samples seeded throughout the batch, equivalent to a worst case scenario anticipated in a cleanroom work environment (e.g. spike positive controls with 10 ul of neat saliva), and observe levels of contamination that meet batch acceptance criteria defined in **3.2.3**. Alternatively, a different measure may be used, such as measuring orders of magnitude reduction in DNA profile peak height for a control DNA extract of defined concentration, provided this is demonstrated to correlate to the same dosage reduction effect as for the aforementioned 10 ul saliva control samples.*

   NOTE 2 Treatment with ethylene oxide may be used as a chemical means to reduce contaminating DNA dosage. This is outlined in Archer et al 2010 [9].

b) The DNA dosage reduction treatment shall not introduce interferents (as specified in **3.3.2**), or negatively impact in any other way on the performance of the kits and consumables. This shall be demonstrated through performance testing of treated consumables.

c) The DNA dosage reduction treatment shall be validated to meet parameters a) and b) and the validation details shall be made available on request.

d) The organization shall maintain records of the process parameters used for post-manufacturing DNA dosage reduction for each batch of consumables and kits, together with testing results for each batch in order to demonstrate that the requirement has been met.

e) If there is any manipulation post treatment, the consumable shall be re-tested for DNA contamination in accordance with **3.2.3**.

A.3 Collection of DNA profiles for contamination detection

Manufacturers and assemblers shall establish and maintain a collection of DNA profiles from all personnel with access to the manufacturing/assembly work environment and pose a risk of contaminating the consumables with their own DNA.

NOTE 1 *The risk assessment (see **4.1**) should be used to establish the scope of the DNA profile collection. For example, personnel who are involved in physically handling the consumables, as opposed to others who are only interacting with items after they have been packed into their outer packaging.*

Manufacturers shall define processes by which the DNA profiles are collected and maintained including their use in investigating potential contamination incidents, and making available the results of internal investigations following a contamination incident or complaint.

NOTE 2 *These profiles can be provided to end users in an anonymized form to create a manufacturer's elimination database (MED) of DNA profiles for routine screening for contamination in crime stain profiles. Alternatively, manufacturers and assemblers may provide DNA samples from the relevant personnel, which end users may then profile to generate a MED.*

NOTE 3 *Attention is drawn to the requirements of the Data Protection Act 1998 [10] and the Human Tissue Act 2004 [11].*

NOTE 4 *DNA profiles should be retained for a minimum of 30 years (see **4.2.4** and **6.3**).*

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For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

BS 6002-1, *Sampling procedures for inspection by variables – Part 1: Guide to single sampling plans indexed by acceptance quality limit (AQL) for lot-by-lot inspection for a single quality characteristic and a single AQL*

BS EN ISO 9000, *Quality management systems – Requirements*

BS EN ISO 13485, *Medical devices – Quality management systems – Requirements for regulatory purposes*

BS EN ISO 14644 (series), *Cleanrooms and associated controlled environments*

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Further reading

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Useful websites

BSI
www.bsigroup.com

Forensic Science Regulator
www.homeoffice.gov.uk/agencies-public-bodies/fsr

Faculty of Forensic and Legal Medicine
www.fflm.ac.uk

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