



Quality Management System Audit Checklist

(a cumulative audit report/summary and management summary)

Intelex Audit Report #

LEAD AUDITOR	DEPARTMENT CONTACT INFORMATION/AUDIT PLANNING			AUDIT DATE (RANGE)
	Name: (Contact)	Department:		
AUDITORS	Email:	Locations Sampled:	TO	
	Phone:	Audit Scope/Criteria: (e.g., area(s) being audited, applicable clauses from ISO 9001, applicable Administrative Directive requirements, state or federal regulations, etc.)		
	Fax:			
FINDINGS		SUMMARY OF AUDIT RESULTS		
MAJOR		Audit Summary:		
Minor		System Strength:		
Comment		System Weakness:		

CLAUSE	TYPE OF EXPECTATION			EXPECTATION DEFINED	SYSTEM TRAIL	AUDITOR COMMENTS	FINDING			Intelex NC # & CA #	
	Documented	Proven	Recorded	This is what the standard is requesting we document, define, prove, and/or record. A description of the types of expectations (shown to the left) is embedded electronically in the cell for each expectation as a comment. (<i>Italics</i> tends to identify a note or summary of what is being covered somewhere else.)	This is where we note the location of the answer to the EXPECTATION in our system. Grayed out boxes do not require a response, as they will be addressed in the sections referenced. When the SYSTEM TRAIL entry is BOLD ITALIC , this is a required record for the records control procedure addressed in 4.2.4.	Evidence reviewed and/or issues identified. (black font is comment/evidentiary, blue is opportunity for improvement, and red is a nonconformance [issue that must be resolved])	Comment	Minor	MAJOR	NC#	CA#
Relationship with ISO 9001:2008 General questions during all audit		✓		Do you know your Quality Policy? What does it mean? What are the organization quality objectives? How do you contribute to meeting organizations quality objectives? Who is the ISO Management Representative? Do you think you have received adequate training?							
4.2.1 Documentation Requirements 4.2.2 Quality Manual	✓			Does the Organization have a documented Quality Manual? Does the organization have stated Quality Policy & Objectives? Does the organization have the 6 required procedures stated by the standard? What other additional Documents does the organization provide to show effective planning, operation & control of its processes? Does the quality manual describe the scope of the QMS? Does the quality Manual describe the interaction between processes? Does the quality Manual identify exclusions, if any?							
4.2.3 Control of Documents	✓			Does the organizations Document Control procedure address the following: - Approval of documents - Review of documents - Revision control of documents - proper identification controls of documents - reapproval of documents, as necessary - control of external documents - control of obsolete documents to prevent unintended use. If so, how? Does the organization have a Master Document list? If so how is it controlled & managed? Does the Master Document List identify all the organizations documents with accurate information? Does the Master Document List include external documents?							
4.2.4 Control of Records	✓		✓	Does the organization have a documented Records control procedure that addresses the following? - identification controls for records - storage requirements for records - protection requirements for records - retrieval/access controls for records - retention policy for records - define disposition of records after their intended use Are the records legible & identifiable? Do the records have proper revision controls? Does the organization has a records control list? If so, does it address all the required controls for records?							