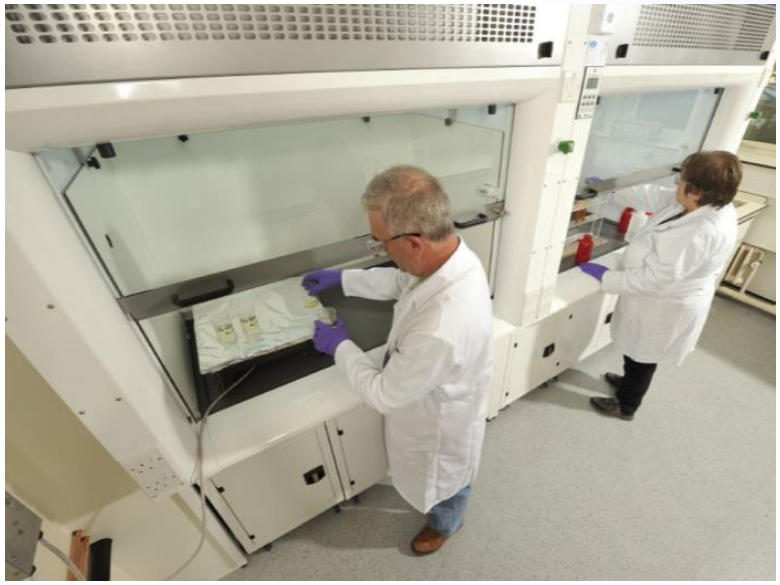
IAEA
International Atomic Energy Agency

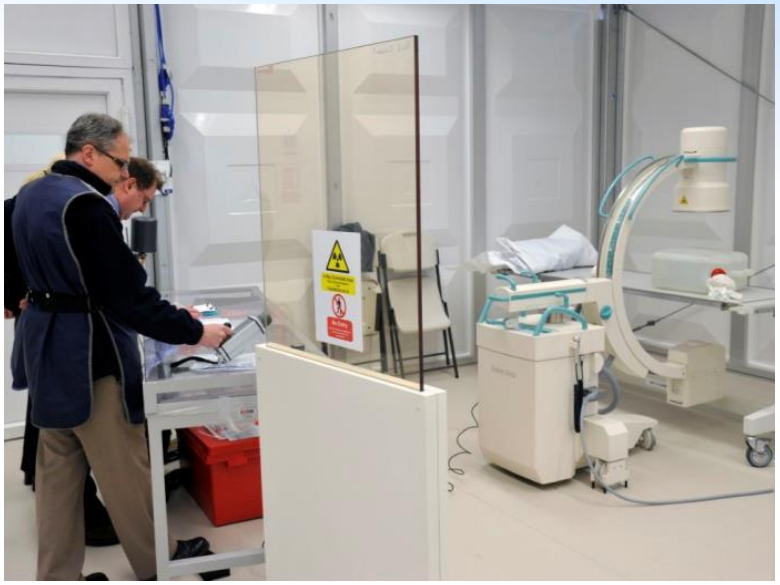
Occupational Radiation Protection (GSG7)

7. Management System Providers of Technical Services

GSG7: Sections 8

Contents





GENERAL CONSIDERATIONS

Technical service categories

Technical service categories include:

1. Consultancy and maintenance
   - ❑ Radiation safety consultancy
   - ❑ Shielding calculation
   - ❑ Modelling for dose assessment, containment and ventilation
   - ❑ Maintenance services (in-house & contracted out)
   - ❑ Decontamination

2. Calibration and testing/assay services
   - ❑ Monitoring (individual, workplace and environmental)
   - ❑ Calibration and verification of monitors and radiation sources

General considerations

- Service providers require a documented management system for their facilities
- Management system should be in accordance with IAEA safety standards
- Service provider must comply with its management system free of influence regarding its technical judgement
- Third party organizations should not engage in activities that could endanger trust
- Third party audit and compliance with management standards (eg ISO/IEC 17025)

Safety culture

Established by

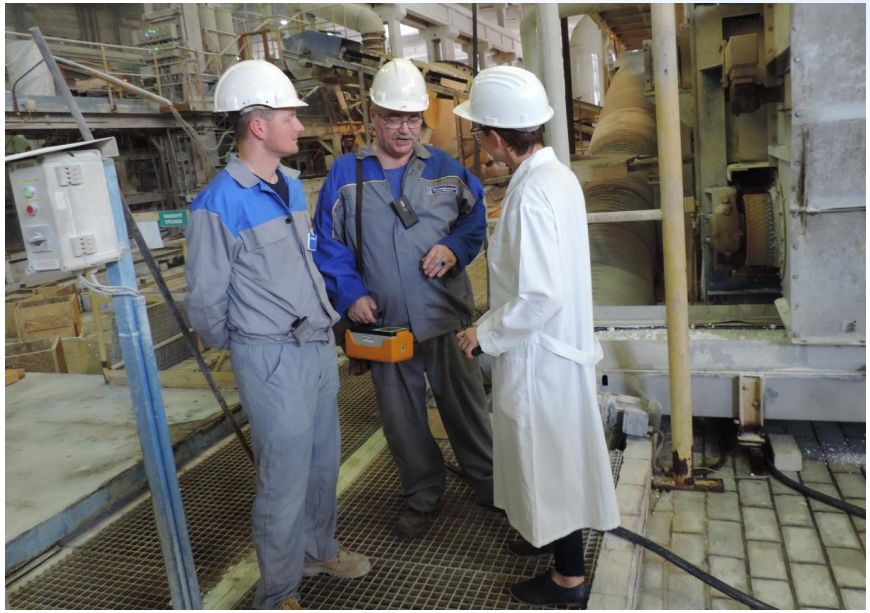
1. Promoting knowledge of safety standards
2. Carrying out risk analysis of procedures
3. Establishing rules, procedures and observing regulatory requirements
4. Evaluating the effectiveness of procedures
5. Employing relevant management and staff
6. Periodic training on and procedures
7. Discussion of training with staff
8. Updating training to comply with regulatory requirements
9. Learning from actual incidents and accidents
10. Encouraging staff to suggest safety improvements

Grading managements system requirements

- Controls on products and services should be based on their influence in affecting quality
- Small organizations should ensure adequate resources to fulfil critical functions (eg safety culture, independence, documentation and record keeping etc)

Documentation of managements system

- Documents may be in any relevant medium
- Management system should include a quality manual referencing:
  1. Description of the management system
  2. Management documents
  3. Working documents and job descriptions
  4. Additional technical documents and data
     - Databases (eg radionuclides)
     - Operating manuals
     - Reagent data sheets
     - Laws and regulations
     - Managerial and technical standards
- Document control procedure should include periodic review of documents



MANAGEMENT RESPONSIBILITY

Management commitment

A ‘management commitment’ document should be signed at a senior level regarding the management system, resources, revision, policies and objectives

- ❑ Staff should be made aware of management commitment

Customer satisfaction

- Customers are the most important stakeholder
- A contract for a service should include:
  - Customer needs
  - Related regulatory requirements
  - Resources required
  - Customer communication needs
- Feedback should be collected and evaluated
- A client confidentiality procedure should be in place

Organizational policies

A concise and understandable policy addressing:

- Defining and maintaining customer satisfaction
- Opportunities for continual improvement
- Resources required
- Contributions of suppliers and partners
- Commitment to professional good practice
- Commitment to competence (qualification) of staff
- Commitment to meet relevant standards
- Ensuring safety, heath, quality, environmental, security, societal and economic aspects met

Planning

- A plan should be in place to meet objectives
- Information (eg audit reports, process reviews and customer feedback) can assist in objective setting
- Objectives may evolve as the organisation develops and improves
- Objective planning should be systematic, documented and resourced

Responsibility and authority for the management system

A person should be designated as the management system manager, authorised to:

- Develop and manage the system, compliant with standards, harmonize procedures, review operations, address non-compliances and raise staff awareness
- Communicate quality issues to regulatory and accreditation bodies
- Communicate with management
- Be the focal point for non-compliance and improvement
- Stop work, if performed inadequately
- Conduct reviews of the system

PROCESS IMPLEMENTATION

Process implementation

Provision of resources

- Staff, equipment and supplies, information, facilities, services, workplace and finance

Human resources

- Human resources should be adequate to meet predetermined requirements
  - Staffing levels, education, training, experience, qualifications and performance review

Infrastructure and working environment

- Infrastructure should be adequate
  - For calibration and testing laboratories the regulatory body may impose requirements

- Process for control of monitoring and measuring devices should ensure results are accurate
  - Process should confirm devices are suitable, tested, calibrated, functional and protected

Infrastructure and working environment (cont.)

- Software should be validated, protected and checked

- Working environment should be suitable for human and physical factors

Developing processes

- New services should be carefully planned with a technical project leader
- Planning should include traceability of measurements to standards and uncertainties in results

Process management

- Two types of process
  1. Process of the management system
  2. Process to deliver services and products
- Monitoring of process
  1. Timeliness
  2. Capability
  3. Efficiency
- Data derived from monitoring can be used to determine trends, customer satisfaction and reduce non-conformances

Control of products

- The service or product should meet the requirements and expectations of customers
- For consultancy, measures could include
  - Additional calculations, checks on data entry, comparison of results
- For measurement and calibration, measures could include
  - Repeated tests, checks on blanks or test samples, plausibility tests on results
- Results should be recorded as proof of control

Process implementation- control of products

- Product conformance ensured by specifying conditions for identification, storage, handling, protection and delivery
- Processes that contribute to production should be verified against suitable criteria
  - Records should be created (eg checklists)
- Customers property (including intellectual) should be protected
- Information in relation to radiation protection belongs to the customer and is confidential

Process of implementation

Communication

- ❑ Internal and external communication
  - Regular meetings
  - Using communication tools

Managing organizational change

- ❑ Change should not adversely affect product or service quality

PERFORMANCE MEASUREMENT, ASSESMENT AND IMPROVEMENT

Monitoring of the management system

- Service provider should define, plan and conduct activities to ensure conformance with applicable standards
- The process of performance measurement, analysis and improvement includes:
  - Ongoing monitoring of effectiveness
  - Analysis of customer satisfaction, equipment performance, measurement throughput etc
  - Proactive prevention of non-conformance, to improve and optimize services
  - Reactive action following self-assessment, complaints or outcomes of audits

Performance measurement

Self assessment

- Tool used to stimulate learning and improve performance

Independent assessment

Conducting internal audits through the year

- Emphasizes continual improvement
- Reduces workload on auditors
- Promptly identifies non-conformances
- Monitors progress in addressing corrective actions

- Independence can be achieved by a cross-audit department with a clear mandate and scope

Independent assessment

- Ad hoc internal audits can be carried out after customer complaints, non-conformances or major changes
- Rotation of auditors increases job satisfaction
- Annual audit programme should address all aspects of the management system
- Customers affected by problems identified by audits should be notified
- Follow up audits should be considered if quick action is required or checks on effectiveness of corrective actions needed

Management system review

- Consider inter-laboratory comparisons or proficiency tests
- Management review reports should include
  - Persons involved
  - Factors considered
  - Decisions reached
  - Actions planned, persons responsible and timescales
  - Review and approval of the report

Management system review

- Results incorporated into laboratory planning system include goals, objectives and action plans for the year
- Management should ensure actions are carried out
- Radiation safety audit will highlight protection and safety action status

Non-conformance and corrective actions

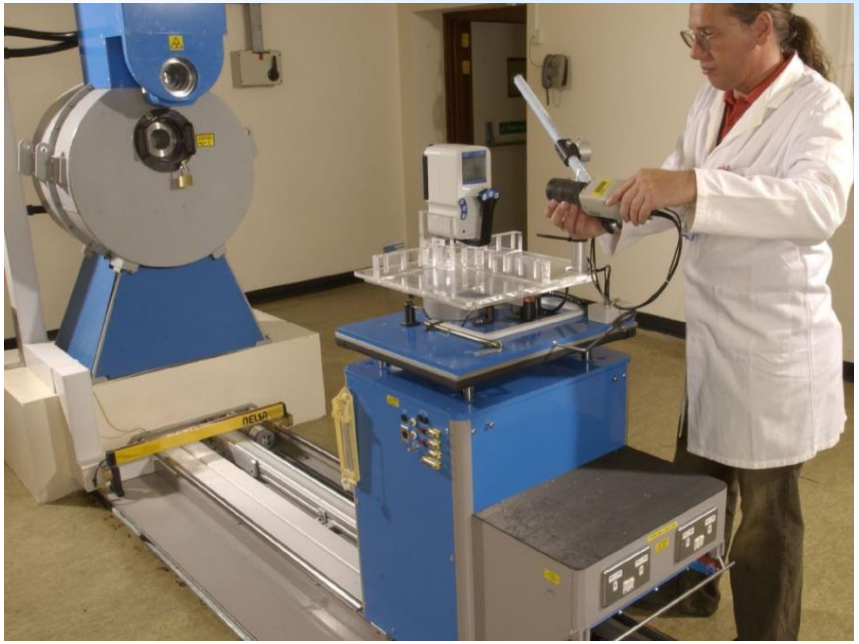
- Non-conformances could include
  - Incorrectly entered raw data
  - Application of incorrect algorithms
  - Incorrect calibration data or factors
  - Measurements with instruments out of their range
  - Calibration data using wrong irradiation conditions
  - Incorrect output data
  - Incorrectly performed sampling or sample treatment
- Impact of non-conformances on safety should be assessed and management notified

Non-conformance and corrective actions

- A policy/procedure for resolution of complaints is required
  - Implemented following a complaint, customer feedback or a non-conformance. Records to be maintained
- Preventative (prospective) action may follow a corrective (retrospective) action

Non-conformance and corrective actions

- Root cause investigation
  - Is the issue a validated problem?
  - Have the clients requirements changed?
  - Have the sample characteristics changed?
  - Has the working environment changed?
  - Are the methods/procedures adequate?
  - Is there a need for training/skill development?
  - Does equipment function properly?
  - Has calibration of equipment been verified?
  - Have specifications for consumables changed?



ADDITIONAL GUIDANCE FOR CALIBRATION AND TESTING SERVICES

Organization

- Organizations may seek third party accreditation (eg ISO/IEC standard 17025)
- Adequate supervision required by persons familiar with testing and calibration
- Laboratories should have deputies for key personnel

Requests, Tenders and Contracts

- Laboratory staff should select test or calibration methods to meet customer requirements

Subcontracting of tests and calibrations

- Obtain approval of customer
- Ensure subcontractor is competent (eg holds appropriate accreditation or audit)
- Maintain a register
- Retain evidence how subcontractor meets relevant standards

Service to client

- Laboratories may need to allow client performance monitoring (eg witnessing tests & calibrations, verification surveys, feedback etc)

- Any activity should preserve other clients' confidentiality

Control of records

- Retain records of original information for audit trail
- Information should allow identification of uncertainties and conduct of repeat tests
- Record identity of persons sampling, testing and checking results
- Records may include: forms, worksheets, workbooks, check lists control graphs… etc
- Mistakes in records should be crossed out, correct values entered and initialled. If electronic record, equivalent measures to be taken

Internal audit

If audit identifies doubt on test or calibration results, corrective action should be taken. Notify client if results affected

Laboratory facilities

- Management should provide adequate facilities
  - Meet technical standards and requirements
  - Technical documents available
  - Environmental conditions appropriate
  - Access to facilities is appropriately controlled
  - Good housekeeping is maintained
  - Work does not disturb work in other areas

Test, calibration and validation

- Step by step procedure in place for tasks
- Staff follow procedures and up to date methods
- Uncertainties should be evaluated and results validated
  - Methods should be planned and documented
  - Documents should specify steps and records
  - Validation should be included
  - Actions when an error occurs should be clear
  - Data flow of results should organized

Test and calibration equipment

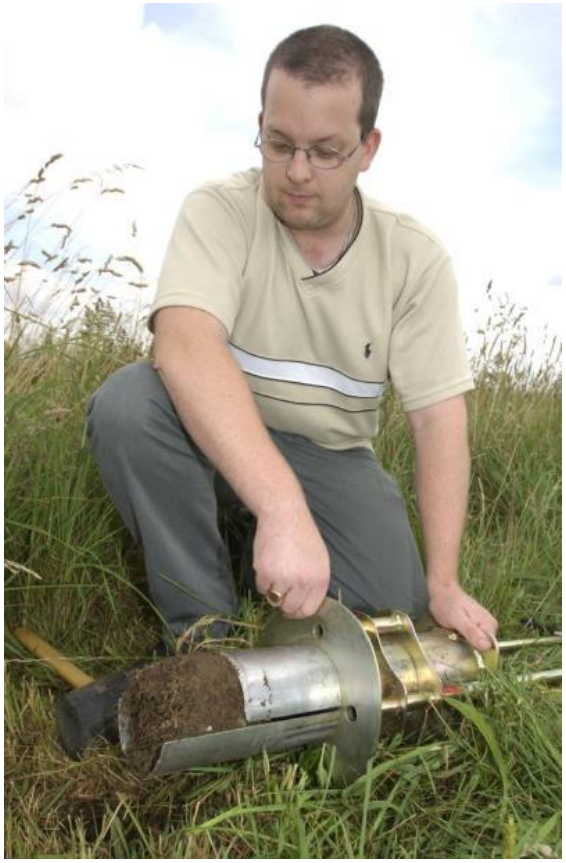
- Adequate equipment should be available
  - Periodic calibration
  - Functional tests between calibrations
  - Maintenance by manufacturer and recorded
  - Checks on outgoing and incoming equipment
  - Calculations using software checked and validated

Measurement traceability

- Measurement devices calibrated before use and periodically
- Calibration services should have standards traceable to the SI system
- A calibration service should
  - Organise information and calibration standards
    - Calibration data, serial number of units calibrated, date of last and next calibration, location and name of tester
  - Store calibration procedures and certificates
  - Support periodic calibration
  - Keep calibrated spare parts

Sampling

- Sampling procedures:
  - Relevant standards: sampling location, sample time, name of person, conditions etc
  - Negative influences on samples, during sampling, handling, storing and analysis
  - Good documentation identifying appropriate methods for identifying samples and data
  - Information to customer if there is a problem



Handling of items

- Testing and calibration items should be handled carefully. Procedures should address:
  - Identification and labelling of incoming test and calibration items
  - Reporting of abnormalities
  - Instructions for handling, storage and transport and required environmental conditions
  - Instructions on return of items or approved disposal

Quality of test and calibration

- Laboratory should have a procedure to ensure continuous quality to the customer. Process should:
  - Use certificated materials for calibration and quality control
  - Carry out measurements and calibrations as specified in procedures
  - Participate in inter-comparison exercises

Quality of test and calibration

- Replicate tests or calibrations
- Retest or recalibrate items
- Correlate results for characteristics of an item
- Use statistical methods to determine quality of calibration results over time

Reporting of results

- Results should be reported accurately, comprehensively meeting customer needs
- The layout of reports should consider
  - Requirements of regulatory bodies
  - Requirements of relevant standards
  - Organizational rules on reporting
- Data from contractors should be identified
- A procedure should be in place for changing reports

Key messages

- Senior management commitment
- Providers of technical services should establish a documented management system
- Planning should include traceability of measurements to standards and uncertainties in results
- Service provider should define, plan and conduct activities to ensure conformance with applicable standards
- Assessment and review of the system provide opportunity to identify non-conformance and corrective actions
- International guidance is available for providers of calibration and testing services

QUESTIONS AND DISCUSSION

Class discussion

Participants to share their own experience of Technical Service Providers, eg:

- What types of TSP do you have in your country?
- What are the arrangements for approval or accreditation of these TSP?
- Have you experienced any problems with TSP? If so, what are common problems?