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Forensic Science Regulator
Overseeing Quality

Codes of Practice and Conduct

Sexual Assault Examination: Requirements for the Assessment, Collection and Recording of Forensic Science Related Evidence

FSR-C-116

Issue 1

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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 complainants with the option to assist in any criminal investigation. This can increase the likelihood that the best evidence can be obtained to investigate and aid a criminal prosecution, so that if a criminal offence has occurred, the perpetrator can be caught and prevented from continuing to commit further sexual offences. Scientific evidence can also assist with exoneration of the innocent.

1.1.2 The provision of dedicated high quality healthcare alongside forensic and medical examination [1] for the collection of evidence has considerable benefits for both the health and well-being of complainants and the delivery of justice. 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), wrongful acquittal(s) and delaying investigation(s).

1.1.3 For the purpose of this document, the term 'patient' is used to refer to victims and complainants of sexual assault, both those alleging and those suspected to have been subjected to sexual assault.

1.1.4 In order to achieve high quality and consistent forensic science related evidence provision, defined standards are necessary for all stages of the complainant's 'journey' immediately before and during the forensic medical examination [2]. These standards should not intrude on the healthcare of the patient, but 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 care pathway for the patient varies based on the individual case and the local variation of service delivery.

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

2 Activity includes recording, collecting samples for scientific analysis and documenting injuries.

However, this should not detract from achieving the best health and justice outcomes for the patient.

1.1.5 Forensic healthcare practitioners include doctors, paediatricians and other healthcare professionals (including nurses and midwifes) (7.1) who provide medical and related care to individuals alleging that they were subjected to sexual offences and to persons detained on suspicion of committing these crimes.

2. Scope

2.1.1 This standard applies to cases for which submission to criminal courts in England and Wales applies. Scotland and Northern Ireland may also institute parallel arrangements for their jurisdictions.

2.1.2 The remit of the Forensic Science Regulator covers the forensic sampling for criminal investigations and not medical practices; any reference to medical practice is included for context as forensic sampling and the medical care of patients overlap. The General Medical Council (GMC), the Nursing and Midwifery Council (NMC) and the Health and Care Professions Council (HCPC) regulate doctors, nurses and paramedics respectively.

2.1.3 The Forensic Science Regulator has determined that ISO 15189 Medical laboratories – Requirements for quality and competence is the appropriate international standard for the forensic medical examination services to be accredited to.

2.1.4 The purpose of this appendix to the Forensic Science Regulator's Codes of Practice and Conduct [3] (the Codes) is to set the requirements for the forensic medical examination of patients relating to alleged sexual assault. This covers where the medical examination and collection of evidence [4] from a patient [5] routinely [6] takes place. The names, locations and settings where

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3 Forensic Science Regulator's Codes of Practice and Conduct for Forensic Science Providers and Practitioners in the Criminal Justice System.

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

5 These requirements apply to both self-referrals and patients referred by the police.

6 The use of ad hoc locations such as emergency departments and care homes are not included; however, anti-contamination good practice for the examination and recovery is expected.

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.

2.1.5 Figure 1 (for adults, see page 7) and Figure 2 (for children, see page 8) outline where the facility, procedures and practices occur within the patient's 'journey' from allegation to court. [7] The figures identify the stages where the standards and guidance apply within and outside the control of the facility. The facility shall identify those stages in their local care pathway which are within their control and therefore within the scope of accreditation they require.

2.1.6 The requirement applies to personnel involved in performing and supporting the delivery of the forensic medical examination service 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

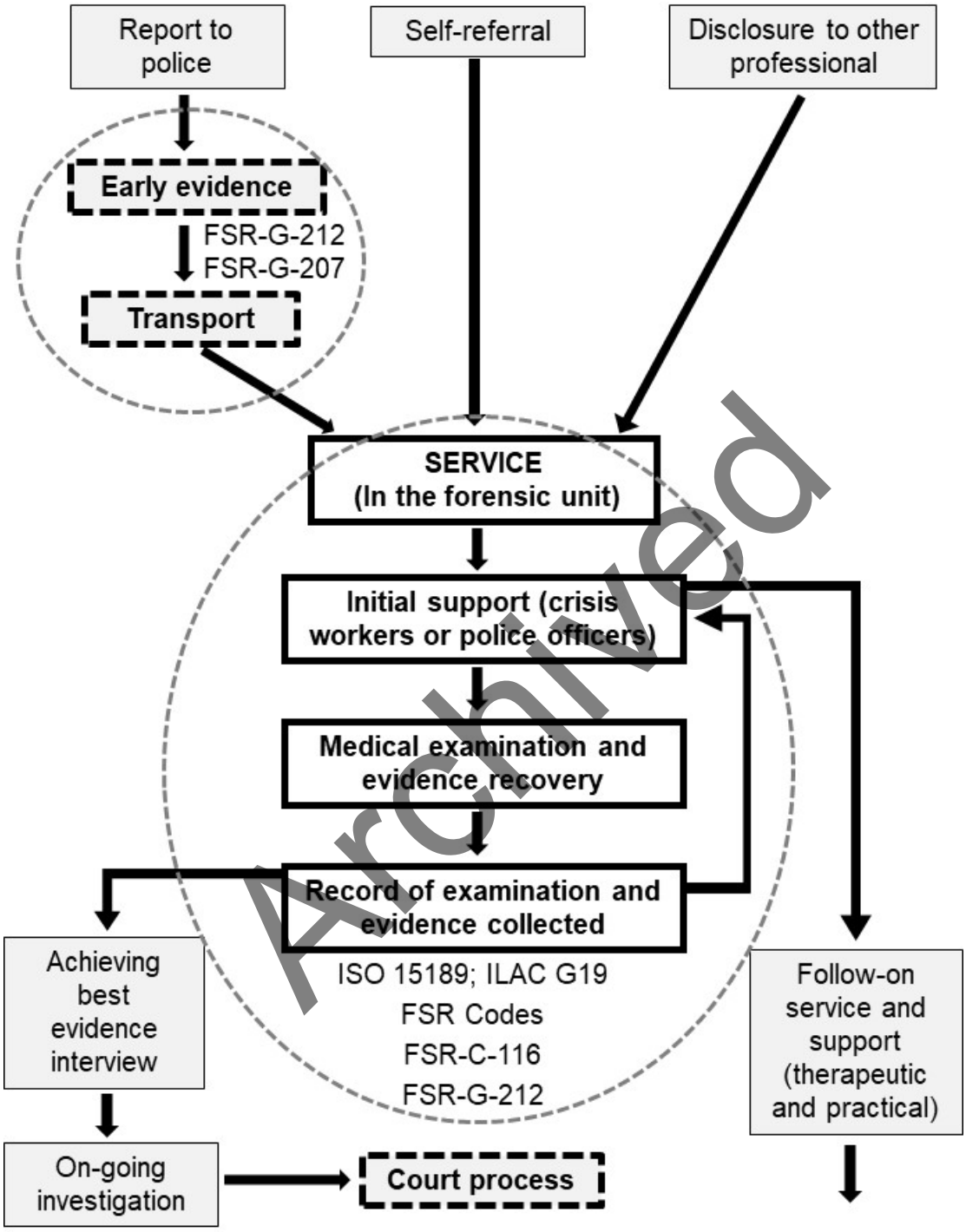
b. those with responsibility for managing the processes, personnel and the facility.

2.1.7 The Forensic Science Regulator's Guidance for the Assessment, Collection and Recording of Forensic Science Related Evidence in Sexual Assault Examinations, FSR-G-212, provides guidance on the forensic science aspects of this standard.

2.1.8 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.

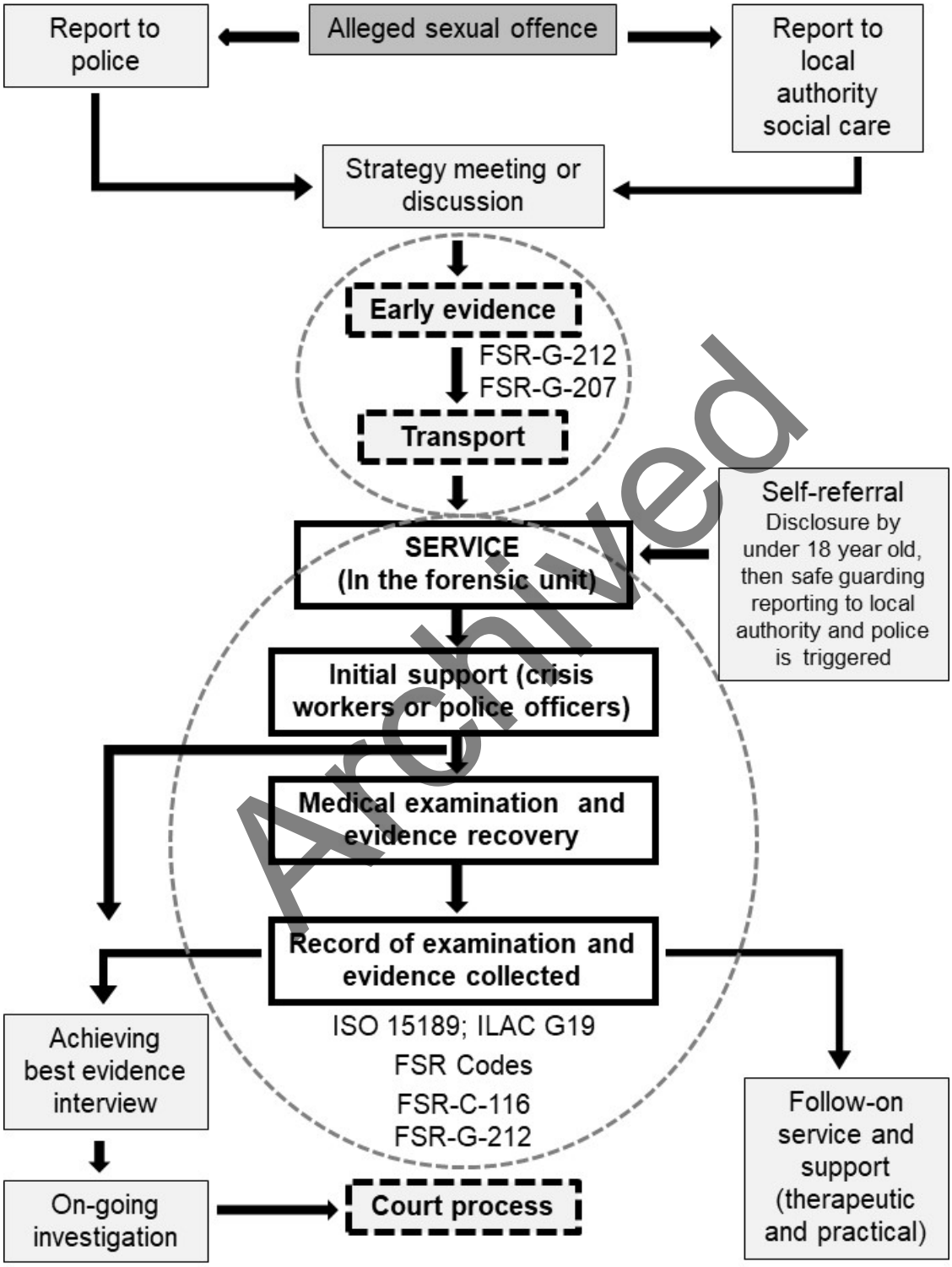
[7] These diagrams are not care pathways nor are they intended to be used as referral routes.

Figure 1. Adult Patient's Journey from Allegation to Court via the (Medical Examination and Sample Collection) Facility.



The standards and guidances apply at the stages in bold text within the facility (solid lines) and outside the control of the facility (dashed lines).

Figure 2. Child Patient's Journey from Allegation / Disclosure / Professional Concern of Abuse to Court via the (Medical Examination and Sample Collection) Facility.



The standards and guidances apply at the stages in bold text within the facility (solid lines) and outside the control of the facility (dashed lines).

3. Implementation

3.1.1 Within the remit of clinical governance the service provider with responsibility for the facility shall ensure that there is a named person with responsibility for ensuring the facility's compliance with this standard. [8]

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 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, DNA Anti-Contamination – Forensic Medical Examination in Sexual Assault Referral Centres and Custodial Facilities FSR-G-207; and
e. Forensic Science Regulator, Guidance for the Assessment, Collection and Recording of Forensic Science Related Evidence in Sexual Assault Examinations FSR-G-212.

3.1.3 This document is available for incorporation into an organisation's standard operating procedures and quality management system from the date of publication.

3.1.4 The following stages with implementation dates apply.

Stage	Implementation Date
Quality management system, quality manual drafted, and quality personnel appointed.	October 2020
Job roles, skills, training and competency requirements framework and standard operating procedures (SOPs) developed.	April 2021

[8] This role may be included as part of the role of 'laboratory director' as given in ISO 15189 (4.1.1.4) and would be in addition to their clinical governance role.

Stage	Implementation Date
Validation/verification of methods and processes and staff competency evidenced against final SOPs.	October 2021
Internal audits, improvement implementation, management review in place. Initial assessment visit scheduled.	April 2022
Accreditation to ISO 15189 Medical laboratories – Requirements for quality and competence with compliance to the Codes.	1 October 2023

3.1.5 A self-assessment readiness checklist is provided in Annex A of this document.

4. Modification

4.1.1 This is issue 1 of this document.

5. Terms and Definitions

5.1.1 The terms and definitions set out in the glossary section apply specifically to this document.

5.1.2 The word 'shall' has been used in this document where there is a corresponding requirement in ISO 15189 or the Forensic Science Regulator's Codes of Practice and Conduct and guidance; the word 'should' [9] has been used to indicate generally accepted practice where the reason for not complying or any deviation shall be recorded.

6. Management Requirements

6.1 General

6.1.1 The management requirements set out in ISO 15189 Medical laboratories – Requirements for quality and competence shall be met to achieve

[9] 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 the guidance can be followed.

accreditation through assessment by the accreditation body. In the UK, assessment against international accreditation standards is undertaken by the United Kingdom Accreditation Service (UKAS).

6.2 Organisation and Management Responsibility (ISO 15189 4.1)

6.2.1 A senior manager from the service provider with responsibility for the facility shall be identified, to support the quality standards.

6.2.2 Management within the facility shall conform to the requirements of the international quality standard ISO 15189 Medical laboratories –Requirements for quality and competence, substituting 'facility' where the standard states 'laboratory'. The management requirements shall include:

a. the organisation and management responsibility of the facility shall be defined and documented;
b. legal entity shall be determined so that it is clear which organisation can be held legally responsible for the facility's activities (ISO 15189 4.1.1.2).

6.3 Quality Management System (ISO 15189 4.2)

6.3.1 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:

a. a quality manual (ISO 15189 4.2.2.2 and 4.1.2.3);
b. procedures, instructions and forms (ISO 15189 4.2; 5.5.3);
c. a document control system (ISO 15189 4.3);
d. service agreements (ISO 15189 4.4) that set out the deliverables to the 'customers' – these may be police forces or health trusts – and other bodies as relevant shall be documented;
e. the assessment of external services and critical supplies, for example, provision of critical consumables and external cleaning services with maintenance of the list of authorised suppliers (ISO 15189 4.6);
f. a documented complaints/customer feedback and resolution process (ISO 15189 4.8);

g. a documented process for identifying and controlling non-conformances (ISO 15189 4.9), such as errors, inadequate cleaning service and contaminated consumables;
h. events of non-conforming work that could potentially cause a miscarriage of justice being referred to the Forensic Science Regulator (ISO 15189 4.9);
i. a documented corrective and preventative action processes (ISO 15189 4.10; 4.11);
j. a continual improvement process (ISO 15189 4.12);
k. evaluation and audits scheduled and completed (ISO 15189 4.14); and
l. 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; FSR-G-212)

7.1.1 The employing body, whether responsible for the facility directly or as a service provider commissioned to work at that facility, shall for the staff in their employ 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 including retraining for any lapse of competence for each role profile;
c. where relevant, expert witness and criminal justice system (CJS) [10,11] related training including written evidence, court skills and avoiding cognitive bias; [12]
d. assessment of training and competency;

10 CPS Guidance for Experts on Disclosure, Unused Material and Case Management.
11 Criminal Procedure Rules and Criminal Practice Directions.
12 Forensic Science Regulator, Cognitive bias effects relevant to forensic science examinations, FSR-G-217.

e. authorisation and commencement for the activities that their staff undertake;
f. continuing professional development to maintain ongoing competency;
g. regular review and appraisal regarding each individual's performance; and
h. 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, prior to the start of any contract.

7.1.3 Guidance on roles within the facility and other related roles is provided in Guidance for the Assessment, Collection and Recording of Forensic Science Related Evidence in Sexual Assault Examinations, FSR-G-212.

7.2 Accommodation and Environmental Conditions (ISO 15189 5.2; ILAC G19 3.11; FSR-G-207; 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 secure environment for both users and staff.

7.2.2 In order to meet the accommodation and environmental requirements if physical building changes or new build have been identified or are necessary, and where the timescale for these are beyond the implementation date for accreditation, the facility shall undertake the following.

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 mitigation and record quality failures (6.3.1j above).
c. Have a documented plan for improvements with timescales that are regularly reviewed.
d. As a minimum disclose in all 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. These shall include controlled areas and rooms that require access to be recorded (7.2.5 and 7.5.9 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 patient bathroom and medical examination areas cleaned to DNA standards as set out in FSR-G-212. 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; FSR-G-208)

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

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. [13] Workstation/work surfaces shall be kept clear, other than for equipment in daily use.

[13] 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.

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). This shall include:

a. the routine cleaning regimes for rooms, areas, equipment [14] 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 7.5.9 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 and denaturing DNA in conjunction with appropriate cleaning procedures. 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 continues to be effective at removing and denaturing DNA through environmental monitoring (8.6 below).

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 of their intended use. [15,16] These shall also include use, handling instructions and disposal.

14 This includes mobile equipment and consumables carried by medical practitioners on call.
15 ISO 18385:2016.
16 British Standard BS PAS 377.

7.4 Examination Methods and Procedures (ISO 15189 4.4, 5.4.2, 5.5)

7.4.1 The service provider 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 patients;
b. documenting and recording relevant information pertaining to the patient throughout the process (9.1 of this report); and
c. prior to patient's arrival at the facility – initial contact.

7.4.2 The facility shall provide accessible correct information and advice about the facility to other relevant on-site service providers and the services that are provided to potential end users (general).

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

a. options available to them for examination, treatment and advice;
b. documentation of the presence or absence of injuries;
c. importance of body fluids and the recovery of forensic science related evidence;
d. impact that actions following the incident might have on the collection of evidence;
e. requirement for an early evidence kit (EEK) sample, as appropriate;
f. 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 forensic healthcare practitioner (7.1 above).

7.4.5 The forensic healthcare practitioner shall provide advice on the recovery of potential forensic science related evidence.

a. Where there is concern about child sexual abuse a paediatrician should be consulted, as part of the strategy discussion, in order to determine whether the child should be examined and if so, at what time and by which practitioner(s).

b. Where it is necessary for the patient to be taken to an emergency department (or undergo an examination in other premises, for example, residential property) the forensic healthcare practitioner shall either attend and/or instruct other healthcare providers.

7.4.6 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 healthcare practitioner

7.4.7 Local policy shall dictate who has the responsibility for requesting the attendance of the forensic healthcare practitioner and the expected time frames for attendance at the facility.

7.4.8 The facility or provider of the forensic medical workforce shall ensure that a timely response can be provided to reflect the needs of the patient.

7.4.9 The forensic healthcare practitioner attending the forensic medical examination should not provide any service to custodial facilities, for example, police stations and detention centres during that shift. [17] Where more than one patient is referred who may be involved in the same incident, or different patients are thought to be part of a linked series of cases, they should be examined in separate suites and by different healthcare practitioners. Where this is not possible, this should be documented, and an explanation provided; measures taken to minimise the potential for cross-contamination shall be documented.

Arrival of the patient

7.4.10 The process for the end-to-end journey through the facility for a patient (and their supporters) shall be defined. This shall include:

a. who shall meet, accompany and support the patient;

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17 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 CJS.

b. their role in supporting and advocating for the patient throughout their time at the facility;
c. information on the options available, the purpose of the forensic medical examination to the patient, and how they will be supported throughout;
d. pre-examination activities to be undertaken, and by whom;
e. how the examination will be conducted; and
f. follow-up and referrals post-examination.

7.5 Examination and Evidence Collection (ISO 15189 5.4.4, 5.4.3, 5.5; ILAC G19 4.3.3)

Preliminary matters

7.5.1 The forensic healthcare practitioner shall introduce themselves to the patient (and their supporter[s]). For younger children or those who are not Gillick competent, [18] the supporter(s) should be a parent or someone with parental responsibility; an older competent child may wish to have a responsible or trusted adult with them. The practitioner shall 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 is to be used, explaining its purpose, function and how it will be used;
c. explaining that the patient can stop the examination at any time for any reason or indeed no reason, since consent is freely given and withdrawn, but the potential implications of stopping the examination should also be explained; and
d. explaining about early evidence samples if these have previously been taken by police or other personnel.

[18] A Gillick competent child (under 16 years of age) is able to consent for their own medical treatment, without the requirement for parental permission or knowledge.

Obtaining consent

The forensic healthcare practitioner shall obtain informed consent [19] from the patient. Ordinarily written consent is required, but where the patient cannot read or write, then verbal consent (ideally witnessed) would be sufficient. The procedure for obtaining consent shall include the following.

e. That it is given in accordance with current guidelines from the Faculty of Forensic and Legal Medicine (FFLM) [20], the General Medical Council (GMC) and the Nursing and Midwifery Council in accordance with the Mental Capacity Act 2005.

f. It should confirm the patient (or representative/person with parental responsibility if the child or young person is not Gillick competent, see section 7.5.4 below) 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.

g. It should advise that if consent to any part of the examination is declined at any stage, that refusal and any reason, should it be offered, shall be recorded.

h. It should also advise that the notes, images recorded and any reasons for refusal shall be documented and may subsequently be used for evidential purposes, second opinions from medical experts, peer review and audit.

i. It should provide details of with whom information will be shared or to whom it will be disclosed, for example, for the purposes of the investigation/criminal justice, safeguarding, follow-up/ongoing care.

7.5.2 In situations where there is no capacity to consent, the detail and basis of the decision made in the patient's best interests shall be documented such that

19 UK Supreme Court (2015) *Montgomery* v. *Lanarkshire Health Board* UKSC11 2015.

20 FFLM (2011).

the basis for the decision can be reviewed by another competent healthcare practitioner.

7.5.3 Where the patient is a child, reference shall be made to the GMC [21], the Royal College of Paediatrics and Child Health (RCPCH) [22] and FFLM [23] guidance's for obtaining valid consent.

7.5.4 Where the patient does not want to proceed with a police complaint, having taken due regard of the provisions in the Human Tissue Act 2004 [24,25], if available the retention for anonymous analysis of samples could be offered.

First account

7.5.5 Where the patient has already reported the assault to the police or another, an initial account of the incident shall be obtained from the appropriate source(s).This account shall be:

a. confirmed by the professional who has undertaken the first account;
b. confirmed or further clarification obtained where appropriate, minimising traumatisation;
c. if not confirmed, the reason shall be clearly documented in the notes;
d. recorded in the case notes (9.1 below);
e. used to determine the forensic medical examination strategy; and
f. added to medical/social history

7.5.6 The forensic healthcare practitioner shall obtain and record the medical/social history in sufficient detail to enable them to undertake a holistic assessment of the needs of the patient. 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;

21 General Medical Council (2012).
22 RCPCH Child Protection Companion.
23 RCPCH and FFLM (2015).
24 Available at: www.legislation.gov.uk/ukpga/2004/30/contents
25 FFLM (2016).

d. support any subsequent forensic laboratory examination and findings; and

e. address practical and emotional needs.

7.5.7 Prior to commencing and during an examination, the forensic healthcare practitioners should ensure that the therapeutic, practical and emotional needs of the patient are considered. This shall include immediate:

a. treatment of serious injuries;
b. addressing of any time-dependent medical needs or interventions;
c. crisis intervention and support; and
d. translation and interpretation, if required. [26]

Record of attendees

7.5.8 A record of all persons in attendance at any time during the forensic medical examination shall be made. In addition to retaining this record on the patient's case notes, it shall be retained in the facility and readily accessible for contamination investigations.

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 these should be documented.

Removal of clothing

7.5.10 The facility shall have a documented procedure for the removal, packaging and labelling of clothing to minimise contamination and the loss of evidence. The integrity of the items once packaged shall be maintained, prior to handing over to the police.

7.6 The Examination Process (ISO 15189 5.5; ILAC G19 4.7)

7.6.1 The examination process shall be defined and documented. The process shall include:

[26] Where interpreters are necessary, family members shall not be used and the gender preference of the patient shall be taken into account.

a. the collection and documentation of relevant information;
b. the examination strategy;
c. the order of the examination activities;
d. photography; and
e. 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; FSR-G-207 and the Codes)

7.7.1 The facility shall have a documented procedure for taking appropriate forensic samples on a case-by-case basis. These shall include:

a. DNA anti-contamination good practices;
b. sample recovery good practice;
c. recording, labelling and packaging of samples; and
d. chain of evidence and sample transfer.

Storage of samples

7.7.2 The facility shall have a policy and procedures in place for the taking, storage, retention and destruction of samples. These shall include due consideration of the Human Tissue Act 2004.

Sample documentation

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

Images

7.7.4 The facility or service provider shall have a policy and procedures in place for the electronic capture, storage and transfer of images. 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; and

f. disclosure of images for CJS proceedings and dealing with the information security implications.

8. Ensuring the Quality of Examination Procedures (ISO 15189 5.6; the Codes)

8.1 Contamination Minimisation

8.1.1 The facility shall have a policy and procedures in place that minimise the possibility of contamination from the moment a patient arrives at the facility to undertake a forensic medical examination until the completion of that examination. The requirement to minimise contamination shall be balanced against the needs of the patient at every stage.

8.1.2 Although the main focus is to minimise DNA contamination, other forensic science related evidence 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/Barrier Clothing (ISO 15189 5.2.5; FSR-G-207; FSR-G-212)

8.2.1 Personal protective equipment (PPE)/barrier clothing shall be worn and changed between each patient to minimise contamination. Further guidance is provided in FSR-G-212.

8.2.2 The policy and procedures for the use of PPE/barrier clothing shall as a minimum include:

a. the PPE/barrier clothing that the forensic healthcare practitioner and attendees at the medical examination shall wear;
b. the order in which to put on PPE/barrier clothing;
c. the frequency of changing PPE/barrier clothing; and
d. the disposal of PPE/barrier clothing.

8.3 DNA Elimination Samples (ISO 15189 5.2.6; FSR-P-302)

8.3.1 A policy and procedures shall be in place to obtain a DNA elimination sample for its inclusion on a searchable elimination database from all staff who work

at the facility prior to entering any part of the forensic area of the facility. These will include (but is not limited to) forensic healthcare practitioners, paediatricians, crisis workers (CWs), cleaning staff and contractors.

8.3.2 All other attendees entering the facility, (including the patient, whether police-referral or self-referral cases, interpreters, friends and family) are not required to give a DNA elimination sample prior to entry but shall have their details recorded in case there is a need to request a sample at a later date for contamination elimination purposes.

8.3.3 Consideration should be given to excluding from the medical examination room any individuals who are not willing to provide their details. These policy and procedures shall take into account the requirements and guidance set out in the Forensic Science Regulator's Protocol FSR-P-302 [27] and shall include the following.

a. The taking of the DNA elimination samples.
b. Agreement/consent for sample donation from:
    i. practitioners and support staff, for example, CWs; 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. Details of those with whom the profile will be shared.

8.4 Decontamination Measures (ISO 15189 5.2.6; FSR-G-208)

8.4.1 A policy and procedures shall be in place for dealing with the event that multiple patients from the same incident attend the facility at the same time.

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

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

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

a. training and authorisation of staff (7.1 above);
b. good practice cleaning methods equivalent to those used in forensic DNA laboratories; [28]
c. frequency of good practice cleaning and deep cleaning;
d. decontamination of re-usable equipment (ISO 15189 5.3.1.3); and
e. records of cleaning including the name of the cleaner and when.

8.6 Environmental Monitoring and Gross Contamination (ISO 15189 5.2.6; FSR-G-208; FSR-G-212)

8.6.1 A policy and procedures shall be in place for monitoring of the level of background DNA and the effectiveness of the cleaning regimes in place (7.3.3 above). These 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 EMS;
c. 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. DNA analysis of the EM samples by a forensic science provider which is accredited to ISO 17025 and required to provide timely processing and reporting of results;
g. advice and feedback from the forensic science provider undertaking the EMS;
h. defined follow-up processes to investigate gross contamination and address unacceptable levels of DNA contamination.

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

9. Documentation – Recording of Notes and Reports

9.1 Note Taking and Record Keeping (ISO 15189 4.13; ILAC G19 3.5; the Codes)

9.1.1 A policy and procedures shall be in place for documenting, recording and storing information pertaining to each patient. 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 patient;
c. recording the notes contemporaneously;
d. recording barrier clothing/personal protective equipment (PPE) worn by the forensic healthcare practitioner(s) and attendees during the medical examination;
e. identification of the forensic healthcare practitioner, and the date and time (if appropriate) of the activity;
f. amendments made to the record(s);
g. the generation of preliminary findings or final reports; [29,30]
h. the secure retention of notes, including permanent records such as colposcope images, [31] complying with data protection requirements; and
i. access to notes and images for second opinion, peer review, investigation and criminal justice proceedings.

9.2 Reports (ISO 15189 5.7.1, 5.8.1; the Codes; FSR-G-200; and FSR-G-225)

9.2.1 The service provider shall have a process for the production of statements and reports in a format that takes due regard to the disclosure obligations, the requirements set out in the Criminal Procedure Rules and Criminal Practice Directions[32] for experts. Legal obligations are set out in FSR-I-400

29 Forensic Science Regulator, Expert Report Guidance, FSR-G-200.
30 Forensic Science Regulator, Non-Expert Technical Statement Guidance, FSR-G-225.
31 FFLM (2017).
32 Available at: www.justice.gov.uk/courts/procedure-rules/criminal/rulesmenu-2015.

[33] and disclosure requirements in the Guidance for Experts on Disclosure, Unused Material and Case Management [34].

9.2.2 Forensic healthcare practitioners shall be appropriately trained (7.1 above) and supported to produce a report that is acceptable for use within in the criminal justice system. 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 a suitable level of knowledge, experience and authority to perform such a review.

10. Review

10.1.1 This published document will form part of the review cycle as determined by the Forensic Science Regulator.

10.1.2 The Forensic Science Regulator welcomes comments. Please send them to the address as set out at: www.gov.uk/government/organisations/forensic-science-regulator, or email: FSREnquiries@homeoffice.gov.uk

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[33] Forensic Science Regulator, Legal Obligations, FSR-I-400.

[34] Available at: www.cps.gov.uk/legal-guidance/cps-guidance-experts-disclosure-unused-material-and-case-management

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12. Abbreviations

Abbreviation	Meaning
BS EN	British Standard European Norm
CJS	Criminal justice system
CPS	Crown Prosecution Service
CW	Crisis worker
DNA	Deoxyribonucleic acid
EEK	Early evidence kit
EM	Environmental monitoring
EMS	Environmental monitoring sampling
FFLM	Faculty of Forensic and Legal Medicine
FSR	Forensic Science Regulator
GMC	General Medical Council
ILAC	International Laboratory Accreditation Cooperation
ISO	International Organization for Standardization
PAS	Publicly available specification
PPE	Personal protective equipment
QMS	Quality management system

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

13. Glossary

CHILD(REN): A child is anyone who has not yet reached their 18th birthday. [Back]

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

COMPLAINANT: A person who makes a complaint or allegation of having been the victim of a criminal offence. See Patient. [Back]

CONSUMABLES: Single-use commodities used in the collection, preservation and processing of material for forensic analysis. [Back]

CRITICAL CONCLUSIONS CHECK: another suitably qualified and competent healthcare practitioner scrutinises the report to ensure that (i) the report is internally consistent, (ii) the conclusions drawn are justifiable from the information set out in the report and (iii) the report is capable of being understood without reference to other material. See Peer Review. [Back]

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

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 or all of the following reasons (not an exhaustive list).

a. Poor practice [35] employed by staff using fixtures and fittings and/or collecting forensic samples.

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

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 patient 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. [Back]

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

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. [Back]

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. [Back]

EVIDENCE: Facts, information and samples taken to support or contradict an assertion. It also includes the absence or presence of injuries (fresh and healing), scars, and elements of the history pertaining to and provided by the patient. [Back]

EXAMINATION: Activity or process of observing, searching, detecting, recording, prioritising, collecting, analysing, measuring, comparing and/or interpreting. [Back]

EXAMINATION STRATEGY: Plan outlining the roles, task and requirements for the examination phase of a forensic process. [Back]

FACILITY: The physical environment used for any medical examination and sample collection, which in part is a forensic unit. [Back]

FINDING: Information obtained from an investigation or examination. [Back]

FORENSIC: Scientific methods, techniques and processes used to aid an investigation into a crime. [Back]

FORENSIC HEALTHCARE PRACTITIONER: The term is used to describe forensic physicians (both doctors and paediatricians), forensic nurses, forensic midwives and paramedics. [Back]

FORENSIC MEDICAL EXAMINATION: Activity or process of observing, assessing, prioritising, recording, collecting samples for scientific analysis, documenting injuries and interpreting with reference to sexual assault offences. [Back]

FORENSIC PROCESS: The joining up and interaction of various forensic plans or activities.

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. [Back]

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.] [Back]

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 sampling (EMS) where a profile from multiple persons from an unidentified number of events is obtained and the donors cannot be identified. [Back]

ITEM: Object, substance or material that is collected or sampled as part of the forensic process. [Back]

PATIENT: In the context of this document, a patient is an individual subjected to or suspected of being subjected to sexual assault. [Back]

PEER REVIEW: Evaluation of the work of other competent practitioners in the same field to assess that there is sufficient basis for the conclusions and/or opinions, and the implications for the disclosure of unused material in criminal investigations. See Critical Conclusions Check. [Back]

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 patient. 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. [Back]

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

REPORT: Communication method of the forensic findings. These include but are not limited to:

a. streamlined forensic reports (SFRs);
b. section 9 statements (Criminal Justice Act 1967);
c. interim reports. [Back]

STANDARD: A standard is an agreed way of doing something that is a level of quality or attainment. [Back]

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

14. Annex A: Self-Assessment Readiness Guide

14.1 About this Self-Assessment

14.1.1 This self-assessment contains an overview of the standards that a facility shall achieve in order to meet the Forensic Science Regulator's (FSR's) Codes of Practice and Conduct (the Codes) relating to the forensic medical examination of sexual assault patients.

14.1.2 The purpose of the self-assessment is to provide a guide that can give an indication of the areas where a facility may need to improve, or where it is doing well. It is important to note that this self-assessment template does not provide information about 'how' to demonstrate compliance with the standard, as some of this level of information is contained within the guidance FSR-G-212.

14.1.3 This self-assessment is divided into two categories: Management Requirements and Technical Requirements. The requirements contained in each of these two categories are there to provide a general overview as to how your facility is performing in each area.

14.2 Self–Assessment Completion

14.2.1 Against each requirement there are four possible assessment options. These indicate where a facility currently stands on any particular requirement.

a. Fully Met – Every aspect of the standard has been met or exceeded. A facility can evidence this by both documented and practical examples where applicable.
b. Partially Met – Some or most of the standard has been met and can be evidenced. This option should be selected if a facility undertakes activities to meet the standard but cannot evidence it, or has not effectively communicated with employees about it.
c. Not Met **–** None or very little of the standard has been met. This option should be selected if activities, procedures or systems are still under development or have not been implemented.

d. Not Applicable – The standard covers an area that does not relate to a facility due to the nature of its activities, location or other practical reason.

14.2.2 Against each requirement evidence to support the assessment score is recorded, these could include standard operating procedures (SOPs), completed forms, logs, audit, activity witnessing and demonstrations.

Part A. Management Requirements

1	**Organisation and Management Responsibility**	**Assessment**	**Evidence**
1.1	The organisation and management responsibility of the facility is defined and documented.		
1.2	The facility has an organogram/organisation chart or similar that clearly shows the lines of management/reporting (e.g. responsibility, clinical governance structures and legal responsibilities) that cover all aspects of the facility, including the personnel working therein.		
1.3	The facility is managed by a person or persons with the competence and delegated responsibility for all aspects of the services provided.		
1.4	Policies on business continuity, independence, impartiality, integrity and confidentiality are in place at the facility.		
2	**Quality Management System**	**Assessment**	**Evidence**
2.1	A quality management system (QMS) is in place that directs and controls the activities for all providers of services at the facility with regard to quality.		
2.2	The QMS for the facility includes all of the elements listed below: • quality manual; • procedures, instruction and forms; • document control system; • non-conformance process; • continual improvement process; • risk evaluation and audit; • management review; • customer feedback and complaints process; • provision of goods and services (contracts and service-level agreements [SLAs]).		

2	Quality Management System	Assessment	Evidence
2.3	A quality manager (however named) has been appointed to ensure that the QMS functions correctly.		

Part B. Technical Requirements

3	Training and Ongoing Competence of Personnel	Assessment	Evidence
3.1	All professionals working within the facility have undergone training in both theoretical and practical aspects of forensic science according to the roles within which they are working. These would include sampling, packaging and anti-contamination procedures.		
3.2	All professionals working within the facility have been assessed for competency in the theoretical and practical aspects of forensic science according to their roles. Records are kept showing how competency was achieved and is maintained.		
3.3	Each individual has access to continuing professional development to maintain ongoing competency.		
3.4	Records of individuals' continuing professional development are maintained and retained.		
3.5	All professionals working within the facility have the required background checks/clearances.		
4	**Accommodation and Environmental Conditions**	**Assessment**	**Evidence**
4.1	Accommodation at the facility is age-appropriate and accessible to the communities it serves, including service deliverers.		
4.2	Accommodation at the facility has adequate security for the service, users and staff (e.g. security camera at facility entrance/alarm system linked to local police response). There is an entrance for use by the patient and their companions that is separate and not open to the public.		

4	Accommodation and Environmental Conditions	Assessment	Evidence
4.3	The forensic areas of the facility include a pre-examination waiting room (a separate waiting area for patients who may undergo a forensic medical examination), which is cleaned to DNA standards. There is a policy regarding its use and whether it can be designated and maintained as a DNA clean area.		
4.4	The forensic area of the facility includes a dedicated forensic medical examination room, of sufficient size and appropriate layout, which is the designated DNA clean area.		
4.5	The forensic area of the facility includes a dedicated bathroom/toilet facility, cleaned to DNA standards, accessed from the medical examination room and corridor, where early evidence collection can be conducted and where the patient can shower post-examination.		
4.6	There is a dedicated area for staff and visitors to change into or put on barrier/personal protective clothing that is away from the DNA clean examination areas.		
4.7	The forensic area of the facility is secure at all times with controlled entry into and exit from the designated forensic medical examination room. Records of all personnel (date, time and activity/role) entering the room are maintained.		
4.8	Air movement within and between rooms is managed with measures taken to minimise the risk of contamination from environmental background DNA.		
4.9	Air flow within and between designated forensic areas of the facility is kept to a level that minimises the risk of trace evidence being transferred from the patient to the room environment and vice versa.		
4.10	The layout of the rooms and corridors enables the patient and workflow to progress through the facility in one direction preventing the patient from revisiting any designated DNA clean rooms or areas.		
4.11	The style and finish of fixtures and fittings, such as air-conditioning, ceilings, lighting and working space allow for effective repeat cleaning.		

5	Furnishings and Equipment used for the Examination	Assessment	Evidence
5.1	Workbench surfaces, storage cupboards, seating and examination couches are impervious to water, easy to clean and resistant to disinfectants and cleaning reagents.		
5.2	Batch numbers, expiry dates and the maker of the reagent are displayed on the packaging of reagents/consumables. Batch/lot information is recorded in the case records.		
5.3	Consumables are stored in a secure main store cupboard or room and transferred in small numbers into the medical examination room storage area. Those used for sampling are free from detectable levels of human DNA or forensic DNA grade.		
5.4	In areas where a patient undresses and where they are subsequently forensically examined, floor surfaces are impervious and any joins in the floor are sealed.		
5.5	Computer keyboards, colposcopes and equipment controls are protected by removable flexible covers that can be cleaned or replaced (e.g. colposcope arm and head covers).		
5.6	Where a curtain shields the examination couch, the curtain is disposable.		
5.7	Guidance is provided on the frequency of curtain replacement and a record is kept of the date and reason for changing the curtain.		
5.8	There is a designated hand-wash basin in the forensic examination room. The taps are capable of being operated without being touched by hand.		
5.9	The medical examination couch has height and position adjustments to allow for ease of movement. Disposable covering is changed between each examination.		
5.10	There is a labelled storage area for keeping consumables used for the forensic medical examination and packaging of samples, which is kept suitably clean and protected from contamination.		
5.11	Equipment records and unique identifiers per key item are used. For example, which colposcope was used is noted.		

5	Furnishings and Equipment used for the Examination	Assessment	Evidence
5.12	There is an approved sharps box and clinical and domestic waste receptacles; appropriate disposal provisions are in place.		
5.13	A general forensic clean of the waiting room, forensic medical examination room and bathroom is undertaken prior to and/or after each examination. Additionally, an up-to-date cleaning protocol is held with a cleaning log, recording the cleaner, date, time and areas cleaned.		
5.14	Deep cleaning of the forensic medical examination room is undertaken in accordance with the cleaning procedure and takes place at least every month.		
5.15	The forensic medical examination room is sealed after each clean and the door labelled.		
5.16	The cleaning products and spillage kits used, and the manner of application, have been demonstrated to be effective in removing detectable levels of DNA.		
5.17	The application of the cleaning product is carried out according to the manufacturer's guidelines and in a manner compliant with health and safety requirements.		
5.18	Standards used for the collection of evidence are the same for both patients who self-refer to the facility and those who are referred to the facility by the police.		
5.19	Where appropriate (e.g. colposcope) records are kept of equipment calibrations, cleaning, maintenance and/or service records.		
6	**Examination Methods and Procedures**	**Assessment**	**Evidence**
6.1	All healthcare professionals working at the facility who come into contact with patients of sexual violence have the relevant skills, knowledge and competency to work with patients in the immediate aftermath of an alleged sexual assault.		
6.2	Facility staff have a clear understanding of the different ways that patients of sexual assault may behave following an assault. A non-judgemental approach is adopted in every case.		

6	Examination Methods and Procedures	Assessment	Evidence
6.3	Staff at the facility ensure that patients (and their accompanying person) are always given the correct information and advice regarding a forensic medical examination and the options available to them.		
6.4	Staff at the facility are able to provide basic information to patients and their accompanying person about: • options to attend the facility and the opportunity to undertake a forensic medical examination; • options to report the sexual offence to the police if they so choose; • potential medical concerns of the patient that relate to the alleged sexual assault; • the importance of body fluids and the recovery of such forensic evidence; • the provision of early evidence samples; • the impact different actions may have on the collection of evidence; and • the value of clothing in providing evidence.		
6.5	Staff at the facility are aware that the time spans for conducting a forensic examination will vary on a case-by-case basis. The decision whether or when to carry out a forensic medical examination is made in consultation with a forensic healthcare practitioner. The collection of forensic samples is only one aspect and consideration is always given to other forensic evidence, such as interpretation of injuries and the therapeutic needs of the patient.		
6.6	The facility has a policy in place that identifies who has the responsibility for requesting the attendance of the forensic healthcare practitioner and/or paediatrician, and the expected time frames for attendance at the facility.		
6.7	The provider of the forensic medical workforce ensures that they are able to 'provide a timely response' (within two hours, or as agreed for a particular case, specifically if a child is involved) to reflect the clinical and forensic needs of the patient.		
6.8	Separate rotas are in place to ensure that the forensic healthcare practitioner available for sexual offence forensic medical examinations is not also used for custody medicine during the same time period.		

6	Examination Methods and Procedures	Assessment	Evidence
6.9	Where more than one patient is referred who may be involved within the same incident, or different patients are thought to be part of a linked series of cases, they are examined in separate suites and by different forensic healthcare practitioners.		
6.10	Where it exceptionally becomes necessary to use the same forensic healthcare practitioner for both forensic medical examinations of a patient and custody medicine examination, the reasons are recorded together with the steps undertaken to reduce the risk of contamination.		
6.11	A crisis worker (or equivalent) is available to meet the patient (and their accompanying person), accompany them to the pre-examination waiting area of the facility and provide immediate support.		
6.12	The crisis worker is able to ensure that a urine sample or oral sample is taken using the early evidence kit and that non-intimate skin swabs are taken where appropriate		
6.13	The forensic healthcare practitioner or paediatrician (where appropriate) uses the medical history, together with the first account, to guide the examination, evidence collection and support any subsequent forensic laboratory examination and findings.		
6.14	Where more than one person conducts the examination, all forensic healthcare practitioners agree their roles and responsibilities before the examination commences and document this.		
6.15	A record of all persons in attendance at any time during the forensic medical examination is made. The name and contact details for each visitor, including non-facility professionals in attendance, are recorded, including details of the areas they accessed, together with information about which PPE if any was worn in DNA controlled areas.		

7	Collection, Storage and Transport of Forensic Samples	Assessment	Evidence
7.1	The facility has clear policies for uniquely labelling, sealing and storage of samples to provide a clear documented chain of continuity for all forensic samples and for sexually transmitted infection (STI) samples where they may be relevant to the forensic case.		
7.2	Where the patient has reported the alleged assault to the police, it is the responsibility of a police officer to transfer evidence from the facility to the appropriate laboratory or other designated storage site used by the police. This is recorded appropriately to demonstrate the chain of custody.		
7.3	Where the patient has not reported the alleged assault to the police, it shall be the responsibility of the forensic healthcare practitioner or crisis worker to transfer evidence from the examination room to the storage room(s) within the facility. This is recorded appropriately to demonstrate the chain of custody.		
7.4	Samples collected before or during the forensic medical examinations are stored in secure locations at the facility with access restricted to authorised nominated personnel (for self- and non-police referrals).		
7.5	The facility follows sample storage policies agreed with the police and the forensic science provider to ensure that optimal storage conditions for all samples collected as part of the forensic medical examination are maintained. A policy on storage timescale requirements and a destruction timeline is also in place and agreed.		
7.6	Where samples are held in cold storage at the facility, a system is in place to ensure that samples are kept at a specified temperature at all times, which includes maintaining temperature monitoring logs and use of alarms to notify failure of the equipment.		
7.7	The facility has ensured that policies are in place to address evidence storage in cases where the patient is undecided about reporting to the police.		
7.8	There is adequate space and provision at the facility to store samples taken from patients who self-refer.		

7	Collection, Storage and Transport of Forensic Samples	Assessment	Evidence
7.9	The sample collection, labelling, transfer and storage of evidence collected as part of the forensic medical examination is documented to ensure that there has been no loss or alteration of evidence prior to criminal proceedings.		
7.10	Forensic healthcare practitioners or paediatricians (where appropriate) are appropriately trained and familiar with how to operate the equipment required to capture a permanent record/image.		
7.11	Imaging records taken by forensic healthcare practitioners or paediatricians (where appropriate) are stored securely by the facility.		
7.12	The facility has a defined system for the secure storage of records, which protects the anonymity of the patient.		
7.13	Procedures are in place to enable the disclosure of notes and images where a request is made in court proceedings.		
8	**Ensuring the Quality of the Examination Procedure**	**Assessment**	**Evidence**
8.1	System wide auditing the quality of forensic medical examination procedures to include the following: • adherence to procedures that minimise the possibility of contamination; • record keeping for the use of locks/security seals for rooms in the forensic area; • steps that have been taken to identify contamination; • that staff understand the scientific basis for preventative and decontamination procedures; • that staff are competent in conducting cleaning and the associated record keeping; and • that an audit plan is in place.		

8	Ensuring the Quality of the Examination Procedure	Assessment	Evidence
8.2	To undertake a medical examination, the forensic healthcare practitioners wear barrier clothing/personnel protective equipment (PPE) as defined below: • disposable barrier clothing such as scrubs or aprons and disposable sleeve covers; • face mask; and • non-latex powder-free gloves (available in a range of sizes). In addition, it is preferable to wear the following: • mob caps; • shoe covers. Where it is considered inappropriate to wear a face mask (or other PPE item), this is recorded with the reasons.		
8.3	Forensic healthcare practitioners know the correct order in which to put on barrier clothing/PPE and change it after every forensic examination, cleaning or maintenance task.		
8.4	The facility has processes in place to address: • agreement/consents for DNA elimination sample donation and use of profile information; • security and access of information at a local/national level; • secure and recorded transfer of samples in accordance with guidance provided by the forensic science provider that will undertake the DNA profiling for elimination purposes; and • sharing agreement of DNA profile information (between staff member, facility management, forensic medical provider, police investigator).		
8.5	All staff working within the facility have provided a DNA elimination sample prior to entering any part of the forensic area of the facility.		
8.6	DNA elimination samples are taken taking account of the requirements and guidance in the Forensic Science Regulator's Protocol FSR-P-302.		
8.7	A record is kept of: • which room is used for each examination; • the date and times of the examination; and • the names of all persons who enter the examination room during the examination, including interpreters and any person who supports the patient.		

8	Ensuring the Quality of the Examination Procedure	Assessment	Evidence
8.8	Cleaning of the facility is carried out and recorded on a cleaning log for audit purposes.		
8.9	Cleaning is conducted by appropriately trained staff every time the forensic waiting, examination and bathroom areas of the facility have been used.		
8.10	Cleaning is undertaken using cleaning equipment dedicated solely for use in each DNA clean area and using a cleaning regime validated or verified to provide effective DNA decontamination.		
8.11	Deep cleaning is regularly scheduled and conducted at least every month.		
8.12	The environmental monitoring sampling (EMS) scheduling plan is in place (appropriate frequency established through trend analysis) and sampling is conducted midway between each deep clean.		
8.13	When contamination is identified, the room or equipment is immediately deep cleaned and EMS swabs are taken. The quarantine or use of the room or equipment is determined by risk, and the criteria to be reinstated are clearly defined.		
9	**Records, Notes and Statements**	**Assessment**	**Evidence**
9.1	Each contact with the patient by any professional is clearly, accurately and legibly recorded in the set of case notes pertaining to that patient.		
9.2	Notes are recorded contemporaneously or, where this is not possible, notes are made as soon as possible after the activity has taken place. Batch numbers of consumables/reagents/equipment/barrier clothing/PPE, and who used/wore them, are recorded in the case notes.		
9.3	All notes (including permanent records such as colposcope images) are retained by the facility in a secure location that complies with data protection requirements.		
9.4	The notes are available and accessible if they are required for the purpose of the investigation, peer review, second opinion and any court proceedings.		

9	Records, Notes and Statements	Assessment	Evidence
9.5	Where notes are required to be removed from the facility, the reason for removal is documented. A record is kept by the facility of the professional removing and returning the notes within an agreed timescale.		
9.6	The facility has defined a process for the production of statements and reports in an agreed format and to an agreed standard. There is a policy regarding quality assurance of statements/reports.		
9.7	Where preliminary findings are provided, these are recorded in writing with appropriate caveats.		
9.8	The facility has defined a process for a critical conclusion check of the report/statement by a second competent individual.		
9.9	Forensic healthcare practitioners are appropriately trained to produce a statement that is acceptable for use within in the criminal justice process.		
9.10	All forensic healthcare practitioners are provided with ongoing support from an appropriately experienced forensic physician to assist them with statement writing.		

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