Introduction www.iso-9001-checklist.co.uk

Process Assessment

3 = High

= Critical

The process assessment is not a strict requirement in ISO 9001:2015 but it will help to substantiate your audit programme and to introduce risk based thinking into your audit process.

Step 1 Enter the process name(s) in cells 'B27' to 'B48'.

Once you have entered the process name(s), they will copy through to the relevant sections of the remaining worksheets.

Step 2 Assess the criteria for ranking the status of processes.

1= Low All performance indicators, metrics, objectives, audit results, etc. show stability and consistently achieve targets;

2 = Medium Minor problems exist, minor process or product changes planned;

Poor performance/adverse trends, expected results not achieved;

Metrics are non-conforming. Any process with major audit finding in past 12 months.

Step 3 Assess the criteria for ranking how well the process is performed.

1= Low Consistently applying documented practice, possible benchmark performer;

2 = Medium Current practices conform but are not documented;

3 = High Practices are applied inconsistently;

4 = Critical Practices are non-conforming.

Step 4 Assess the criteria for ranking the importance of processes.

1= Low Little to no risk of adversely affecting customer satisfaction, product quality, delivery, or profitability;

2 = Medium Adverse effect on customer satisfaction, product quality, delivery, or profitability;

3 = High Likely have a significant adverse effect on customer satisfaction, product quality, delivery, or profitability;

Likely cause safety or regulatory compliance issues.

Step 5 The audit frequency indicators will transfer to the other work sheets within this workbook for future reference during the next steps.

An audit should be scheduled at least once per year unless otherwise justified;

() An audit should be scheduled within 12 weeks and an additional audit within 6 months;

🔯 An audit should be scheduled within 4 weeks with an additional audit after 12 weeks and then reoccurring quarterly.

Audit Programme

Step 6 Enter the start and finish date for each planned, or additional audit, based on the frequency shown by the indicators.

Please note that Columns A, B & C will automatically populate with information form the 'Process Assessment' worksheet.

Only enter information in the grey coloured cells in Columns 'E', 'F', 'G' & 'H'.

The formulas will then colour the relevant date/day cell(s) in the programme.

Please note that all cells between '17' & '196' to 'ACA7' & 'ACA96' contain a hidden '0' which is required for the 'date cell' shading formula - DO NOT DELETE!

Begin auditing your system and processes, using the internal audit checklist.

Audit Findings Tracker

Step 7 From the 'Findings Summary' of the Audit Checklist, copy and paste the grey coloured cells into the corresponding cells in the tracker.

Please note that Columns 'A', 'B' & 'C' will automatically populate with information from the 'Process Assessment' worksheet.

Remember that when pasting data from the internal audit checklist into the tracker to select 'paste without formatting' from paste options menu.

Audit Findings Charts

Step 8 Copy and paste the charts into your internal audit reports or management review reports.

Please note that the grey coloured columns will automatically populate with data from the 'Audit Findings Tracker' worksheet.

Non-conformity & Corrective Action Tracker

Step 9 Issue corrective actions to process owners. Monitor progress and verify close-out.

Please note: the drop down box menu in Column 'B' is based on the processes that you entered in the 'Process Assessment' worksheet.

Process Assessment www.iso-9001-checklist.co.uk

Step 1	Enter the process name(s) in cells 'B27' to 'B48	8'.	Once you have entered the process name(s), they will copy through to the relevant sections of the remaining worksheets.
Step 2	Assess the criteria for ranking the status of processes.	= Low = Medium = High = Critical	All performance indicators, metrics, objectives, audit results, etc. show stability and consistently achieve targets; Minor problems exist, minor process or product changes planned; Poor performance/adverse trends, expected results not achieved; Metrics are non-conforming. Any process with major audit finding in past 12 months.
Step 3	Assess the criteria for ranking how well the process is performed.	= Low = Medium = High = Critical	Consistently applying documented practice, possible benchmark performer; Current practices conform but are not documented; Practices are applied inconsistently; Practices are non-conforming.
Step 4	Assess the criteria for ranking the importance of processes.	= Low = Medium = High = Critical	Little to no risk of adversely affecting customer satisfaction, product quality, delivery, or profitability; Minor adverse effect on customer satisfaction, product quality, delivery, or profitability; Likely have a significant adverse effect on customer satisfaction, product quality, delivery, or profitability; Likely cause safety or regulatory compliance issues.
Step 5	Audit frequency indicators will transfer to the 'Audit Programme' and the 'Audit		An audit should be scheduled at least once per year unless otherwise justified; An audit should be scheduled within 12 weeks and an additional audit within 6 months;

Findings Tracker' for reference.

		Perce	ived Process Ra	ankina	Perceived	Effects on QEH&	S Ranking	Customer Complaints	Any Known Co	rective Actions	Prod
Audit Ref.	Process Name		, High 3, Medium	3		4, High 3, Medium 7		Actual No. of Complaints	Internal CA (Audits/N/Cs)	External CA (Audits/N/Cs)	Sta
		Status	Practices	Importance	Quality	Environment	H&S	Quantity	Quantity	Quantity	Indic
IA001	Quality Management System	2	1	3	3	1	1	0	0	0	
IA002	Document Control	1	1	2	2	1	1	0	0	0	
IA003	Design & Development	3	2	3	3	2	2	0	1	0	(
IA004	Manufacturing	1	2	3	3	2	2	0	2	0	•
IA005	Customer Service	1	2	2	2	1	1	2	0	1	•
IA006	<enter description="" name="" process=""></enter>										
IA007	<enter description="" name="" process=""></enter>										
1A008	<enter description="" name="" process=""></enter>										
IA009	<enter description="" name="" process=""></enter>										
IA010	<enter description="" name="" process=""></enter>										
IA011	<enter description="" name="" process=""></enter>										
IA012	<enter description="" name="" process=""></enter>										
IA013	<enter description="" name="" process=""></enter>										
IA014	<enter description="" name="" process=""></enter>										
IA015	<enter description="" name="" process=""></enter>										
IA016	<enter description="" name="" process=""></enter>										
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IA018	<enter description="" name="" process=""></enter>										
IA019	<enter description="" name="" process=""></enter>										
IA020	<enter description="" name="" process=""></enter>										
IA021	<enter description="" name="" process=""></enter>										
IA022	<enter description="" name="" process=""></enter>										

An audit should be scheduled within 4 weeks with an additional audit after 12 weeks and then reoccurring quarterly.

Audit Programme

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Step 6 Enter the start and finish date for each planned, or additional audit, based on the frequency shown by the indicators.

An audit should be scheduled at least once per year unless otherwise justified;

An audit should be scheduled within 12 weeks and an additional audit within 6 months;

An audit should be scheduled within 4 weeks with an additional audit after 12 weeks and then reoccurring quarterly.

 $Please \ note \ that \ Columns \ A, \ B \ \& \ C \ will \ automatically \ populate \ with \ information \ form \ the \ 'Process \ Assessment' \ worksheet.$

Only enter information in the grey coloured cells in Columns 'E', 'F', 'G' & 'H'.

The formulas will then colour the relevant date/day cell(s) in the programme.

Please note that all cells between 'I7' & 'I96' to 'ACA7' & 'ACA96' contain a hidden '0' which is part of the 'date box' shading formula - **DO NOT DELETE!**Begin auditing your system and processes using the internal audit checklist.

	, , , , , , , , , , , , , , , , , , ,																														
									11-Ja	n-16			1	18-Jan	1-16				Jan-16				1-Feb-1				eb-16				Feb-16
Audit Ref.	Process Name	Indicator	Туре	Start	Finish	Duration	Complete (Yes/No)	11-Jan-16 12-Jan-16	13-Jan-16	15-Jan-16	16-Jan-16	18-Jan-16	19-Jan-16	20-Jan-16 21-Jan-16	22-Jan-16 23-Jan-16	24-Jan-16	25-Jan-16	27-Jan-16	28-Jan-16 29-Jan-16	30-Jan-16		02-Feb-16 03-Feb-16	04-Feb-16	05-reb-16	 08-Feb-16 09-Feb-16		11-Feb-16 12-Feb-16	13-Feb-16 14-Feb-16	-Feb-1	16-Feb-16 17-Feb-16	18-Feb-16 19-Feb-16
			Planned	19-Jan-16	20-Jan-16	1 day																					ш				
IA001	Quality Management System	•	Additional	03-Feb-16	05-Feb-16	2 Day																					ш				
17.001	quality Management System		Additional	15-Feb-16	17-Feb-16	3 Day																					ш				
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IA002	Document Control		Additional																		\blacksquare		++						\vdash	$+\!\!\!-\!\!\!\!\!-\!$	\vdash
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IA003	Design & Development	8	Additional										++								-	_	++			++	+	+	\vdash	+	
			Additional										++	-							-		++			++	+		\vdash	+	
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			Additional									-		-							Н	+	++		+	++	+		H	+	
IA004	Manufacturing	8	Additional																			-	+ +			++	+		H	+	
			Additional					\vdash	++				++				H					1	$\dagger \dagger$			+			H	+	
			Planned						T				T								Н		\top				$\dashv \dashv$		\vdash	+	一
			Additional																								$\neg \neg$			\top	
IA005	Customer Service	8	Additional																								$\neg \neg$			\top	
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IAOOO	venter process name/description/	•	Additional																												
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			Planned																		ш									/	
IA007	<enter description="" name="" process=""></enter>		Additional										$\bot \bot$								ш		$\perp \perp$			$\sqcup \!\!\! \perp$	44		Ш	/	ota
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Audit Findings Tracker

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Step 7 Using the 'Findings Summary' section from the Internal Audit Checklist.docx, copy and paste grey the coloured cells into the corresponding cells below.

Please note that Columns 'A', 'B' & 'C' will automatically populate with information from the 'Process Assessment' worksheet.

Please note	that Columns 'A', 'B' & 'C' will automatical	ally populate w		ille FIO	CC33 /\33	C33ITICI	it woi	KSITIECT.		_						_	_		_				_	_			_		_				
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			Clause ►	4.1	4.2	2			4.3			4.4				4.4.1				4.4.2	on 4				5.1.1					5.1.2		5.2.1	
Audit Ref.	Process Name	Indicator	Question No. ►	1 2	3 4	. 5	6	7 8	9	10	11 1	2 13	14	15 1	6 17	18	19 2	20 21	22	23 24	secti	25 2	6 27	7 28	29 3	0 31	32	33 34	35	36 37	38	39 40	41 42
			Criteria ▼																		V,												
			OFI	1				1									1				3	1		1									
IA001	Quality Management System		Minor N/C	1								1								1	2		1										
			Major N/C OFI	1								- 1									1		- 1				1						
IA002	Document Control	Ø	Minor N/C		1				1							1					3		1							1			
			Major N/C																		0												
			OFI															1			1	1											
IA003	Design & Development	8	Minor N/C					1							1						2				1				1				
			Major N/C											-							0	1											
14004	Manufacturing	8	OFI Minor N/C	1				1						1				1			1	1						1					
17004	Wandactumg	•	Major N/C												1			'			1	1	1										
			OFI																		0			1									
IA005	Customer Service	8	Minor N/C			1															1												
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IA009	<enter description="" name="" process=""></enter>	Ø	OFI Minor N/C																		0												
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Audit Findings Charts

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Step 8 Copy and paste the charts into your internal audit report or management review report.

Please note that the grey coloured columns will automatically populate with data from the 'Audit Findings Tracker' worksheet.



neet.						
	Compliance Process Name	Total OFI	Total Minor N/C		Total Audit Findings	Process Compliance Chart
IA001	Quality Management System	22	11	13	46	Audit Findings per Process
IA002	Document Control	2	5	0	7	Quality Management System 22 11 13
IA003	Design & Development	2	4	0	6	Document Control 2 5 0
IA004	Manufacturing	2	4	2	8	Design & Development 2 4 0
IA005	Customer Service	2	2	1	5	Manufacturing 2 4 2
IA006	<enter description="" name="" process=""></enter>	0	0	0	0	Customer Service 2 2 1
IA007	<enter description="" name="" process=""></enter>	0	0	0	0	<enter description="" name="" process=""> () <enter description="" name="" process=""> ()</enter></enter>
IA008	<enter description="" name="" process=""></enter>	0	0	0	0	<enter description="" name="" process=""> ()</enter>
IA009	<enter description="" name="" process=""></enter>	0	0	0	0	<enter description="" name="" process=""> (</enter>
IA010	<enter description="" name="" process=""></enter>	0	0	0	0	<enter description="" name="" process=""> (</enter>
IA011	<enter description="" name="" process=""></enter>	0	0	0	0	<enter description="" name="" process=""> 0</enter>
IA012	<enter description="" name="" process=""></enter>	0	0	0	0	<enter description="" name="" process=""> 0</enter>
IA013	<enter description="" name="" process=""></enter>	0	0	0	0	<enter description="" name="" process=""> 0</enter>
IA014	<enter description="" name="" process=""></enter>	0	0	0	0	<enter description="" name="" process=""> 0</enter>
IA015	<enter description="" name="" process=""></enter>	0	0	0	0	<enter description="" name="" process=""> 0</enter>
IA016	<enter description="" name="" process=""></enter>	0	0	0	0	<enter description="" name="" process=""> 0</enter>
IA017	<enter description="" name="" process=""></enter>	0	0	0	0	<enter description="" name="" process=""> 0 <enter description="" name="" process=""> 0</enter></enter>
IA018	<enter description="" name="" process=""></enter>	0	0	0	0	<enter description="" name="" process=""> ()</enter>
IA019	<enter description="" name="" process=""></enter>	0	0	0	0	<enter description="" name="" process=""> 0</enter>
IA020	<enter description="" name="" process=""></enter>	0	0	0	0	<enter description="" name="" process=""> 0</enter>
IA021	<enter description="" name="" process=""></enter>	0	0	0	0	<enter description="" name="" process=""> 0</enter>
IA022	<enter description="" name="" process=""></enter>	0	0	0	0	■ Total OFI ■ Total Minor N/C ■ Total Major N/C

Non-conformity & Corrective Action Tracker

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Step 9 Issue corrective action reports to process owners to initiate the close-out of any non-conformances. Monitor progress and verify close-out.

Please note: the drop down box menu in Column 'B' is based on the processes that you entered in the 'Process Assessment' worksheet.

CAR Ref.	Process Name	CAR Type	How was it identified?	Description of the CAR	Non-conformance Report	Root Cause	Description of Corrective Action	Date Assigned Assigned to	Target		Date Close-out
	Design & development Manufacturing & warehousing				Ref. (If applicable) Not applicable NCR001	Version control - using superseded template	Department to ensure templates are updated	01-Jan-16 Jane Doe 20-Feb-16 John Doe	Completion 20-Jan-16 07-Mar-16	Yes Visually confirmed that the correct template is available and is being used	Verified 30-Jan-16
CAR003	Manufacturing & warehousing	Major N/C	reedback - Customer	incorrectly snipped item	NCRUU I	item was mis-identified prior to storage	Warehousing to investigate and correct labelling errors	20-reb-16 John Doe	07-IVIAI-16	NO NO	
CAR004 CAR005 CAR006											
CAR006 CAR007 CAR008											
CAR009											
CAR010 CAR011											
CAR012 CAR013											
CAR014 CAR015											
CAR016 CAR017											
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