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ISO 9001 Auditing Practices Group **Guidance on:**

External Providers

1. Introduction

When developing a management system, many organizations will have put in place systems to control the purchasing of products, the procurement of services and any outsourcing of processes. They will have to verify externally provided products and services in a way in which they consider satisfies the relevant requirements of ISO 9001.

These may include any processes, products and services provided by any external source, which can be a supplier, partner, sister/parent organization, customer, etc.

Auditors may consider it sufficient to evaluate conformity by checking that:

- there is documented information (e.g. a list) indicating which are the approved external providers and that this documented information is kept up to date,
- orders have been placed to external providers satisfying the defined criteria
- there is effective performance monitoring of outsourced processes providers, and
- the activities necessary for ensuring that the specified requirements have been met are carried out.

Auditors have to verify that risk based thinking has been applied by an organization in determining appropriate controls over external providers.

In many instances, however, that may not be sufficient to ensure that externally provided products, processes and services simply meet original specifications in all respects. In such instances, it would be preferable to review the wider processes for procurement management, outsourcing and the supply chain.

2. Auditing the Procurement Process

In auditing the process for the management of procurement, the following should be considered:-

- Procurement starts during the design and development of a product and service when a specification is prepared;
- Inter-departmental discussions take place to ensure that potential external providers can provide a process, products and service that meets the design specification at the required cost;
- The organization should ensure that the specified purchase requirements are correct prior to their communication to the external provider;
- Statutory and regulatory requirements have been included in the purchase requirements; and,
- The degree of risk associated with a component, product or part of the service, and the controls required to ensure that it meets the design specification, have been assessed.

Practical suggestions of ways in which to confirm that the above points have been considered are:-

- Confirm that the specification quoted in a purchase order is the same as the specification contained in the design (or the specification received from the customer);
- Identify whether or not there were discussions between the organization and potential suppliers regarding the design specification of critical components during the design process or prior to an order being placed;
- Was there some form of “approval” of the specification before the final specification/order was confirmed to the external provider?
- Does the purchase order contain or refer to any statutory or regulatory requirements?

3. Auditing the Supply Chain

In many cases, audits of the evaluation and selection of external providers simply consists of a review of the organization’s approved external provider list and whether this list has been reviewed at regular intervals. In many cases this may not be sufficient to ensure that the organization has effective control of all of those external providers within its supply chain. Issues to consider include:-

- Are external providers of critical component products or critical services selected based only on their ability to supply at an economical price, or is their ability to supply consistently to specifications also taken into consideration?
- Are outsourced processes considered in the supply chain and relevant levels of controls are in place?
- Are external providers included in approved lists solely on their continued registration against a recognised quality standard, or is the scope of this registration reviewed?

- Note: In some cases, it may be advantageous for the organization to audit the intended external provider to establish clear lines of communication, product specifications, delivery parameters, etc.
- How frequently are credit notes raised by the organization for products or services that are initially rejected, but then subsequently accepted ?
- How many concessions have been raised allowing the organization to accept previously rejected products or services?

4. Conclusion

Generally, for an experienced auditor, reviewing the procurement process and supply chain of an organization is straight forward common sense but there are situations where the nature of the products (or components) and services may indicate that additional investigation is necessary. Every product is unique just as all audit situations are unique.

For further information on the ISO 9001 Auditing Practices Group, please refer to the paper: *Introduction to the ISO 9001 Auditing Practices Group*

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