Quality Management Review

Auditing Platform

Quality Management Review

Why is a quality management review needed?

- The aim of the QMR is to assess the organisation's quality management system for its adequacy or sufficiency, suitability to purpose, and effectiveness.
- In addition, a QMR allows the CTU to decide what next steps are needed to improve the current quality approach.
- In accordance with requirements set out in the SCTO's Guidelines for Good Operational Practice (GGOP), each CTU needs to ensure ongoing efficiency and quality performance.

Audit observations: What was missing?

- There was either no or an inadequate annual quality management review (QMR) in place to assess the overall efficiency and performance of a CTU and/or the effectiveness of its quality management system (QMS).

Recommendations

- Define a QMR process to ensure that processes and services are adequate.
- Define and document the acceptance criteria for KPIs.
- Conduct and formally document a QMR with the appropriate CTU management (e.g. director, executive board, or quality management team).
- Define and collect key performance indicators (KPIs) addressing, for example, the following areas:
    - changes within a CTU (regulatory, business-related, etc.)
    - results of internal (and possible external) audits/assessments
    - customer feedback and complaints
    - opportunities arising from risk review and nonconformity.