R20.44MD16   Process Matrix for ISO 13485:2016

PRI Certification
PERFORMANCE REVIEW INSTITUTE

CLIENT INSTRUCTIONS: The management representative or delegate is to indicate the processes needed for their management system (refer to section 4.1.2 of ISO 13485:2016) in the blank area under "auditee process" along with the appropriate process owner and placing an "X" in the matrix indicating the clause(s) that support the noted process. **These processes must match those identified in your quality management system documentation.** See notes below.

This is not a responsibility matrix. This completed matrix or an equivalent, is required to plan upcoming audit activities i.e., registration, surveillances. (See example of Delivery, note this may not reflect your actual practices.) Please return to PRI.

PLEASE PRINT

Company Name	
Plant/facility	
Completed by & Date	

X = Identifies auditee processes, process owner, and corresponding applicable clauses		Applicable Clauses																							
		4.1	4.2	5.1	5.2	5.3	5.4	5.5	5.6	6.1	6.2	6.3	6.4	7.1	7.2	7.3	7.4	7.5	7.6	8.1	8.2	8.3	8.4	8.5
Auditee Process	**Owner**																							
example only Delivery	General Foreman	X	X		X		X		X			X	X					X			X	X	X	X
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Auditee Process	**Owner**																							
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Important Notes: Processes must include those required for Product and Service Realization (often known as "Key" processes). Please limit or consolidate other processes which either are part of the Quality, Management, Resource, and Improvement activities, or support these activities. Remember that each process must have measurements and objectives for these measurements. Auditors will review your progress toward meeting these objectives during each audit. Also remember that Corrective Actions, Preventive Actions, Internal Audits, and Management Reviews are also assessed at each audit.