Agenda for Half Day Workshop on Implementing ISO 9001:2015

Management Planning (Plan)

1. The New Structure of ISO 9001:2015

An overview is given for the new ISO 9001 structure, the main changes and ISO 9001:2015 requirements. The need for a gap analysis is explained, providing an analysis of each area of the business with the ISO 9001:2015 requirements. The method for addressing the areas which require attention is outlined. A Project Team should be established engaging a key person from each function in the business to support the function leader and also be responsible for championing the quality system in their function.

2. Business Mapping and Scoping

The issue of 'scope and exclusions' in the new standard is explained. The scope and boundaries of the business to become registered are agreed by mapping the business and agreed by reviewing the business map. The preferred method of mapping is explained. This is where the 'business level' processes and their linkages are specified. The map enables indication of initial risk.

3. Business Context and Interested Parties

The external and internal issues that affect business strategy and that affect the ability to achieve objectives are determined. A ***Case study*** addresses risk identification in a service industry business in order to focus on transactional risk. From this assessment the relevant interested parties will also be identified. A plan to mitigate these external and internal issues will be initiated.

4. Quality Statement linking to the Measurement Plan

The organization's quality policy statement should contain the key strategic objectives of the business and the standard also requires measurement of processes, performance of external providers and customer satisfaction. Points where the organization is at risk have been identified and the type of monitoring required is identified. The ***Case Study Measurement Plan*** is drafted.

5. Measurable Objectives

The measurable objectives attached to each process in the ***Case Study*** are agreed. Customer Satisfaction Measurement is not time consuming but is a critical path in the project and should be initiated early. Guidance will be provided.

System Development (Do)

6. Documented Information

The key documents in the quality management system are identified from the "plan do check act" cycle. It is important to "document the system . . . not create a system of documents" (ISO 9001). The Quality Manual Development is now optional and this should be a high level description of the business. Manual development techniques are explained

7. Risk Mitigation

The opportunities and risks associated with the issues identified in the ***Case Study*** and agreed objectives are addressed by Risk Mitigation. This ensures the business can achieve its objectives and prevent, or reduce, undesired effects. Choices are made on how to address the risks identified in the case study.

8. Methods of Mitigation

Procedures are tools for controlling processes but are not the only tool available. Checklists, Technology and Competence can also be developed at risk points. The organization makes its own decision on whether a documented procedure has value. The processes which require control are agreed based on criteria of risk, complexity and criticality.

9. Procedure Workshop

Unique tools are provided which dramatically shorten the time required to develop a procedure e.g. linear flowcharting, title page development, procedure evaluation checksheet. The knowledge and experience of persons involved in given process should be engaged in order to refine processes. The six mandatory 'system' procedures required by the 2008 standard will also be discussed.

10. Education and Engagement

Supervisors and employees must become familiar with the new standard. All supervisors, team leaders and employees who are not part of the leadership or project teams must be active participants in the development of the quality system. Alternative methods of Education and Engagement, such as ISO 10018 are explained.

Performance Evaluation (Check)

11. Internal Auditing

A number of tools for Internal Auditing are provided such as the Audit Risk Assessment Tool, and the Audit Checklist. The structure of the opening and closing meetings will be explained. The role of the Corrective Action System and the importance of feedback to the Management Review will be shown. The key to success is ensuring that staff sees Internal Audit as a supporting resource and not as an intrusion.

12. Management Review

Reporting on the performance of the Quality Management System is very similar to reporting by the financial controller and the report is provided to the Management Review. The new areas to be reported on are explained and also the linkage to internal audit. The non-financial measurables from the QMS can be used to support the financial measurables.

Improvement (Act)

13. Corrective Action Process (and N/C Product)

The data collected from the Measurement plan, Customer Satisfaction measurement and Supplier performance measurement is used to create knowledge for process improvement. An organization typically wastes 25% to 35% of its resources through not 'doing it right the first time' or through duplication of effort. Problem solving techniques are explained to drive continual improvement and cost reduction (See Appendix).

14. Registration

The registrar should be given a briefing of how the quality system has been developed and invited to quote for registration services. The registrar will conduct a 'system level' audit to highlight any gaps in the quality system. This gives the benefit of a 'fresh pair of eyes' and the registrar becomes familiar with the quality system details. The registration process and the transition period for ISO 9001:2015 are explained