

Internal Audit 4.2.4 Quality Management System Record Control

1

Control of Records

- *The internal auditor should ensure that policies governing the controls that apply to management system records in-general are also employed for electronic documents through appropriate procedures.*
- *The internal auditor should ensure to review control elements such as record identification and revision level.*
- *The internal auditor should ensure controls are being employed for the management of obsolete records are considered within the record control procedure*
- *The auditor should review “Point-of-use” requirements associated with the applicable management system records are addressed in the record procedure.*
- *The auditor should ensure that the quality management system includes all the compulsory records required by the ISO9001:2008 standard (See next 2 slides).*

Internal Audit 4.2.4 Quality Management System Record Control

2

Records specifically required by ISO 9001:2008 :

- **Management Review - Clause 5.6.1**
- **Education, training, skills and experience - Clause 6.2.2 e)**
- **Evidence that the realization processes and resulting product fulfill requirements - Clause 7.1 d)**
- **Results of the review of customer requirements prior to supply related to the product and actions arising from the review - Clause 7.2.2**
- **Design and development inputs relating to product requirements - Clause 7.3.2**
- **Results of design and development reviews and any necessary actions - Clause 7.3.4**
- **Results of design and development verification and any necessary actions - Clause 7.3.5**
- **Results of design and development validation and any necessary actions - Clause 7.3.6**
- **Results of the review of design and development changes and any necessary actions - Clause 7.3.7**
- **Results of supplier evaluations and any necessary actions arising from the evaluations - Clause 7.4.1**

Internal Audit 4.2.4 Quality Management System Record Control

3

Records specifically required by ISO 9001:2008 :

- **As required to demonstrate the validation of processes where the resulting output cannot be verified by subsequent monitoring or measurement - Clause 7.5.2 d)**
- **The unique identification of the product, where traceability is a requirement - Clause 7.5.3**
- **Customer property that is lost, damaged or otherwise found to be unsuitable for use - Clause 7.5.4**
- **Basis used for calibration or verification of measuring equipment where no international or national measurement standards exist - Clause 7.6 a)**
- **Validity of the previous measuring results when the measuring equipment is found not to conform to requirements - Clause 7.6**
- **Results of calibration and verification of measuring equipment - Clause 7.6**
- **Internal audit results and follow-up actions - Clause 8.2.2**
- **Indication of the person(s) authorizing release of product - Clause 8.2.4**
- **Nature of the product nonconformities and any subsequent actions taken, including concessions obtained - Clause 8.3**
- **Results of corrective action - Clause 8.5.2 e)**
- **Results of preventative action - Clause 8.5.3 d)**