

UKAS Observations with Recommendations

This news article provides recommendations to address observations raised by UKAS in a recent pre assessment visit to a SARC. Please note that these observations are specific to the operating model and processes within this SARC observed at that time.

This is one in a series of FCN SARC News articles to address the UKAS observations raised in Issue #07

If you have any questions relating to these findings, please do not hesitate to get in contact: michelle.gaskell@dorset.pnn.police.uk

Audit Type:	Pre-Assessment (Pilot)
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Observations

Objectives & Policies ISO 15189 Section 5.5
UKAS Observation
No objectives or quality indicators have yet been established.
FCN Recommendations
<p>A quality indicator is a measure of the degree to which a large number of characteristics of an object fulfils requirements. Indicators can measure how well an organisation meets the needs and requirements of users and the quality of all operational processes.</p> <p>SARC management must establish and maintain objectives and policies to:</p> <ol style="list-style-type: none"> 1) meet the needs and requirements of its patients and users, e.g., a quality indicator might be to provide a forensic medical examination within 2 hours of a request. 2) commit to good professional practice, e.g., FHPs to attend x case reviews annually (you would need to justify this number). 3) provide examinations that fulfil their intended use, e.g., Review of DNA results from casework. 4) conform to ISO15189. e.g., maintain UKAS accreditation. <p>These quality indicators shall evaluate performance throughout key aspects of pre-examination, examination, and post-examination processes and monitor performance in relation to objectives. e.g., the objective maybe to ensure the integrity of forensic evidence and a quality indicator could be 98% of forensic evidence submissions have no transcription errors, this could for example be measured by feedback from police submissions.</p> <p>Objectives shall be measurable, and consistent with policies and must be implemented and understood at all levels of the SARC organisation. Personnel must be aware of what their contribution is to the effectiveness of the management system, including the benefits of improved performance and know the consequences of not conforming with the management system requirements. This might be achieved through PDR where personnel could be set targets that align with each of the organisation’s quality indicators.</p> <p>The quality indicators should be considered when there are any changes within the organisation to ensure the integrity of the management system is maintained. e.g., any changes made to address a non-conformance should first consider if this change has any impact on the organisation’s quality objectives.</p> <p>The quality indicators must be monitored which includes establishing the objectives, methodology, interpretation, limits, action plan and duration of monitoring. This might be achieved by including quality indicators as a standing agenda item in monthly quality meetings.</p> <p>The indicators shall be periodically reviewed, to ensure continued appropriateness. This should be achieved by including quality indicators as a standing agenda item in the annual management review meetings.</p> <p>The Quality Manual or Procedure or Policy should include the SARC objectives and quality indicators.</p>

Facilities: ISO 15189 Section 6.3
UKAS Observation
An environmental monitoring regime is in place and although work is underway to hone this further, the EM procedure needs work to accurately describe the process including responsibilities and record keeping.
FCN Recommendations
<p>The purpose of Environmental Monitoring (EM) is to check that the forensic cleaning process has been effective. EM is one way of demonstrating effectiveness (but not necessarily the only way).</p> <p>The EM sampling locations and frequency of sampling should be determined based on risk and a sampling schedule must be in place, for example using FCN-SAR-TEM-0026 Environmental Monitoring Log available on the Knowledge Hub. The forensic cleaners should not have access to this EM sampling schedule and the person collecting the EM swabs should be different to the person conducting the forensic clean.</p> <p>Further guidance on EM has been provided in FSR-GUI-0017 Section 6.4 e.g.:</p> <p><i>EM samples should take the form of a dip sample exercise and be conducted midway between deep cleans; this may be done by using monitoring forms with pre-printed sample collection sites.</i></p> <p><i>Initially the monitoring should be carried out monthly to build a picture of the background level of DNA across the operational work areas and to achieve a steady state of acceptable levels. Based on the results returned, the frequency of the sampling and/or cleaning can be adjusted, and areas targeted based on risk and previous results.</i></p>

Samples should be taken by swabbing selected areas, (for example the work bench, the sample trolley and the examination couch) and equipment which are in contact with operators, patients at all stages of the forensic medical examination process. The development of a training manual explaining the EM dip-sampling procedure, which includes photographs of the areas/items to be swabbed, is good practice.

All of the above information should be set out in a procedure including responsibilities and information on the forensic service provider turnaround times and reports. Section 6.4.6 sets out the FSP criteria for evaluating EM results.

The actions required based on the EM results must be clearly defined within the procedure along with details of how EM is recorded, where this information is and how it is monitored. Personnel conducting the EM sampling must be trained.

Facility ISO 15189 Section 6.3

UKAS Observation

Records are kept in a locked cabinet.
However, the cabinet is not fireproof, and the cabinet key is kept on top of the cabinet.
Further, the office window (which takes up the entire wall) faces a public space.
Overall, this set up poses a security risk to the security of these records.

FCN Recommendations

Keys should be stored in a locked storage and a list of staff who have access to those keys should be maintained using for example FCN-SAR-TEM-0014 Access Rights which is available on the [Knowledge Hub](#).

A risk assessment of data storage can be used to assess the risks of the storage processes in place and actions taken to mitigate the risks identified which may include electronically backing up data or using fireproof cabinets. Example risk assessments (e.g. FCN-SAR-REP-0002 Glove Process Risk Assessment) are available on the [Knowledge Hub](#).

The layout of the facility should consider the location of windows in office spaces and the examining room, screens or window frosting or transfers could be considered.

Equipment: ISO 15189 Section 6.4

UKAS Observation

It is apparent that different roles within the SARC are required to wear different attire during the examination of a patient.
The attire of the Sexual Offence Examiner is still to be decided and must take account of the FSR requirements.

FCN Recommendations

PPE is an important anticontamination measure to reduce the risk of cross contamination.

We recommend you take a risk-based approach to determine what PPE is appropriate in the different areas of the SARC, this can be achieved by mapping out the end-to-end process of the Forensic Healthcare Practitioner, the crisis worker and the supporters and identifying where the risks are within that process. Mitigations, proportionate to the risk identified can then be established, this can be recorded on for example FCN-SAR-REP-0002 Glove Process Risk Assessment available on the [Knowledge Hub](#). This completed risk assessment will provide your justifications for the level of PPE required.

FSR-GUI-0017 section 7.5.2 provides guidance on PPE:

PPE should include as a minimum:

- a. Disposable barrier clothing: such as scrubs or aprons and disposable sleeve covers, this should cover all clothing or skin;*
- b. Gloves: Two pairs of disposable non-latex powder-free gloves (for example, nitrile). The outer pair of gloves should be changed; between sampling different areas; before handling equipment; or after touching frequently touched surfaces, such as taps, door handles, bins, curtains. The outer pair of gloves should also be changed after manoeuvring the curtain around the couch regardless of whether it is a disposable curtain or not.*
- c. Face mask, mob cap, and overshoes: it is preferable that these are worn. Ideally a pinch-nose type face mask should be used and talking should be kept to a minimum when recovering DNA samples*

The PPE requirements and process should be defined within a procedure or work instruction for example FCN-SAR-WIN-0004- PPE Work Instruction available on the [Knowledge Hub](#). This should include the PPE requirements, where PPE should be donned and doffed and how, for all personnel and supporters that might enter a forensic area of the facility.

Impartiality: ISO 15189 Section 4.1

UKAS Observation

Impartiality and conflict of interest was discussed, the following need defining:
Is this a Force process (If so which Force in the collaboration)?
Where is this information kept? E.g., In a procedure or training record?
Do all staff have a signed statement of declaration?

The organisation will need to ensure that they can demonstrate what the risks to impartiality are and how they are managed and reviewed. This should include staff awareness of the process to escalate any concerns regarding potential risks to their impartiality. See also the FSR Code of Practice Section 17.

FCN Recommendations

Each individual SARC operating model may be different, some involving a number of different service providers therefore it is important that there is an impartiality procedure and agreement that is in place which is followed by all staff.

There will need to be clear evidence that the legal entity approves the various policies being followed and that they form part of document control/review to ensure they remain fit for purpose for the requirements of the legal entity.

If there is more than one organisation within a collaboration, it needs to be clear which organisation's impartiality process/policy is followed and by which staff.

The location of the impartiality formal agreement (which may be within staff contracts or an agreement that is signed by all staff) should be stated within a procedure and should be easily accessible as evidence for an audit.

A risk assessment would be a suitable means to demonstrate what the risks to impartiality are and how they are managed. This risk assessment should then be reviewed on a regular basis along with a mechanism in place for staff to add to this risk assessment/register.

The impartiality procedure/policy should explain this process and how the process and any associated risks are managed.

Staff should have awareness of the principles and escalation procedures regarding risks to their impartiality. How mitigations are embedded in processes etc. will be assessed by UKAS.

Ensure that procedures & training are in place to make staff aware of the risks of conflicts of interest & threats to impartiality (lots of examples listed in FSR Code 17.1.2).

Ensure the procedure(s) detail the process where a practitioner identifies there may be a conflict of interest, including immediate declaration to the commissioning party.

Risk registers should identify what the risks to impartiality are rather than just having 'impartiality' detailed as a risk. For example: The SARC staff having personal relationships with or knowledge of the victim/suspect relating to the case they have been allocated.

It is recommended that the management review has an additional section to cover a review of threats to impartiality. This may assist the SARC in making the review process more transparent.

Consider providing bespoke confidentiality and impartiality training /awareness to Crisis Workers and Forensic Healthcare Practitioners to highlight expectations and including examples relating to the operational environment they work in.

Requirements for confidentiality at the SARC should be documented in technical procedures to give clear guidance to staff. This could include but is not limited to:

- How case information or updates are discussed verbally within the SARC either face to face or via mobile phone or radio, e.g., in a suitable area, away from the victim or members of the public that could potentially hear the conversation.
- Sensitive information, case notes etc. should be shielded from other staff working within the SARC facility e.g., cleaners.

Risks to impartiality and confidentiality could be included in any competency exercises or knowledge checks and documented in the staff members' training records

Complaints ISO 15189 Section 7.7

UKAS Observation

There is currently no documented process for the handling and management of complaints. Documentation to describe the process for handling complaints must be publicly available.

Considerations to the process for and circumstances under which the FSR must be notified must be included (see FSR Code 23.2)

FCN Recommendations

A process must be in place for receiving and actioning complaints from patients, commissioning parties, internal and external staff and the judicial system.

This process shall be recorded in a procedure clearly defining what constitutes as a complaint, the SARC must ensure that appropriately scaled reviews are instigated on receipt of any complaints.

This procedure must contain the following information:

- A description of the process for receiving, substantiating and investigating the complaint, and deciding what actions shall be taken in response. (The resolution of complaints can lead to implementation of corrective actions or be used as input into the improvement process).
- Tracking and recording the complaint, including the actions undertaken to resolve it; ensuring appropriate action is taken.
- A description of the process for handling complaints shall be publicly available.

Leaflets left with patients could include details on how to feedback on the SARC service, or feedback could be sought through Independent Sexual Assault Advisor (ISVA) contact.

Complaints could be received via a central and confidential location e.g., a Quality Team inbox. There should be options to leave feedback both electronically (via an email address or link to internet page) or via telephone/letter for members of the public who may not have access to the internet.

Upon receipt of a complaint, the SARC shall confirm whether the complaint relates to SARC activities that the SARC is responsible for and, if so, shall resolve the complaint.

The SARC receiving the complaint shall be responsible for gathering all necessary information to determine whether the complaint is substantiated.

Whenever possible the laboratory shall acknowledge receipt of the complaint, and provide the complainant with the outcome and, if applicable, progress reports.

Investigation and resolution of complaints shall not result in any discriminatory actions. The resolution of complaints shall be made by, or reviewed and approved by, persons not involved in the subject of the complaint in question. Where resources do not permit this, any alternative approach shall not compromise impartiality.

As per the FSR Code section 23.2.3: The forensic unit shall inform the Regulator via FSREnquiries@forensicscienceregulator.gov.uk or the address given at www.gov.uk/government/organisations/forensic-science-regulator at the earliest opportunity about any complaint or non-conforming work in respect of FSAs if it has significantly disaffected any relevant party such that it could attract adverse public comment, be against the public interest, or lead to a miscarriage of justice.

You are advised to ensure these points raised above are addressed within your organisation before your UKAS visit and having evidence ready to share with UKAS demonstrates you are aware of the issues, know how to address them, have prepared well and therefore increases the likelihood of a successful visit. **Please share your UKAS findings with us from any preassessments or assessments to help support SARCs nationally in achieving accreditation.**