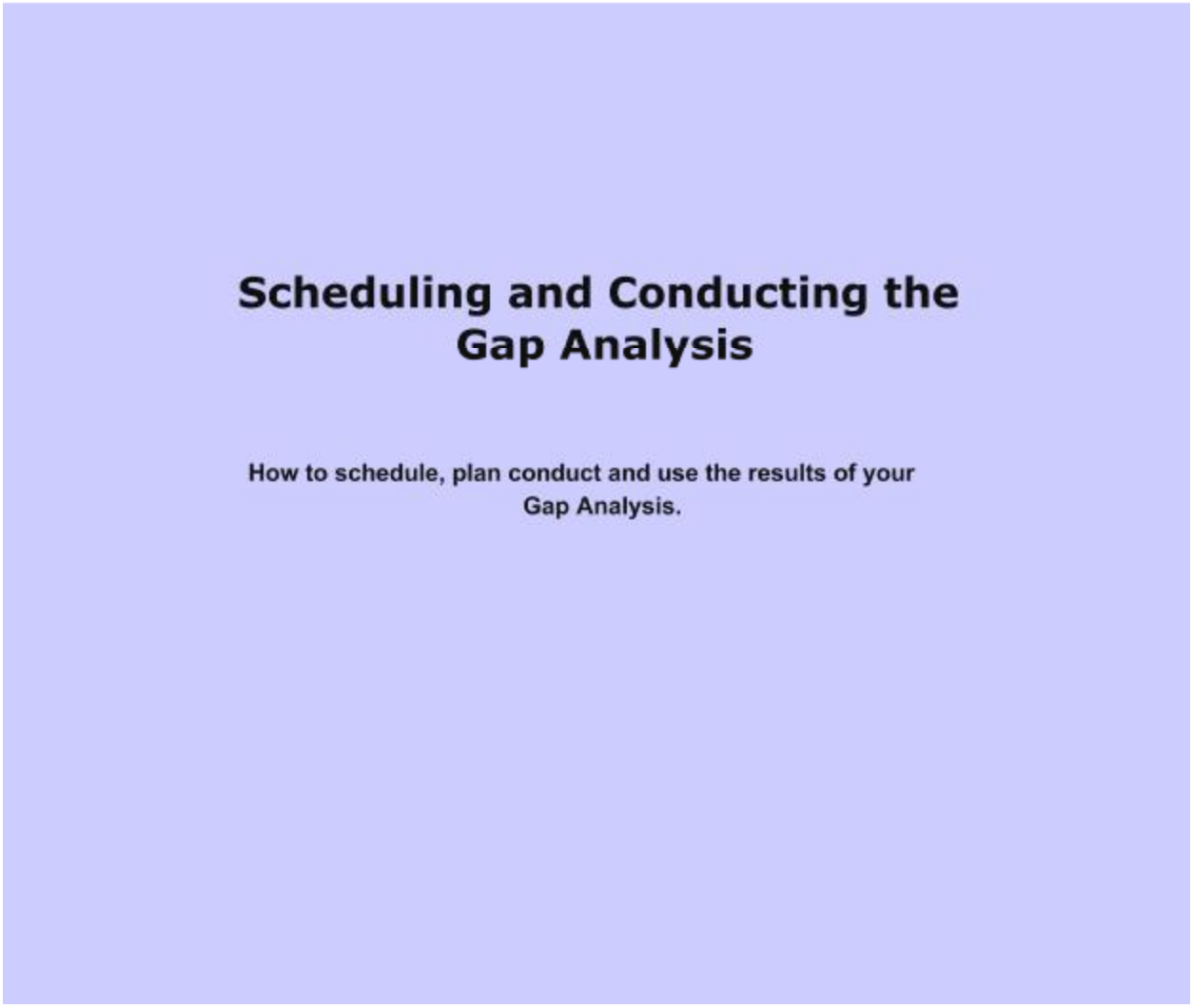
Gap Analysis Tutorial

Slide 1



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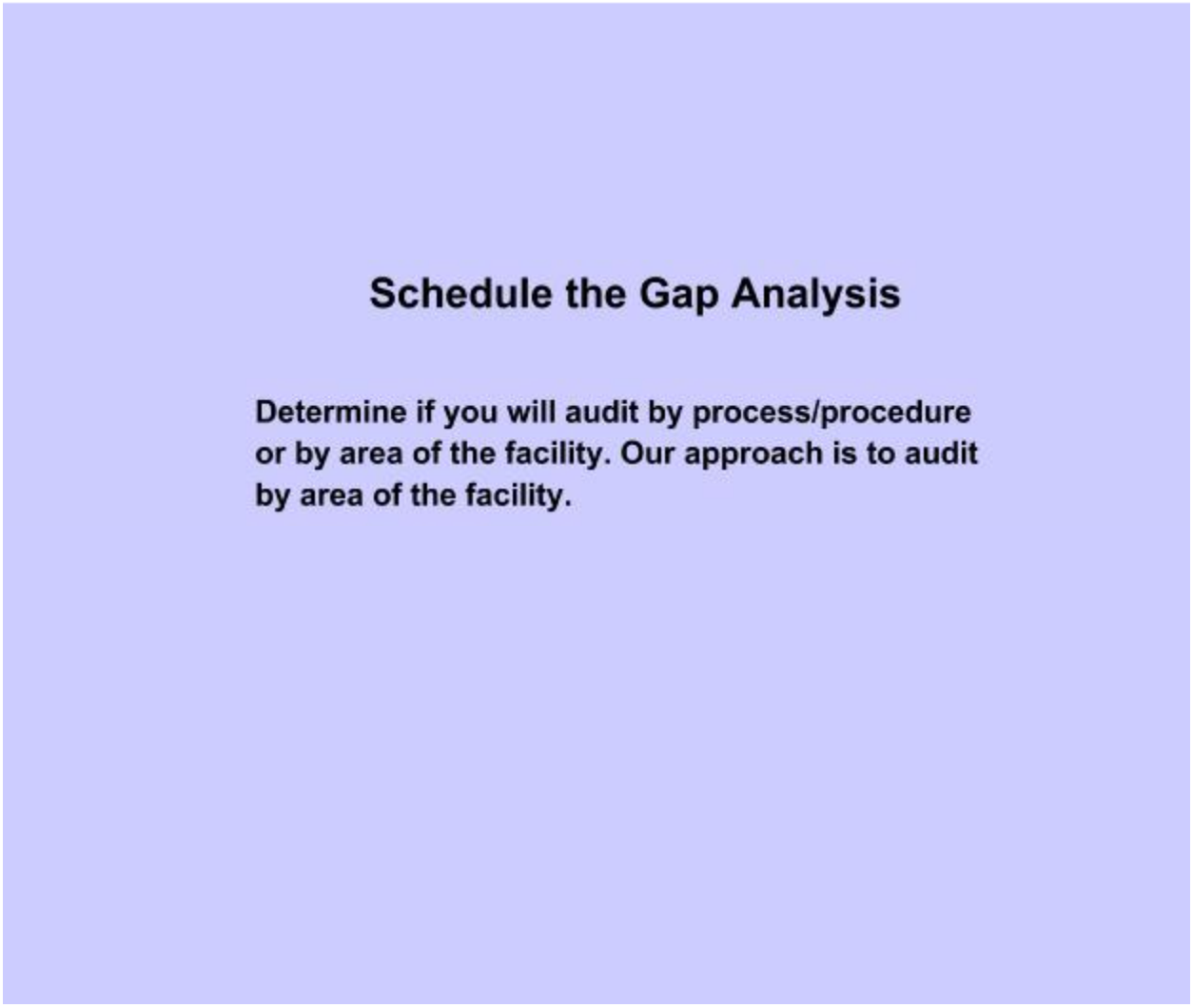

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Area of Facility and Applicable Elements of ISO 9001:2000
(Example; Modify for Your Facility)

Procedure	Administration	Quality Assurance	Sales	Manufacturing	Engineering
Document Control		X			X
Control of Quality Records		X		X	
Management Responsibility	X				
Competence, Awareness and Training	X				
Infrastructure	X			X	X
Planning of Product Realization Processes	X			X	X
Customer Related Processes	X		X		
Design and Development					X
Purchasing	X				
Control of Production and Service Provision				X	
Identification and Traceability				X	
Customer Property				X	
Preservation of Product				X	
Control of Measuring and Monitoring				X	

Example table of a plan for auditing by area of facility

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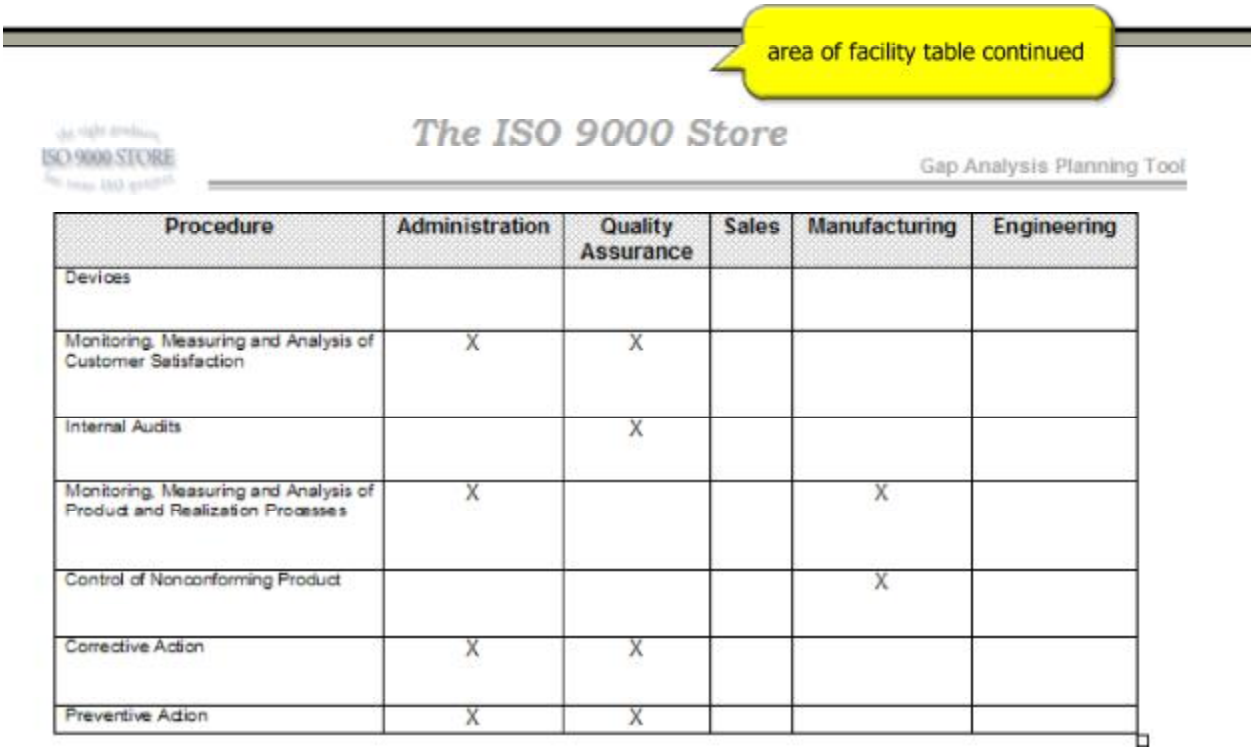

Procedure	Administration	Quality Assurance	Sales	Manufacturing	Engineering
Devices					
Monitoring, Measuring and Analysis of Customer Satisfaction	X	X			
Internal Audits		X			
Monitoring, Measuring and Analysis of Product and Realization Processes	X			X	
Control of Nonconforming Product				X	
Corrective Action	X	X			
Preventive Action	X	X			

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Complete a Gap Analysis Schedule

This shows who will audit each area and which points of the standard they will cover for each.

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The ISO 9000 Store

Gap Analysis Schedule

Gap Analysis	Lead Auditor: John Doe
Date: October 8-10	
Area(s) to be audited: Manufacturing Sales Administration Quality Control Engineering	**Audit Teams:** Team 1: John Doe, Jane Smith Team 2: Mary Moore, Sam Johnson
Comments: *Example schedule, modify to be appropriate to your facility and audit teams.*	Standard: **ISO 9001:2000**

Proposed Schedule

Time	Area:	Elements:	Team	
Day 1				
8:00	Manufacturing	Infrastructure	Team 1	
9:00		Planning Product Realization	"	
10:00		Control of Production and Service	"	
11:30		ID and Traceability	"	
1:00		Customer Property	"	
2:00		Preservation	"	
2:30		Control of Measuring Devices	"	

Divide the facility into manageable areas. Schedule time to audit each section of the standard that applies to the area.

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			Team 2	
8:00	Administration	Management Responsibility	"	
9:30		Training	"	
10:30		Infrastructure	"	
11:00		Planning of Product Realization Processes	"	
11:30		Customer Related Processes	"	
1:00		Purchasing	"	
2:00		Monitoring of Customer Satisfaction	"	
3:00		Monitoring of Product Realization Processes	"	
Day 2				
8:00	Manufacturing	Monitoring and Measuring of Product Realization Processes	Team 1	
10:00		Control of Nonconforming Product	"	

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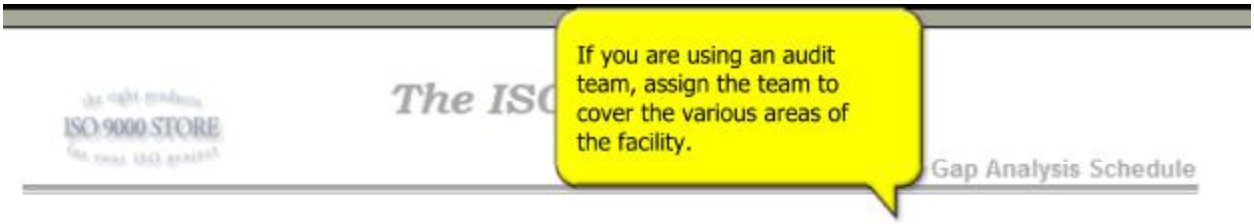

Day 2				
11:00	Engineering	Document Control	Team 1	
1:00		Infrastructure	"	
1:30		Planning of Realization/ Design and Development	"	
8:00	Administration and Quality Assurance	Corrective and Preventive Action	Team 2	
9:30	Quality Assurance	Document Control	"	

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Gap Analysis Schedule

Day 2				
11:00	Engineering	Document Control	Team 1	
1:00		Infrastructure	"	
1:30		Planning of Realization/ Design and Development		
8:00	Administration and Quality Assurance	Corrective and Preventive Action		
9:30	Quality Assurance	Document Control		
10:30		Control of Quality Records		
1:00		Measurement of Customer Satisfaction		
2:00		Internal Audits		
3:00	Sales	Customer Related Processes		

Show each area of the standard that the auditor will cover in each area. Then arrange the checklists so each auditor will have the sections of the standard that are applicable in the areas they will cover.

Additional information:	
Signature of Lead Auditor:	Date

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Conducting the Gap Analysis

After you have prepared your audit schedule, and assigned responsibility to your auditors for different areas or processes to audit, copy each section of the checklist for the auditors working with that section.
Follow the schedule that you have prepared.
Go into each area of the facility to evaluate the current quality system.
Focus on what is in place, and what is not in place.

**Remind auditors* that you are not focusing on commpliance or non compliance to the current system, but on the design of the current system, and how it matches the ISO 9001:2000 requirements.

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4 QUALITY MANAGEMENT SYSTEM

	REQUIREMENTS	CURRENTLY IN PLACE (List documents or evidence)	COMPLIANT Y/N? Estimated % Complete	ITEMS NEEDED
	General Requirements			
This clause addresses asks you to identify how management applies the process approach to achieve the effective and efficient control of processes, resulting in performance improvement. Specifically this section is looking for an overall process evaluation of all quality related processes and their interrelationships. Look to see that your organizational processes are defined and that consideration is given to those items described in a) through f).				
	a) Look for documentation of the processes included in the QMS			
	b) Look for information on the relationship and sequence of the QMS processes.			
	c) Ask Management if operation and control of processes is effective. How do they know if it is effective?			
	d) Ask how they are able to know if resources and information needed to support processes have been provided.			

As you work through the checklist take notes on what is in place, and what needs to be developed. Reference procedures or other documents that you have reviewed and that will provide information for the new QMS. Take notes on the status of the documents, will they need to be revised for the new system? Or can they be used as is. Also note where processes are in place, but documentation is needed.

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Reporting

Summarize the audit findings in the form of a task list. You will generally identify several categories of tasks.

Processes that comply with the standard and are documented.
Processes that comply with the standard and must be documented.
Processes that do not comply with the standard and must be redesigned.
Processes required by the standard that are not currently in place.

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Task List

Clause Number and Requirement	Responsibility	Start Date	Completion Date
Establish a process for identifying data required for review of the QMS Processes	John Doe and Lisa Smith	10-31	11-15

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Use the Task List for Planning

For each requirement (or set of requiremetns) of the standard, you will want to identify the status of the current system. The ISO 9001:2000 Steering Team will use this information as they assign responsibility and timelines to teams. Task Group teams will be assigned responsibility for development of a procedure.

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Tools to help you with your project

A thorough 41 page Gap Analysis Checklist is available from the ISO 9000 Store for $25. You can download it and begin using it right away.

You can also download the following documents FREE from www.iso-9000-2000. Just click on the links below.

- Area of Facility template
- Project Plan template
- Gap Schedule template