

B Reporting and Quality Systems

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B.1 Reporting

The principle of reporting appropriately and accurately is essential to effective communication. Where possible, SEPA *pro formas* should be used. Deviations from such templates should be discussed with SEPA prior to submission. Summary reports not containing raw data may be adequate in some instances. Technical reports should however include relevant raw data and basic statistics usually as appendices. These should include details of methods and sub-sampling procedures if used. Simple graphical or tabular presentations should be used to summarise major trends. Reports should make reference to the quality control systems used and evidence of quality control may be required by SEPA.

B.2 External Data Sources and Self Monitoring

There are clear implications surrounding quality issues particularly regarding data received from external sources. These should, ideally, be from organisations with Quality Systems of a similar standard to the SEPA system. However, in the majority of instances this will not be the case. Therefore SEPA must have systems in place to ensure that third party submissions contain as good quality assurance as possible.

In particular the quality and reliability of scientific data must be reviewed. Incoming data sets must be assessed for completeness, quality of analysis and the reliability and validity of data. Good data are dependent on good position fixing, sampling techniques, analytical techniques, adequate replication and expertise.

B.3 Quality Assurance and Control

B.3.1 Quality Assurance

In order that decision making has a valid scientific basis, it is essential that all data collected are of a sufficient quality. Quality can be considered to have three aspects:

- Degree of excellence
- Fitness for purpose
- Compliance with requirements

The best way to ensure quality is achieved is to put a documented Quality System in place. This can be defined as “The organisational structure, responsibilities, procedures, processes and resources for implementing Quality Management”.

This Quality System is documented by means of the following:

- (1) Quality Policy Manual - this sets out the policy in addressing the requirements of the Quality Standards.
- (2) Quality Manual - this describes the Quality System in some detail, including Quality Procedures and references to Work Procedures.
- (3) Work Procedures - these detail the day-to-day tasks carried out by the particular laboratories and functions. Included in this category are manufacturer’s instruction manuals and relevant national or international standards.

The Work Procedures include all required information on all methods used:

1. Purpose and Principle of the Method
2. Performance Characteristics of the Method
3. Personnel
4. Safety
5. Reagents
6. Equipment
7. Sampling Procedure
8. Quality Control
9. Collation of Sampling Data
10. References.

B.3.2 Analytical Quality Control

One essential element of each work procedure is the Analytical Quality Control (AQC) protocols adopted. These must form part of each procedure and can have two aspects;

- internal AQC; and
- external AQC.

Internal AQC may involve the parallel analysis of blank and spiked samples in a water chemistry procedure or re-sorting and/or re-identification of infaunal samples for a biological procedure. The aim in both cases is to check the accuracy of results obtained.

The requirement for external QA for data, produced or received by UK Competent Monitoring Authorities (CMA’s), derives from DEFRA policy requiring QA of all data contributing to national, European, or international programmes, such as UK CSEMP (NMMP), European WFD, or ICES. With the implementation of the WFD by various UK CMA’S, including SEPA, it is now regarded as imperative that all data utilised for any Ecological Quality Assessment is validated via a recognised national AQC scheme (where such a scheme exists).

External AQC may involve sending previously analysed samples to an external laboratory for re-analysis and/or participation in an appropriate national QA scheme. In the UK schemes for chemical, biological, or biological effects AQC include Aquacheck, QUASIMEME (Quality Assurance of Information for Marine Environmental Monitoring in Europe), NMBAQC (National Marine Biological AQC scheme), BEQUALM (Biological

Effects Quality Assurance in Monitoring Programmes), and DTAPS (Direct Toxicity Assessment Proficiency Scheme).

Good biological QA schemes do not simply provide a sample auditing service but should offer analytical training exercises including ring tests, reverse ring tests, lab reference tests, real sample tests as well as required audits on a random selection of submitted own samples. There should be extensive feedback and reporting of exercises nationally, guidance on required remedial actions and collation of AQC information into annual reports. In addition the schemes should offer training workshops and issue statements of performance for participants.

For submission of benthic biological data to be accepted, SEPA requires consultants employed by the Responsible Person (named in the CAR authorisation) to participate in an appropriate national AQC scheme, such as the NMBAQC scheme (or any similar marine biological scheme). Consultants are encouraged to participate in all relevant exercises but this must include a random audit of real own samples. For the NMBAQC scheme the minimum participation level is the Benthic Invertebrate Component/Own Sample module (see www.nmbaqcs.org.uk for further details). Consultants must present all relevant benthic biological data and selected samples to the scheme as requested and ensure any required remedial action is carried out. The aim of SEPA's policy is to ensure that all relevant data is fit for purpose and that all relevant samples are available for audit.

B.3.3 Qualified Expert

SEPA requires that biological surveys and tests must be carried out by a 'Qualified Expert' in order to ensure the highest possible quality of outputs. A "Qualified Expert" means a person or persons having the knowledge and training necessary to undertake monitoring surveys on behalf of the Responsible Person (named in the CAR authorisation), as set out in the monitoring protocol specification.

Evidence of such knowledge or training will be required by SEPA. Evidence shall take the form of CVs, or similar statements of experience for all staff directly involved in surveys and analytical tests (or for sub-contractees utilised for similar purposes).

Evidence of membership of an appropriate QA scheme, such as the NMBAQC scheme, and of appropriate knowledge or training for "Qualified Experts" must be submitted to SEPA prior to, or in tandem with, the first survey report submitted to the Agency. Additionally SEPA may on occasion require a copy of the consultant's Statement of Performance from the QA scheme, which is sent to the member annually. Information contained in this statement will be treated as confidential.

B.4 United Kingdom Accreditation Service Requirements and Reporting

Details of the various scientific reporting styles can be obtained from the notes to authors, usually found at the end of each volume of any scientific journal. A useful reference for general writing is Fletcher & Gowing (1987) and many interesting ideas for the graphical presentation of data can be obtained from Crothers (1981).

For all United Kingdom Accreditation Service (UKAS) and/or ISO9002 accredited laboratories, reports must adhere to the UKAS reporting standard as a minimum and it is therefore recommended that all laboratories should adopt this standard. These requirements include: appropriate laboratory and client address, unique identifiers for each report, page numbering, appropriate dates and signatures, methods, results etc.

Each calibration certificate and test report or test certificate shall also convey at least the following information:

- (a) Name and address of the Laboratory;
- (b) Name and address of client;
- (c) Unique identifier of certificate or report (such as serial number);
- (d) On each sheet of the certificate or report, a unique form of sheet identifier (such as serial number of certificate or report, with unique page number in the form "page – of – pages");
- (e) Date of receipt of calibration or test item, and date(s) of performance of calibration or test, as appropriate;
- (f) Date of issue of certificate or report;
- (g) Signature and legible name of approved signatory or signatories taking responsibility for content of certificate or report, or equivalent form of technical authorisation;
- (h) Unambiguous identification of item(s) calibrated or tested (including name of manufacturer of items(s), any model or type designation, any relevant serial numbers as appropriate);
- (i) Any abnormalities or departures from standard condition;
- (j) Reference to calibration or test method and procedure used;
- (k) Any standard or other specification relevant to the calibration or test method or procedure, and deviations, additions to or exclusions from the specification concerned;
- (l) Where relevant to the validity or application of the calibration or test result(s) details of any sampling, item preparation, or data analysis;
- (m) Calibration or test result(s);
- (n) Any design or performance specifications met or failed;
- (o) Estimated uncertainty of the calibration or test result (this information need only appear in test reports and test certificates where it is relevant to the validity or application of the test result, where a client's instructions so require or where uncertainty affects compliance to a specification or limit);
- (p) Any other available information requested by a client, relevant to the validity or applicability of the calibration or test result.

B.5 Management of Database

It is important that SEPA has comprehensive data on the location, size and other details of all marine (and freshwater) fish farms. This information is held in a relational database. The Fish Farm database is the key to linking information on inspections, fish farm records and monitoring data (as described in Section 8.0 of the Manual).

The database is the primary tool for the production of data outputs to inform other internal SEPA systems, e.g. Scottish Pollutant Release Inventory, and also external customer requirements, e.g. FRS Locational Guidelines.

The database is used in conjunction with SEPA's Geographical Information System (GIS) so that farms in different categories can be shown on maps and linked to other available data. The information will be able to be queried using any variable to produce reports to the user. For example to list all the farms in any defined marine system or the fish biomass in any system.

The management of the database is controlled and it is important that the database is updated regularly in a structured way with any authorisation reviews, monitoring survey data or changes in use of chemicals.

B.6 References

Crothers J H, 1981. On the graphical presentation of quantitative data. *Field Studies* 5. 487 - 511

Fletcher J A and Gowing D F, 1987. *The business guide to effective writing.* Institute of Chartered Accountants