Guidance

The Control and Avoidance of Contamination in Laboratory Activities involving DNA Evidence Recovery and Analysis

FSR-G-208

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1. **INTRODUCTION**

1.1.1 For the purposes of this appendix, contamination is defined as “the introduction of DNA, or biological material containing DNA, to an exhibit or subsample derived from an exhibit at or after the point when a controlled forensic process starts”. This is distinct from the adventitious transfer of biological material to an exhibit that can also occur, usually prior to the exhibit or sample being recovered\(^1\) and before investigative agencies have intervened.

1.1.2 From a forensic science perspective, crime investigation activities can be considered as two distinct phases:

a. the pre-submission phase (scene/victim/suspect) during which investigative agencies are involved in locating, recovering, packaging, storing and transporting exhibits; and

b. the analytical phase (laboratory) in which the recovered exhibit is processed within a laboratory.

1.1.3 Contamination can occur at any point in these investigation phases. The principal sources of DNA contamination are:

a. from personnel to the exhibit/DNA sample;

b. from contaminated equipment or consumables, for example, swabs, tubes, personal protective equipment (PPE) to the exhibit/DNA sample; and

c. from exhibit to exhibit or DNA sample to DNA sample.

1.1.4 Contamination may occur as follows:

a. directly,\(^2\) for example, saliva or dandruff from an examiner falling on to an exhibit; or

b. indirectly,\(^3\) for example, biological material present on the outside of exhibit packaging being transferred on to the gloves of an examiner who opens the package and fails to change their gloves before handling the contents, resulting in the indirect transfer of contamination to the exhibit.

1.1.5 Anti-contamination measures fall into two core areas of activity.

\(^1\) Often referred to as background DNA.

\(^2\) Also described as primary transfer.

\(^3\) Also described as secondary transfer.
a. Prevention of contamination as far as is practicable. Preventative measures include:
   i. minimising the chance of contamination occurring by, for example, staff using barrier clothing;
   ii. ensuring effective separation of exhibits from different scenes and individuals;
   iii. restricting access to areas containing exhibits;
   iv. cleaning laboratory surfaces;
   v. rendering consumables ‘human DNA free’/forensic DNA grade;
   vi. ensuring that equipment used at scenes of crime is adequately decontaminated between scenes; and
   vii. ensuring that trained staff follow standard operating procedures (SOPs) and work using anti-contamination measures.

b. Detection of contamination. This primarily entails:
   i. comparing DNA profiles generated from items against elimination databases containing DNA profiles from personnel from whom there is a significant risk of contamination (see FSR-P-302, Forensic Science Regulator);
   ii. cross-checking profiles within the same batch of samples and from different batches of samples processed within the same laboratory; and
   iii. investigating unexpected results.

1.1.6 It is recognised that DNA contamination incidents cannot be eliminated completely, given the prevalence of human DNA within the living and working environment, and the issue is exacerbated by the increasing sensitivity of DNA analytical techniques. Therefore, an effective DNA anti-contamination process requires a combination of approaches both to minimise the risk of occurrence and to maximise the ability to detect contamination (Lapointe et al., 2015) when it does occur.

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2. SCOPE

2.1.1 This appendix provides requirements, guidance and recommendations primarily on anti-contamination measures for the analytical phase of investigations, namely the control and avoidance of contamination in laboratory activities involving DNA evidence recovery and analysis.

2.1.2 This builds on section 19.2 of the Forensic Science Regulator’s (FSR’s) Codes of Practice and Conduct for Forensic Science Providers and Practitioners in the Criminal Justice System and section 7 of the DNA Analysis, appendix to the Codes, FSR-C-108 (Forensic Science Regulator).

2.1.3 Both prevention and detection of contamination within the laboratory are included in this appendix and should be used in conjunction with DNA contamination detection: The management and use of DNA elimination databases, FSR-P-302 (Forensic Science Regulator) which provides guidance and requirements for the elimination databases required for the complete criminal investigation process, including laboratory activities.

2.1.4 Laboratories that use drying cabinets/rooms should comply with the requirements as set out in The control and avoidance of contamination in crime scene examination involving DNA evidence recovery, FSR-G-206 (Forensic Science Regulator, in draft) when published.

2.1.5 The interaction of the FSR’s guides together with the consumables’ standards (PAS 377:2012 and ISO18385:2015) is shown in Figure 1.

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5 The Codes
2.1.6 Forensic laboratories undertaking DNA recovery and/or analysis are required to demonstrate compliance with the requirements within this document and demonstrate a review of the recommendations. This will be reviewed and assessed as part of the ISO/IEC 17025:2005 assessment. Therefore any alternative approaches to the recommendations adopted by laboratories shall be demonstrated to be justifiable.

2.1.7 This appendix applies to England and Wales. Scotland and Northern Ireland should also institute parallel arrangements for those jurisdictions.

3. IMPLEMENTATION

3.1.1 This appendix is available for incorporation into a forensic science provider’s quality management system from the date of publication. This guidance comes into effect from 6 April 2016.

4. MODIFICATION

4.1.1 This is the first issue of this document.

5. TERMS AND DEFINITIONS

5.1.1 The terms and definitions set out in the following documents also apply to this guidance.

a. Codes of Practice and Conduct for Forensic Science Providers and Practitioners in the Criminal Justice System (Forensic Science Regulator).

Figure 1: Interaction of anti-contamination guidelines
b. *DNA Analysis, appendix to the Codes*, FSR-C-108 (Forensic Science Regulator).

c. *DNA contamination detection: The management and use of staff elimination DNA databases*, FSR-P-302 (Forensic Science Regulator).

d. *The control and avoidance of contamination in crime scene examination involving DNA evidence recovery*, FSR-G-206 (Forensic Science Regulator, in draft).

e. See also Abbreviations and the Glossary 16 at the end of this appendix.

5.1.2 Although this document is presented as guidance, it is written using the language of a standard. This is because from October 2017 the requirements set out in this guidance will be mandatory as codes of practice. In addition, any new laboratory build commencing post-December 2015 will be required to meet the standard as set out in this appendix.

5.1.3 The word ‘shall’ has been used in this document where there is a corresponding requirement in ISO/IEC 17025:2005 or the Codes the word ‘should’ has been used to indicate generally accepted practice and the word ‘may’ has been used for recommendations. Recommendations have been used to indicate what ideal practice is when it is practicable.

6. **METHODS AND PROCEDURES (ISO/IEC 17025:2005 ref. 5.4.3, 5.4.5)**

6.1 **Overview**

6.1.1 Where the method has been designed or determined, whether this is new or a modified process that is intended for introduction into casework, there shall be an assessment to identify any risks or potential risks to the criminal justice system (CJS) related to its use (The Codes, ref 20.4.1).

6.1.2 This should ideally be undertaken at the design stage and include identification of components within the overall process that represent a significant risk in terms of contamination. Steps shall then be taken, as far as is practicable, to design out both the opportunities and mechanisms by which contamination can occur.
6.2 Reducing Risk by Design

Generic

6.2.1 In general terms, segregation between activities is the single most effective measure for the avoidance of contamination. For DNA processes this includes the following.

a. Segregation of the processing of casework and reference material (for example, reference samples from individuals) – separate dedicated laboratories, equipment and personnel (8.2) shall be utilised.

b. Minimise contamination by polymerase chain reaction (PCR) product of upstream processes by:

   i. segregation of pre-PCR (DNA amplification stage) and post-PCR processing – separate dedicated laboratories, equipment and personnel shall be utilised and staff may only transfer from a post-PCR area to a pre-PCR area in the same day if they change their outer clothing; or

   ii. utilise a validated\(^7\) fully automated enclosed DNA analysis system in which samples, once loaded, are automatically extracted and amplified without human intervention.

c. Segregation between high yield (for example, a heavily bloodstained garment) and low yield (for example, ‘touch’ or trace DNA) items at any stage of their examination and processing, by utilising separate search and recovery areas as far as possible, and by processing in different batches.

Minimising Manual Processing

6.2.2 The risk of contamination from an operator’s DNA should be minimised by making the best use of robotic handling devices, thereby minimising human contact.

\(^7\) Validation of integrated extraction and amplification systems shall determine contamination vulnerability order to inform, but not limited to, batch size, spatial arrangements and batch monitoring requirements.
Batch Processing (DNA Sample to DNA Sample Contamination)

6.2.3 To ensure efficient operation, DNA samples are almost always processed in batches. Reducing risk of sample to sample contamination is primarily achieved by minimising the opportunities for occurrence through process design, including the following.

a. Minimise the time that samples are held in open receptacles such as unsealed microtitre plates and uncapped microfuge tubes.

b. Minimise the opportunity for sample to sample transfer by keeping batch sizes manageable:

   i. for processing reference samples, large batches using a full microtitre plate are manageable;

   ii. for processing samples for low template analysis the number of samples in a batch should be substantially smaller than that used for reference sample processing, and spatial separation between samples in a batch should be maximised by using individual tubes or a proportion of wells in a microtitre plate.

c. Design robotic handling so that samples are processed in a sequential fashion, ensuring that no sample is moved above another unprotected sample whilst, for example, being transferred in a pipette tip.

d. Pay careful attention to the detailed programming of sample manipulation steps in automated systems such as pipetting and centrifugation, both in terms of transferring samples and in mixing, to avoid splashing, dripping or the creation of aerosols.

e. Where samples are stored in microtitre plates, the mechanisms used for sealing plates shall ensure that a watertight seal is maintained, and that contamination risks are minimised on re-sampling from individually sealed wells, for example, by including a spin stage to remove any liquid from the internal surface of the seal prior to re-sampling.
f. Ensure that effective cleaning procedures (Ballantyne et al., 2015\(^8\); Kings College London and Metropolitan Police Service, 2015\(^9\)) are in place to minimise the risk of a build-up of background levels of DNA over time.

**Process Flow**

6.2.4 Access to DNA clean areas including lobbies shall be controlled and only permitted for individuals who have submitted a DNA sample for inclusion on the laboratory’s elimination database.

6.2.5 To reduce the migration and introduction of contaminants, DNA clean areas should not be used as a through corridor and the number of people accessing the area should be kept to a minimum.

6.2.6 Samples and associated materials such as carrying racks should ideally be moved from pre-PCR areas to post-PCR areas by means of a service hatch, with separate in and out doors, as a means of preventing contamination of pre-PCR areas with PCR product. Movement of items in the reverse direction shall be minimised and only after thorough decontamination.

6.3 **Evaluation of New Processes for Effectiveness of Anti-Contamination Measures**

6.3.1 Once a new or modified process intended for introduction into casework has been developed, prior to its implementation it shall be validated in accordance with the Codes. This includes an assessment to identify any risks or potential risks to the CJS related to its use that it has not been possible to eliminate by process engineering as detailed above. For any processes that are linked to DNA analysis, this risk assessment shall include the following.

a. Consideration of contamination, the acceptable levels of which shall be defined in:

i. the end user requirements; and

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\(^9\) Kings College London and Metropolitan Police Service (2015) *Cleaning project*. Personal communication to the Forensic Science Regulator DNA specialist group, 10 July 2015.
ii. the acceptance criteria that must be met in the formal validation of the technique prior to implementation.

b. Evaluation of the impact of introducing technology that increases the sensitivity of the DNA analysis process compared with existing processes is crucial, as this also inevitably increases the detection of contamination.

c. Each validation exercise shall be designed to test the method or system under consideration against the minimum requirements for that method or system. However, the following examples of elements of validation exercises are useful for evaluating contamination risk:

i. testing automated pipetting systems by processing ‘chequer-boards’ – microtitre plates (or equivalent plate or tube layout used by the system) where negative controls and positive samples are arranged alternately across the plate – the positive samples here should represent the ‘worst case scenario’, that is, the highest sample concentration expected to be encountered using the system;

ii. evaluations of all negative controls on every batch of samples run throughout the validation exercise, and comparison with existing systems;

iii. evaluation of all positive samples on each batch of samples run throughout the validation exercise to assess whether minor components could be from contamination, and comparison with existing systems;

iv. checking for operator contamination throughout the validation exercise;

v. checking for contamination from consumables throughout the validation exercise – evaluating all new consumables used in the process and designing suitable quality assurance/control (QA/QC) procedures;

vi. where contamination is identified in the validation work, the root cause should be investigated and identified, and modifications made to the process to minimise the risk of recurrence.

6.3.2 Once a new system or method has been implemented, a post-implementation review should be carried out after an appropriate interval. This shall include
detailed evaluation of any contamination observed and any resulting requirements for modifications to procedures.

7. LABORATORY DESIGN AND LAYOUT (ISO/IEC 17025:2005 ref. 5.3)

7.1 Overview

7.1.1 Areas for examining, extracting DNA and post-DNA amplification polymerase chain reaction analysis areas shall be kept physically separated as the containment of post-DNA amplification product is of great importance. Likewise, processing of casework and reference samples shall also be kept physically separated.

a. Fully automated rapid DNA analysis systems are emerging that integrate the processes undertaken in both pre- and post-PCR laboratories without human intervention and in a single instrument. The requirement remains for PCR product to be kept physically separated from pre-PCR stages of the process even within the instrument, and this shall be demonstrated through extensive validation of the instrument in question.

b. Regarding the room within which these new analysis systems operate, the forensic science provider shall demonstrate that all stages, including disposal of waste from the instrument, minimise the risk of PCR product generated from previously processed samples contaminating items in subsequent batches within the live operating environment.

7.1.2 In essence a DNA clean area is a room or specified enclosed area or cabinet that can be easily cleaned, and that is kept clean using validated cleaning procedures. This is facilitated by, for example, avoiding dust-traps. Ideally this should be compliant with BS EN ISO 14644 Class 7 standards.

7.1.3 The requirements for a DNA clean area are detailed in 7.2 to 7.9.

7.2 Structure

7.2.1 DNA clean areas shall have a designated area for gowning up, a separate lobby area (7.8) is the ideal practice.\(^{10}\)

\(^{10}\) Laboratory build post-December 2015 shall be required to meet the ideal practice as standard.
7.2.2 Entry into and exit from the DNA clean area is only through the lobby (designated gowning) area, and access shall be controlled, for example, by an electronic swipe card system.

7.2.3 Walls should be of smooth finish, sealed and resistant to degradation from frequent cleaning.\textsuperscript{11}

7.2.4 Floors should ideally be of a readily cleanable laboratory standard material, for example, vinyl, fully sealed, and it is recommended that it continues part way up adjoining walls to facilitate cleaning.

7.2.5 Ideally the edges between the floors, walls and ceilings utilise coving that provides a smooth curved join rather than a right angle, to facilitate cleaning by avoiding crevices.

7.2.6 Ideally ceilings are made of a material resistant to degradation from frequent cleaning, for example, laminated tiles of smooth finish.

7.2.7 Window glazing shall be sealed to prevent draughts and ideally the sills slope downwards with an easily cleanable surface. Where blinds are required, ideally these should be on the outside of the window.

7.3 Furniture

7.3.1 Bench surfaces shall be sealed and of laboratory grade, resistant to chemicals such as strong acids, alkalis and solvents, and withstand frequent cleaning.

7.3.2 White benching is recommended, to facilitate cleaning.

7.3.3 Laboratory chairs shall be height adjustable and covered in a non-porous material such as vinyl, which can withstand frequent cleaning.

7.3.4 Bench workstation drawer units should provide sufficient storage capacity to enable bench surfaces to be kept clear, other than equipment in daily use.

\textsuperscript{11} The active agent, corrosive nature and downstream effects from the cleaning materials used need to be understood; surfaces need to be resistant to degradation as a result of frequent contact with the cleaning reagents.
7.4 Lighting

7.4.1 Lighting to ISO 8995 standard is recommended in recessed units finished flush with the ceiling (international [ingress] protection rating IP rated IP65) in order to provide a smooth waterproof surface for cleaning purposes.

7.4.2 The optimum lighting level should be a minimum of 1,000 lux at bench level, supplemented by variable task lighting at the point of examination, whilst accounting for Health and Safety Executive (HSE) requirements to minimise glare.

7.5 Air Quality and Air Flow

7.5.1 Air movement within and between rooms shall be managed with measures taken to minimise the risk of contamination from environmental background DNA.

7.5.2 Airborne particulate cleanliness equivalent to ISO 14644-1 Class 7 is recommended.

7.5.3 A minimum airflow of 20 times whole room replacement per hour is recommended. Higher replacement rates may be required to maintain ambient temperature in laboratories utilising equipment such as sequencers with high heat outputs.

7.5.4 Filtration of input air to all DNA clean areas by suitable high efficiency particulate air (HEPA) filtration units is recommended. This can be achieved, for example, by utilising a HEPA-filtered clean air cabinet as a DNA clean area.

7.5.5 Management of air flow systems is essential to prevent output of unfiltered air from post-PCR areas from re-entering pre-PCR areas including search areas.

7.5.6 Minimise adverse draughts or uncontrolled turbulence.

7.5.7 Samples likely to generate particles during their examination should be examined in a containment hood, unless the bulkiness of the item renders this impractical. Under these circumstances the item should still be examined in an area where the risk of contaminating other items is minimal (See section 8).
7.6 **Air Pressure Regime**

7.6.1 An ideal air pressure regime is outlined in Figure 2 below where ‘0’ denotes ambient pressure outside the building, ‘+’ denotes positive air pressure, and ‘++’ is positive air pressure higher than +. This prevents accidental ingress of contaminating material into a pre-PCR DNA clean area and egress of PCR product from a post-PCR area.

![Diagram](image_url)

Figure 2: Schematic of relative air pressures for laboratory housing DNA clean rooms/areas

7.7 **Containment of Biohazards**

7.7.1 For items that are believed to contain pathogens such as HIV and hepatitis a risk assessment shall be undertaken and the following shall apply:

a. items shall be examined in Containment Level 2 or 3 facilities depending on HSE requirements and local risk assessment;

b. items shall be handled in a microbiological safety cabinet of appropriate level in accordance with HSE requirements and local risk assessment;
c. where items are too large for handling within a microbiological safety cabinet, an individual risk assessment shall be undertaken and a decision taken on whether or not to proceed with appropriate safeguards in place.

7.8 Lobby Area

7.8.1 The lobby\(^\text{12}\) should ideally have interlocking doors to minimise ingress of contaminants, and the door from the outside corridor should open inwards into the lobby.

7.8.2 Lobby areas for DNA clean laboratories should contain a hand-wash sink with hot and cold water, dispensers for soap and disposable towels.

7.8.3 Lobby areas for containment laboratories shall use sanitisation gel in preference to hand-wash sinks.

7.8.4 Lobby areas shall have coat pegs for hanging up laboratory coats and storage shelves/cupboards for barrier clothing and personal protective equipment.

7.9 Other

7.9.1 Laboratory equipment and stationery are dedicated to each particular DNA clean area, and to each individual workstation within a given area.

8. CONTAMINATION PREVENTION

8.1.1 Procedures for the Receipt of Exhibits at the Laboratory and Initial Examination – DNA Clean Areas (ISO/IEC 17025:2005 ref. 5.8)

8.1.2 Exhibits in cases that may require DNA analysis shall only be examined in DNA clean areas and processed in accordance with practices defined in this appendix.

8.1.3 Where it is not possible to examine items in a dedicated DNA clean area (for example, for health and safety reasons or bulky items) then:

- a. the examination area shall be decontaminated as far as possible;

\(^{12}\) Existing build as of December 2015 may not be able to accommodate a separate lobby, but can have a designated gowning area. In this case the risk of transfer of DNA from the gowning area to the DNA clean area shall be taken account of in the organisation’s cleaning and environmental monitoring regimes.
b. background swabs shall be taken from relevant examination areas; and

c. surfaces and processed as required to demonstrate the integrity of the DNA results obtained.

8.1.4 If there is any issue with the integrity of the item packaging or package seals, the reporting officer (RO) or supervisor/manager shall be made aware and the case notes and report annotated accordingly.

8.1.5 Consideration should be given to wiping down the outside of plastic exhibit packaging with an appropriate cleaning solution that is known to reduce levels of DNA contamination.

8.1.6 Gloves shall be changed after opening and handling the packaging in order to reduce the risk of secondary transfer. Care shall be taken to ensure that the outer surfaces of the packages do not come into contact with the items therein or with the surface on which the item is being examined.

8.1.7 Treatment of split cases:

a. where DNA analysis is required in addition to other work that is not compatible with DNA clean working practices, sampling for the former shall, wherever possible, be undertaken before the exhibit is taken to any other part of the laboratory;

b. where it is impossible for sampling to be undertaken in a DNA clean area, the customer and the RO shall be made aware of the contamination risks and the case notes and report annotated accordingly.

8.1.8 Where an exhibit has been handled in a DNA non-clean area and it is subsequently determined to require DNA analysis, this shall be reported to the appropriate individuals who shall be made aware of the contamination risks and the case notes annotated accordingly. The information shall be made readily available for items transferred between different units/organisations that shall continue to maintain the exhibit handling information (continuity). Any profiles generated from the exhibit shall be checked against all staff who handled the unpackaged exhibit and, if necessary, against previous casework undertaken in the DNA non-clean area. Any resulting witness statement shall explicitly refer to the contamination risk and any gaps, for example, where it has not been
possible to carry out relevant profile elimination checks and the significance of this in the context of the case. This is a particular issue when items from historic cases are re-sampled.

8.2 Personnel (ISO/IEC 17025:2005 ref. 4.1.5, 5.2)

Staff Training

8.2.1 This appendix to the Codes shall be introduced to all members of staff and new members of staff as part of their induction training.

8.2.2 Issues relating to contamination risks and their avoidance in specific processes and methods shall be an integral part of staff training and the relevant issues shall be included within the training plans and manuals.

8.2.3 When competencies are being assessed, assessors should ensure that the contamination risks of any process and the means of avoidance are fully understood.

Medical Conditions

8.2.4 Where a member of staff has a cold or other medical condition that risks compromising forensic casework, such as persistent coughing or sneezing, consideration should be given to excluding them from DNA clean areas.

Restriction of Staff Movement

8.2.5 Staff shall not move from a polymerase chain reaction (PCR) product area to a pre-PCR area in the same day unless they change their outer clothing before entering the pre-PCR area.

a. The exception to the above requirement is where a fully validated (6.3.1c) automated rapid DNA analysis system is utilised in which samples, once loaded, are automatically extracted and amplified without human intervention.

8.2.6 Staff shall not enter a dedicated casework processing area after working in a reference sample processing area(s) on the same day, unless they change their outer clothing. However, movement from casework to a reference sample processing area is permitted.
8.3 Protective Clothing

8.3.1 Outdoor clothing, for example, coats, gloves, scarves, and other personal belongings are not permitted within any DNA clean areas.

8.3.2 The following protective clothing shall be worn by all individuals including staff, visitors and service engineers when entering a DNA clean area.

Laboratory Coats

8.3.3 Dedicated disposable/non-disposable overcoats covering the full upper body from the neck downwards, with full length sleeves shall be worn and properly fastened.

8.3.4 Dedicated cloth coats shall be laundered to ensure that coats from pre-PCR areas are handled entirely separately from coats from post-PCR areas.

8.3.5 Dedicated coats shall be changed before searching items from a different case, individual or location, and where other circumstances dictate, for example, after searching a heavily stained exhibit.

a. It is acceptable not to change laboratory coats when examining different items of clothes that have been worn at the same time by the same individual. However, the laboratory shall document standard practice and how any variation shall be recorded.

b. For examination and processing of volume crime samples, it is acceptable to use a lower cost alternative of wearing disposable paper aprons and sleeve covers over the laboratory coat and changing the apron and sleeve covers between cases, rather than the laboratory coat. Alternatively, the laboratory can determine the frequency of changing laboratory coats/aprons based on documented practices. For example, if the item/sample comes into contact with apron/laboratory coat/sleeves or a frequency determined and based on evidence of background DNA sampling (similar to substrate/blanks) of sleeves/coats for specified time periods through the environmental monitoring of the regime.

13 The changing of sleeves may be more frequent than laboratory coats and aprons as contamination is more likely to transfer via sleeves than the front of a laboratory coat/apron.
8.3.6 Dedicated coats shall not be worn outside the DNA clean area to which they have been assigned.

Gloves
8.3.7 Disposable gloves shall be worn at all times in a DNA clean examination area, and removed when leaving the area. Two layers of gloves should be worn prior to handling a sample and should be non-powdered nitrile or other suitable alternative.

8.3.8 The wrist of the glove should cover the wrist of the laboratory coat. Where this is not possible, disposable cuffs shall be used to cover the gap.

8.3.9 The outer pair of gloves shall be either changed or thoroughly cleaned with a validated method for effective removal of DNA whenever they come into contact with a potentially contaminated surface, for example, an opened exhibit package, face, door handle, or retrieval of items from the floor.

8.3.10 Gloves (outer) shall be changed between the examination of different items or between batches of DNA samples.

8.3.11 Gloves do not need to be changed between exhibits whilst these are still in their packaging, for example, when transporting intact exhibit bags to new locations.

8.3.12 Staff shall use their judgement to decide whether gloves need to be changed during item examination or when processing a batch of DNA profiling samples.

Face Masks
8.3.13 When examining exhibits pinch nose face masks shall be worn that are properly tied and adjusted to cover the nose and mouth.

8.3.14 Touching the mask with a gloved hand shall be avoided; if it is necessary to adjust the mask then gloves shall be changed.

Hair Cover
8.3.15 Disposable mob caps or similar hair cover entirely covering the head hair shall be worn upon entering the DNA clean area.

8.3.16 Where necessary, for example, with bearded individuals, additional hair cover (snoods) should be used to ensure that all facial hair is covered when used in conjunction with the face mask.
Gowning Procedure

8.3.17 The gowning/disrobing procedure shall be undertaken in a lobby area or in a designated area proximal to the entrance/exit of the DNA clean area.

8.3.18 Gowning-up shall be documented and be undertaken in an appropriate sequence, for example:

a. on entering the lobby area, immediately put on a mob cap and ensure that all hair is secure within the cap;

b. put on a face mask;¹⁴
c. put on clogs or overshoes;
d. put on goggles or other eye protection where necessary;
e. put on gloves;
f. put on a disposable/laundered laboratory coat; and
g. change gloves where necessary, for example, when a laboratory coat has been worn previously.

8.3.19 When entering the DNA clean area:

a. change or clean gloves where necessary, for example, if a door appendage was touched on entering, then put on a second pair of gloves as required.

8.3.20 When leaving the DNA clean area:

a. on re-entering the lobby (designated gowning) area, take off the laboratory coat and gloves and wash hands;¹⁵ and

b. remove goggles, face mask, mob cap and overshoes.

8.4 Control of Bench Environment

Cleaning

8.4.1 In addition to a daily decontamination regime (section 8.6) the search bench shall be decontaminated between items, cleaning top and sides of the bench using a detergent/cleaning solution. The only exception is when clothes are submitted as having been worn by the same individual at the same time, and in

¹⁴ Do not talk at all until the mask is securely fitted.
¹⁵ If taking samples/tubes out of the laboratory, clean gloves shall be worn.
the professional judgement of the RO there will not be an impact on the potential interpretation of any evidence by not undertaking this cleaning regime. In this situation the variation from standard practice shall be recorded in the case notes.

8.4.2 Each item should be examined on a suitable non-porous surface; a disposable surface used as an additional barrier or to collect debris, such as a sheet of paper, plastic sheeting or Benchkote¹⁶, shall be changed between items. The only exception is when clothes are submitted as having been worn by the same individual and at the same time. The laboratory shall document standard practice and how any variation shall be recorded.

8.4.3 As far as possible all bench surfaces used for searching examination and processing of exhibits shall be kept clear. This makes it much easier to decontaminate the surface.

**Exhibits Left on Benches**

Exhibits, including those that need to dry prior to re-packaging, should not be left uncovered on the bench when not being examined. The exhibits should be covered with disposable paper sheeting.

**Bench Log**

8.4.5 A record of date, time and examiner of all exhibits/cases/batches examined/processed at every workstation or defined area of bench shall be kept. This may be required following a contamination incident, if it is thought necessary to check other cases/batches processed at the same bench or workstation.

8.4.6 Records of the movement and handling of samples within DNA processing should also be kept; these records can be electronic, for example, by means of a laboratory information management system (LIMS)/electronic management system (EMS) tracking of samples.

¹⁶ Benchkote is the name for a commercially available white absorbent paper, laminated with an impermeable layer of polyethylene that is universally used.
**Paperwork**

8.4.7 Use of paperless case file management systems is strongly recommended. If paper case files are utilised, these shall not be taken into DNA clean areas unless kept in a segregated area of the laboratory; only the relevant pages such as submission forms and examination instructions should be taken in, preferably within a cleaned plastic wallet and wherever possible kept to one side of the work area/station.

8.4.8 Other items required for note taking (pens, pencils, other stationery) shall be provided within the laboratory DNA clean area and not removed.

8.5 **Use of DNA Laboratories for Activities Other Than Casework**

8.5.1 At times it may be necessary to use laboratory space for non-casework activities including for training purposes, preparation of body fluid controls for presumptive test reagents, and seeding of items for trials and audits.

**Seeding of Items using Body Fluids for Training, Trials or Reference Controls**

8.5.2 When clothing, swabs and other items are seeded with significant quantities of liquid body fluids for training, setting up proficiency and inter-laboratory tests or for demonstration purposes, the following apply:

a. all preparations shall be undertaken in an area not being used for DNA casework at the time, and the area shall not be returned to casework use until a deep clean has been undertaken supported by appropriate environmental DNA test results;

b. all human body fluids shall be provided by donors whose profiles are held on the staff elimination database (SED);

c. disposable pipettes and containers, or dedicated re-usable pipettes that are not used for any other purpose and are labelled to this effect, shall be used at all times;

d. a record shall be kept of which samples have been used and where the training items are utilised.
Body Fluid Controls Used For Check of Presumptive Test Reagents

8.5.3 Semen used for acid phosphatase (AP) control papers should be prepared from samples provided by a vasectomised donor wherever possible, as the sperm cells that contain DNA are absent. If this is not available, the supernatant from a spermic sample can be used. The test papers shall be prepared in a non-DNA casework area.

8.5.4 Supernatants of saliva can be used as controls to reduce the risk of DNA contamination.

8.5.5 Animal blood should be used, rather than human; typically horse blood is used.

Examination of Seeded Training Items

8.5.6 When (several) people are receiving training with seeded items, a complete laboratory shall be designated for the duration of the training. No casework items shall be subsequently brought into this area until a deep clean has been undertaken and a check has been undertaken via environmental monitoring (Section 8.7).

8.6 Cleaning Processes

8.6.1 Each DNA clean area shall have a cleaning schedule, with the frequency of cleaning dependent on the extent of use of the area and the equipment within it. A cleaning log shall be maintained to show the daily, weekly or monthly activities undertaken as per the schedule.

Minimum Cleaning Requirements

8.6.2 As a minimum the following shall be undertaken using cleaning equipment dedicated solely for use in each DNA clean area and using a cleaning regime validated (Ballantyne et al 17, 2015; University College London and Metropolitan Police Service, 2015 18) to provide effective DNA decontamination.

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18 Kings College London and Metropolitan Police Service (2015) Cleaning project. Personal communication to the Forensic Science Regulator DNA specialist group, 10 July 2015.
8.6.3  Daily or after each use, clean:
   a. bench work surfaces – identify and decontaminate all surfaces that may either directly or indirectly come into contact with the exhibit (these surfaces shall also be cleaned before use); and
   b. centrifuges – inside and out.

8.6.4  In addition the following shall be decontaminated before and after use, and in between the examination of different items:
   a. individual pieces of equipment including fibre rollers, pens, rulers, barcode scanners, low power microscopes; and
   b. IT equipment (graphic pads and pens, and keyboards, etc.).

8.6.5  On a weekly basis the following shall be decontaminated:
   a. floors and chairs;
   b. equipment such as microscopes, computers and all exposed cables;
   c. all contact surfaces such as cupboards, door handles and fridges; and
   d. keyboards.

8.6.6  Routine or regularly scheduled whole area deep clean to include areas not covered by the other cleaning:
   a. lights and vents;
   b. walls and ceiling; and
   c. the insides of drawers.

8.6.7  Cleaning or replacement of air filters should be undertaken at a frequency recommended by the manufacturers.

8.6.8  For DNA clean rooms that are used on an infrequent basis, i.e. less than once a month, the cleaning as detailed in sections 8.6.3 to 8.6.6 shall be undertaken prior to re-commencing use.

8.6.9  Where a spill or leak of biological material occurs, it should be removed using a cleaning regime validated to provide effective DNA decontamination. Depending on the circumstances and extent of the spillage it may be appropriate to undertake environmental monitoring of the affected area to provide assurance that all contamination has been removed.
8.7 Environmental Monitoring

**Principle**

8.7.1 The principle of environmental monitoring is to undertake a programme of testing on a periodic basis to check that particular rooms or areas are DNA clean and to assess whether the decontamination policy for the area in question is both effective and has been carried out properly.

8.7.2 Results from such monitoring should be carefully assessed given that, unlike other classes of testing, DNA analysis does not typically include the additional safeguard of processing substrate/search bench controls within batches.

8.7.3 Samples should be taken by swabbing selected areas and equipment that are in contact with operators and/or the casework items themselves at all stages in the casework supply chain.

8.7.4 The sampling regime reflects the risk profile of operation and is proportionate to the risk. For example, drying rooms in which large amounts of biological material are inevitably present should be sampled most frequently. Components typically sampled vary according to the function of the area and examples are given at 8.7.16.

**Sampling Schedule**

8.7.5 All work areas for which assurance of cleanliness is required, that is, DNA clean areas, shall be assessed on a routine basis.

8.7.6 The required frequency of sampling should be determined empirically, specified in the sampling plan and evidence provided through use of trend analysis that the risks of contamination for a particular area are being adequately controlled by the cleaning regime. Thus an area that has basic air flow management and where many people regularly work will require more frequent cleaning and monitoring than a low throughput facility with state of the art air flow management.

8.7.7 Depending on circumstances, additional non-routine testing may be required, for example:

a. after a contamination incident has occurred;
b. after a laboratory work area has changed function; or  
c. after maintenance has been completed within the area rendering it ‘unclean’.

8.7.8 In addition to DNA clean areas, environmental monitoring of specified areas should be undertaken where DNA contamination poses less of a risk, for example, areas where exhibits are regularly handled but remain sealed within packaging.

8.7.9 Results from monitoring these areas should be treated as an indication of background levels of DNA and used to inform the effectiveness of cleaning regimes within these areas.

Sampling and Analysis

8.7.10 As a minimum, swabs from 20 areas shall be taken from a fully equipped DNA extraction laboratory or an appropriate number\(^\text{19}\) from a dedicated work area on each assessment. These shall be taken from a variety of surfaces and items as stipulated in 8.7.16.

8.7.11 Sampling shall be undertaken to maximise the recovery of DNA utilising consumables (for example, swabs moistened and/or dry as appropriate) certified as free from detectable levels of human\(^\text{20}\) DNA (forensic DNA grade).

8.7.12 The swabs shall be extracted, amplified and analysed in accordance with the most sensitive process employed on samples that are processed through the particular laboratory/facility under test, including the use of positive and negative controls.

8.7.13 For each work area a record shall be kept of:

a. the date that sampling was undertaken;

b. the person undertaking the sampling;

c. the number of areas sampled, and details of what these are;

d. the number of failures and items/areas affected;

\(^{19}\) Depending on the size and scope of the laboratory all relevant areas should be covered within the matrix of the sampling schedule based on risk assessment and trend analysis from monitoring results.

\(^{20}\) Human DNA is not detectable by the most sensitive DNA profiling techniques available.
8.7.14 Areas to swab should be assigned different priorities, based on general experience of potential contamination hot-spots, plus specific past experience of environmental results for a specific laboratory/room.

a. Priority 1: These require swabbing in every environmental monitoring exercise, for example, workbenches, fridge freezers, keyboards, laboratory coats, sleeves, surfaces in robotic workstations.
b. Priority 2: A selection of these should be included in each exercise, for example, chair seats, drawer handles.
c. Priority 3: These should be included occasionally, for example, reagent bottles.

8.7.15 Areas that are not swabbed are chemical waste bins and sharps bins.

Areas to be Sampled

8.7.16 Listed below are areas that are vectors for contamination and should be typically sampled. This is not necessarily an exhaustive list.

<table>
<thead>
<tr>
<th>Aprons</th>
<th>Drawers under benches</th>
<th>Racking in stores</th>
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</thead>
<tbody>
<tr>
<td>Automated equipment</td>
<td>Fibre optics</td>
<td>Reagent bottles</td>
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<tr>
<td>Barcode scanners</td>
<td>Forceps</td>
<td>Robotic workstation surfaces</td>
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<tr>
<td>Benches</td>
<td>Fridge/freezer handles</td>
<td>Safety cabinets/hoods</td>
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<tr>
<td>Bench canopies</td>
<td>Handles to consumables’ boxes</td>
<td>Shakers</td>
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<tr>
<td>Bench screens</td>
<td>Heat sealers</td>
<td>Sleeves/cuffs</td>
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<tr>
<td>Centrifuges</td>
<td>Incubators</td>
<td>Stationery</td>
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<tr>
<td>Chairs</td>
<td>Instrument knobs</td>
<td>Surfaces in sequencers</td>
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<tr>
<td>Cross-linkers</td>
<td>Laboratory coats</td>
<td>Telephones</td>
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<tr>
<td>Cupboard handles</td>
<td>Lids, tops of containers</td>
<td>UV lamps</td>
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<tr>
<td>Digital cameras</td>
<td>PCs, keyboards, etc.</td>
<td>Vortex mixers</td>
</tr>
<tr>
<td>Door handles</td>
<td>Pipettes</td>
<td>Water sprays</td>
</tr>
</tbody>
</table>
8.7.17 The DNA analysis carried out on environmental samples should be the most sensitive profiling system that the recovered samples will be subjected to from that location. Where multiple profiling systems are in use the laboratory shall specify the analysis required for environmental samples taken from different areas. The DNA analysis and acceptance criteria are not the same as that required for consumables’ quality control (QC) batch testing (See 8.8.4 and 8.8.5).

**Cellular contamination monitoring**

8.7.18 The use of adenosine triphosphate (ATP)-based luminometry methods may be used as means of assessing the degree of cellular contamination on a surface in real time, by swabbing the surface and measuring the ATP activity using a handheld device (Forensic Science Northern Ireland).

8.7.19 Any ATP luminescence methods shall be ‘calibrated’ for the handheld model used against the absence and low levels of detectable DNA.

8.7.20 The monitoring of ATP activity would not be a direct replacement for all monitoring activities, but can indicate ineffective cleaning and can be used in combination with DNA profiling to allow for efficient and effective monitoring.

8.7.21 Extracted DNA, that is, ‘naked’ DNA (existing outside of the cell) will give no ATP result and therefore ATP-based methods shall not be used as a means of monitoring for cellular contamination in DNA processing laboratories.

**Interpretation of Results and Corrective Actions**

8.7.22 The presence of allelic peaks is considered at all loci, including amelogenin. Results are assessed based on the validated interpretation rules applied by the

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21 ATP is a molecule found in all living cells, including plants, animals and humans as well as bacteria, yeasts, etc. The use of ATP luminometry methods has been routinely used in hospitals and the food and beverage processing industry for many years as a means of assessing the degree of cellular contamination on a surface in real time. It is, however, relatively new within forensic science, hence the need for validation by the laboratories wishing to use this approach.

22 Measurement of luminescence

laboratory undertaking the testing. These give consideration to the approach taken where peaks above background are observed and this monitoring data should be accessible to the DNA RO, together with details of any improvement and corrective actions taken around the period that peaks above background were identified.

8.7.23 A mechanism should also be established to enable feedback to the DNA processing unit by the DNA RO where any suspicious (unexpected) or anomalous results have been observed suggesting contamination, so that the DNA unit can investigate and check whether this is the case and undertake decontamination if necessary.

**Gross/Systemic Contamination of an Area**

8.7.24 In the event of gross/systemic contamination or after maintenance staff have entered a DNA clean area, a deep clean shall be undertaken as detailed in 8.6.

**Gross/Systemic Contamination of Specific Items/Areas**

8.7.25 Where gross/systemic contamination of a particular bench surface or item has occurred or is suspected, the affected area/item should be treated using a validated cleaning regime.

Note: Disinfectants can be potent inhibitors of PCR, and if they are not removed from areas that come into contact with DNA exhibits, the DNA results can be adversely affected. Great care should therefore be taken to remove all traces of detergent after its use as part of the validated decontamination process. If an inhibition problem attributable to the cleaning regime persists, consideration should be given taking due account of Health and Safety Executive requirements, of replacing the detergent used with Virkon, the latter being a far less potent PCR inhibitor (Bright et al., 2011).

**Worst Case Scenario**

8.7.26 In the event that, due to the time required to process the environmental monitoring swabs, a case is reported that has the same profile as the identified contaminant, the designated manager shall recall the case or take appropriate action.

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action as required by the circumstances, and shall inform stakeholders as appropriate (section 10.4).

8.8 Consumables (ISO/IEC 17025:2005 ref. 6.4.2)

8.8.1 Laboratories shall purchase consumables where available that are quality assured to be ‘human DNA free’/forensic DNA grade. These shall be utilised in the recovery and processing of DNA samples within the laboratory. This also applies to reagents used in processes upstream from DNA processing in joint, split or sequential cases.

8.8.2 Assurance can be provided by the consumables being independently certified as compliant with PAS 377:2012, ISO 18385:201525 or through QC testing of batches of reagents and consumables.

8.8.3 Post-production treatment of consumables, such as ethylene oxide treatment, shall include some form of QC for each treatment, such as DNA spiked samples strategically placed across the batch to be treated, and demonstrate the reduction level of amplifiable DNA as determined through the validation of the method. If no measure of the efficiency of the post-production treatment is carried out then appropriate post-treatment QC testing is required (see 8.8.4).

8.8.4 If QC testing is relied upon, then for short tandem repeat (STR) profiling, a single increased PCR amplification cycle number to the recommended manufacturer’s protocol, combined with the most sensitive DNA detection method (for example, post-PCR clean up) for which the consumables are intended shall be used in the QC procedure. The laboratory shall assure itself that sufficient test samples to detect contamination26 in a batch of consumables are processed.

8.8.5 QC acceptance of a consumables batch tested using STR profiling for:

26 Sporadic contamination is difficult to detect, therefore it is not viable to test a representative sample. However, systemic or gross contamination is quickly identified by a check on a small number of samples. The inclusion of unused consumables, for example, with environmental monitoring samples or as negative controls for DNA batch processing provides for ongoing monitoring of those batches of consumables in use.
a. a DNA reagent (for example, extraction or amplification kits) is the detection of no more than one designated allele peak obtained by replicate analysis, i.e. the same alleles are detected above the analytical threshold; or

b. other products (for example, swabs, tubes, tapes) is the detection of no more than two designated allele peaks obtained by replicate analysis, i.e. the same alleles are detected above the analytical threshold.

9. **CONTAMINATION DETECTION**

9.1 Positive and Negative Controls

9.1.1 The presence of one or more allelic peak(s) in a batch negative control or allelic peak(s) additional to those expected in a positive control is indicative of contamination associated with the DNA laboratory processes. This could have originated from:

a. samples within the same batch or other batches;

b. individuals within the DNA laboratory environment;

c. contaminated consumables; or

d. other sources through secondary transfer mechanisms.

All such contamination shall be logged internally by the forensic science provider (FSP) in an appropriate system, to enable contamination to be monitored over time.

9.2 Contamination Checks Between Cases/Samples Processed (Within Batch and Between Batch Comparisons)

9.2.1 Potential instances of cross-contamination shall be screened, both within and between batches of samples by means of appropriate software comparison programmes, which highlight the degree of similarity (number of shared alleles)

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between different processed samples. A rolling 6 to 18-month window of
between batch comparisons shall be undertaken. Where casework materials
are processed in microtitre plates, in order to facilitate detection of potential well
to well splash-over, DNA samples from the same case should not be positioned
in adjacent wells. If this occurs then reasons and additional checks carried
out shall be documented.

9.2.2 All instances of cross-contamination shall be logged and monitored by the FSP,
with investigation of all incidents and corrective actions being undertaken as
required.

9.3 Unexpected Results

9.3.1 DNA reporting officers should be suspicious of results that do not fit with case
circumstances, including a mixture that is not expected from the material
processed and that is difficult to explain, based on their organisation’s validated
interpretation guidelines. In some situations it is appropriate to conduct an
investigation into the source of the profile including a full assessment of the
potential for contamination. Retesting the item may confirm that the profile is
unrelated to the case. All opportunities to discover the cause should be taken as
described elsewhere in this appendix.

9.4 Comparison Against Elimination Databases

9.4.1 Local elimination databases shall be established and kept up to date
comprising:

a. all personnel working within the facility;

b. all visitors to the facility who pose a risk of contaminating the DNA
samples processed within the organisation; and

c. any unexplained/unsourced profiles believed to be as a result of
contamination.

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28 The timescale routinely used as the limit for detecting laboratory staff contamination. It will not be
relevant for manufacturing staff contamination checks as it is dependent on the shelf life of the
consumables in use.

29 It has been communicated that contamination has been identified 18 months after an individual has
left.
9.4.2 Prior to submission to the National DNA Database® (NDNAD) or reporting of casework results including those that do not require loading to the NDNAD, all DNA profiles\(^{31}\) shall be compared against:

a. the locally held database comprising staff, visitors and unsourced profiles; and

b. once in operation, a subset of profiles held centrally within an elimination database comprising profiles of manufacturing staff, police personnel and medical personnel who pose a significant risk of contaminating with their own DNA.

9.4.3 These elimination databases and requirements are detailed in FSR-P-302 (Forensic Science Regulator).

10. MANAGEMENT OF CONTAMINATION INCIDENTS INCLUDING DECONTAMINATION PROCEDURES

10.1.1 If contamination is suspected, the following five-step corrective action process shall be undertaken.

10.2 Identify the Problem

10.2.1 Where contamination is suspected the first stage is to investigate and determine the origin of the contaminant profile and the full extent of the problem. This may be achieved by working backwards in a step by step investigative process. Typically, this may involve comparison of the contaminant profile with:

a. other samples processed within the same batch;

b. samples from other batches processed in the same time frame, that is, up to the last six months within the laboratory;

c. staff who pose a significant risk of contamination throughout the end to end process of location, collection, handling and analysis, see also FSR-P-302 (ibid.) and whose profiles are held on local staff elimination databases.

\(^{30}\) National DNA Database is a registered trademark owned by the Secretary of State for the Home Department.

\(^{31}\) The DNA profile shall as far as possible be single-sourced, thereby taking into account the complexity to determine individual contributors from DNA profiles originating from two or more individuals (mixtures).
(SEDs) – forensic science provider (FSP) staff, and visitors including maintenance staff and defence examiners – or on central elimination databases (CEDs) – manufacturers, medical staff, unsourced contaminants – or on police elimination databases (PEDs); and
d. positive and negative controls.

10.2.2 If the contaminant profile contains too few alleles to allow effective screening against the above, the FSP should aim to rework the sample to produce a more informative result by any appropriate means available such as:
   a. re-extraction;
   b. additional purification steps;
   c. dilution of inhibitors;
   d. concentrating the extract; and/or
   e. application of low template methods.

The use of these troubleshooting procedures shall be validated by the laboratory prior to their application.

10.3 Determine the Root Cause

10.3.1 The point at which contamination has occurred may be determined by reworking the samples in reverse in a step by step manner – re-electrophoresis, re-polymerase chain reaction (re-PCR), re-extraction. Although alleles under a minimum detection threshold are not reported, these should be considered when performing investigations and corrective actions to assist in determination of the root cause. Typical root causes may be categorised as follows.

a. Human factors: These include failure of staff to comply with standard operating procedures or lack of competence that was either not addressed during training or not identified in competency assessments.

b. System-related: These include a contamination risk not being adequately mitigated during system design and development, which only becomes apparent after validation and implementation, or that the system has materially changed post-validation.
c. A combination of factors including human-related, systems, and others: These include SOPs being insufficiently explicit and therefore open to misinterpretation or omitting information considered to be too obvious to require inclusion, resulting in deviation from the intended procedure by an individual or subset of staff.

10.3.2 Where human factors are the root cause, it is essential to determine whether this is limited to the work of just one individual or more than one, and over what timescale. This shall be ascertained by reviewing all potentially affected work, starting at the time of the originally observed contamination incident and working outwards. Dip-testing may be an appropriate means of achieving this in some circumstances. Similarly where there is a systemic issue it is necessary to consider that similar events may have previously gone unnoticed and it may be necessary to review previous work.

10.4 Communication

10.4.1 Case file: In all instances where contamination has been detected or suspected, the facts relating to the incident and any actions agreed either with the customer or internally shall be recorded in the case file of any affected case.

10.4.2 Report: Any detected contamination is revealable and disclosed to the Crown Prosecution Service (CPS) and should be notified to the police for inclusion in any schedule of unused material prepared for the purposes of criminal proceedings. The summary on the disclosure schedule needs to assist the prosecutor in determining whether a report is required, or whether there is a need to disclose (see FSR-P-302, Forensic Science Regulator; section 24.1.2).

10.4.3 Stakeholders: Where the occurrence of contamination has consequences beyond the reporting of an individual case, relevant stakeholders shall be informed including:
   a. the customer;
   b. the Forensic Science Regulator/Regulation Unit;
   c. the CPS; and
   d. the UK Accreditation Service (UKAS).
This is required so that additional measures may be considered and taken by the criminal justice system as a whole if required.

10.5 **Implement Preventative Measures**

10.5.1 Actions taken to prevent recurrence depend on the root cause.

a. Where a workspace has been affected by a contamination incident, and the contamination may still present an issue, processing of material within the affected workspace shall cease until it has been subject to the decontamination regimes detailed in 8.6 and demonstrated to have been effective through environmental monitoring detailed in 8.7.

b. Human factor-related issues may require the individuals in question not to continue with the work activities under investigation until additional awareness training and competency re-assessment have been successfully completed.

c. System-related issues may require modification of procedures. These shall be verified as fit for purpose prior to implementation.

d. In all instances, a post-implementation review should be conducted to provide assurance that the preventative measures have been effective.

10.6 **Document Events**

10.6.1 Full documentation of all contamination events shall be generated and maintained, including the investigation and corrective actions taken in all serious instances. This shall describe:

a. the deficiency;

b. the root cause of the deficiency;

c. the impact on past work;

d. the remedial action taken; and

e. evidence from the post-implementation review that the issue has been resolved.

10.6.2 All corrective actions identified shall be logged and managed within an improvement and corrective action process in accordance with the requirements of ISO/IEC 17025:2005.
11. **MANAGEMENT OVERSIGHT AND CONTINUOUS IMPROVEMENT (ISO/IEC 17025:2005 ref. 4.10, 4.11)**

11.1.1 There shall be governance and oversight of contamination avoidance, monitoring and detection by the forensic science provider's senior management. This shall include a technical authority with responsibility for assessment and review of contamination, including responsibility for escalating contamination issues to senior management where required.

11.1.2 Maintaining a log of contamination events and periodically reviewing these to identify trends and potential for further anti-contamination measures shall be undertaken by the management technical authority. This shall be part of an overall continuous improvement process.

11.1.3 There should be good communication with staff and staff ownership of contamination issues. Improvement at the team/unit level should also be encouraged.

11.1.4 Periodic management reviews of contamination shall be undertaken by the FSP on a six-monthly basis as a minimum. These reviews shall monitor all serious contamination events plus provide a summary of low-level contamination observed within DNA processes including:

- contamination observed;
- testing of consumables where this is undertaken;
- contamination rates within batch controls;
- batch re-run and re-extraction rates due to contamination; and
- environmental monitoring results.

These reviews shall assess contamination trends within the laboratory and be made available to:

- the Forensic Science Regulator/Forensic Science Regulation Unit;
- the UK Accreditation Service; and the
- National DNA Database® Unit.  

This enables overall trends within the industry to be monitored.

32 Low-level contamination can also include minor components in mixture profiles.
33 National DNA Database unit is currently within the Home Office.
11.1.5 After implementation of new methods/systems, post-implementation reviews shall be carried out, which shall include monitoring of any change in contamination rates.

12. REVIEW

12.1.1 This document is subject to review in accordance with the Codes and other appendices to the Codes.

12.1.2 Please send any comments to the address as set out on the Internet site at www.gov.uk/government/organisations/forensic-science-regulator or email: FSREnquiries@homeoffice.gsi.gov.uk.

13. REFERENCES


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

BS EN ISO/IEC 17025:2005 *General requirements for the competence of testing and calibration laboratories*.


ISO 18385:2015 Minimizing the risk of human DNA contamination in products used to collect, store and analyse biological material for forensic purposes.

Kings College London and Metropolitan Police Service (2015) Cleaning project. Personal communication to the Forensic Science Regulator DNA specialist group meeting, 10 July 2015.


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.


14. FURTHER READING


15. ABBREVIATIONS

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Meaning</th>
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<tbody>
<tr>
<td>AP</td>
<td>acid phosphatase</td>
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<tr>
<td>ATP</td>
<td>adenosine triphosphate</td>
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<td>BS</td>
<td>British Standard</td>
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<td>CED</td>
<td>central elimination database</td>
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<td>criminal justice system</td>
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<td>electronic management system</td>
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<td>International Electrotechnical Commission</td>
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<td>international (ingress) protection rating</td>
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</table>
ISO  International Organisation for Standardization
IT    information technology
LIMS  laboratory information management system
NDNAD National DNA Database
PAS   publicly available specification
PC    personal computer
PCR   polymerase chain reaction
PED   police elimination database
PPE   personal protective equipment
QA    quality assurance
QC    quality control
RO    reporting officer
SED   staff elimination database
SOP   standard operating procedure
STR   short tandem repeat
UKAS  UK Accreditation Service
UV    ultra violet

16. GLOSSARY

Allelic peak: A peak that falls within an allelic window, has well defined allele morphology and a peak height greater than the defined limit of detection of the laboratory.

Casework: Items believed to contain biological material relating to a person of interest (perpetrator) recovered from specific crime events.

Crime sample: An item or sub-item recovered and believed to provide evidence to investigate or prosecute a criminal offence, i.e. crime-related.

Consumables: Single-use commodities used in the collection, preservation and processing of material for forensic analysis, and are bought and used up
recurrently. These include PPE, tamper evident containers, swabs, and packaging that comes into direct contact with the material for forensic analysis. A consumable can also be equipment used in the collection, processing and safe handling of the material, for example, disposable tweezers and scissors.

**DNA clean area:** Area in which appropriate DNA contamination prevention measures shall be maintained at all times as defined in section 7.9.1.

**DNA contamination:** The introduction of DNA, or biological material containing DNA, to an exhibit or subsample derived from an exhibit during or after its recovery from the scene of crime or a person.

**Elimination database:** Collection of DNA profiles held in a searchable format from staff whose access/role/activities are deemed to be a potential DNA contamination risk. This may include not just the staff working within a specific facility, but also profiles from visitors to the facility, staff of manufacturers supplying consumables for DNA processing, and unsourced contamination profiles. The profiles are used to identify instances of inadvertent contamination.

**Forensic DNA grade:** Consumables certified to having met the requirements in ISO 18385:2015.

**Forensic science provider:** Organisation that undertakes any part of the DNA sample recovery and analytical process on behalf of the police or other CJS customers; police evidence recovery laboratories are also included.

**Gross contamination:** The transfer of DNA from a single person where a partial or complete DNA profile (these alleles are ‘dependent’) is obtained as a result of a contamination event. This is unlike the *drop-in* phenomenon, which is associated with random allelic events (the alleles are ‘independent’ of each other). Consequently, *drop-in* is routinely used to refer to the observation of just one or two extra alleles per profile (also see **Systemic contamination**).

**Human DNA free:** Human DNA is not detectable by the most sensitive DNA profiling techniques available.

**Laboratory:** Any area in which the packaging of an exhibit is opened, or items for DNA analysis are processed, including drying rooms.
Reference: See reference sample.

Reference sample: A biological sample obtained from a known person with the purpose of creating a DNA profile for comparison.

Sporadic contamination: Unpredictable, erratic contamination event that is not detected by QC batch testing.

Systemic contamination: General, universal contamination event seen across a batch or between batches of test results (also see Gross contamination).

Unsourced contaminant: A DNA profile identified as a contaminant, i.e. following all relevant elimination database checks of which the source has not been identified. No template (negative) controls and quality control batch tests are considered as having originated from the manufacturing supply chain, historically most have been found to come from manufacturing staff.

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