

Quality management

Organi

Standard

1SO 9001

**Training** 

Customer

Require

Business

Certification

Continual improvement









## This course will help the participants

To get acquainted with and understand the requirements of ISO 9001:2015 standard

To understand risks, opportunities, context of the organization and interested parties

To understand Internal and External Audits





## ISO 9001:2015 Principles

1

**Customer Focus** 

2



Leadership

3



**Engagement** 

4



**Processes** 

5



Continuous improvement

6



**Evidence based** decision making

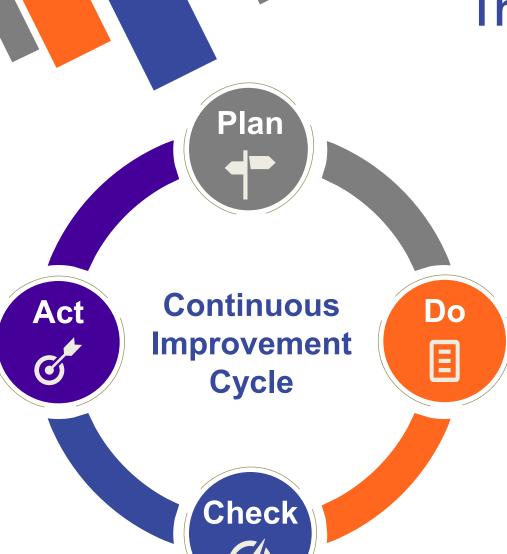
7



Relationship Management ISO 9001 is defined as the international standard that specifies requirements for a quality management system (QMS). Organizations use the standard to demonstrate the ability to consistently provide products and services that meet customer and regulatory requirements.



## The PDCA Cycle



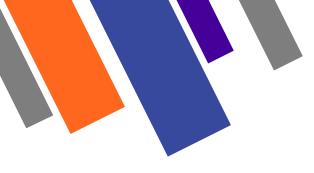
This is the "Plan-Do-Check-Act" improvement cycle. You may hear it called the PDCA cycle or the Deming cycle. You can apply it to all processes and you can use it to plan and implement process change.

Plan – Plan the improvement and plan how you will know if it has worked

Do - Do what you planned to do and measure it as planned

**Check - Check the results against expectations** 

**Act** – Act to maintain the improvement, address any shortfall and learn from experience





## **IRCA & Certifying Body**



### **International Register of Certificated Auditors (IRCA)**

The gold standard for management systems. Its members are highly valued and globally recognized as skilled management systems auditors. While Charted Quality Institute (CQI) members are known for delivering excellence in business. While Charted Quality Institute(CQI) is the professional body for experts in improving products, projects, and services.

### **ISO Certifying Body**

An independent third party that handles a certification process. So, ISO certification bodies assure each business follows its ISO standards. This includes all the necessary conditions for each standard a company has

## **Context of the Organization**





### Clause 4.1

O1 Internal Factors
Culture Values
Performance
Knowledge

**O2** External Factors Political Economic Social/ Cultural Technological Legal Environmental/ Geographical

03 Levels
Local/ Regional National
International

GUIDE doc. no. 2746 - Internal & External Factors affecting SMSA

## **Context of the Organization**



Clause 4.2



### **Interested Parties**

Needs Expectations

GUIDE doc. no. 2740

# Ingredients of QMS Management





Clause 4.3

The staff

## Scope of the Quality Management System





Clause 4.3



## **Leadership & Commitment**



### **Top Management**

Takes accountability for the effectiveness of the Quality Management System

Ensures business processes are integrated to Quality Management System



Ensures quality policy and quality objectives are compatible with SMSA strategy and up-to-date

Ensures that resources needed are available

Clause 5.1

### **Customer Focus**





Fair Treatment of Customers

(GUIDE doc. no. 3212)

Customer Journey Map (GUIDE doc. no. 2818)

**Clauses 5.1.2** www

Identifying customer requirements (Surveys, complaints)

Meeting customer requirements (Delivery commitment)

**Enhancing customer satisfaction** (Surveys, complaints, SLA)

Customer Ethics Policy (GUIDE doc. no. 3587)

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## **Quality Policy**

Clauses 5.2.1 & 5.2.2

### **Shall Be**





Available and displayed prominently (posters, TV screens)



Reviewed at regular intervals



Communicated and understood by relevant interested parties



Maintained as documented information

### **Quality Policy**



SMSA is perpetrated to being the leading provider of logistics, freight, mailroom, courier, and E-commerce solutions. Moreover, SMSA provides Healthcare storage and transportation solutions including solutions that are aligned with internationally recognized "Good Distribution Practices". SMSA shall optimize its clients' benefits for these services by providing them with state-of-the-art support.

Quality is considered to be a personal responsibility for all our employees at SMSA. To preserve it, the top management shall provide the required support and training, whereas the effectiveness of the company operations will be ensured and the associated risks will be systematically avoided.

In addition, SMSA shall implement a working environment for enabled, satisfied, motivated, and committed employees making SMSA "The Employer of Choice".



Naif Sultan Al-Athel Chairman of the Board



## Roles Responsibilities & Authorities



Clauses 5.3





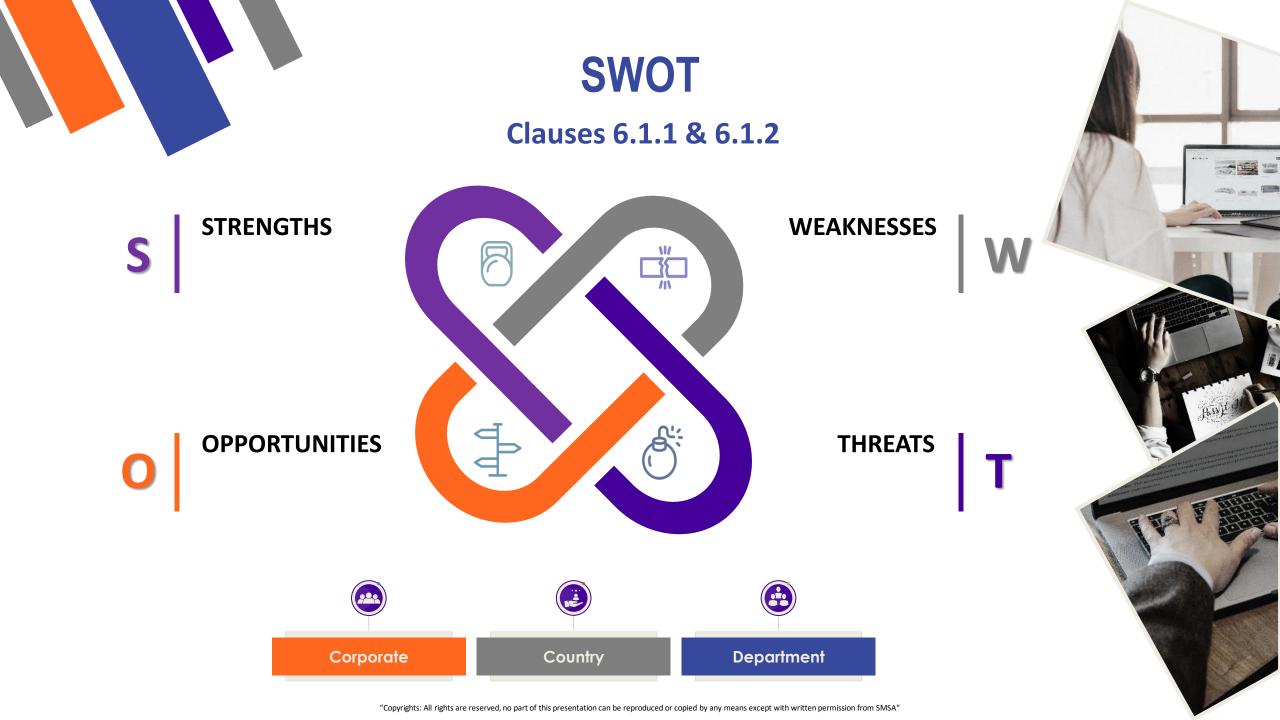
All process maps will have the responsible person to do the job function



Delegation of Authority



Organizational structure up to date





## Risk & Opportunities

Clauses 6.1.1 & 6.1.2

Methods of Risk Identification (GUIDE doc. no. 2770)

Methods of Opportunity Identification (GUIDE doc. 2769)

Risk Ranking Criteria (GUIDE doc. no. 2801)

**Reviewed annually** 

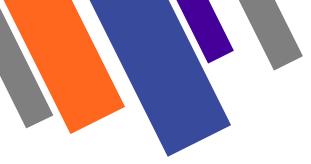
**Residual Risk** 

### **Risk Mitigation Strategies**

Five ways of mitigating risk

- 1. Fix the risk immediately
- 2. Risk can be set as a KPI for a department
- 3. Risk can be set as a strategy
- 4. Transfer the risk to a third party
- 5. Accept the risk due to cost vs risk









Clauses 6.1.1 & 6.1.2

Severity					
Low	Medium	High			
Affecting location Affecting employee Affecting Satisfaction	Affecting Individual Customer Affecting SMSA Service Affecting Department	Affecting Corporate SMSA Affecting Revenue Affecting Image Affecting Govt. Regulation Affecting Key Acct customers Affecting Health & Safety			

				(multiply)	Severity				
				X	Low (1)	Medium (2)	High (3)		
Probability	Low	Probability of incidents occuring beyond 24 months	Probability	≥	τ <b>λ</b>	Low(1)	Low Risk (1)	Low Risk (2)	Med Risk (3)
	Medium	Probability of incidents occuring within 12 to 24 months		Medium (2)	Low Risk (2)	Med Risk (4)	High Risk (6)		
	High	Probability of incidents occuring within 12 months or less		Ā	P	High (3)	Med Risk (3)	High Risk (6)	High Risk (9)

**GUIDE doc. no. 2801 - Risk Ranking Criteria** 

## **360° Strategy Planning**



Clauses 6.2.1 & 6.2.2



MISSION & AIZION

CORE **VALUES** 

QUALITY **POLICIES** 



**Employees Opinions** 



Kaizen

**Previous Results** 



**Lessons Learnt** 



Risks



Opportunities



Interaction Feedback



Customer Survey

Brand & Market Survey Mystery Shopping





Social Media Feedback









Vision 2030







Actions

Business Objectives **SMSA Wheel** 

Strategy Committee



Consultant



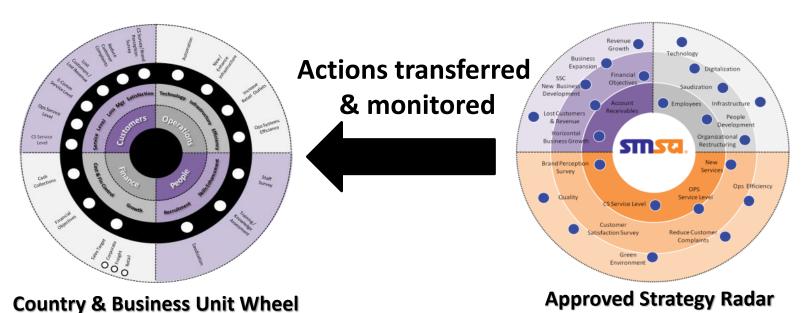




## **Strategy Formation**



Clauses 6.2.1 & 6.2.2



### \_\_\_\_\_

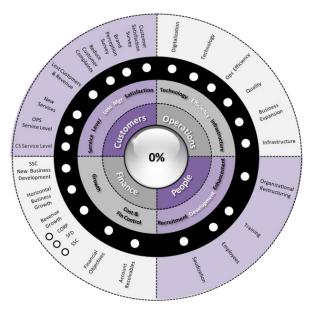






Clauses 6.2.1 & 6.2.2

### **Corporate Wheel**



### **KPI Dashboard**

Area	KPI No.	Description	Measurement Criteria	Value out of 100%	Value out of Overall Wt %	Yearly Target
	KPI-1	New Automation	Cold Chain Management System Oracle Fusion New Customer Portal Website New SMSA Billing Module Dev't.	20%	6.00%	100.00%
IONS	KPI-2	Enhance Automation	Mobile App Ph4 MRM Enhancement V4 SMSA Auto Tool SAM Heavy/ SAM Light Ph3 Self service Enhancement IVR SECOM & SDC Enhancement Ph3 SDC App – SDM System	10%	3.00%	100.00%
АТ	KPI-3	Enhance E-Commerce Efficiency	Logistics / Fulfillment	40%	12.00%	100.00%
OPER	KPI-4	OPS Efficiency	Control Room Fleet Categorize Facilities DG Operations Automatic Data Capture	10%	3.00%	100.00%
	KPI-5	New / Enhance Infrastructure	As per plan	10%	3.00%	100.00%
	KPI-6	Increase Retail Outlets	24 New Retails	10%	3.00%	100.00%
		Total		100%	30.00%	
		OVERALL WEIGHT		30%		







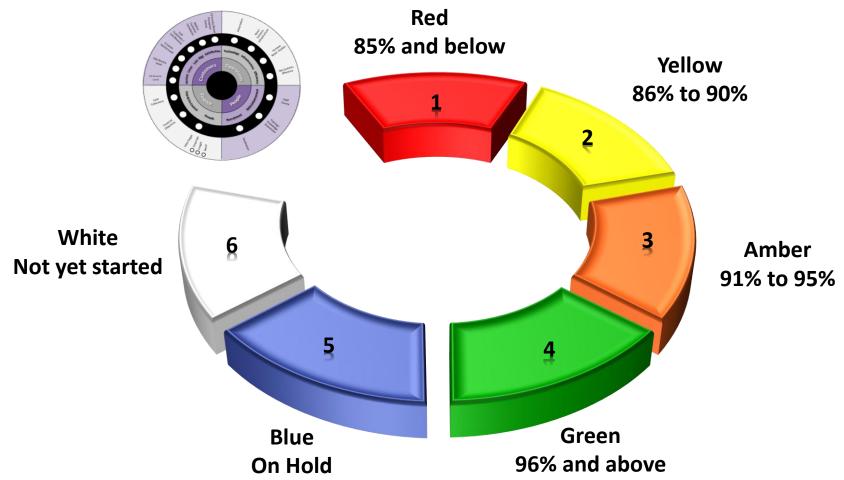


NC will be issued for Red KPIs



## KPI Performance Color Coding



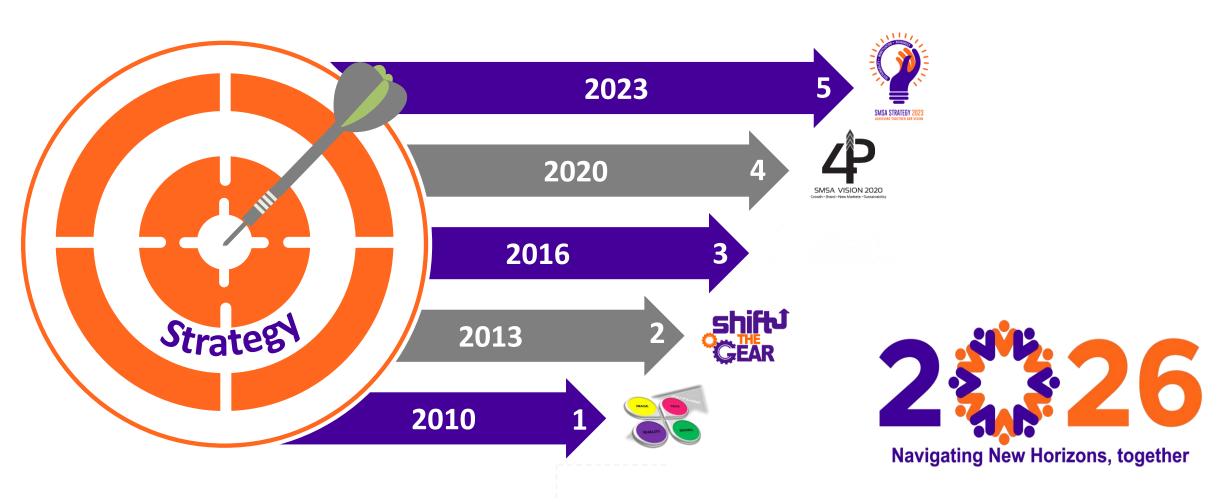




## **Previous Strategies**

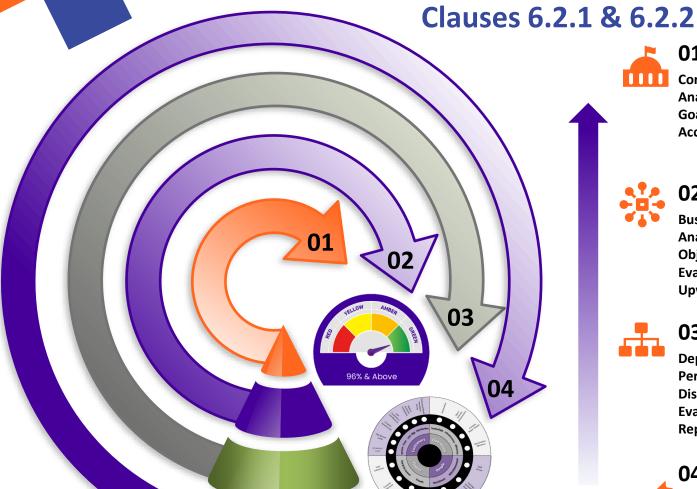


Clauses 6.2.1 & 6.2.2



## **Levels of KPIs**







### 01. Corporate

**Corporate steering wheel Analytical Dashboard for Performance Metrics** Goals Disseminated to business unit / country tiers **Accomplishments Reported Upward** 



### 02. Country / Business Unit

Business Unit / country steering wheel **Analytical Dashboard for Performance Metrics Objective Distribution to Departmental Levels Evaluation of Performance (Performance review) Upward Reporting of Achievements** 



### **03.** Departments

**Department-Specific Objectives and Key Performance Indicators Performance Monitoring Dashboard Distribution of Objectives to Employees Evaluation of Performance (Performance review) Reporting Achievements to Higher Management** 





**Goal settings Evaluation of Performance (Performance review) Upward Communication of Achievements** 

## **Aligning KPIs with Strategy**



Clauses 6.2.1 & 6.2.2





## **Key Performance Indicators**





Specific



Measurable



**Attainable** 



Relevant



**Time Based** 





**Clauses 7.1.2** 

**GUIDE doc. no. 2764 - Manpower Formula** 





**Clauses 7.1.3** 

...shall determine, provide and maintain the infrastructure –



Adequate space



**Required equipment** 



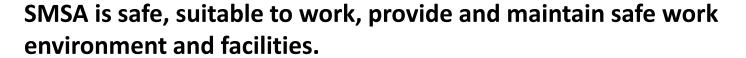
**Properly maintained locations** 



## **Resources - Environment**



**Clauses 7.1.4** 



- Facility Cleaning/ Housekeeping
- Floors and other surfaces
- Work Areas/ Work Stations
- Lighting
- Ventilation and Air Conditioning
- Temperature

All the above are maintained through ticketing system which can be found in the <a href="helpdesk.smsaexpress.com">helpdesk.smsaexpress.com</a> or ticket can be open by sending email to <a href="helpdesk@smsaexpress.com">helpdesk@smsaexpress.com</a>





## **Measurement Traceability**



**Clauses 7.1.5.2** 



Standard states that all measuring equipment's must be calibrated, which is done in 2 ways

By the auditors using test weights

Through an authorized outsourced company

GUIDE doc. nos.

2803 - Calibration Control Sheet

**2655 – Scales Calibration Policy** 

**2693 – Scales Calibration & Weight Checks** 

## **Competence & Awareness**



**Training Calendar (Internal courses)** 

**Basic, Intermediate & Advanced courses** 

**External Courses** 

**Coaching front line staff** 

**Competency job description** 

**Measurement of KPIs** 

**Appraisals** 

**Knowledge Assessment** 









**Internal & External Communications** 

**Message Centre** 

Newsletter

**SMSA Website** 

SMSA Video on TV screens in SSC & OPS

All changes on GUIDE communicated through

**Champions** 

**Regional Meeting & Department Meetings** 



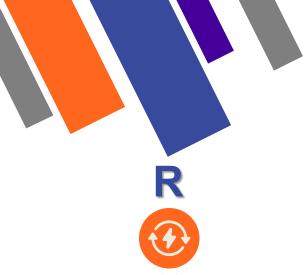
### **GUIDE doc. nos.**

2727 – Gaps Template

2790 – Project Plan Template

**2771** – Minutes of Meeting Template





## **Communication**











### Responsible

The 'Doer

Person who complete a particular process or steps or leads the people who do

Responsibility level determine by individual who is accountable

Makes decisions

Several people can be responsible

#### Accountable

The buck stops here

The person who is held accountable by top management for implementation

Position with yes/no authority

There can be only one person accountable

Signs off tasks decisions

#### Consulted

In the loop

Person whose advice is sought before the final decision is made or implementation takes place.

Position involved prior decision or action

Two way communication

#### Informed

Keep in the picture

People who need to be kept in the picture

Does not contribute directly to the tasks or decisions but need to know the progress



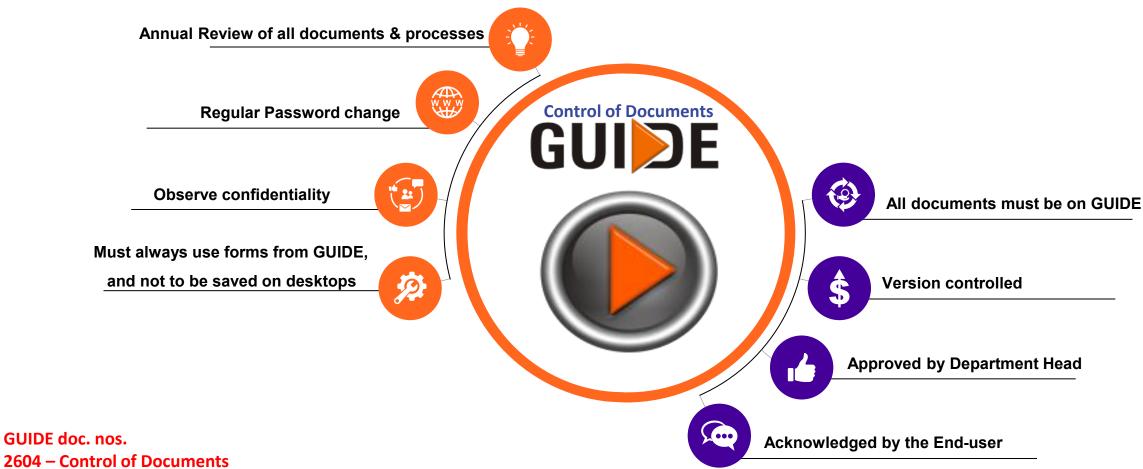
**2601 – Confidentiality Policy** 

2733 - GUIDE System Access Rights

## **Documented Information**



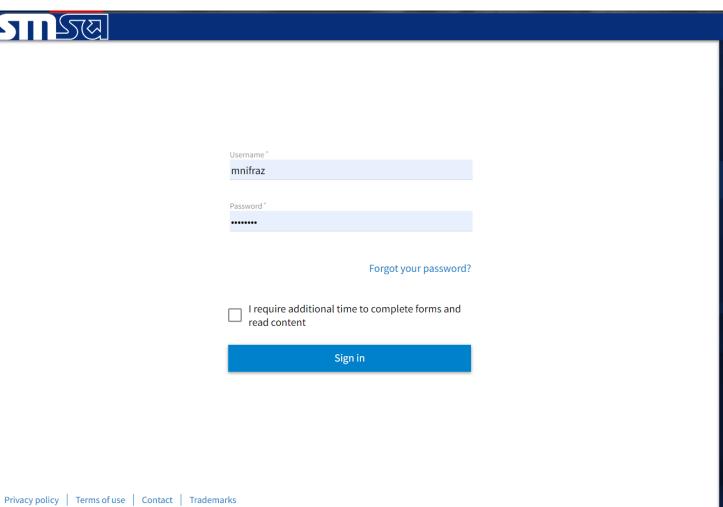
Clauses 7.5.1; 7.5.2 & 7.5.3





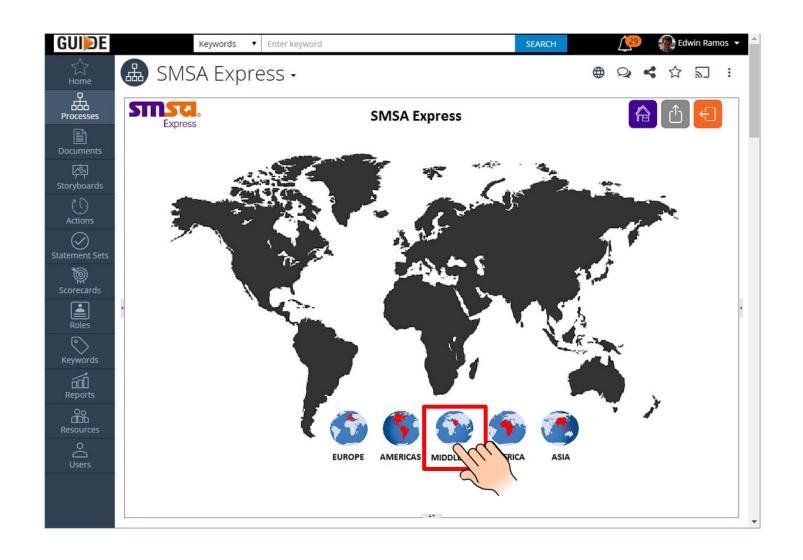
### STEP 2: Sign in to GUIDE using your own LDAP login & password

SINSE

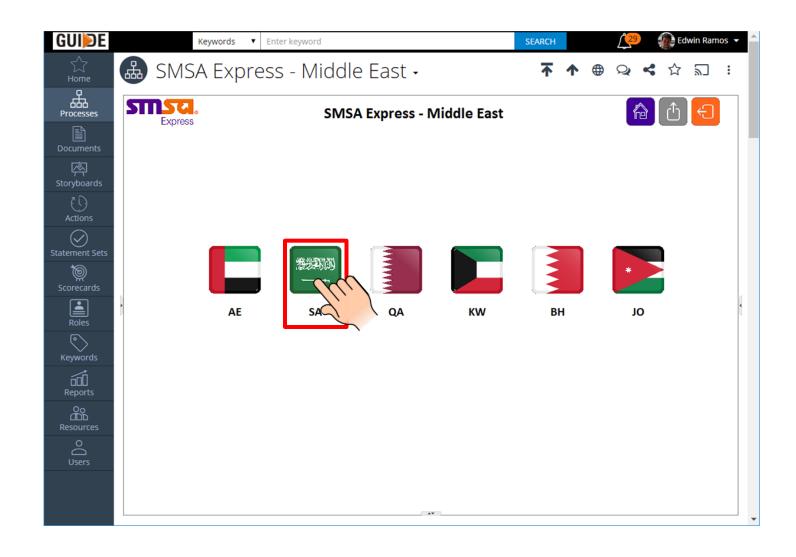


**TIBCO Nimbus provide quality process** diagrams that simplify communication and improve how your business runs. Describe processes in an easy-to-understand visual Simplify Collaborate on improvements and change. Share Approve processes and tasks. Change Send and track notifications for maps and procedures. Copyright © 2021 TIBCO Software Inc. • All rights reserved.







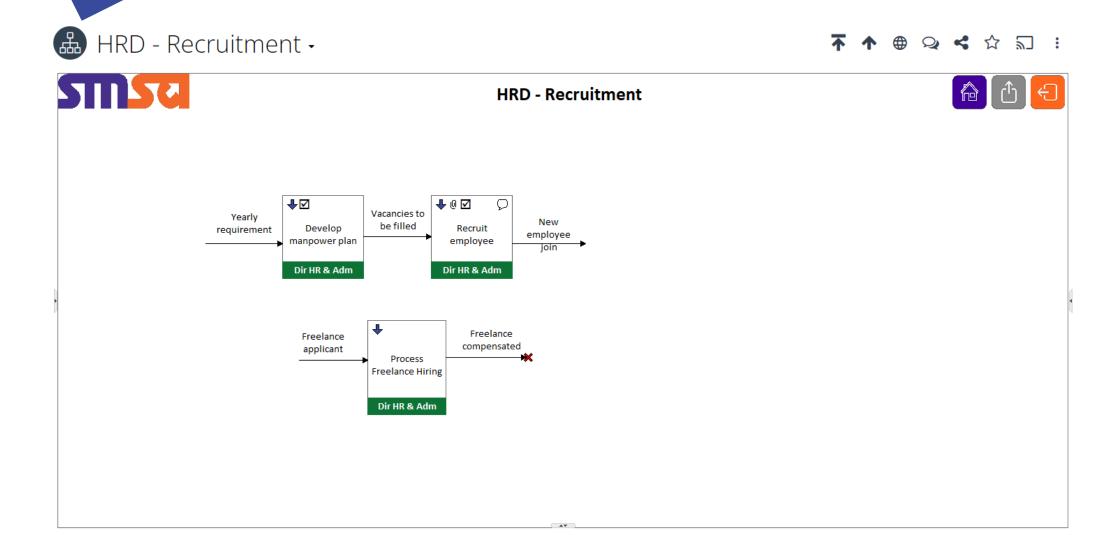






## **Quality Management System**





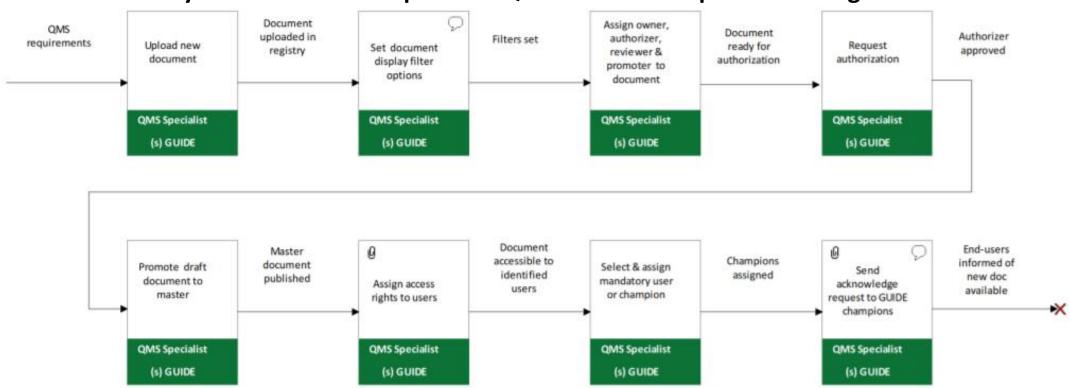




Clauses 7.5.1; 7.5.2 & 7.5.3

#### **New Document Upload**

#### Any new document required in QMS has to be requested through GUIDE



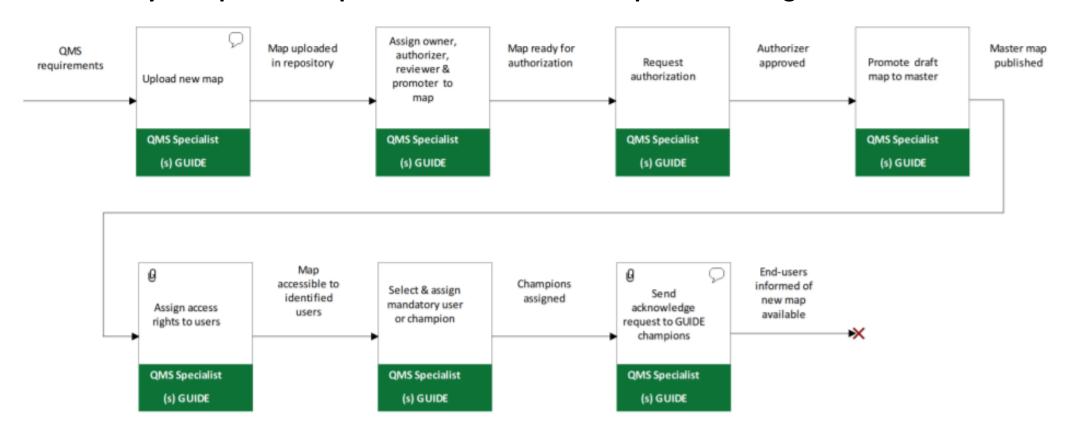




Clauses 7.5.1; 7.5.2 & 7.5.3

#### **New Process Upload**

#### Any new process required in QMS has to be requested through GUIDE



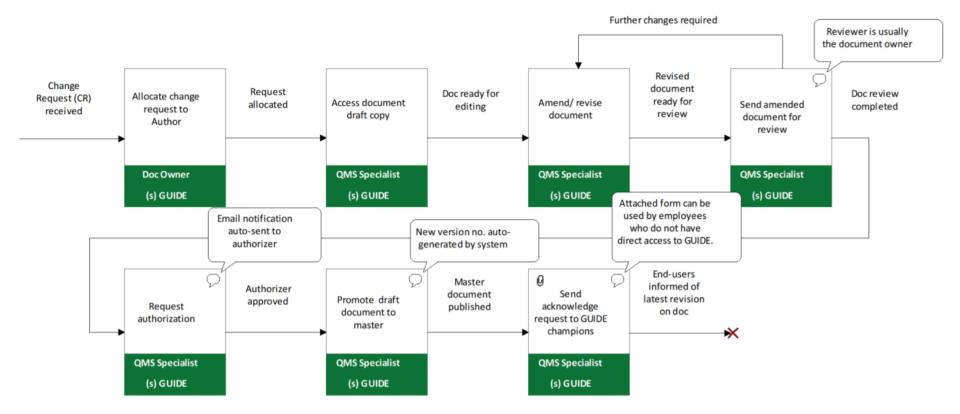




Clauses 7.5.1; 7.5.2 & 7.5.3

#### **Change Management**

#### Any document change required in QMS has to be requested through GUIDE



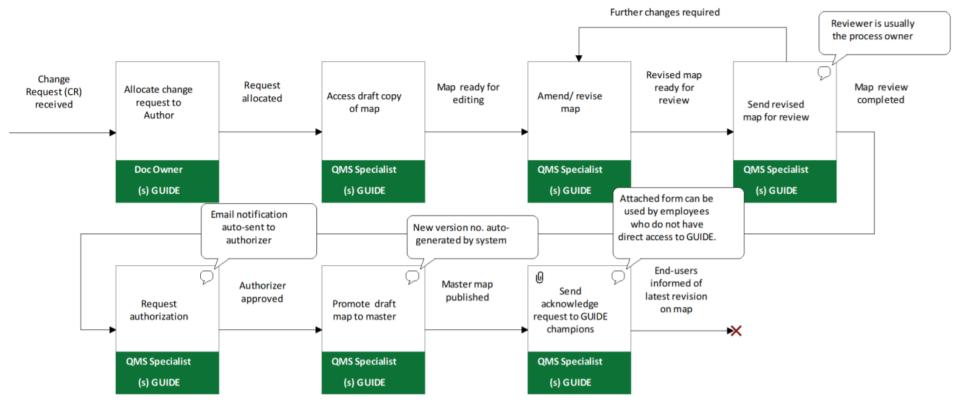




Clauses 7.5.1; 7.5.2 & 7.5.3

#### **Change Management**

#### Any process map change required in QMS has to be requested through GUIDE







**Clause 7.5.3** 



CR 007 ENVIRONMENTAL HEALTH & SAFETY NUMERIC CONFIDENTIAL INDEFINITE

**Control of Records** 

Labeling **Storage / Archiving** Retrieval Retention **Disposal** 

Classification

Confidential Restricted **Public** 

All CONFIDENTIAL documents must be kept in locked cabinets

> GUIDE doc. nos. 2604 – Control of Records 2690 - Box File Template 2721 – File Archive Register

## Difference Documents & Records 511154



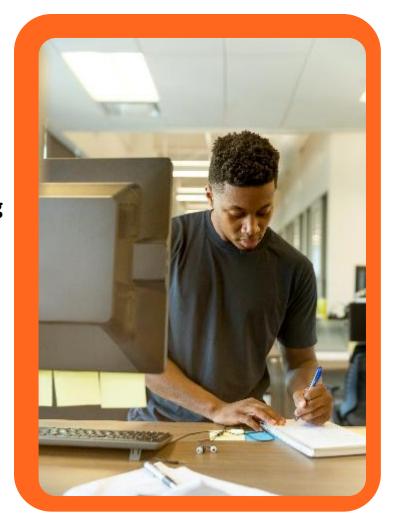


#### **Documents**

Describe what needs to be done, and this includes quality manual, procedures, work instructions etc. Documents get changed or revised with time. A document can be in any media capable of storing information, including paper, electronic documents, photographs, software, etc.

#### **Records**

Evidence of work been done. Records can not be changed (generally) and are retained



## **Customer Communication**



**Clause 8.2.1** 



**Services / Delivery commitments / Indemnity / Insurance** 



## **External Service Providers**



Clauses 8.4.1; 8.4.2 & 8.4.3

Externally Provided Processes,
Products & Services
Standard requires the following:

GUIDE doc. nos.

GUIDE doc. nos.

2844 - Sample Vendor

2844 - Sample Vendor

Evaluation Form

Evaluation Suppliers

Approved Supplier Pre
Vendor Selection Questionnaire

Vendor Supplier Pre
Ven







Evaluate the vendors using the Vendor Evaluation Form

Evaluation carried out annually, in which vendors/ service providers are retained or removed based on the evaluation results

**Production & Service Provision** 

the results

Clauses 8.5.1 & 8.5.2

**Quality Control** 

In SMSA, we measure Quality Control through

various means

KPI (Key Performance Indicator)
Service Level (Delivery Commitment)
Customer Complaints
Mystery Shopping
Customer Satisfaction Survey

Coaching

**Employee Opinion Survey** 

**Scan Compliance** 

**Lost Shipments** 

**Damaged Shipments** 

**Missed Pickups** 

**Previous Audits** 

**HR Figures** 



### **Customer Satisfaction**



**Clause 9.1.2** 



#### **Customer Satisfaction**

Annually, Semi- Annually and Quarterly surveys carried out on our customers.

Action plans required for areas of concern.

**Customer Satisfaction are measured based on four points Likert scale -**

- Highly Satisfied (>85%)
- Satisfied (84% 65%)
- Somewhat Dissatisfied (64% 50%)
- Dissatisfied (<50%)



## **Brain of a Quality Auditor**



**Clause 9.1.2** 

Understanding

How does the auditor understand your rights?

#### Fact:

- The auditor understands your rights including –
- 1. Your right that he will listen to your explanation.
- 2. Your right to propose an effective corrective action

#### TIP

Auditor will not issue non-conformities based on personal preferences . He will issue them based on evidences.

#### Happiness

What will make him happy?

#### Fact:

If an auditor finds everything in order this will make his life much easier as he does not have to come back to do a re-audit.

#### TIP

This will make him happy – contrary to popular belief; auditors do not like giving NC's.

#### **Expectations**

What will the auditor expect?

#### Fact

An audit is not a one time thing. The auditor will visit you as planned . All plans are based on the audit plan work instructions found on GUIDE Doc#2954. The plan can be found on GUIDE under Doc#2748

#### TIP :

Besides leaving a good impression, you should also make sure your system and documentation are maintained. – this is what the auditor will be looking at the most when he comes back.

<u>Fact</u>: The auditor will assess whether – 1. You have all the necessary documentation.

What will the auditor look for?

- 2. If your activities and documentation comply with the standards/GUIDE
- 3. If your activities comply with your own documentation.

#### TIP

- 1. Don't write policies and procedures that you don't need and that you don't intend to comply with.
- 2. He will check the effectiveness of the documented system
- 3. He will jointly identify with you opportunities for improvement.

#### Knowledge

Which Standard is the auditor familiar with?

Fact: The auditor will perform an audit in SMSA against 4 standards (eg: ISO 9001, 14001, 45001 & TAPA)

#### TIP:

Use the auditors knowledge and experience to get a wider picture of the standards i.e. how you could further improve your department.

#### **Authorization**

What can the auditor do?

<u>Fact</u>: During the audit the auditor is allowed to speak to anyone who is within the scope of the audit, he is allowed to see any document and he is allowed to walk around all your premises.

#### TIP:

Make sure that everyone in your area is ready and aware of the audit and that your documentation is completed and available

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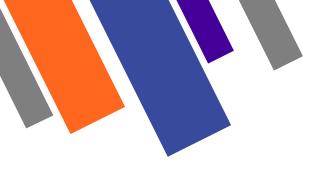




Clause 9.3



Held every last Thursday of the month
Attended by Senior Management Team with MD
Actions points updated regularly



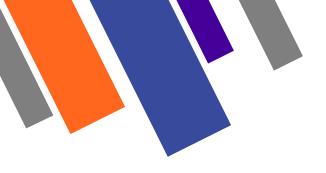
## Non-Conformity Corrective Action Clause 10.2



Clause 10.

Non conformity is issued when the following are not complied with:





## Non-Conformity Corrective Action



**Clause 10.2** 

#### **CAPA (Corrective and Preventive Action)**

#### What is Corrective Action?

CA- Action taken to eliminate the causes of non-conformities or other undesirable situations.

#### What is Preventive Action?

PA- Action taken to prevent further reoccurrence of such non-conformities.

http://nc.smsaexpress.com:8081/





## Non-Conformity Corrective Action



**Clause 10.2** 

When an NC is issued, the following applies

Department has to fill the Corrective and Preventive action on the CAPA System within 7 business days



Department has 30 days to resolve the NC



CAPA

Corrective
And
Preventive
Action

Auditor will verify the CAPA and either close the NC or keep the NC open



## **Continual Improvement**



**Clause 10.3** 



#### **Continual Improvement**

The auditor wants to see continual improvement on the figures achievement.

Department should learn from previous audit findings, gaps, database analysis and Lessons Learnt document

	5 Years Data Comparison (2018-2022)											
Department	Elements	Year 2018		Year 2019		Year 2020		Year 2021		Year 2022		Remarks
		Target	Achieved	Target	Achieved	Target	Achieved	Target	Achieved	Target	Achived	Nemarks
Human Resources	Staff turn over	1.23%	1.23%	1.70%	1.53%	1.70%	1.72%	1.50%	1.04%	NA	1.20%	Staff turnover is in target from 2018-2021.
	Saudization	25%	28%	25%	27%	23.8%	23%	25%	25%	25%	30%	Saudzation in line with the target required.
	Saudi Employees	NA	722	NA	760	NA	835	NA	1085	NA	13940	Saudi female call center
	Staffing level	97%	100%	97%	99%	97%	99%	97%	99%	50%	99%	Number of overall staff increased and new rules of labor office regards to non Saudi.
	Total number of staff left	NA	448	NA	557	NA	542	NA	598	NA	745	
	Number of vacancies	230 (97%)	221	255 (98%)	248	458 (94%)	431	NA	390	NA	534	
	Number of promoted	NA	220	NA	179	NA	368	NA	124	NA	146	
	Number of trained staff (Technical)	337	349 (100%)	431	224 (52%)	1010	1072 (100%)	1726	1618 (94%)	1243	1202 (97%)	
	Number of trained staff (Middle Management)	400	383 (96%)	120	111 (93%)	143	132(92%)	69	46 (67%)	114	98 (86%)	

## **Quality Manual**





QUALITY ASSURANCE MANUAL

150 9001: 2015

Quality Management System

Director - Quality & Risk Management



#### QUALITY POLICY

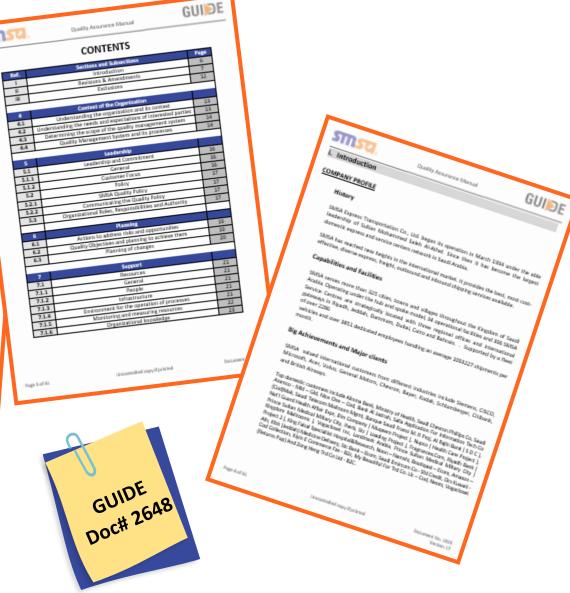
The management of SMSA is committed to continually improve the company's performance and meeting its customer's expectations while offering them a safe,

SMSA is perpetrated to being the leading provider of logistics, freight, mailroom, courier and E-commerce solutions. SMSA provides Healthcare storage and transportation solutions including solutions that are aligned with internationally recognized "Good Distribution Practices". SMSA also provides specialized services to its customers and together SMSA shall optimize its client's benefits for these services by providing them with state-of-the-art support.

Quality is considered to be a personal responsibility of all our employees at SMSA. To preserve it, the top management shall provide the required support and training, whereas the effectiveness of the company operations will be ensured and the

In addition, SMSA shall implement a working environment for enabled, satisfied, motivated, and committed employees making SMSA, "The Employer of Choice"

> Neif Sultan Al-Athel Chairman of the Board





# Any Questions

## Thank You!



#### **QRM Contact Numbers**



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#### **QRM Email Addresses**

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tellus@smsaexpress.com

