

Joint Code of Practice for Research

Guidance arising from the baseline assessments carried out by the United Kingdom Accreditation Service (UKAS).

Following the launch of the Joint Code of Practice for Research (henceforth referred to as “the Code”) in May 2003, Defra commissioned the United Kingdom Accreditation Service (UKAS) to perform baseline assessments against the Code at a selection of our research contractors. The aim of the baseline assessments was to gauge the level of preparation for the introduction of the Code ahead of it coming into force in June 2004. This would help us identify if there were any areas of the Code that organisations had difficulty addressing (difficulties that could be evident across the whole contractor base), enabling us to offer guidance on possible solutions to those difficulties.

The assessments, which were undertaken between December 2003 and May 2004, examined how a selection of current^a Defra-funded projects (deemed to be representative of all Defra-funded projects carried out at the organisation) were being performed. The quality assurance measures in place, as well as those planned, were considered in light of the requirements of the Code, and UKAS reported on where those measures could be improved to fully meet the Code’s requirements.

A number of opportunities for improvement were identified across the assessed organisations. This document summarises the guidance offered by UKAS in response to their findings. The guidance has been generalised and indicates the type of activities that UKAS consider would fulfil the Code’s requirements. The over-riding principle of the Code is that processes should be fit for purpose and, as such, this guidance should be interpreted appropriately.

The guidance is not a prescriptive method for meeting the Code’s requirements and is not exhaustive. It is supplied for information, and is intended to aid an organisation in its plans to implement a successful quality assurance scheme.

^a Projects starting before June 2004 are not subject to the Code of Practice. Thus, the projects assessed in the baseline assessments were not audited, but used illustratively to investigate the quality measures that would be applied to Defra-funded projects once the Code comes into force.

Joint Code of Practice for Research

– summary of UKAS guidance on the specific requirements of the Code of Practice

1. Responsibilities

“The organisation is responsible for the overall quality of research conducted within it, including compliance with in-house research and management policies. Managers, group leaders and supervisors have a responsibility to ensure a climate of good scientific practice in the research teams, including a commitment to the development of scientific and technical skills.

The Principal Investigator or Project Leader is responsible for all the work conducted in the project including that of any subcontractors. All staff and students should have defined responsibilities in relation to the project and be aware of these responsibilities.”

Summary of findings:

The roles and responsibilities of project staff should be well defined. Organisations should always use the latest version of the Defra application form (available for downloading). Principle investigators are responsible for the all the work conducted in the project, including that of subcontractors. Organisations should chose to use subcontractors who are able to meet the requirements of the Code and can satisfy themselves of this. Where a subcontractor can not provide suitable assurances that the Code’s requirements can be met, the organisation may wish to review their need to use that subcontractor. However, where compelling reasons for using a particular subcontractor exist, a risk assessment should be supplied with the Defra application form for consideration by the Project Officer.

Detail of UKAS guidance:

- Organisation structure:** i. Aim to have an up-to-date organisational structure in place which is regularly reviewed to account for staff changes.
- Project personnel:** ii. It would be useful to create a list of all personnel associated with a project (including support and casual staff) with defined roles and responsibilities. This will allow continuity of the project in circumstances of unforeseen absence. This is particularly important in the case of Principle Investigators. Whilst the Defra application form includes details of key staff associated with a project, an internal record would have greater depth

and clarity of precise roles and therefore may be useful.

- Subcontractors:**
- iii. As described in the Joint Code of Practice, the Principle Investigator or Project Leader is responsible for all work conducted on the project, including that of subcontractors. It would be advisable to formulate subcontractor agreements at the start of a project. It may be useful to request an assessment of compliance with the Code at the end of a subcontract arrangement.
 - iv. Defra will not audit subcontractors, and does not expect research organisations to do so. However, Defra expects the project's main contractor to assure itself of the quality assurance measures in place at the subcontractor. Defra are responsible for the review and approval of research proposals which should include an assessment of risk associated with a proposed subcontractor. It is important that Defra is informed if alternative subcontractors are chosen subsequently.
 - v. A policy should be developed on whether 'supply work' (for example, testing) performed by another group within the contractor organisation should be considered a subcontract arrangement, or whether key staff involved should be included in the Defra application form and their roles and responsibilities defined. Supply work that is performed under the project by organisations/personnel not listed in the Defra application form, should, wherever possible, be performed in accordance with the Code. Evidence of such should be sought and a record maintained on the project file.

2. Competence

"All personnel associated with the project must be competent to perform the technical, scientific and support tasks required of them. Personnel undergoing training must be supervised at a level such that the quality of the results is not compromised by the inexperience of the researcher."

Summary of findings:

It is important that an organisation is able to demonstrate that project staff are competent to perform their duties. The maintenance of up-to-date records, such as CVs and training records will facilitate this. Before undertaking work, competency should be demonstrated either through appropriate evidence of

previous experience or by performing checks. Ongoing competency should also be monitored.

Detail of UKAS guidance:

- CVs:**
- i. Consideration of a standard format for staff CVs may help the process of submitting research applications. The CVs of staff (especially key members of staff) should be kept on a central file. It is important that CVs for junior or casual members of staff, which do not accompany the Defra application form, are held on file and show evidence for their involvement in the project.
 - ii. The Defra application form application form requires the CV of key members of staff to be included. Where there is a change to project personnel, it is important that new CVs are supplied to the Defra project officer.
- Training records:**
- iii. Develop competency criteria required for a project at the outset followed by initial training and evaluation of results. Common application of competency criteria should result in consistency.
 - iv. The skills, knowledge and experience of new personnel should be determined on appointment to ascertain level of competency, either from evidence of previous experience or from witnessed assessment. This information can be used in the formulation of a suitable training programme (both internal and external) to ensure that skills are developed appropriately.
 - v. Competency criteria should be determined for staff in the execution of general laboratory duties and in the performance of the range of test methods undertaken. Determination of competency can be based on comparison of results generated by a competent analyst for a defined number of replicates or against suitable reference material. Where measurements have an element of subjectivity and are potentially subject to observer bias, an acceptable level of inter- and intra-assessor variation should be determined. Establish these criteria by comparing results of an experienced observer with the novice for a defined number of observations and by further monitoring at appropriate frequency.
 - vi. Training can be extended as required, including techniques and procedures specific to particular

projects. Ongoing competence should be assessed at suitable time intervals and may be demonstrated by ensuring specified criteria are achieved. For example, for quantitative methods define a permissible percentage error for each parameter measured, or for qualitative methods by the use of reference material or internal quality controls. Objective evidence should be retained in training files and should be subject to review by competent, authorised personnel.

- vii. Where objective information is inappropriate, it may be useful to maintain information relating to the projects that staff have been involved in, with a brief outline of responsibilities. This could be an expansion of their current CV and may provide useful information supporting their subsequent involvement in future, related projects.
- viii. If staff are never signed off as being competent to perform a particular task then record that they have been instructed in a technique/procedure and keep records to show that they have worked under direct supervision. Where training is a process of self-development, a record of this would suffice. When a new protocol results from this process and new staff are instructed, record this information in their training records.
- ix. Laboratory personnel should be subject to assessment of competency in general lab duties, either by witnessed assessment or checks.

3. Project planning

“An appropriate level of risk assessment should be conducted to demonstrate awareness of the key factors that will influence the success of the project and the ability to meet its objectives. There should be a written project plan showing that these factors (including research design, statistical methods and others) have been addressed. Project plans must be agreed in collaboration with the Funding Body, taking account of the requirements of ethical committees or the terms of project licences, if relevant. Significant amendments to the plan or milestones must be recorded and approved by the Funding Body if applicable.”

Summary of findings:

It is important that due consideration is given to risk assessment and statistical validation. This would include recording any statistical advice sought during the project and who gave the advice. Where procedures for sampling materials are

specified in the project plan, it is suggested that protocols are suitably documented, and where possible, standardised.

Detail of UKAS guidance:

- Risk Assessment:** i. A full risk assessment for factors that could potentially affect the ability of a project to deliver its objectives should be made on the Defra application form application form. As new risks emerge, these should be communicated to the Defra Project Officer.
- Statistical validation:** ii. Appropriate statistical advice should be sought in preparing the project design and this should be described on the Defra application form application form. Where statistical advice is sought during the project (e.g. on analysis of results etc), this advice should be recorded on the project file.
- Project plan:** iii. It is recommended that copies of the application form submitted to Defra be retained (i.e. signed copies) as this will show the date signing and a signed declaration of compliance with the Code.
- Approved procedures for sampling materials:** iv. Standard/routine sampling procedures should be adequately documented. Procedures could outline sampling protocols, equipment required, any contamination/health and safety risks, labeling and sample storage. Where, and as far as possible, procedures should be standardised across the organisation.
- v. Consider preparing a list of procedures available within the organisation for use as a reference document for Principle Investigators to use as a basis for similar procedures to reduce duplication of effort.
- vi. Where procedures are required and not documented, these can be drafted by suitably qualified personnel and implemented on the projects. These should be documented and maintained on the project file for reference. Alternatively, samplers can document the protocol in their log books/notes. It may be possible to adapt standard procedures to be project specific.
- vii. Determine and document the procedures that are routine and suitably generic across scientific disciplines and research themes (for example; equipment servicing, maintenance and calibration; data recording; document control).

4. Quality Control

“The organisation should have planned processes in place to assure the quality of the research undertaken by its scientists. Projects should be subjected to formal reviews of an appropriate frequency.

The authorisation of outputs shall be as agreed by the Funding Body, and subject to senior approval in the organisation, where appropriate. Errors identified after publication must be notified to the Funding Body and agreed corrective action initiated.

Processes and procedures should be regularly reviewed against a policy of continual improvement.”

Summary of findings:

Whilst Defra projects are normally subject to regular monitoring by Defra Project Officers, organisations should review projects at planned intervals. Material discussions about a project should be recorded to provide an effective audit trail. This will include developing a policy for storing project-related email.

Detail of UKAS guidance:

Internal project reviews:

- i. It is important that the salient points from discussions with project personnel (including subcontractors and collaborators) are recorded in a note, ideally to a central file. This will allow easy access of information and will establish an audit trail.
- ii. File notes should contain a minimum of information, for example, date, contact person, main points of discussion, further action required or agreed and impact on project (if any). It is important that the format and style of file notes are not overly prescriptive, to ensure that staff are not deterred from recording conversations in this way.
- iii. Determine a policy for storage of project-related email. For example, a central account for project mail could be created that is accessible to all project staff. Alternatively, the policy could be to print emails from individual accounts and maintain a hard copy in the project file. Likewise, policy on which emails should be kept (all, or only those judged important) should be developed:

Auditing/assessment procedures:

- iv. Quality control arrangements should be established at the outset of a project to ensure that analysis is adequately controlled. For standard methods, document QC either in the method, or in a standalone QC document.

- v. QC documents should include the use of blanks, internal standards, certified reference materials, repeat samples, etc. as appropriate. The use of QC charts will show ongoing method control. Limits of acceptability should be defined for all QC parameters and any failures require action.

5. Health and Safety

“All research must comply with the relevant Health and Safety regulatory requirements.”

Summary of findings:

In addition to an organisation’s adherence to health and safety regulations, it is suggested that project specific health and safety plans considerations are made prior to the project commencement and details of this consideration recorded on the project file.

Detail of UKAS guidance:

Documentation on specific projects/health and safety plan:

- i. Records of specific consideration for the health and safety aspects of a project should be retained on a central project file. The use of a standard form at the outset of a project will allow health and safety plans to be drawn up for each project. These should be updated appropriately. If not in place, risk/COSHH assessments should be in place for laboratory activities.

6. Handling of samples and materials

“All samples and other experimental materials should be labelled (clearly, accurately, uniquely and durably), and retained for a period to be agreed by the Funding Body. The storage and handling of the samples and materials should be as specified in the project plan (or proposal), and must be appropriate to their nature. If the storage conditions are critical, they must be monitored and recorded.

Samples must be readily tracked through the stages of analysis or use, and have designated disposal routes and dates.”

Summary of findings:

In order that sample integrity is assured, it is recommended that clear instructions are prepared for sample handling, detailing any critical conditions. Sample

provenance must be assured by adequate labelling to ensure traceability throughout the life of the sample.

Detail of UKAS guidance:

Sample handling and storage:

- i. Instructions for handling samples (labeling, storage, transport etc) both before and after analysis should be established at the outset of the project. Where transport and/or storage conditions/times are critical this should be detailed and evidence retained that the conditions have been met. If no evidence of appropriate storage is available, this may question a sample's use. Storage conditions should be monitored where appropriate to ensure sample integrity.
- ii. It is suggested that samples be given a unique identification number which is traceable and legible throughout the life of the sample
- iii. Policy relating to the retention of samples should be determined at the project outset, bearing in mind space constraints. This should be agreed with the Defra project officer. The policy should also cover the disposal of samples, records of which are required by the JCoP.

7. Facilities and equipment

"The working environment must be appropriate for safe operation of equipment, maintenance of sample quality and integrity, and good working practices. Where special facilities are used (e.g. fume cupboards) they must be regularly checked and maintained.

All equipment must be appropriate for the measurements to be made, calibrated if necessary, and be in good working condition. If critical, there should be contingency plans in case of power failure or other disruption".

Summary of findings:

Laboratory, testing and analytical equipment must be serviced, maintained and calibrated appropriately. This would be effectively achieved through the preparation of a planned programme. Pieces of equipment should be individually identifiable in order to trace back to service/calibration records and/or calibration standards. Such measures will ensure that equipment is appropriate for the measurements to be made.

Detail of UKAS guidance:

Maintenance and calibration records (equipment):

- i. Prepare a programme for the calibration and maintenance of equipment within the laboratories and prepare documented procedures for the use and/or calibration of equipment (e.g. pH meters, pipettes, thermometers, balances). Prepare generic procedures for equipment that will apply across all the laboratories in the organisation. The frequency of cleaning should also be considered and documented. The records of calibrations/maintenance should be maintained, to include the date checked and the initials of staff involved. It would be beneficial for staff to see the results of a calibration or service, or to have a robust agreement that they are notified of any correction factors/problems following this activity.
- ii. For items such as fridges, freezers, hot blocks, incubators etc, use calibrated thermometers to check the temperature. Label the thermometers with a reference number and ensure that the internal calibration of the thermometers is traceable to the reference thermometer used (calibrate the thermometers within the range in which they are to be used).
- iii. Develop a suitable labeling mechanism for items in the laboratory and label units with a unit number. This will aid tracing to calibration and maintenance records. Fridges, incubators, hot blocks etc should also be labeled with their target temperature and the permissible tolerance. The temperature should be recorded at an appropriate frequency and, in the event that the temperature exceeds the stated tolerances, a note of remedial action should be made along with information on potential damage to sample integrity. These data should be recorded on a proforma along with the initials of the recording laboratory worker.

8. Documentation of procedures and methods

“All the procedures and methods used in a research project must be documented, at least in the personal records of the researcher. This includes analytical and statistical procedures and the generation of a clear audit trail linking secondary processed information to primary data.

There must be a procedure for validation of research methods as fit for purpose, and modifications must be trackable through each stage of development of the method.”

Summary of findings:

To ensure that only current protocols, proformas etc are being used, suitable document control should be exercised. Where appropriate, protocols should be standardised and subjected to document control. Where this is not appropriate (i.e. during method development) it is sufficient to record the procedure followed. It should be considered whether results generated from non-validated procedures represent a risk to the project which should be flagged up to the Defra Project Officer.

Detail of UKAS guidance:

**Validated standard
operating procedures:
Document control
procedures:**

- i. Prepare procedures for the range of activities performed in the laboratory.
- ii. Document control procedures should be put in place to ensure that project personnel adhere to the protocols to be implemented. For effective document control, each page of a document should be marked with the page number (page x of y), a unique document reference number and a version number or effective date. Where required, also an authorisation.
- iii. Changes to protocols should be authorised by the appropriate designated personnel and the changes highlighted, either in a cover note to the renewed protocol or by the use of highlighted text. The effective date or version number should change to reflect the amendment. Document control should be applied to proformas also.
- iv. Confirmation should be sought from personnel in possession of superseded documents that they have been destroyed or returned. One copy of any superseded document should be retained to facilitate an audit trail (e.g. to determine which protocols were in operation during a particular phase of a project) and for this purpose, it is necessary to detail the effective date of an updated procedure.
- v. In some cases there will be no need to formally issue procedures e.g. during project development

where a standard approach can not be used. In this case a record of the procedure that has been followed is all that is required. Ideally this will be held centrally and include evidence from the PI that the changing protocol is appropriate.

9. Research/work records

“All records must be of sufficient quality to present a complete picture of the work performed, enabling it to be repeated if necessary.

The Project Leader must ensure the validity of the work by carrying out regular reviews of the records of each scientist.

The location of all project records, including critical data, must be recorded. They must be retained in a form that ensures their integrity and security, and prevents unauthorised modification, for a period to be agreed by the Funding Body.”

Summary of findings:

Records and measurements should be traceable back to staff and should be subject to review. Raw data (which should be permanent and secure) should be maintained and stored appropriately. Agreements should be made with joint- and subcontractors to store data (and samples) for an agreed period.

Detail of UKAS guidance:

Laboratory notebooks/computer files/data recording sheets:

- i. Records (readings, measurements, interventions) should be traceable to the staff involved. Sample recording forms and similar should bear a column to record staff initials. These should be subject to review (for example, to identify outlying values or unusual observations) and records should be countersigned to demonstrate this.
- ii. Raw data (such as fieldwork records, laboratory worksheets, rough notes, original observations, etc) must be maintained and archived to facilitate an audit trail if required.
- iii. Records are required to be kept in an appropriately secure form. Where recording in pencil is required (for example in damp, outdoor conditions), the form can be photocopied to constitute a permanent record which can be signed and annotated as such.

Archiving procedures

- iv. Where data are to be stored electronically, policy needs to be developed to ensure that storage is secure, that data are traceable and that they have been subject to review.

- v. Records do not have to be held in a standard format, but acceptable formats should be decided. Ideally create a central job file to hold information relating to changes, reviews etc. Consider whether email correspondence is to be held electronically or as hard copy. Increased standardisation will aid auditing.
- vi. Ensure subcontractor (and joint contractor) organisations archive data (and samples if required) for a specified period agreed with the lead contractor and Defra. This requirement could be incorporated in subcontract agreements.