Forensic Science Regulator
Overseeing Quality

Forensic Science Regulator Protocol

Forensic Pathology Audit

FSR-P-304

Issue 2

1. Purpose

1.1.1 The purpose of this document is to set out the process employed by the Forensic Science Regulator (the Regulator), and those acting on behalf of the Regulator, in relation to audits of the work of forensic pathologists.

2. Scope

2.1.1 This document covers the audit of forensic pathologists in the UK undertaken on behalf of the Regulator.

3. Modification

3.1.1 This is the second issue of this document published by the Regulator.

3.1.2 Previous documents covering this subject have been produced by the Forensic Pathology Specialist Group (FPSG).

3.1.3 Substantial changes from the previous version are highlighted.

3.1.4 The modifications made to create Issue 2 of this document were, in part, to ensure compliance with The Public Sector Bodies (Websites and Mobile Applications) (No. 2) Accessibility Regulations 2018. [1]

3.1.5 The Regulator uses an identification system for all documents. In the normal sequence of documents this identifier is of the form 'FSR-#-###' where (a) the '#' indicates a letter to describe the type or document and (b) '###' indicates a numerical, or alphanumerical, code to identify the document. For example, the Codes are FSR-C-100. Combined with the issue number this ensures each document is uniquely identified.

3.1.6 In some cases, it may be necessary to publish a modified version of a document (e.g. a version in a different language). In such cases the modified version will have an additional letter at the end of the unique identifier. The identifier thus becoming FSR-#-####.

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[1] To facilitate compliance with the Regulations changes to the document are noted here. The following sections of the document have been changed – 3.1.3, 3.1.4, 3.1.5, 3.1.6, 3.1.7, 4.1.1, 5.1.3, 5.2.1, 5.3.2, 5.3.7, 5.4.3, 5.4.7, 5.4.8, 5.4.10, 5.4.11, 5.4.12, 5.4.13, 5.4.16, 5.4.17, 5.4.18, 6, 8, 9, 11.4.1 and 15. The following footnotes have been altered - 3.

3.1.7 In all cases the normal document, bearing the identifier FSR-#-###, is to be taken as the definitive version of the document. In the event of any discrepancy between the normal version and a modified version the text of the normal version shall prevail.

4. Effective Date

4.1.1 Issue 2 of this protocol becomes effective on 1 August 2021.

5. Provisions

5.1 The Purpose of Audit

5.1.1 The FPSG acts on behalf of the Regulator to recommend standards and monitor the quality of investigations carried out by forensic pathologists. While the primary concern of the FPSG is all those practitioners registered with the Home Office operating within England and Wales, the Group also includes representatives from both Scotland and Northern Ireland and promotes the adoption of similar standards across the whole of the UK.

5.1.2 Home Office registered forensic pathologists operate to standards enshrined in a Code of Practice [1] published by the Regulator. The Code is regularly reviewed and updated by the FPSG, and is issued in partnership with the Royal College of Pathologists, the Home Office and the Northern Ireland Department of Justice. One way in which adherence to the Code is monitored is through audit.

5.1.3 The purpose of audit is to monitor standards, identify and disseminate examples of best and less good practice, and thus work to ensure the high quality of forensic pathology. The FPSG will review on a regular basis the best ways in which this can be achieved, and agree the format of an appropriate programme.

5.1.4 In devising an audit programme the FPSG will consider:

a. The aims and objectives of the exercise;
b. The format of the exercise;
c. The frequency of audit exercises;

d. The appointment of an audit lead, a co-ordinator, and a supporting team to undertake the exercise (the appointment of auditors is dealt with in the note approved by the FPSG on 13 June 2013) [2] [3]; and

e. The manner in which feedback of the results is provided to participants.

5.1.5 Pathologists registered with the Home Office are obliged to participate in the FPSG audit. Those practitioners working in Northern Ireland and Scotland take part by invitation.

5.1.6 The FPSG will report to the Regulator regularly on the standards of the profession as revealed during audit.

5.2 Audit Team

5.2.1 The audit is performed by a group comprising a co-ordinator, a number of forensic pathologists, one or more coroners and a number of senior police officers.

5.2.2 This ensures the audit can consider the technical aspects and the usability of the reports by the intended users.

5.2.3 The coroner and police members of the Team are referred to as the "lay members".

5.3 Audit Protocol

5.3.1 The protocol for audit was introduced in 2010. The current version is set out in this document. Other audit formats may, of course, be considered and introduced as required.

5.3.2 The audit programme is based on anonymised post mortem examination reports, with the name of the pathologist and identifying details of the examination redacted prior to scrutiny. The term report shall be considered to mean all reports issues in relation to the case.

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[2] Annex 1 provides the Terms of Reference for Appointment to the Audit Team.

[3] The note was drafted at a time when the Audit Team included one coroner. That has changed so the note must be read in that context.

5.3.3 The Audit Team recommends the focus of the exercise, which may well reflect current concerns within the profession, often obtained through meetings of the British Association in Forensic Medicine (BAFM). The FPSG considers whether these recommendations are appropriate, and agrees the focus and nature of the audit. Exercises are currently undertaken approximately annually.

5.3.4 Material for audit is requested from participants by the co-ordinator, who assigns a unique code to each case report and ensures that it is redacted so as to prevent identification by the auditors of both the author and the deceased. This code is used to identify the material throughout the exercise so that names of individual participants are not revealed to Audit Team members. The key to the code remains confidential to the co-ordinator.

5.3.5 The anonymised reports are assessed by a small group of experienced forensic pathologists, a coroner, and one or more police senior investigating officers. Using the Code of Practice [1] [4] as the standard, the pathologists review technical aspects of the report in order to identify examples of both good and less good clinical practice. The lay assessors scrutinise the material on behalf of the user, commenting as appropriate on the perceived value of the document to a non-medical reader who needs to understand the import of the scientific findings.

5.3.6 It sometimes happens that an auditor has already had some active involvement in a case presented for audit, for instance, they may have carried out an examination on behalf of defence lawyers. In these circumstances that fact should be notified to the co-ordinator who will then arrange for the case to be submitted to other members of the team.

5.3.7 The assessments are collated by the co-ordinator, who compiles confidential individual summaries which are provided to the participants concerned. This feedback to each of the participants will be in a formal manner suitable for use within the revalidation process. Where appropriate the feedback may compare the participant's performance across different audits.

[4] There is a separate Code for Scotland but in technical issues there is no significant difference between the Codes.

5.3.8 The co-ordinator also prepares and publishes a report in which significant audit findings are presented anonymously, and produces an action plan to ensure follow up of significant issues.

5.4 Discovering Potentially Serious Errors

5.4.1 The primary purpose of audit is quality assessment. It is a way of identifying examples of good practice, feeding back this information to participants, and in this way encouraging the spread of good practice across the profession. Audit carried out by the FPSG will normally be anonymous; the intention is not to be a method of discovering errors in a practitioner's work. This concept is important in order to maintain general acceptance of audit.

5.4.2 It has to be accepted, however, that during scrutiny of a case report some error or deficiency may be discovered which appears to have the potential to lead to a miscarriage of justice. In this event audit may move outside the realm of straightforward quality assessment as far as a particular practitioner is concerned. It is important that a robust procedure is in place to cope with this situation.

5.4.3 The FPSG has agreed three well-defined stages to deal with such a situation. At each stage the potential seriousness must be assessed; the next stage will be triggered only if the deficiency is considered so serious that further action must be instituted. Adherence to these stages is important.

Stage 1

5.4.4 Where a member of the Audit Team has some slight concern about an aspect of a case report the co-ordinator will be informed in order that the report in question can be circulated to every auditor for assessment. Following this scrutiny the Audit Team will agree whether the issue can be addressed by appropriate advice and if so, such feedback will be agreed by the Audit Team and relayed to the practitioner by the co-ordinator.

5.4.5 Recirculation of cases in this way is considered to be a completely normal aspect of audit; experience indicates that up to 5% of cases may require such consideration.

5.4.6 During this stage the name of the author of the report will not be revealed to the auditors.

Stage 2

5.4.7 If the concerns are more significant or if Stage 1 did not address concerns the Audit Team may decide, by decision of the Audit Team lead, it would be appropriate to examine more work from the pathologist concerned. The audit co-ordinator will then request the practitioner to submit further reports, the number and type of which will be decided by the Audit Team. On receipt the co-ordinator will anonymise the reports in the same manner as previously and then circulate them to members of the Audit Team for scrutiny.

5.4.8 This is a normal part of the audit process.

5.4.9 Having carried out this further assessment team members will agree whether any identified deficiencies can still be satisfactorily addressed by appropriate advice to the practitioner concerned. Such feedback, containing the comments agreed by the team, will be prepared by the audit lead and forwarded to the individual pathologist by the co-ordinator.

5.4.10 During this stage the name of the author of the report will not be revealed to the auditors.

5.4.11 In the event of the stage 2 process being initiated the forensic pathologist involved may wish to engage with the relevant responsible officer.

Stage 3

5.4.12 If the Audit Team, by decision of the Audit team lead, does not consider the action taken in Stage 2 sufficient to address the problem it will be necessary to proceed to Stage 3, which moves the procedure away from the audit process. The co-ordinator will inform the Chair of the FPSG of the name of the practitioner involved and such other information as is necessary to allow the Chair to act as set out below.

5.4.13 The Chair of the FPSG will, if satisfied the concerns are justified, refer the concerns of an individual, as highlighted by the audit process, if they practise in England and Wales, to the Responsible Officer of the Pathology Delivery Board (PDB) through the Secretary of the PDB. .

5.4.14 Action taken in Stage 3 of this process is likely to go outside the limits of quality assessment and thus will no longer fall within the remit of the FPSG. The FPSG will not become involved in such action and the identity of the pathologist involved will not, as part of this process, be disclosed to the auditors.

5.4.15 In the event that auditors identify serious deficiencies in the work of a pathologist working outside the Home Office system, that is, one operating in Northern Ireland or Scotland, reference cannot be made to the PDB as this body has no responsibility outwith England and Wales. The action to be taken in any particular case may need to be considered on its merits by the Chair of the FPSG in conjunction with the Regulator.

5.4.16 The Chair of the FPSG will, if satisfied that the concerns are justified, refer the concerns of an individual, as highlighted by the audit process, if they practise in Northern Ireland, to the Responsible Officer of the Department of Justice. through the Director of Safer Communities.

5.4.17 The Chair of the FPSG will, if satisfied that the concerns are justified, refer the concerns of an individual, as highlighted by the audit process, if they practise in Scotland, to the relevant responsible officer.

Potential Miscarriages of Justice

5.4.18 It is possible, albeit unlikely, that the Audit Team will consider a serious error (identified in the audit process) has created a significant risk of a miscarriage of justice. In such cases the audit co-ordinator will provide the name of the practitioner and necessary information about the matter to the Chair of the FPSG and the Regulator. The Regulator, following discussions with the Chair of the FPSG, will determine what steps are necessary to deal with the risk of the potential miscarriage. This will normally involve informing the relevant prosecuting authority of the issues surrounding the case.

5.4.19 This process may be followed regardless of whether any other steps are taken in respect of the error.

6. Data Protection

6.1.1 Data protection issues are considered in Annex 2.

7. Review

7.1.1 This document is subject to review at regular intervals.

7.1.2 If you have any comments please send them to the address or e-mail set out on the Internet at URL: www.gov.uk/government/organisations/forensic-science-regulator

8. References

1 Code of Practice and Performance Standards for Forensic Pathology in England, Wales and Northern Ireland, Forensic Science Regulator, Royal College of Pathologists, Home Office and Northern Ireland Department of Justice.

2 Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation).

9. Abbreviations and Acronyms

Text	Meaning
BAFM	British Association in Forensic Medicine
FPSG	Forensic Pathology Specialist Group
PDB	Pathology Delivery Board
RO	Responsible Officer
SI	Statutory Instrument
UK	United Kingdom
URL	Uniform Resource Locator

Annex 1 – The Appointment of Members to the Audit Team

10. Forensic Pathology Specialist Group Audits

10.1.1 Audit of the work of forensic pathologists is undertaken by the FPSG on behalf of the Regulator. and will be carried out by an Audit Team consisting of suitably qualified and experienced individuals.

10.1.2 Audit will normally be carried out through the scrutiny of individual forensic pathologists' case reports and will involve completion of documentation by the auditors on each case submitted for assessment. Audit may also necessitate face to face meetings to discuss matters of concern. Administration of the programme will be carried out by a co-ordinator appointed by the FPSG.

11. The Audit Team (Pathologists)

11.1.1 Up to five forensic pathologists will comprise the Audit Team. The FPSG retains responsibility for agreeing the criteria for the selection of individuals who comprise this group.

11.2 Criteria for Appointment of Pathologists to Audit Team

11.2.1 In order to serve on the Audit Team a pathologist must:

a. Be registered with the Home Office, including specialist registration with the General Medical Council in a relevant category;
b. Possess at least five years experience of active casework in forensic pathology;
c. Be affiliated to a Home Office group practice; and
d. Be subject to no current investigation by a regulatory body.

11.2.2 Forensic pathologists from outside England and Wales will be eligible to join the Audit Team provided their status, experience and current working practice is deemed equivalent to that of a Home Office registered practitioner.

11.2.3 Forensic pathologists who possess extensive experience in case investigation but who do not meet the above criteria, for example, those who have recently retired, may also be eligible to join the group.

11.2.4 The Responsible Officer (RO) [5] has wide-ranging responsibilities across the whole of the profession of forensic pathology, some of which may conflict with the independent nature of audit. Accordingly, while not specifically barred from membership it will not normally be appropriate for the RO to be a member of the Audit Team.

11.3 Representation within the Profession

11.3.1 Within the criteria outlined above, the Audit Team should be as representative of the profession as is practical, in terms of:

a. The geographical spread of practices (need to represent the diversity of practices; should not normally have more than one auditor from a practice); and
b. Age (preferable that not all members be retired or approaching retirement)

11.4 Appointment

11.4.1 Pathologists appointed to the group will normally serve for between three and five audits; reappointment may be permitted. Appointment to the group will be made by the FPSG which may institute specific arrangements, for example elections, to identify appropriate candidates. In order to ensure rotation of the membership while retaining appropriate continuity, it will normally be necessary to appoint one or two new members to the group each year.

11.5 Audit Lead

11.5.1 The lead member of the Audit Team will be appointed by the FPSG. Subject to the agreement of the Regulator, the audit lead may attend meetings of the FPSG if not already a member of the group.

12. Non-Medical ('Lay') Members of The Audit Team

12.1.1 A coroner will normally be a member of the Audit Team. His/her function will be to assess the material from the perspective of the coroner.

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[5] The Responsible Officer is that person appointed by the Pathology Delivery Board under the provisions of The Medical Profession (Responsible Officers) Regulations 2010 [S.I. 2841 of 2010].

12.1.2 One, or two, police Senior Investigating Officers with significant experience in the investigation of homicide are nominated on an annual basis by the National Homicide Working Group to be a part of the Audit Team. Their function will be to assess the ease of understanding of the report to the lay reader, and to advise on the potential value of the material to the investigating officer.

12.1.3 The function of the non-medical auditors will not be to comment on the medical aspects of the examination.

12.1.4 The FPSG will be responsible for appointment of the non-medical members of the Audit Team.

13. Audit Co-Ordination

13.1.1 The Regulator, who may act on the advice of the FPSG, will appoint a co-ordinator to administer audit and prepare such reports on the results of audit exercises as are required by the FPSG.

13.1.2 Subject to the agreement of the Regulator, the audit co-ordinator may attend meetings of the FPSG if not already a member of the Group. It will not usually be necessary for both the audit lead and the co-ordinator to attend meetings of the FPSG.

14. Resolution of Contentious Issues

14.1.1 Should any cases(s) being scrutinised at audit prove particularly contentious an independent pathologist, nominated by the FPSG, may be asked to advise the Team.

Annex 2 – Data Protection

15. Data Protection

15.1 Personal Data

15.1.1 The performance of the audit will require the processing of personal data. This may include the processing of special category personal data under the provisions of Art 9 and Art 10 General Data Protection Regulation [2].

15.1.2 The extent to which personal data is processed is reduced by the anonymisation, by the co-ordinator, of the material submitted for audit.

15.2 Legal Provisions

15.2.1 The processing must comply with the provisions of the Applied General Data Protection Regulation as implemented by the Data Protection Act 2018.

15.3 Lawful Processing

15.3.1 The processing of personal data for the purposes of the audit is lawful as it is undertaken in the public interest (see Art 6(1)(e) General Data Protection Regulation).

15.4 Information

15.4.1 The controller of the personal data is the Forensic Science Regulator. The contact details for the Regulator are as follows.

Forensic Science Regulator

5 St Philip's Place

Colmore Row

Birmingham

B3 2PW

15.4.2 The data protection officer designated by the Forensic Science Regulator, and who has agreed to act in that capacity, is the Home Office Data Protection Officer. The contact details are as follows.

Email: dpo@homeoffice.gov.uk

Telephone: 020 7035 6999

15.4.3 The personal data will be processed for the purposes of the audit as set out in this protocol. The data shall not be provided to any person (outside the audit process) unless that is necessary to address a potential miscarriage of justice or serious concerns about the work of a forensic pathologist. In the event of a potential miscarriage the information may be provided to relevant public authorities including (but not limited to) the police, the Crown Prosecution Service and the Criminal Cases Review Commission. In the event of serious concerns as to the work of a forensic pathologist the information may be shared with appropriate regulators.

15.4.4 The Regulator will disclose information from the audit if forced to do so by an order issued by a court of competent jurisdiction but will seek to prevent such orders being made.

15.4.5 The personal data collected for the purpose of the audit will be retained for a period of 10 years.

15.5 Rights

15.5.1 The subjects of the personal data held in relation to the audit have certain rights. These include.

a. Access to the personal data held.
b. Request rectification of the personal data.
c. Request erasure of the personal data.

15.5.2 It must be recognised the right to request does not equate to a right to have the data rectified or erased as there are restrictions on the requirements to accede to a request.

15.5.3 Anyone wanting to find out how to access the data or request changes to the data should contact:

Home Office Science Secretariat

14th Floor

Lunar House 40

Wellesley Road

Croydon

CR9 2BY

Email: sciencesupportfoi@homeoffice.gsi.gov.uk

15.5.4 The subjects of the data also have the right to complain to the Office of the Information Commissioner. This can be contacted at:

Information Commissioner's Office

Wycliffe House

Water Lane

Wilmslow

Cheshire

SK9 5AF

Telephone: 08456 30 60 60 or 01625 54 57 45

Fax: 01625 524510

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