

Code of Practice

Forensic Medical Examination Standard

Adult and Child Sexual Assault Complainants

FSR-C-116 CONSULTATION

This is a consultation issued to allow comments from interested parties; all comments will be given consideration when finalising the final document prior to publication. Comments should be sent to FSRConsultation1@homeoffice.gov.uk and should be submitted by **28 December 2018**. This mailbox is not for general correspondence and is not routinely monitored so no acknowledgement will normally be sent.

CONTENTS

1.	INTRODUCTION	4
2.	SCOPE	5
3.	IMPLEMENTATION	6
4.	MODIFICATION	7
5.	TERMS AND DEFINITIONS.....	7
6.	MANAGEMENT REQUIREMENTS	10
6.1	General (ISO 15189:2012 4.1).....	10
7.	TECHNICAL REQUIREMENTS	10
7.1	Personnel: training and competence (ISO 15189 4.4, 5.1, ILAC G19 3.3 and FSR-G-212)	10
7.2	Accommodation and environmental conditions (ISO 15189 5.2, ILAC G19 3.11, FSR-G-207 and FSR-G-208)	11
7.3	Forensic medical examination room furnishings, equipment, reagents and consumables (ISO 15189 5.2, 5.3, ILAC G19 3.12, FSR-G-207 and FSR-G-208)	12
7.4	Examination methods and procedures (ISO 15189 4.4, 5.4.2 and 5.5)	14
7.5	Medical examination and evidence collection (ISO 15189 5.4.4; 5.4.3, 5.5 and ILAC G19 4.3.3)	16
7.6	The examination process (ISO 15189 5.5 and ILAC G19 4.7)	19
7.7	Sample collection and handling (ISO 15189 5.2.5; 5.4.3; 5.4.4.3; 5.4.5; 5.4.6; 5.4.7, ILAC G19 4.3.3 and FSR-G-207).....	19
8.	ENSURING THE QUALITY OF EXAMINATION PROCEDURES (ISO 15189 5.6 and the Forensic Science Regulator’s <i>Codes of Practice and Conduct</i>)	21
8.2	Use of personal protective equipment (ISO 15189 5.2.5, FSR-G-207 and FSR-G-212).....	21
8.3	DNA elimination samples (ISO 15189 5.2.6 and FSR-P-302).....	21
8.4	Decontamination measures (ISO 15189 5.2.6 and FSR-G-208).....	22

8.5	Cleaning (ISO 15189 5.2.6 and FSR-G-208)	22
8.6	Environmental monitoring and gross contamination (ISO 15189 5.2.6; FSR-G-208 and FSR-G-212)	22
9.	DOCUMENTATION – RECORDING OF NOTES AND STATEMENTS	23
9.1	Note taking and record keeping (ISO 15189 4.13, ILAC G19 3.5 and the Forensic Science Regulator’s <i>Codes of Practice and Conduct</i>).....	23
9.2	Statements and reports (ISO 15189 5.7.1; 5.8.1, the Forensic Science Regulator’s <i>Codes of Practice and Conduct</i> , FSR-G-200 and FSR-G-225).....	24
10.	ACKNOWLEDGEMENTS.....	24
11.	REVIEW	24
12.	REFERENCES.....	25
13.	ABBREVIATIONS	30
14.	GLOSSARY.....	31
	ANNEX A : SELF-ASSESSMENT QUESTIONNAIRE	35

1. INTRODUCTION

- 1.1.1 Sexual offences are devastating crimes and the impact of sexual violence can include significant consequences to the long-term health and well-being of [complainants](#). The timely collection of [evidence](#) can provide them with the option to assist in any criminal investigation. This can increase the likelihood that the evidence will aid a criminal prosecution, so that the perpetrator can be caught and brought to justice and prevent further sexual offending.
- 1.1.2 The provision of dedicated high quality healthcare alongside [forensic medical examination](#)¹ for the collection of evidence has considerable benefits for the health, well-being and delivery of justice for complainants. Such services provide both the police and the complainant with the best possible opportunity to recover evidence for use within an investigation, and minimise the risk of a miscarriage of justice. This includes the risk of wrongful conviction(s) or wrongful acquittal(s) or delaying investigation(s).
- 1.1.3 In order to achieve high quality and consistent healthcare and forensic evidence provision, defined [standards](#) are necessary for all stages of the complainant's 'journey' immediately before and during the forensic medical examination. These standards provide confidence in the relevance of any [findings](#) documented during the examination, and any subsequent scientific results from the samples taken during the examination. The complainant's care pathway varies based on the individual case and the local variation of service delivery. However, this should not detract from achieving the best health and justice outcomes for the complainant.
- 1.1.4 The Faculty of Forensic and Legal Medicine (FFLM) is recognised by the Home Office² as being responsible for advising on the standards for healthcare professionals involved in custody healthcare and forensic medical examination. The role of both the Forensic Science Regulator (FSR) and the FFLM in setting standards is confirmed in a further report.³

¹ The medical and therapeutic needs may override the requirement to collect forensic evidence.

² *Hansard*, March 18 2009, Column 1164W.

³ Taskforce on the Health Aspects of Violence Against Women and Children (2010) *Report of the Taskforce on the Health Aspects of Violence Against Women and Children*, Recommendation 21.

1.1.5 For the purpose of this document, the term ‘complainant’ is used to refer to those subjected to sexual assault or suspected of being subjected to sexual assault. It encompasses ‘victim’, ‘patient’, and ‘survivor’.

1.1.6 [Forensic practitioners](#) include doctors and other healthcare professionals (7.1) who provide medical and related care to complainants of both violent and sexual offences, and to persons detained on suspicion of committing these crimes.

2. SCOPE

2.1.1 The purpose of this appendix to the Forensic Science Regulator’s *Codes of Practice and Conduct*⁴ is to set the standards required for the forensic medical examination of adult and [child](#) complainants of alleged sexual assault. It is based on the application of the international standard ISO 15189:2012(E),⁵ which is used to define the requirement for quality and competence in medical laboratories.

2.1.2 This standard covers the processes where the medical examination and collection of evidence⁶ from a complainant⁷ takes place. The names and settings where these examinations take place are varied. For the purpose of this standard they will collectively be known as the ‘medical examination and sample collection facility’ (the [Facility](#)) and will be recognised in part as a [forensic unit](#) for the purposes of relevant forensic science standards and guidance.

2.1.3 [Figure 1](#) (for adults) and [Figure 2](#) (for children) outline where the facility, procedures and practices occur within the complainant’s ‘journey’ from offence to court.⁸ The figures identify the stages where the standards and guidance’s apply within the facility (shown within bold text with solid lines) and outside the

⁴ Forensic Science Regulator *Codes of Practice and Conduct for Forensic Science Providers and Practitioners in the Criminal Justice System*.

⁵ ISO 15189:2012 *Medical laboratories – Requirements for quality and competence*.

⁶ This applies to acute and historic cases where, for example, sexually transmitted infection samples are required for evidential purposes.

⁷ These requirements apply to both complainants referred by the police and self-referrals.

⁸ These diagrams are not care pathways nor are they intended to be used as referral routes.

control of the facility (within bold text with dashed lines). The facility shall identify those stages in their local care pathway for implementation.

2.1.4 This standard applies to all personnel involved in performing and supporting the medical examination at the facility. This includes:

- a. the provision of services provided by different or multiple providers regardless of the commissioning arrangements or funding structure; and
- b. those with responsibility for managing the processes, personnel and the facility.

2.1.5 Areas such as medical evaluation and treatment, suicide risk and mental health assessments, case reviews and post-forensic examination treatment/follow-up are outside the scope of this standard. These come under the responsibility of clinical governance.

3. IMPLEMENTATION

3.1.1 Within the remit of clinical governance there shall be a named person within the facility with responsibility for ensuring the facility's compliance with this standard.⁹

3.1.2 To meet this standard the requirements set out in the following shall be incorporated into the policies, processes and procedures within the facility:

- a. ISO 15189:2012 *Medical laboratories – Requirements for quality and competence*;
- b. ILAC G19:08/2014 *Modules in a Forensic Science Process*;
- c. Forensic Science Regulator, *Codes of Practice and Conduct for Forensic Science Providers and Practitioners in the Criminal Justice System* (the [Codes](#));
- d. Forensic Science Regulator, [FSR-G-207](#) *DNA Anti-Contamination – Forensic Medical Examination in Sexual Assault Referral Centres and Custodial Facilities*; and

⁹ This role may be equivalent to the role of 'laboratory director' as given in ISO 15189:2012 4.1.1.4.

- e. Forensic Science Regulator, FSR-G-212 *Forensic Medical Examination – Assessment, Collection and Recording of Forensic Evidence* (Consultation in press).

3.1.3 A self-assessment audit check list is provided in [Annex A](#) of this document.

3.1.4 This document is available for incorporation into an organisation's standard operating procedures and [quality management system](#) from the date of publication and comes into effect from October 2021.

4. MODIFICATION

4.1.1 This is the consultation version of this document.

5. TERMS AND DEFINITIONS

5.1.1 The terms and definitions set out in the Codes, FSR-G-207, FSR-G-212 and the [glossary](#) section apply to this document. Definitions in BS EN ISO 21043-1:2018¹⁰ *Forensic Sciences Part 1: Terms and definitions* or ILAC G19 apply where there is no corresponding definition set out in the Forensic Science Regulator's Codes and guidance's.

5.1.2 The word 'shall' has been used in this document where there is a corresponding requirement in ISO 15189:2012 or the Forensic Science Regulator's Codes and guidance's; the word 'should'¹¹ has been used to indicate generally accepted practice where the reason for not complying or any deviation shall be recorded.

¹⁰ ISO maintains a terminological database for use in standardization through their ISO online browsing platform: Available at <https://www.iso.org/obp>.

¹¹ General Medical Council *Good Medical Practice*. In this guide 'should' is used when providing an explanation of how to meet the overriding duty, where the duty or principle will not apply in all situations or circumstances, or where there are factors outside the practitioner's control that affect whether or how guidance can be followed.

Figure 1. Adult Complainant Journey from Offence to Court via the (Medical Examination and Sample Collection) Facility.

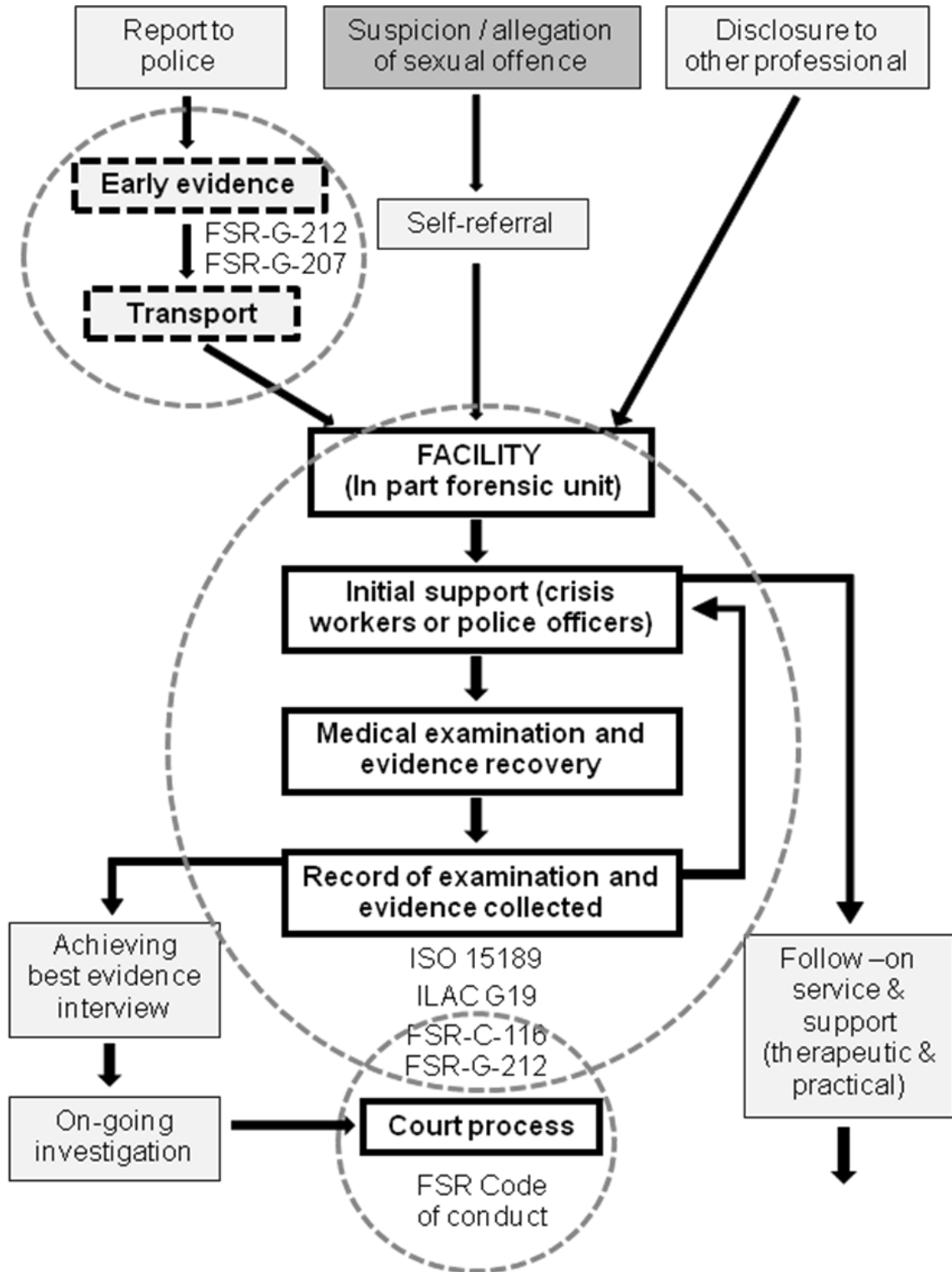
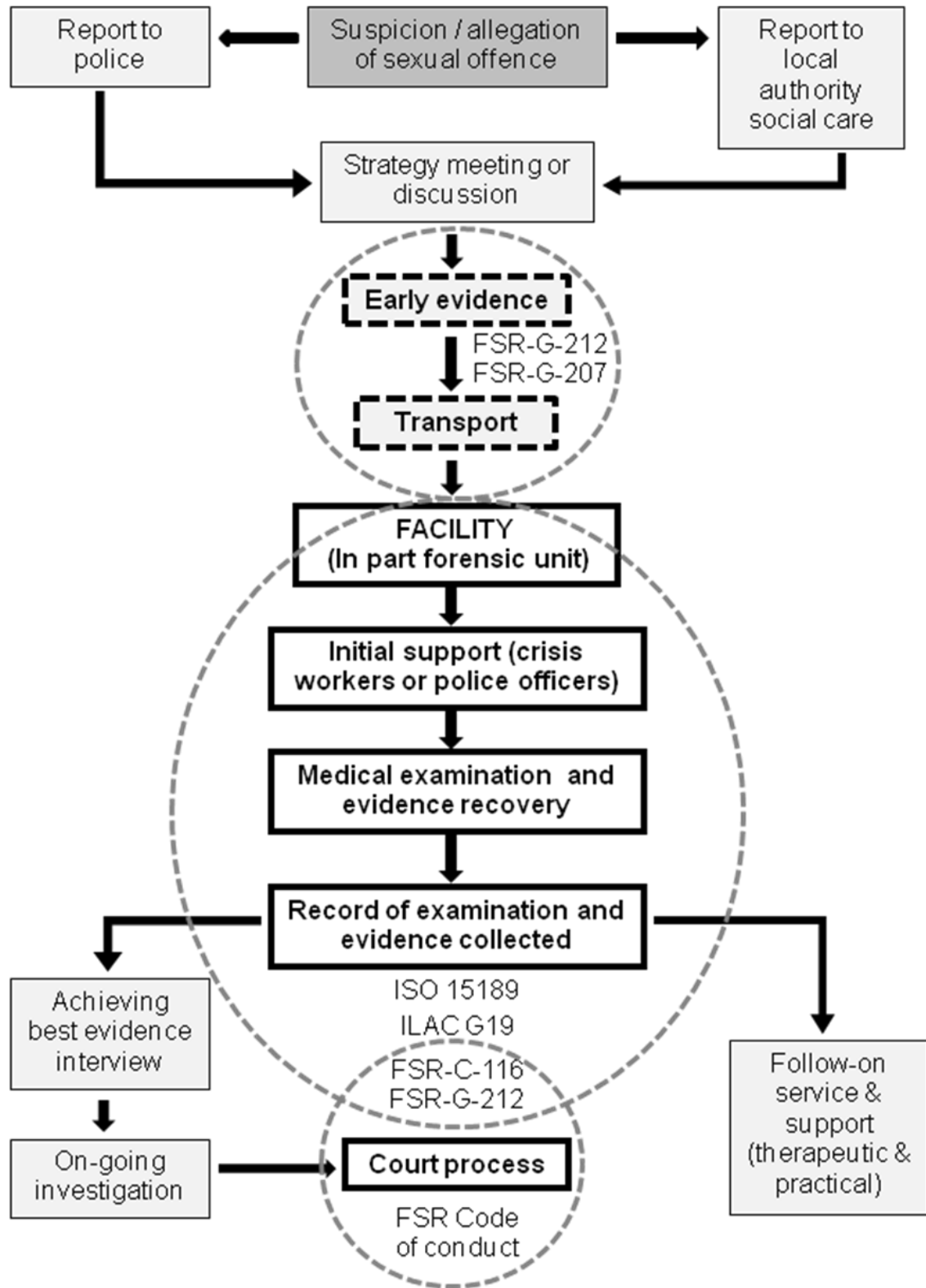


Figure 2. Child Complainant Journey from Offence to Court via the (Medical Examination and Sample Collection) Facility.



6. MANAGEMENT REQUIREMENTS

6.1 General (ISO 15189:2012 4.1)

6.1.1 A nominated senior responsible person in the facility shall be identified, in terms of top management, to support the quality standards.

6.1.2 Management within the facility shall conform to the requirements of the international quality standard ISO 15189:2012 *Medical laboratories – Requirements for quality and competence*, substituting ‘facility’ where the standard states ‘laboratory’. The management requirements shall include:
Organisation and management responsibility (ISO 15189 4.1)

- a. The organisation and management responsibility of the facility shall be defined and documented.

Quality management system (ISO 15189 4)

- b. A quality management system (QMS) (however called) shall be established and maintained by a quality manager. The QMS shall comply with section 4 of ISO 15189 including, but not limited to, the following:
 - c. a quality manual (ISO 15189 4.2.2.2 and 4.1.2.3);
 - d. procedures, instructions and forms (ISO 15189 4.2; 5.5.3);
 - e. a document control system (ISO 15189 4.3);
 - f. a continual improvement process (ISO 15189 4.12);
 - g. events of non-conforming work that could potentially cause a miscarriage of justice being referred to the Forensic Science Regulator (ISO 15189 4.9);
 - h. evaluation and audits (ISO 15189 4.14);
 - i. a management review (ISO 15189 4.15).

7. TECHNICAL REQUIREMENTS

7.1 Personnel: training and competence (ISO 15189 4.4, 5.1, ILAC G19 3.3 and FSR-G-212)

7.1.1 The facility shall have a documented policy defining the knowledge, skills, experience and [competency](#), and a procedure for the training, competency and ongoing competency for each role within the facility. This shall include:

- a. all professionals and personnel working or delivering a service within the facility;
- b. training and competency requirements^{12,13} including retraining for any lapse of competence for each role profile;
- c. expert witness and criminal justice system (CJS)^{14,15} related training including written evidence, court skills and cognitive bias;¹⁶
- d. assessment of training and competency;
- e. authorisation and commencement for the activities that they undertake;
- f. continuing professional development to maintain ongoing competency;
- g. records to evidence competency and authorisation.

7.1.2 If not employed by the legal entity or the facility but providing a service (ISO 15189 4.4, 4.6, 5.1 and ILAC G19 4.1.3), then assessment and approval to work at the facility shall be evidenced and documented by the facility.

7.1.3 Guidance on roles within the facility and other related roles is provided in FSR-G-212, *Forensic Medical Examination – Assessment, Collection and Recording of Forensic Evidence (Consultation in press)*.

7.2 Accommodation and environmental conditions (ISO 15189 5.2, ILAC G19 3.11, FSR-G-207 and FSR-G-208)

General

7.2.1 Accommodation at the facility shall be fit to meet the well-being, medical and forensic examination needs of all its end users in a safe and secure environment for both users and staff.

7.2.2 In order to meet the accommodation and environmental requirements in this standard, physical building changes or new build has been identified or is necessary for some facilities. Where the timescale for this is beyond the implementation date of this standard, the facility shall undertake the following.

¹² Faculty of Forensic and Legal Medicine (2017a) *Child Sexual Abuse Forensic Medical Examinations: Interim Guidance regarding number of examinations and maintenance of competence*.

¹³ Faculty of Forensic and Legal Medicine (2016a) *Quality Standards in Forensic Medicine*.

¹⁴ ACPO/CPS (2010) *Guide Booklet for Experts*.

¹⁵ Criminal Procedure Rules and Practice Directions.

¹⁶ Forensic Science Regulator, FSR-G-217 *Cognitive bias effects relevant to forensic science examinations*.

- a. Complete a full risk assessment and identify areas for strict ongoing monitoring (8.4, 8.5 and 8.6 below).
- b. Implement the risk assessment and record quality failures (6.1.2f above).
- c. Have a documented plan with timescales that is regularly reviewed.
- d. As a minimum disclose in all [statements](#) and [reports](#) to CJS end users that the facility does not meet the requirements in this standard and detail what mitigation is in place (9.2 below).

7.2.3 The facility shall have in place policies and procedures for the authorised access to the building, rooms, areas, equipment and [consumables](#). This shall include controlled areas and rooms that require access to be recorded (7.2.5 and 7.5.8 below).

Layout of the accommodation

7.2.4 Consideration shall be given to the design and layout of the facility. This shall include measures to prevent cross-transfer and environmental contamination.

7.2.5 There shall be designated [DNA clean](#) bathroom, pre-assessment and medical examination areas. These shall be secure at all times and entry and exit shall be controlled.

Air quality and air flow

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

7.3 Forensic medical examination room furnishings, equipment, reagents and consumables (ISO 15189 5.2, 5.3, ILAC G19 3.12, FSR-G-207 and FSR-G-208)

7.3.1 The furnishings, equipment,¹⁷ reagents and [consumables](#) that are utilised within the facility shall be such that they minimise the risk of [DNA contamination](#).

¹⁷ Faculty of Forensic and Legal Medicine (2016b) *Recommendations: Operational Procedures and Equipment for Medical Rooms*.

Environment, furnishings and equipment

- 7.3.2 The walls, floors, work surfaces, chairs should be of smooth finish, sealed, readily cleanable and resistant to degradation from frequent cleaning.¹⁸ Workstation/work surfaces shall be kept clear, other than for equipment in daily use.

DNA decontamination

- 7.3.3 The facility shall have a policy in place that sets out DNA anti-contamination good practice (8.4–8.6 below). For DNA clean areas this shall include:
- a. the routine cleaning regimes for rooms, areas, equipment,¹⁹ and consumables (8.4 and 8.5 below);
 - b. the frequency of deep cleaning for the forensic medical examination room;
 - c. the access control to the DNA clean areas (7.2.5 above and 7.5.8 below);
 - d. records of the name of the cleaner, and where and when cleaning was carried out;
 - e. monitoring the effectiveness of the cleaning through [environmental monitoring](#) (EM) (8.5 and 8.6 below).

Cleaning reagents

- 7.3.4 The facility shall use cleaning products and spillage kits that have been demonstrated to be effective in removing detectable levels of DNA in conjunction with appropriate cleaning procedures.²⁰ These chemicals shall always be used in a manner compliant with relevant health and safety requirements.
- 7.3.5 The facility shall demonstrate that the cleaning product is effective at removing DNA through environmental monitoring (8.6 below).

¹⁸ 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.

¹⁹ This includes mobile equipment and consumables carried by medical practitioners on call.

²⁰ Further guidance is available in FSR-G-206, FSR-G-207 and FSR-G-208.

Consumables including personal protective equipment/barrier clothing

7.3.6 The facility shall have a policy and procedures for the procurement, receipt and storage of reagents and consumables (including barrier clothing) that are fit for the purpose^{21,22} of their intended use. This shall also include use, handling instructions and disposal.

7.4 Examination methods and procedures (ISO 15189 4.4, 5.4.2 and 5.5)

7.4.1 The facility shall have documented procedures for the examination processes undertaken by the personnel at the facility. These shall include:

- a. the relevant skills, knowledge and competency requirements (7.1 above) to work with complainants;
- b. the initial response in prioritising the needs of the complainant;
- c. a non-judgemental respectful approach in every case;
- d. information about the forensic medical examination for the complainant (7.4.2 below);
- e. documenting and recording relevant information pertaining to the complainant throughout the process (9.1 of this report).

Prior to complainant's arrival at the facility – Initial contact

7.4.2 The facility shall provide accessible correct information and advice on the services that are provided at the facility to partners, other relevant services and potential end users (general).

7.4.3 Staff at the facility shall be able to provide basic information to complainants about the:

- a. options available for examination, treatment and advice;
- b. importance of body fluids and the recovery of forensic evidence;
- c. impact that actions following the incident might have on the collection of evidence;

²¹ ISO 18385:2016 *Minimizing the risk of human DNA contamination in products used to collect, store and analyse biological material for forensic purposes.*

²² British Standard BS 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.*

- d. requirement of an [early evidence kit](#) (EEK) sample, as appropriate;
- e. retention of relevant clothing worn at the time and subsequent to the incident.

Decision to undertake an examination

- 7.4.4 The decision to undertake a forensic medical examination shall be made by a competent authorised forensic practitioner (7.1 above).
- 7.4.5 Where children disclose sexual offences the forensic physician and paediatrician should be consulted in a timely manner in order to determine whether the child should be examined²³ and if so, at what time and by which practitioner(s).²⁴ The forensic physician shall provide advice on the recovery of potential forensic evidence.
- 7.4.6 Where it is necessary for the complainant to be taken to an emergency department, depending on local practices the forensic practitioner shall either attend the hospital and work alongside other healthcare providers or provide advice to those treating the complainant.
- 7.4.7 Forensic samples shall be collected using recognised forensic sample kit modules (7.3.1 above). Consideration of the usefulness of blood and urine samples taken at hospitals for forensic analysis shall be based on the individual case circumstances.

Attendance of the forensic practitioner

- 7.4.8 Local policy shall dictate who has the responsibility for requesting the attendance of the forensic practitioner and/or paediatrician and the expected time frames for attendance at the facility.
- 7.4.9 The facility or provider of the forensic medical workforce shall ensure that they are able to provide a timely response to reflect the clinical and forensic needs of complainants.^{25,26,27}

²³ Faculty of Forensic and Legal Medicine (2012a) *Guidelines on Paediatric Forensic Examination in Relation to Possible Child Sexual Abuse*.

²⁴ It may not be necessary for 16 to 18 year olds to be examined by a paediatrician.

²⁵ Faculty of Forensic and Legal Medicine (2016a) *Quality Standards in Forensic Medicine*.

²⁶ Faculty of Forensic and Legal Medicine (2016c) *Quality Standards for Nurses and Paramedics*.

- 7.4.10 The forensic practitioner attending the forensic medical examination should not provide any medical examination or any other service to custody medicine during that shift.²⁸

Arrival of the complainant

- 7.4.11 The process for the end-to-end journey through the facility for a complainant (and their significant others) shall be defined. This shall include:
- a. who shall meet, accompany and support the complainant;
 - b. their role in supporting and advocating for the complainant throughout their time at the facility;
 - c. information on the options available, the purpose of the forensic medical examination to the complainant, and how they will be supported throughout;
 - d. pre-examination activities to be undertaken, and by whom;
 - e. how the medical examination will be conducted;
 - f. follow-up and referrals post-examination.

7.5 Medical examination and evidence collection (ISO 15189 5.4.4; 5.43, 5.5 and ILAC G19 4.3.3)

Preliminary matters

- 7.5.1 The forensic practitioner and/or paediatrician shall introduce themselves to the complainant (and their family if the complainant is a child) and explain what is going to happen during the medical examination. This shall include:
- a. explaining the consent requirements (7.5.2 below);
 - b. if specialised equipment, such as a colposcope^{29,30} is to be used, explaining its purpose, function and how it will be used;

²⁷ Faculty of Forensic and Legal Medicine (2016d) *Guide to Establishing Urgency of Sexual Offence Examination: Flowchart for Pre-pubertal Complainants and Flowchart for Post-pubertal Complainants.*

²⁸ Only in exceptional circumstances (for example, in very remote locations) it could become necessary to use the same forensic practitioner. In these circumstances the reason and rationale behind the decision and the steps that have been undertaken to reduce the risk of contamination shall be recorded, documented and disclosed in any subsequent report or statement provided for the criminal justice system.

²⁹ Faculty of Forensic and Legal Medicine (Reviewed 2017b) *Guidance for best practice for the management of intimate images that may become evidence in court.*

³⁰ Faculty of Forensic and Legal Medicine (2017c) *PICS Working Group Guidelines on Photography.*

- c. explaining that the complainant can stop the examination at any time for a variety of reasons, but the potential implications of stopping the examination should also be explained.

Obtaining consent

7.5.2 The forensic practitioner shall obtain informed verbal and written consent³¹, from the complainant. This shall include the following.

- a. That the consent is given in accordance with current guidelines from the Faculty of Forensic and Legal Medicine (FFLM),³² the General Medical Council and the Nursing and Midwifery Council in accordance with the Mental Health Capacity Act 2005.
- b. It should confirm the complainant (or representative) understands:
 - i. the purpose of the examination;
 - ii. that the consent is freely given
 - iii. that there is no obligation to give consent; and
 - iv. that consent can be withdrawn at any time during the examination.
- c. It should advise that if consent to any part of the examination is refused at any stage, that refusal and any reason offered shall be recorded.
- d. It should also advise that the notes, images recorded and reasons for refusal shall be documented and may subsequently used for evidential purposes, second opinions from medical experts, [peer review](#) and audit.
- e. It should offer anonymous analysis of samples if the complainant does not want to proceed with a police complaint, having taken due regard for the Human Tissue Act 2004.^{33,34}

7.5.3 In situations where there is no capacity to consent, the detail and basis of the decision made in the complainant's best interests shall be documented such that the basis for the decision can be reviewed by another competent practitioner.

³¹ See Supreme Court judgment UKSC11 2015 *Montgomery v. Lanarkshire Health Board*.

³² Faculty of Forensic and Legal Medicine (2011) *Consent from patients who may have been seriously assaulted*.

³³ Available at: www.legislation.gov.uk/ukpga/2004/30/contents

³⁴ Faculty of Forensic and Legal Medicine (2016e) *SARC Storage of Forensic Samples and the Human Tissue Act: Frequently Asked Questions*.

7.5.4 Where the complainant is a child, reference shall be made to the General Medical Council (GMC)³⁵, the Royal College of Paediatrics and Child Health (RCPCH)³⁶ and FFLM³⁷ guidance's for obtaining valid consent.

First account

7.5.5 An initial account of the incident shall be obtained from an appropriate source(s) that are relevant to the individual complainant presented to the forensic practitioner or paediatrician (where appropriate). This account shall be:

- a. confirmed or further clarification obtained where appropriate;
- b. recorded in the case notes (9.1 below);
- c. used to determine the forensic medical [examination strategy](#).

Medical/social history

7.5.6 The forensic practitioner or paediatrician (where appropriate) shall obtain and record the medical/social history in sufficient detail to enable them to undertake a holistic assessment of the therapeutic and forensic needs of the complainant. This information shall:

- a. be confirmed or further clarification obtained where appropriate;
- b. be recorded in the case notes (9.1 below);
- c. be used in conjunction with the first account information to determine the forensic medical examination strategy;
- d. support any subsequent forensic laboratory examination and findings.

Addressing practical and emotional needs

7.5.7 Forensic practitioners or paediatricians (where appropriate) should ensure that the therapeutic, practical and emotional needs of the complainant, both prior to and during the examination are met. Prior to commencing the examination this shall include immediate:

- a. treatment of serious injuries;
- b. crisis intervention and support;

³⁵ General Medical Council (2012) *Protecting children and young people: the responsibilities of all doctors*.

³⁶ RCPCH *Child Protection Companion* at www.rcpch.ac.uk/resources/paediatric-care-online-pco-uk

³⁷ RCPCH and FFLM 2015 *Service specification for the clinical evaluation of children and young people who may have been sexually abused*.

- c. translation and interpretation, if required.³⁸

Record of attendees

- 7.5.8 A record of all persons in attendance at any time during the forensic medical examination shall be made.

Roles and responsibilities of those conducting the examination

- 7.5.9 Where more than one practitioner is conducting the examination, their respective roles and responsibilities shall be agreed in advance of the examination and documented.

Removal of clothing

- 7.5.10 The facility shall have a documented procedure for the removal and packaging of clothing to minimise contamination and the loss of evidence, and maintain the integrity of the [items](#) once packaged.

7.6 The examination process (ISO 15189 5.5 and ILAC G19 4.7)

- 7.6.1 The examination process shall be defined and documented. The process shall include the:
 - a. medical, psychological and safeguarding needs;
 - b. collection and documentation of relevant information;
 - c. medical examination strategy;
 - d. order of the examination activities;
 - e. photography;
 - f. documentation and recording;

7.7 Sample collection and handling (ISO 15189 5.2.5; 5.4.3; 5.4.4.3; 5.4.5; 5.4.6; 5.4.7, ILAC G19 4.3.3 and FSR-G-207)

- 7.7.1 The facility shall have a documented procedure for taking appropriate forensic samples³⁹ on a case-by-case basis. This shall include:
 - a. DNA anti-contamination good practices;

³⁸ Where interpreters are necessary, family members shall not be used and the gender preference of the complainant shall be taken into account.

³⁹ Faculty of Forensic and Legal Medicine (2018a) *Recommendations for the Collection of Specimens from Complainants and Suspects*.

- b. sample recovery good practice;
- c. recording,^{40,41,42} labelling⁴³ and packaging;
- d. chain of evidence and sample transfer.

Storage of samples

7.7.2 The facility shall have policy and procedures in place for the taking, storage, retention and destruction of samples. This shall include due consideration of the Human Tissues Act 2004.⁴⁴

Sample documentation

7.7.3 The facility shall have a procedure in place for documenting and recording the sample collection, labelling, transfer and storage of samples and evidence collected (section 9 below).

Images

7.7.4 The facility shall have policy and procedures in place for the electronic capture, storage and transfer of images.^{45,46} These shall include:

- a. personnel authorised to take images;
- b. the conditions required for obtaining the resolution and image quality to demonstrate the features of interest clearly;
- c. recording on case notes;
- d. the security and integrity of the data;
- e. access to images for peer review/second opinions;
- f. disclosure of images for criminal justice system proceedings and information security implications (the Codes 21.3).

⁴⁰ Faculty of Forensic and Legal Medicine (2016f) *Pro forma forensic medical examinations*.

⁴¹ Faculty of Forensic and Legal Medicine (2010, Revised 2014) *Pro forma for adult female and male forensic sexual assault examinations*.

⁴² Faculty of Forensic and Legal Medicine (2012b) *Pro forma for paediatric medical examination*.

⁴³ Faculty of Forensic and Legal Medicine (2016g) *Labelling forensic samples*.

⁴⁴ Faculty of Forensic and Legal Medicine (2016e) *SARC Storage of Forensic Samples and the Human Tissue Act: Frequently Asked Questions*.

⁴⁵ Faculty of Forensic and Legal Medicine (Reviewed 2017b) *Guidance for best practice for the management of intimate images that may become evidence in court*.

⁴⁶ Faculty of Forensic and Legal Medicine (2017c) *PICS Working Group Guidelines on Photography*.

8. ENSURING THE QUALITY OF EXAMINATION PROCEDURES (ISO 15189 5.6 and the Forensic Science Regulator's *Codes of Practice and Conduct*)

8.1.1 The facility shall have a policy and procedures in place that minimise the possibility of contamination from the moment a complainant arrives at the facility to undertake a forensic medical examination until the completion of that examination.

8.1.2 Although the main focus is to minimise DNA contamination, other forensic evidence sample types such as dried flaking body fluids, hairs, fibres, and particulate debris that can cross-contaminate are just as important and shall be considered within the examination and recovery procedures.

8.2 Use of personal protective equipment (ISO 15189 5.2.5, FSR-G-207 and FSR-G-212)

8.2.1 The policy and procedures for use of [personal protective equipment](#) (PPE) shall as a minimum include:

- a. the PPE that the forensic practitioner and attendees at the medical examination shall wear;
- b. the order to put PPE on;
- c. the frequency of changing PPE;
- d. the disposal of PPE.

8.3 DNA elimination samples (ISO 15189 5.2.6 and FSR-P-302)

8.3.1 A policy and procedure shall be in place to obtain a DNA elimination sample for its inclusion on a searchable [elimination database](#) from all practitioners who work at the facility, and people who come into contact with the complainant and/or the medical examination areas. This includes all attendees present at the forensic medical examination – the complainant, whether referred by the police or self-referral cases, interpreters, friends and family. This policy and procedure shall take into account the requirements and guidance set out in the Forensic Science Regulator's Protocol FSR-P-302⁴⁷ and shall include the following.

- a. Taking of the DNA elimination samples.

⁴⁷ Forensic Science Regulator, FSR-P-302 *DNA contamination detection – the management and use of staff elimination databases*.

- b. Agreement/consent for sample donation from:
 - i. practitioners and support staff, for example, crisis workers: and
 - ii. visitors (for example, interpreters, relatives, service engineers).
- c. Security and access of information at a local/national level.
- d. Secure storage and recorded transfer of samples.
- e. The investigation of an identified contamination event.
- f. Agreement/consent for the sharing of the profile.

8.4 Decontamination measures (ISO 15189 5.2.6 and FSR-G-208)

8.4.1 A policy to ensure that a procedure shall be in place for dealing with the event that multiple complainants from the same incident attend the facility at the same time.

8.5 Cleaning (ISO 15189 5.2.6 and FSR-G-208)

8.5.1 A policy and procedure shall be in place for cleaning rooms, areas and equipment (7.3.3 above). This shall include:

- a. training and authorisation of staff (7.1 above);
- b. good practice cleaning methods equivalent to those used in forensic DNA laboratories (FSR-G-208);⁴⁸
- c. frequency of good practice cleaning and deep cleaning;
- d. decontamination of re-usable equipment (ISO 15189 5.3.1.3);
- e. records of cleaning by the name of the cleaner and when.

8.6 Environmental monitoring and gross contamination (ISO 15189 5.2.6; FSR-G-208 and FSR-G-212)

8.6.1 A policy and procedure shall be in place for the monitoring of the level of background DNA and effectiveness of the cleaning regimes in place (7.3.3 above). This shall include:

- a. an environmental monitoring sampling (EMS) programme that reflects the operational risk profile and is proportionate to the risk;
- b. the frequency of EM sampling;

⁴⁸ Forensic Science Regulator, FSR-G-208 *The control and avoidance of contamination in laboratory activities involving DNA evidence recovery and analysis.*

- c. the training of personnel (7.1 above);
- d. personnel and methodology used for collecting the EM samples;
- e. the areas and equipment to be sampled for each monitoring event;
- f. advice and feedback from the [forensic science provider](#) undertaking the EM sample testing;
- g. defined follow-up processes to investigate [gross contamination](#) and address unacceptable levels of DNA contamination.

9. DOCUMENTATION – RECORDING OF NOTES AND STATEMENTS

9.1 Note taking and record keeping (ISO 15189 4.13, ILAC G19 3.5 and the Forensic Science Regulator’s *Codes of Practice and Conduct*)

9.1.1 A policy and procedures shall be in place for documenting, recording and storing information pertaining to each complainant. These shall include:

- a. the clarity, accuracy, legibility and permanency of notes and records;
- b. detailing all activity and decisions that are directly relevant to the complainant;
- c. recording the notes contemporaneously;
- d. recording barrier clothing/personal protective equipment (PPE) worn by the practitioner and attendees during the medical examination;
- e. identification of the practitioner, date and time (if appropriate) of the activity;
- f. amendments made to the record(s);
- g. statement^{49,50} or generation of preliminary findings report;
- h. retention of notes, including permanent records such as colposcope images,⁵¹ securely that complies with data protection requirements;
- i. access to notes and images for second opinion, peer review, investigation and criminal justice proceedings.

⁴⁹ Forensic Science Regulator, FSR-G-200 *Expert Report Guidance*.

⁵⁰ Forensic Science Regulator, FSR-G-225 *Non-Expert Technical Statement Guidance*.

⁵¹ Faculty of Forensic and Legal Medicine (2017b) *Guidance for best practice for the management of intimate images that may become evidence in court*.

9.2 Statements and reports (ISO 15189 5.7.1; 5.8.1, the Forensic Science Regulator's Codes of Practice and Conduct, FSR-G-200 and FSR-G-225)

9.2.1 The facility shall have a process for the production of statements and reports in a format that takes due regard to the disclosure obligations,⁵² the requirements set out in the Criminal Procedure Rules and Criminal Practice Directions⁵³ for experts. Legal obligations are set out in FSR-I-400⁵⁴ and disclosure requirements in the *Guide Booklet for Experts*.⁵⁵

9.2.2 Forensic practitioners shall be appropriately trained (7.1 above) and supported to produce a statement that is acceptable for use within in the criminal justice process.⁵⁶ The format for expert and non-expert technical reports set out in FSR-G-200 and FSR-G-225 should be adopted.

9.2.3 The facility shall define a process that can be evidenced for the end-to-end peer review stages of the case as it progresses. There should be a critical conclusions check of the report/statement by a second competent individual with the suitable level of knowledge, experience and authority to perform such a review.

10. ACKNOWLEDGEMENTS

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11. REVIEW

11.1.1 This document is subject to review at regular intervals.

⁵² ACPO/CPS (2018) *Disclosure Manual*.

⁵³ Available at: www.justice.gov.uk/courts/procedure-rules/criminal/rulesmenu-2015.

⁵⁴ Forensic Science Regulator, FSR-I-400 *Legal Obligations for Witnesses Providing Expert Evidence*.

⁵⁵ ACPO/CPS (2010) *Guide Booklet for Experts*.

⁵⁶ Faculty of Forensic and Legal Medicine (2018b) *Forensic clinicians (physicians, nurses and paramedics) as witnesses in criminal proceedings*.

11.1.2 If you have any comments please send them to:
www.gov.uk/government/organisations/forensic-science-regulator, or email:
FSREnquiries@homeoffice.gov.uk

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13. ABBREVIATIONS

Abbreviation	Meaning
ACPO	Association of Chief Police Officers, replaced by the National Police Chiefs' Council (NPCC)
CJS	Criminal justice system
CPS	Crown Prosecution Service
DNA	Deoxyribonucleic acid
EEK	Early evidence kit
EMS	Environmental monitoring system
FFLM	Faculty of Forensic and Legal Medicine
FSR	Forensic Science Regulator
ISO	International Organisation for Standardization
GMC	General Medical Council
PAS	Publicly Available Specification
PPE	Personal protective equipment
QMS	Quality management system

RCPCH	Royal College of Paediatrics and Child Health
SOP	Standard operating procedure
STI	Sexually transmitted infection
UKSC	United Kingdom Supreme Court

14. GLOSSARY

CHILD: A child is anyone who has not yet reached their 18th birthday.

COMPETENCY: The ability of an individual to do a job properly.

COMPLAINANT: An individual subjected to, or suspected of being subjected to sexual assault. It encompasses ‘victim’, ‘patient’, and ‘survivor’.

CONSUMABLES: Single-use commodities used in the collection, preservation and processing of material for forensic analysis, and are bought and used up recurrently.

DNA CLEAN AREA: Area in which appropriate DNA contamination prevention measures shall be maintained at all times.

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. In the context of the facility this could occur for any of the following reasons.

- a. Poor practice⁵⁷ employed by staff using fixtures and fittings and or collecting forensic samples.
- b. DNA contamination from anybody who has had access to the forensic waiting room and/or the medical examination room. Here ‘key risk groups’ are people from whom elimination DNA profiles have not been taken and included in an elimination database – they therefore may be inadvertently associated with a crime rather than being identified as contamination. These may include visitors, contractors and people accompanying a

⁵⁷ It should be noted that even good practice does not eliminate the risk of contamination, it only helps to minimise it.

complainant into the forensic waiting room and/or the medical examination room.

- c. Insufficient use of cleaning regimes, or ineffective cleaning reagents used, as part of a general forensic clean or a subsequent deep clean.
- d. Residual DNA from the manufacture/maintenance of fixtures and fittings that have not been deep cleaned.

EARLY EVIDENCE KIT (EEK): A dedicated kit used to collect forensic samples that are affected by both time and the activities undertaken by a complainant post-assault.

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.

ENVIRONMENTAL MONITORING (EM): A sampling and analytical (DNA) process for equipment, furniture and work areas that both monitors and audits the cleaning procedures and decontamination methods applied within the facility.

EVIDENCE: Is wider than just the samples taken. It also includes the absence or presence of injuries (fresh and healing), scars, and elements of the history pertaining to and provided by the [complainant](#).

EXAMINATION: Act or process of observing, searching, detecting, recording, prioritizing, collecting, analysing, measuring, comparing and/or interpreting

Note 1 to entry: Examination can include collecting [items](#) from persons.

[SOURCE: BS EN ISO 21043-1:2018 *Forensic Sciences Part 1: Terms and definitions*]

EXAMINATION STRATEGY: Plan developed to specify the requirements and activities for the [examination](#) phase of a [forensic process](#). [SOURCE: BS EN ISO 21043-1:2018 *Forensic Sciences Part 1: Terms and definitions*]

FACILITY: Physical environment used to protect the [item](#) integrity, conduct testing, or support any other aspect of the [forensic process](#).

EXAMPLE: Buildings, designated area, tents, storage areas, mobile office or laboratories and vehicles. [SOURCE: BS EN ISO 21043-1:2018 *Forensic Sciences Part 1: Terms and definitions*]

For the purpose of this document, this is any medical examination and sample collection facility, which in part is a [forensic unit](#).

FINDING: Information concluded as a result of an [examination](#) [SOURCE: BS EN ISO 21043-1:2018 *Forensic Sciences Part 1: Terms and definitions*]

FORENSIC: Related to methods, techniques and processes used to establish conclusions and/or opinions, facts and [findings](#), which can be used for legal proceedings.[SOURCE: BS EN ISO 21043-1:2018 *Forensic Sciences Part 1: Terms and definitions*]

FORENSIC PRACTITIONER: The term is used to describe both forensic physicians and forensic nurses.

FORENSIC PROCESS: Set of interrelated or interacting [forensic](#) activities. SOURCE: BS EN ISO 21043-1:2018 *Forensic Sciences Part 1: Terms and definitions*]

FORENSIC SCIENCE PROVIDER: An organisation that undertakes any part of the evidence recovery, analytical process and interpretation on behalf of the police or other criminal justice system customers. Police evidence recovery laboratories are also included.

FORENSIC UNIT: A forensic unit is a legal entity or a defined part of a legal entity that performs any part of the forensic science process. [SOURCE: ILAC-G19:08/2014 *Modules in a Forensic Science Process*]

GROSS CONTAMINATION: Is 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 single contamination event and the donor could be identified.

The term is also used in environmental monitoring (EM) sampling where a profile from multiple persons from an unidentified number of events is obtained and the donors cannot be identified.

ITEM: Object, substance or material that is collected, derived or sampled as part of the [forensic process](#). [SOURCE: BS EN ISO 21043-1:2018 *Forensic Sciences Part 1: Terms and definitions*]

PEER REVIEW: Evaluation of the [reports](#), [examinations](#), notes, data and [findings](#) by others competent in the same field to assess that there is an appropriate and sufficient basis for the conclusions and/or opinions. [SOURCE: BS EN ISO 21043-1:2018 *Forensic Sciences Part 1: Terms and definitions*]

PERSONAL PROTECTIVE EQUIPMENT (PPE): Items, for example, clothing and gloves that are used to prevent skin and mucous membrane exposure when in contact with blood and body fluid on or from any complainant. PPE is also worn to protect the practitioner from contact with harmful chemicals, for example, during decontamination and to minimise the chance that the wearer causes inadvertent DNA contamination.

QUALITY MANAGEMENT SYSTEM (QMS): A management system to direct and control an organisation with regard to quality.

REPORT: Communication of outcomes of the forensic process. [SOURCE: BS EN ISO 21043-1:2018 *Forensic Sciences Part 1: Terms and definitions*] These include but are not limited to:

- a. streamlined forensic reports (SFRs);
- b. section 9 statements (Criminal Justice Act 1967);
- c. interim reports;
- d. email; or
- e. oral communication.

STANDARD: In essence, a *standard* is an agreed way of doing something that is a level of quality or attainment.

STATEMENT: A statement is one form of a report. It is formatted to comply with the provisions of s9 Criminal Justice Act 1967.

ANNEX A : SELF-ASSESSMENT QUESTIONNAIRE

The Forensic Medical Examination of Adult and Child Sexual Assault Complainants

The self-assessment questionnaire is part of the consultation on this standard and is published as a separate document for comment.

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