

4.16 Control of Quality Records

No.	Primary Target	GPG	ISO 9001	Question	Y	N	Comments
1	Auditee	1440.7/1.c	4.16	Has the organization appointed a Quality Records List Coordinator?			
2	Auditee	1440.7/2.1		Has the organization identified in a Quality Records List all the Quality Records it holds as a result of implementing QMS procedures and work instructions?			
3	Auditee	1440.7/QRL instructions		Is the QRL available as a paper version that is up to date and appropriately signed and dated?			
4	Auditee	1440.7/1.b		Is there a Quality Records Custodian identified for each of the quality records held by the organization?			
5	Auditee	1440.7/QRL instructions		Is the location of the quality records identified in the Quality Records List?			
6	Auditee	1440.7/QRL instructions		Are retention times and disposition instructions for quality records established and recorded on the Quality Records List in accordance with NPG, GPG, PG, or WI guidance.			
7	Custodian	1440.7/2.1, 2.2, 2.3		Are the quality records: properly identified; collected; indexed; reasonably filed; reasonably retrievable and accessible; properly stored and maintained to avoid loss or damage; legible?			
8	Auditee	1440.7/2 (note)		Are there any organization-specific quality records control procedures? If so, are the procedures compliant with ISO 9001 requirements and are the quality records maintained in accordance with such procedures?			
9	Custodian	1440.7/1.a		Are there any data or records from suppliers or contractors that are a required element of the organization's quality records? Are they available?			

Code audited: _____ Date: _____ List Coordinator: _____

As part of your audit of this element, fill out the above checklist for each organization audited, and submit copies to Bob Bridgers or Helen Saulino in Bldg 6, Room W-106 as soon as your audit of the organization is complete.

Were NCRs generated because of Quality Records? Y/N _____ how many _____?