UIN
RADEN FATAH
PALEMBANG

LAPORAN
AWARENESS ISO
2021

LEMBAGA PENJAMINAN MUTU
UNIVERSITAS ISLAM NEGERI
RADEN FATAH PALEMBANG

KATA PENGANTAR

Assalamu'alaikum Wr.Wb.

Puji syukur ke hadirat Allah SWT, pelatihan awareness ISO mendapatkan limpahan rahmat, taufiq, dan hidayah-Nya, sehingga dapat menjalankan peran dan tanggung jawabnya meskipun dengan beberapa hambatan dan tantangan kegiatan. Penyampaian laporan awareness ISO ini merupakan bentuk laporan resmi tentang hasil pelaksanaan awareness ISO . Penyusunan laporan awareness ISO ini juga merupakan bentuk pertanggung jawaban Lembaga Penjaminan Mutu (LPM) sebagai lembaga yang diamanati untuk pemasok kegiatan yang membantu organisasi mengelola risiko, mengurangi biaya dan memastikan keberlanjutan

Wassalamu'alaikum Wr.Wb

Palembang, 31 Desember 2021

Ketua,

Syahril Jamil

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BAB I

PENDAHULUAN

ISO 9001 Awareness Training adalah standar Sistem Manajemen Mutu/Quality Management System yang dibuat untuk membuat pencapaian kualitas serta konsistensi produk lebih mudah tercapai dengan memberi langkah-langkah spesifik untuk pengembangan sistem manajemen mutu organisasi. Sistem manajemen mutu tersebut dimaksudkan untuk memantau proses dari produk atau layanan dalam setiap tahapannya mulai dari pengembangan, pengujian, perakitan dan umpan balik pelanggan.

ISO 9001 dengan fokus pada kepuasan pelanggan akan meningkatkan produk serta pelayanan dengan kombinasi dari perbaikan terus-menerus serta tindakan korektif-ajaran ISO 9000- menjadikan proses berjalan dengan lancar dan efisien.

Sedikit informasi tentang QMS, ISO berkomitmen akan meninjau serta memperbarui standarnya tiap 5 tahun. Saat ini sudah terbit revisi ISO 9001:2008 menjadi ISO 9001:2015 (ISO 9001 Revisi Terbaru). Banyak perubahan yang terjadi seperti aktifnya manajemen puncak (versi ISO 9001:2008 MR yang aktif), perubahan istilah, manajemen risiko, dll. Layanan Bintang Solusi Utama meliputi training dan konsultasi ISO 9001:2008, maupun training dan konsultasi ISO 9001:2015 (ISO 9001 version 2015).

Manfaat dan Tujuan iso 9001 Competence Awareness And Training

- Memahami pentingnya penerapan Sistem Manajemen Mutu (SMM) ISO 9001
- Mampu memahami persyaratan ISO 9001dan bagaimana penerapannya dalam proses bisnis organisasi
- Mampu merencanakan langkah-langkah pengembangan sistem manajemen mutu berdasarkan persyaratan dokumen ISO 9001
- Mampu mengidentifikasi sumber daya dan kemampuan yang dibutuhkan sistem manajemen mutu ISO 9001
- Mampu bekerjasama dan mendukung Wakil Manajemen
- Mampu memberi saran/ pilihan sumber daya dalam menerapkan ISO 9001 di perusahaan/ institusi
- Mampu melakukan internal audit SMM ISO 9001
- Mampu melakukan continues improvement

Secara ringkas awareness ini adalah untuk memberikan gambaran atau pemahaman kepada kita mengenai konsepsi dasar ISO 9001:2015 (sistem manajemen mutu).

Manfaat bagi peserta: dengan mengenal konsep ISO 9001:2015 membantu kita dalam menerapkannya di unit kita masing-masing.

Manfaat untuk institusi tentu saja berdampak pada reputasi karena ini adalah salah satu bentuk sertifikasi internasional.

BAB II

PELAKSANAAN

Pelatihan diikuti oleh 80 orang mulai dari Kepala Unit, WD1, Kepala Pusat LPM, Sekretaris LPM, Kasub dan Kasubag , GPMF, Kepala Labor, dan tendik dilingkungan UIN Raden Fatah. Pelatihan terbagi ke dalam empat angkatan/batch. Setiap angkatan berbeda peserta. Pelatihan berlangsung sehari untuk setiap angkatan.

Metode pelatihan menggunakan zoom yang berlangsung selama empat hari dengan materi awareness ISO.

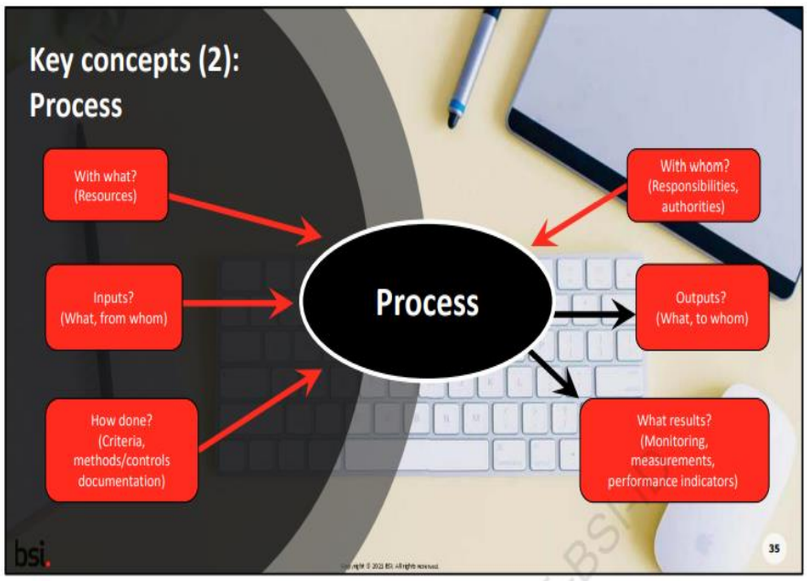
Pelatihan dimulai dari pukul 08.00 s.d 16.00 WIB dari tanggal 27,29,30 dan 31 desember 2021.

Sasaran Setiap peserta mampu memahami klausul ISO yang terkait dengan pelaksanaan system manajemen mutu ISO 9001:2015

Tujuan 1. Memahami konsep system manajemen dan dokumentasi berbasis ISO 2. Memahami perubahan ISO 9001 dari versi 2008 ke versi 2015 serta dampaknya terhadap system manajemen yang telah ditetapkan

Berikut bebrapa materi awareness ISO yang disampaikan :

ISO 9001:2015 Requirements Training Course


Key concepts (2):
Process
With what?
(Resources)
Inputs?
(What, from whom)
How done?
(Criteria, methods/controls documentation)
Process
With whom?
(Responsibilities, authorities)
Outputs?
(What, to whom)
What results?
(Monitoring, measurements, performance indicators)
bsi.
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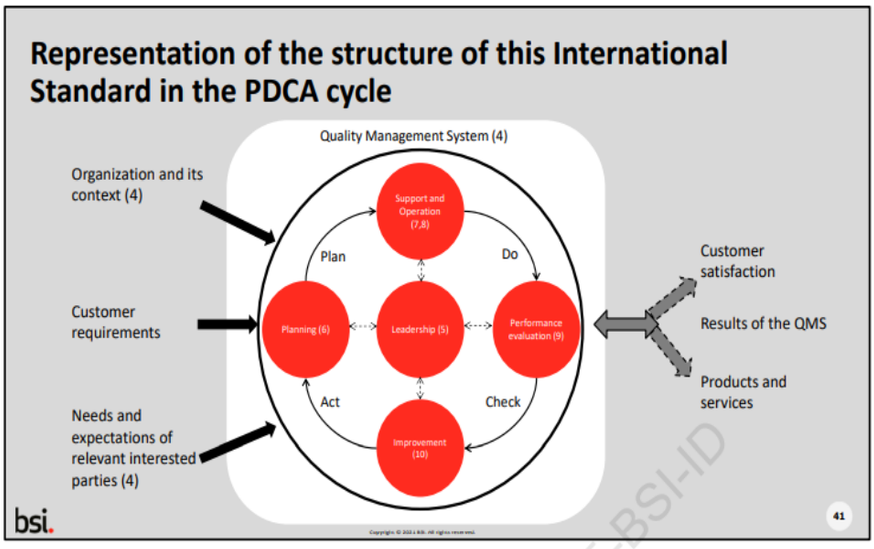
Representation of the structure of this International Standard in the PDCA cycle
Quality Management System (4)
Organization and its context (4)
Customer requirements
Needs and expectations of relevant interested parties (4)
Support and Operation (7,8)
Plan
Do
Planning (6)
Leadership (5)
Performance evaluation (9)
Act
Check
Improvement (10)
Customer satisfaction
Results of the QMS
Products and services
bsi.
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BAB III

EVALUASI

Setelah melakukan pelatihan ini dan dianggap kompeten maka beberapa hal menjadi bahan evaluasi sekaligus menghasilkan rekomendasi sebagai berikut:

1. Mengkomunikasikan awareness ISO kepada pimpinan
2. Setelah mendapat persetujuan perlu dilakukan sosialisasi issu awareness ISO di lingkungan UIN secara berkala

BAB IV

PENUTUP

Pelatihan ini telah selesai dilaksanakan berjalan dengan lancar, karena seluruh tahapan pelaksanaan pelatihan dilaksanakan dengan baik. Antusiasme dan partisipasi peserta sangat baik mengingat masing-masing peserta berasal dari Kepala Unit, WD1, Kepala Pusat LPM, Sekretaris LPM, Kasub dan Kasubag , GPMF, Kepala Labor, dan tendik dilingkungan UIN Raden Fatah.

Dan peserta mampu memahami klausul ISO yang terkait dengan pelaksanaan system manajemen mutu ISO 9001:2015 sehingga sistem yang diterapkan diharapkan akan mengalami perbaikan kedepannya dalam mencapai target dan tujuan sesuai visi misi Universitas Islam Negeri Raden Fatah Palembang.

LAMPIRAN-LAMPIRAN

1. **Lampiran (1) Peserta Pelatiahan**
2. **Lampiran (2) Materi**
3. **Lampiran (3) Sertifikat**
4. **Lampiran (4) Foto**

Lampiran (1) Peserta Pelatiahan

Peserta Pelatihan
ISO 9001:2015 Requirements Training Course
UIN Raden Fatah Palembang

No	Nama	Email	Jabatan	No.HP/WA	Batch Pelatihan	Tanggal
1	Muhammad Taher	muhammadtaher29458@gmail.com	Kasubag Adm umum Rektorat UIN Raden Fatah Palembang	0813 7780 1900	Batch 1	27 Des 2021
2	Fahruddin	fahruddin@radenfatah.ac.id	Ka. PUSTIPD	82315480022	Batch 1	
3	Bety	Bety_uin@radenfatah.ac.id	Ka Labor Adab	81539393257	Batch 1	
4	Musli Darosan	jemebindu@gmail.com	Kabag Perencanaan dan Keuangan	82175333317	Batch 1	
5	Fuadi Azmi	fuadiazmi@gmail.com	Subkoordinator Subbag Ortala	85267131333	Batch 1	
6	Nirmala Kusumawatie	kusuma.ute1969@gmail.com	Kpl Perpustakaan	82122625457	Batch 1	
7	Vaurina	vaurina_uin@radenfatah.ac.id	Kasubbag. Kerjasama	87898228020	Batch 1	
8	Yulion Zalpa	zalpayulion@gmail.com	Kepala Laboratorium Fakultas Ilmu Sosial dan Ilmu Politik	82134742545	Batch 1	
9	Badarudin Azarkasyi	badarudinazarkasyi_uin@radenfatah.ac.id	gpmf fakultas fisip uin raden fatah palembang	82177170678	Batch 1	
10	Karimin	kariminwijaya@gmail.com	Kasubag. Administrasi Akademik	81373365071	Batch 1	
11	Paisol Burlian	paisolburlian_uin@radenfatah.co.id	Ketua LP2M	82397975233	Batch 1	
12	Karoma	karoma1963@gmail.com	Ka. Prodi S3 PAI	82185559346	Batch 1	
13	Mukti Ali	muktialy1210@gmail.com	Sekretaris LPM	85273384013	Batch 1	
14	Gina Agiyani	ginaagiyani123@gmail.com	staf lpm	81271455289	Batch 1	

15	Mahfudz	mahfudz_uin@radenfatah.ac.id	GPMF Pascasarjana UIN Raden Fatah Palembang	81373306374	Batch 1	
16	Indra Yuhanto	yuhantoindra@gmail.com	Kabag. BAK	81273217879	Batch 1	
17	Zhila Jannati	zhila_jannati10@radenfatah.ac.id	Kepala Laboratorium Fakultas Dakwah dan Komunikasi	85764970404	Batch 1	
18	Ulyl Absor	Ulylabsor@radenfatah.ac.id	Staf LPM	82177773914	Batch 1	
19	Fajri Ismail	diah_fajri@yahoo.co.id	Wadir Pascasarjana	811718669	Batch 1	
20	Elismaharfiani	elismaharfiani_uin@radenfatah.ac.id	Kasub BAAB		Batch 2	
1	Rika Lidyah	rikalidyah_uin@radenfatah.ac.id	Wakil Dekan 1 FEBI	811712007	Batch 2	**29 Des 2021**
2	Fifi Hasmawati	fifihasmir@gmail.com	Gpmf FDK	85762504916	Batch 2	
3	Eko Oktapiya Hadinata	ekooktapiyahadinata_uin@radenfatah.ac.id	Ketua GPMF Psikologi UIN Raden Fatah Palembang	82111361258	Batch 2	
4	Irham Falahudin	irhamfalahudin_uin@radenfatah.ac.id	wadek 1	81374665651	Batch 2	
5	Nuraida	nuraida_uin@radenfatah.ac.id	WD 1	85267071004	Batch 2	
6	Ema Yudiani	emayudiani_uin@radenfatah.ac.id	Wakil Dekan 1 FPsi	818268424	Batch 2	
7	Tutut Handayani	Tututhandayani78@yahoo.co.id	Kaprodi PGMI	81374671092	Batch 2	
8	AMILDA	amilda_tarbiyah_uin@radenfatah	Lektor Kepala	82176746753	Batch 2	
9	Ruliansyah	ruli@radenfatah.ac.id	ketua GPMF FST	8127392634	Batch 2	
10	Maya Panorama	maya.izuddin@gmail.com	GPMF FEBI	2Â 895â€‘2693â€‘04	Batch 2	
11	Pathur Rahman	pathurrahman_rahman@yahoo.co.id	Wadek 1 Fushpi	81367520346	Batch 2	
12	Lusiana	lusiana_uin@radenfatah.ac.id	GPMF	82230659221	Batch 2	
13	Eko Oktapiya Hadinata	ekooktapiyahadinata_uin@radenfatah.ac.id	Ketua GPMF Fakultas Psikologi	82111361258	Batch 2	

14	Nico oktario adytyas	nico.oktario_uin@radenfatah.ac.id	Ketua gpmf.	82269649204	Batch 2	
15	Alimron	alimron_uin@radenfatah.ac.id	Sekretaris GPMF/Kaprodi PPG	8127875566	Batch 2	
16	Eti Yusnita	etiyusnita_uin@radenfatah.ac.id	Kaprodi Ilmu Politik FISIP	82178980063	Batch 2	
17	Amalia Hasanah	amaliahasanah_uin@radenfatah.ac.id	Kaprodi PBI	81532776789	Batch 2	
18	Dadang	dadanghanafiah@yahoo.co.id	Kabag TU Fakultas Ekonomi dan Bisnis Islam	81367313292	Batch 2	
19	Almunadi	almunadi_uin@radenfatah.ac.id	Ka. Prodi Ilmu Hadis	81368637781	Batch 2	
1	Fenny Purwani	fennypurwani_uin@radenfatah.ac.id	Ketua Prodi Sistem Informasi	8153804412	Batch 3	**30 Des 2021**
2	saipul Annur	saipul.annur@gmail.com	kaprodi S2. MPI	82183630980	Batch 3	
3	Chandra Zaky Maulana	chandrazakimaulana@radenfatah.ac.id	Ketua Prodi S1 Perbankan Syariah	8127103997	Batch 3	
4	Listya Istiningtyas	listyaistiningtyas_uin@radenfatah.ac.id	Kaprodi Psikologi Islam	85228010516	Batch 3	
5	Ahmad Soleh Sakni	hahmadsolehsakni_uin@radenfatah.ac.id	Kaprodi Tasawuf dan Psikoterapi	81377690525	Batch 3	
6	Leny Marlina	lenymarlina_uin@radenfatah.ac.id	Ka.Prodi PIAUD FITK UIN RF Plg	81273727250	Batch 3	
7	Muhammad Win Afgani	muhammadwinafgani_uin@radenfatah.ac.id	Kaprodi Pendidikan Fisika	89629511120	Batch 3	
8	Nurserihasnah	nurserihasnah78@gmail.com	Ka. Prodi Jurnalistik	81273733616	Batch 3	
9	Mohd Aji Isnaini	mohdajiisnaini_uin@radenfatah.ac.id	Ka Prodi PMI	85273032222	Batch 3	
10	Rinol Sumantri	rinolsumantrimei_uin@radenfatah.ac.id	Kaprodi manajemen zakat dan wakaf	81232344460	Batch 3	
11	Ermis Suryana	ermissuryana_uin@radenfatah.ac.id	Ketua Prodi S2 PAI	81377879526	Batch 3	
12	Ahmad Syukri	ahmadsyukri@radenfatah.ac.id	Ketua Prodi Politik Islam	81273782999	Batch 3	
13	Jamhari	jamharimustafa@gmail.com	Kaprodi AFI	81274743034	Batch 3	

14	Mardeli	mardeli_uin@radenfatah.ac.id	Ka. ProdiPAI	85269890919	Batch 3	
15	Tamudin	m.tamudin_uin@radenfatah.ac.id	Kaprodi Hukum Pidana Islam	8153811546	Batch 3	
16	Indrawati	indrawatiselayar@gmail.com	Kepala Pusat Standar Mutu LPM	81272101395	Batch 3	
17	Imam alhaddy	imam_alhaddy@radenfatah.ac.id	PLT Kasub Kepegawaian	89685829717	Batch 3	
18	Emi Puspita dewi	emipuspitadewi_uin@radenfatah.ac.id	GPMF	82181759703	Batch 3	
19	MUHAMAD FAUZI	mfauzi120674@gmail.com	WD 1	8127358457	Batch 3	
1	Marsi Sulistiawati	marsisulistiawati_uin@radenfatah.ac.id	Kasub Akademik Kemahasiswaan dan Alumni	8127319723	Batch 4	**31 Des 2021**
2	Munjiati	Munjiati_uin@radenfatah.ac.id	Kabag TU	82178820464	Batch 4	
3	Fathiyah Nopriani	fathiyahnopriani_uin@radenfatah.ac.id	GPMF	81373799552	Batch 4	
4	Matbani	matbani.bani@gmail.com	Kabag TU Fak. Adab dan Humaniora	85669349220	Batch 4	
5	Yan Hery Darmansyah	yanpakjo@gmail.com	Ka Lab MIPA FITK UIN Raden Fatah Palembang	8127121625	Batch 4	
6	Muhammad Edy	muh.edy71@gmail.com	APBK APBN Ahli Muda/Sub.koordinator Perencanaan, Akutansi dan Keuangan	82182306189	Batch 4	
7	Mahdi Zanapel,	mahdizanapeluin@radenfatah.ac.id	kepalabagianTUFakultasIlmuSosialdan Ilmu Politik	85380549100	Batch 4	
8	Suharto	suharto_uin@radenfatah.ic.id	Kasubag aka fahum	8127383030	Batch 4	
9	Abdul Raisuddin	abdulrasuddin@gmail.com	Kasubag. Administrasi Akademik dan Kemahasisaaan	82177211949	Batch 4	
10	Jummiana	Jummiana.s3@gmail.com	Kabag	8127390868	Batch 4	
11	Iqbal Firmansyah	iqbalfirmansyah_uin@radenfatah.ac.id	Kasubbag TU Pascasarjana	81288639910	Batch 4	
12	Rian Kartika Sari	riankartikasari_uin@radenfatah.ac.id	Sub Koordinator Tata Usaha TU	82177819393	Batch 4	

13	Dian Hafidh Zulfikar	Dianhafidhzulfikar_uin@radenfatah.ac.id	Kepala laboratorium Komputer Saintek	81333077861	Batch 4	
14	Eli kusrini	elikusrini1972@gmail.com	Kabag TU fakIlmutarbiyahdankeguruan	82177819393	Batch 4	
15	Mila Gustahartati	milayusbahar@gmail.com	Kabag TU	81373639171	Batch 4	
16	Qodariah Barkah	qodariahbarkah_uin@radenfatah.ac.id	Ka Lab FSH	81367195996	Batch 4	
17	Mursilah	Mursilah.adil19@gmail.com	KabagTUFakultassyariahdanhukum	82175710866	Batch 4	
18	Emron.SH	sukauemron@gmail.com	Kasubag Akademik Fak.Psikologi	81373077898	Batch 4	
19	Juwita Anggraini	juwita_uin@radenfatah.ac.id	ka lab	81272483206	Batch 4	
20	Atika	atika_uin@radenfatah.ac.id	Ka.Prodi HES	81532051378	Batch 4	
21	Holijah	holijah_uin@radenfatah.ac.id			Batch 4	

Lampiran (2) Materi

References

This document contains typical activity solutions and additional information referred to during the course.

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Requirements ISO 9001:2015-BSI-ID

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Activity 1: Terms and definitions

Definition	Answer	Term
Person or group of people who directs and controls an organization at the highest level	**I.**	A. Management system
Involvement in, and contribution to, activities to achieve shared objectives	**G.**	B. Quality
Effect of uncertainty	**K.**	C. Organization
Set of interrelated or interacting elements of an organization to establish policies and objectives and processes to achieve those objectives	**A.**	D. Policy
Set of interrelated or interacting activities that use inputs to deliver an intended result	**F.**	E. Objective
Result of a process	**J.**	F. Process
Degree to which a set of inherent characteristics of an object fulfils requirements	**B.**	G. Engagement
Output of an organization with at least one activity necessarily performed between the organization and the customer	**O.**	H. Requirement
Person or group of people that has its own functions with responsibilities, authorities, and relationships to achieve its objectives	**C.**	I. Top management
Output of an organization that can be produced without any transaction taking place between the organization and the customer	**N.**	J. Output
Information required to be controlled and maintained by an organization and medium on which it is contained	**M.**	K. Risk
Intentions and direction of an organization as formally expressed by its top management	**D.**	L. Interested party
Result to be achieved	**E.**	M. Documented information
Person or organization that can affect, be affected by, or perceive itself to be affected by a decision or activity	**L.**	N. Product
Need or expectation that is stated, generally implied or obligatory	**H.**	O. Service

The terms 'product' and 'service' includes all output categories (hardware, services, software and processed materials)

Requirements ISO 9001:2015-BSI-ID

Additional definitions

- **Effectiveness** – extent to which planned activities are realized and planned results achieved
- **Competence** – ability to apply knowledge and skills to achieve intended results
- **Outsource** – make an arrangement where an external organization performs part of an organization's functions or process
- **Monitoring** – determining the status of a system, a process, a product, a service or an activity
- **Measurement** – process to determine a value
- **Corrective action** – action to eliminate the cause of nonconformity and to prevent recurrence
- **Continual improvement** – recurring activity to enhance performance
- **Improvement** – activity to enhance performance
- **Correction** – action to eliminate a detected nonconformity
- **Statutory requirement** – obligatory requirement specified by a legislative body
- **Regulatory requirement** – obligatory requirement specified by an authority mandated by a legislative body

Requirements ISO 9001:2015 BSI-ID

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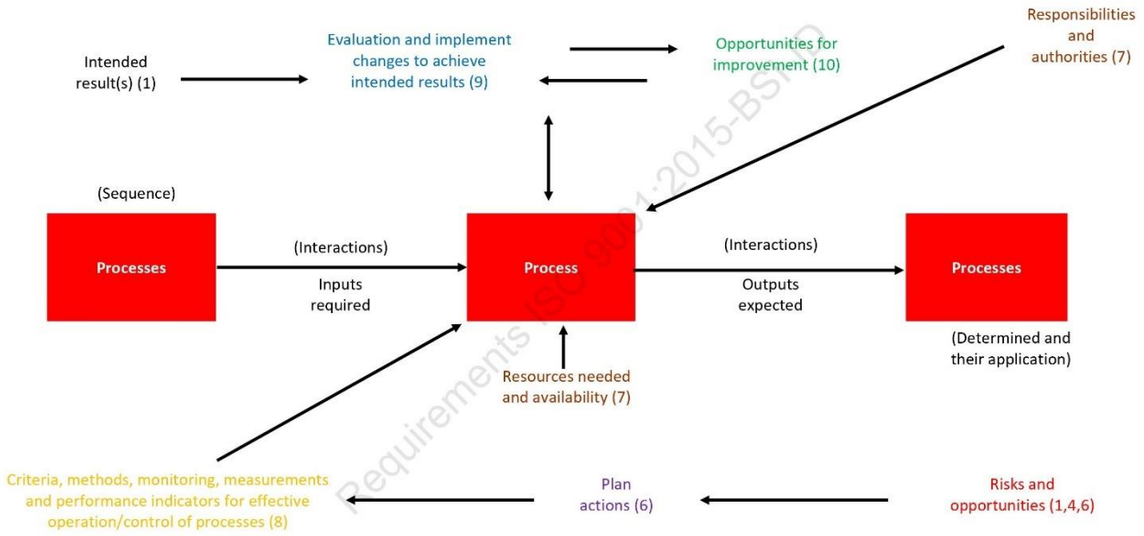
References

Activity 2: **Requirements considered essential to the adoption of the process approach**



Requirements ISO 9001:2015-BSI ID

Documented information requirements	=	Maintain documented information - support operation (7)	+	Retain documented information – confidence (8)

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Activity 3: **Quality Management Principles**

Quality Management Principle	Benefit	How to apply
Customer focus (The primary focus of quality management is to meet customer requirements and to strive to exceed customer expectations)	Attracts and retains the confidence of interested parties. Sustained success and creates more value	Understand current and future needs. Strive to exceed expectations
Leadership (Leaders at all levels establish unity of purpose and direction and create conditions in which people are engaged in achieving the organization's quality objectives)	Enables an organization to create unity of purpose and align its strategies, policies, processes and resources to achieve its objectives	Create conditions in which people are engaged by creating unity of purpose, direction and engagement
Engagement of people (Competent, empowered and engaged people at all levels throughout the organization are essential to enhance the organization's capability to create and deliver value)	Increased attention to shared values and culture throughout the organization	Facilitate open discussion and sharing of knowledge and experience
Process approach (Consistent and predictable results are achieved more effectively and efficiently when activities are understood and managed as interrelated processes that function as a coherent system)	Organization can optimize its performance when activities are understood and managed as a coherent system	Understand how results are produced by the QMS, including all its resources, controls and interactions
Improvement (Successful organizations have an ongoing focus on improvement)	Enhanced drive for innovation	React to changes in its internal and external conditions, and create new opportunities
Evidence-based decision making (Decisions based on the analysis and evaluation of data and information are more likely to produce desired results)	Increased ability to review, challenge and change opinions and decisions	Understand cause and effect relationships, potential unintended consequences including facts, and data analysis
Relationship management (For sustained success, organizations manage their relationships with interested parties, such as providers)	Sustained success through interested party influence	Manage associations with interested parties to optimize impact on performance

Requirements ISO 9001:2015-BSI (1)

Activity 4: Determining risks and opportunities

Organization: Business telecommunications installer of IT cabling and IT cabinets

#	Issues (internal)	Expected result	Uncertainty	Risk (-ive) H/M/L (Effect)	Opportunities
1	Structure of the organization	Workforce are happy to work and work better in within a network organizational structure	Workforce may feel that the network type of organizational structure is overcomplicated for their needs and slows processers down	**L**	Opportunity to get feedback from an anonymous survey to understand whether the structure of the organization is conducive to the organizations type of business or would prefer to work within a conventional hierarchical or flat organizational structure
2	Stability of workforce	The workforce believe that they have job security there is procedural fairness in operation and good communication	As structured data cabling is generally better paid than other communication industry sector type jobs, operatives may be exposed to poaching tactics by competitors	**M**	Opportunity to benchmark both competitors and customers salaries but also privileges and incentives and make sure that the organization is still competitive

Requirements ISO 9001:2015-BSI-ID

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s ISO 9001:2015

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#	Issues (internal)	Expected result	Uncertainty	Risk (-ive) H/M/L (Effect)	Opportunities
3	External providers competence and availability	External providers are competent to fulfill the contractual work that they have been allocated and credentials are readily available to prove it	Initially selected contractors based on competency get replaced by contractor management for less competent staff mid-way through a contract	**M**	Opportunity for regular site check and contract meetings to check allocated staff that have been agreed to be committed to the contracted work for the duration of the contract work
4	Working hours	Workforce are happy with the working hours and get a fair share of overtime allocation	Workforce are happy with the working hours arrangements and would prefer a pay rise to reduce overtime commitments	**M**	Opportunity to benchmark both competitors and customers salaries and daily rates of pay for this industry sector
5	Roles within the organization	Workforce are content with their roles within the organization and clear on promotion opportunities	Workforce feel that their roles are static and would expect to get passed over for promotion	**L**	Opportunity to review over the last 5 years, how many members of the organization have been promoted versus new position vacancies that went to new external candidates

Requirements for ISO 9001:2015-BSI-IN

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#	Issues (internal)	Expected result	Uncertainty	Risk (-ive) H/M/L (Effect)	Opportunities
6	Availability and quality of candidates to fulfil vacancies	Workforce are actively encouraged to apply for new vacancies as well as there is wealth of potential talent in the job's marketplace	Workforce may want to stay static and not be prepared for new challenges and there may not be the available external talent as was initially assumed	**L**	Opportunity to review with recruitment consultants to see the availability of external talent and the current trend within this industry sector
7	Workforce morale	Workforce feel valued and continually praised for their contribution	Workforce feel undervalued and are only criticized for mistakes	**M**	Opportunity to review via an anonymous survey what the workforce feel about how they are perceived by the organization
8	Workforce training levels	Workforce training and competency is regularly reviewed by line management and retraining is conducted at regular intervals	Workforce training is not as regularly reviewed as planned and updated and refresher training is not completed as scheduled	**H**	Opportunity to make this the first item on the workforce regular PDR's for both annual and mid-year reviews
9	Internal politics	There is little internal politics and workforce are cooperative and customer focused	There are high levels of nepotism within the organization who drive and manipulate the workforce unfairly or influence form Trade Union members	**H**	Opportunity to all workforce and Trade Union alliances and actively hold meetings with the organization to ensure that internal politics is not an issue and to reduce inequality if it exists via consultation and debate

Requirements of ISO 9001:2015-BSI-ID

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#	Issues (external)	Expected result	Uncertainty	Risk (-ive) H/M/L (Effect)	Opportunities
1	Contractual arrangements within the sector	There are fair arrangements in place to safeguard against bribery and corruption by competitors	Unfair competition due to links to bribery and corruption by competitors	**H**	Opportunity to seek fair and transparent monitoring from the trade association for the structured data cabling industry sectors
2	Regulation within the industry generally	This industry sector is regulated and fair to all organizations	The industry is not regulated as closely as it portrays	**M**	Opportunity review NGO web sites and annual reports by the relevant trade associations
3	Health, safety and environmental requirements	The organization conforms and complies with all health, safety and environmental requirements	The organization may not conform with all health, safety and environmental requirements al of the time	**M**	Opportunity for regular site checks and contract meetings to check continual with all health, safety and environmental requirements

Requirements of ISO 9001:2015-BSI-UK

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#	Issues (external)	Expected result	Uncertainty	Risk (-ive) H/M/L (Effect)	Opportunities
4	Competitive environment – overall low cost of entry into the market	The overall low cost of entry into the market is realistic and does not affect the winning of contracts at the proposal and tender stages. A competitive environment is a system where different businesses compete with each other by using various marketing channels, promotional strategies, pricing methods	Unfair competitive tactics with inflated medium to higher cost of entry into the market is absorbed in the contract giving a less detectable offset and unfair using various marketing channels, promotional strategies, pricing methods that are hidden	**H**	Opportunity to question the clients on why competitors were successful in winning contracts over the organization and transparency on the price of proposal/ tender phases of perspective contracts
5	Overall competition within the recruitment sector	Engaged recruitment agencies supply the best available candidates for all industry sector organizations fairly	Competitors paying retainer fees for holding back the best candidates	**M**	Opportunity to review over the last 5 years. New position vacancies that went to new external candidates from certain agencies also should pitch one recruitment agency against another to see the full range of available talent at the time of interviewing

Requirements ISO 9001:2015-BSI-ID

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#	Issues (external)	Expected result	Uncertainty	Risk (-ive) H/M/L (Effect)	Opportunities
6	Technology advances	The organization is up to date with the latest technology	Falls behind as technology develops improves updates	**L**	Opportunity to review at trade forums to make sure that the organization is forewarned of technology advance before they are introduced into this industry sector and plan adopt them
7	Legislation, e.g. employment of non-nationals	Employment of non-nationals is compliant with all relevant legislation consistent with the region	Employment of non-nationals is not compliant with all relevant legislation consistent with the region	**M**	Opportunity to review the employment of non-nationals and retain copies of or update the credentials held by HR i.e. passport details, visa extensions, work permit renewals etc.
8	Overall economic climate in the country	The overall economic climate in the country is good and buoyant	The overall economic climate in the country is weak or unstable	**L**	Opportunity to monitor this issue closely especially around government elections periods
9	Client design changes during installation	Clients stick to the contracts and agreed designs	Clients increase organization project costs that should have been written into the contract	**M**	Opportunity to hold regular site meetings or negotiations at the installation phase of projects

Requirements ISO 9001:2015-BSI-UK

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#	IP requirements	Expected result	Uncertainty	Risk (-ive) H/M/L (Effect)	Opportunities
1	Executive board	Good financial performance, legal compliance/avoidance of fines	There may be delays in communicating accurately if there are problems with legislative compliance, with board meetings being held annually and management review meetings being held bi-annually	**M**	Opportunity to explore increasing board meetings and management review meeting to quarterly and monthly respectively
2	Local residents	No complaints re: noise, parking, health and safety, pollution, waste, employment	Local residents may not complain to the organization but directly to enforcement authorities	**M**	Opportunity review hold local residents meeting in the neighborhood

Requirements of ISO 9001:2015-BSI-ID

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#	IP requirements	Expected result	Uncertainty	Risk (-ive) H/M/L (Effect)	Opportunities
3	Law enforcers/ Regulators	Identification of applicable statutory and regulatory requirements for the products and services provided, understanding of the requirements, application within the QMS and update/maintenance of them	May not always be compliant with applicable statutory and regulatory requirements for the products and services provided	**M**	Opportunity for regular reviews of all applicable statutory and regulatory requirements for the products and services provided and update training and awareness for all workforce
4	Bank/finance	Good financial performance	Reduced profit margins due to customers changing designs at the installation phases of a project	**M**	Opportunity for regular contract review meetings and analysis of past and current financial performance
5	Employees	Professional development, prompt payment, health and safety, work/life balance, employment security	Due to excessive workload and contract commitments the work/life balance is not as good as it should be	**H**	Opportunity to review new contract proposals and tenders to ensure that the work/life balance is accommodated in project deadlines

Requirements of ISO 9001:2015-BSI-ID

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#	IP requirements	Expected result	Uncertainty	Risk (-ive) H/M/L (Effect)	Opportunities
6	Customers	Value for money, high quality, expectations for design innovation, on time, low cost, quick response, installation expertise, health and safety/EMS	Can lose the voice of the customer once the projects commence	**L**	Opportunity to meet regularly and improve communication with the customer so they become a member of the project team, and ultimately play an active role in their own projects
7	Insurers	No claims/prompt payment/risk management	May not always be up to date with risk assessments	**M**	Opportunity for regular reviews of all risk assessments and hold regular meetings with insurers to ensure ongoing risk management
8	External providers	Prompt payment, health and safety, work relationship	Delays in payment due to long contract stipulations, such as 3 months from invoicing and external provider workforce may tend to want to manage themselves, rather than follow the agreed organizational rules as written into the contracts	**L**	Opportunity for regular reviews of all external provider activities and engagement with respect to health and safety, law and relevant work relationships by holding regular meetings with external providers

Requirements of ISO 9001:2015-BSI-IP

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#	IP requirements	Expected result	Uncertainty	Risk (-ive) H/M/L (Effect)	Opportunities
9	Trade Unions	Compliance (employment law)	May not always be compliant with applicable employment law	**M**	Opportunity for regular reviews of all applicable employment law and hold regular meetings with Trade Union representatives to ensure ongoing compliance

*Risk (Effect) could be purely a description rather than a H, M, L.
If H, M, L is used then a description as to what constitutes this would be necessary.
A simple combination of likelihood and consequence is equally valid, to derive risk.
Your tutor will review any opportunities (not deriving from a negative effect) that you may have identified, and its associated risk.

Requirements ISO 9001:2015-BSI-IP

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Activity 5: Organizational knowledge (processes)

7.1.6 Requirements	**Organization:** Large 24-hour food retailer **Process location:** 9 food checkout counters **Process:** 'Food checkout'
1. What knowledge is necessary here?	Security protocols for handling/retaining customer money in counter cash box, operation of bar code reader, operation of moving food belt, suspect theft protocols, getting help, keying in discounts and food codes, customer food packing, abuse/violence protocols, credit/debit card payments, cash back.
2. How is this knowledge maintained within the organization?	All protocols and activities above are maintained in documented information by the Quality Manager with Human Resource (HR) assistance.
3. How is it made available?	Through the organization's intranet portal, and available to all persons (to the extent necessary) working for it. Also contained in hard copy format at each checkout counter (version and distribution controlled). Also made available through the shift managers.
4. Are there any changing needs/trends?	Yes, promotion codes sold by other retailers that add points to a customer's rewards card (incentives schemes).
5. Is any additional knowledge required for (4.)? How is this to be acquired/accessed?	Yes, how to scan these codes in to add points to their reward card and give a rewards discount on purchases made. IT Systems workforce are to train and write instructions to be included in the documented information above. See 'Objective 156'.
6. Required updates?	Frequent, as promotion codes change monthly. Suggest a monthly check on changes/knowledge needed.

Requirements ISO 9001:2015

(The balance between knowledge held by competent people and knowledge made available by other means is at the discretion of the organization, provided conformity is still achieved)

Activity 6: Operation

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#	ISO 9001 Clause	STATEMENT	True/ False
1	8.4.1	The Standard is concerned with externally provided products and services, but not processes.	F
2	8.4.1	Appropriate documented information of the results of re-evaluations of external providers is required.	T
3	8.4.1	Criteria for external providers monitoring of performance, based on their ability to provide processes in accordance with requirements, is required.	T
4	8.4.1	Specified requirements (for externally provided products and services) must be applied when a process is provided by an external provider, but is not required if only part of a process is provided.	F
5	8.4.2	When determining type and extent of control (for the external provision) consideration of the external providers own controls (effectiveness) is required.	T
6	8.4.2	Externally provided processes do not need to be included within the organizations QMS Scope.	F
7	8.4.2	The organization can choose defining either: Controls applied to the external provider, or controls applied to the resulting output.	F
8	8.4.2	Verification, or other activity, needs to be established to ensure the external provider's processes meet requirements.	T
9	8.4.3	The Standard does not indicate what information might need to be communicated to external providers.	F
10	8.4.3	Applicable requirements relating to external providers competence of personnel needs to be communicated.	T
11	8.4.3	Applicable requirements relating to external providers interactions with the organization need not be communicated.	F
12	8.4.3	Applicable requirements relating to verification activities at the organization's premises, and external provider's premises, needs to be communicated.	F
13	8.5.1	Controlled conditions for production and service provision will also include post-delivery activities.	T

Requirements of ISO 9001:2015 - BSI-PUB

#	ISO 9001 Clause	STATEMENT	True/ False
14	8.5.1	Controlled conditions does not include the use of suitable environment (as this is an environmental management system concern i.e. ISO 14001).	F
15	8.5.1	Controlled conditions include, as applicable: Actions to prevent human error	T
16	8.5.1	Required qualification of persons is not a controlled condition; as the Standard is concerned with training.	F
17	8.5.2	Suitable means to identify outputs is always required.	F
18	8.5.2	Identification of the status of outputs (with respect to monitoring/measurement requirements) is optional.	F
19	8.5.2	The unique identification of outputs needs controlling, where traceability is a requirement.	T
20	8.5.3	Identification, verification, protection and safeguarding of external provider's property is required, when provided for use into its products and services.	T
21	8.5.3	If customer property is damaged then this should be subject to internal training. There is no actual requirement to inform the customer.	F
22	8.5.4	Preservation of outputs would not include contamination control.	F
23	8.5.5	Consideration of customer feedback is necessary when determining the extent of post-delivery activities.	T
24	8.5.5	Recycling would not be an included action, when considering post-delivery activities (as this is an environmental management system concern i.e. ISO 14001).	F
25	8.5.6	All changes need to be reviewed and controlled, to the same extent.	F
26	8.6	Traceability of the person(s) authorizing release of products and services (for delivery to the customer) is required, in the form of documented information.	T
27	8.7	Outputs that do not conform to requirements must be identified to prevent unintended use.	T

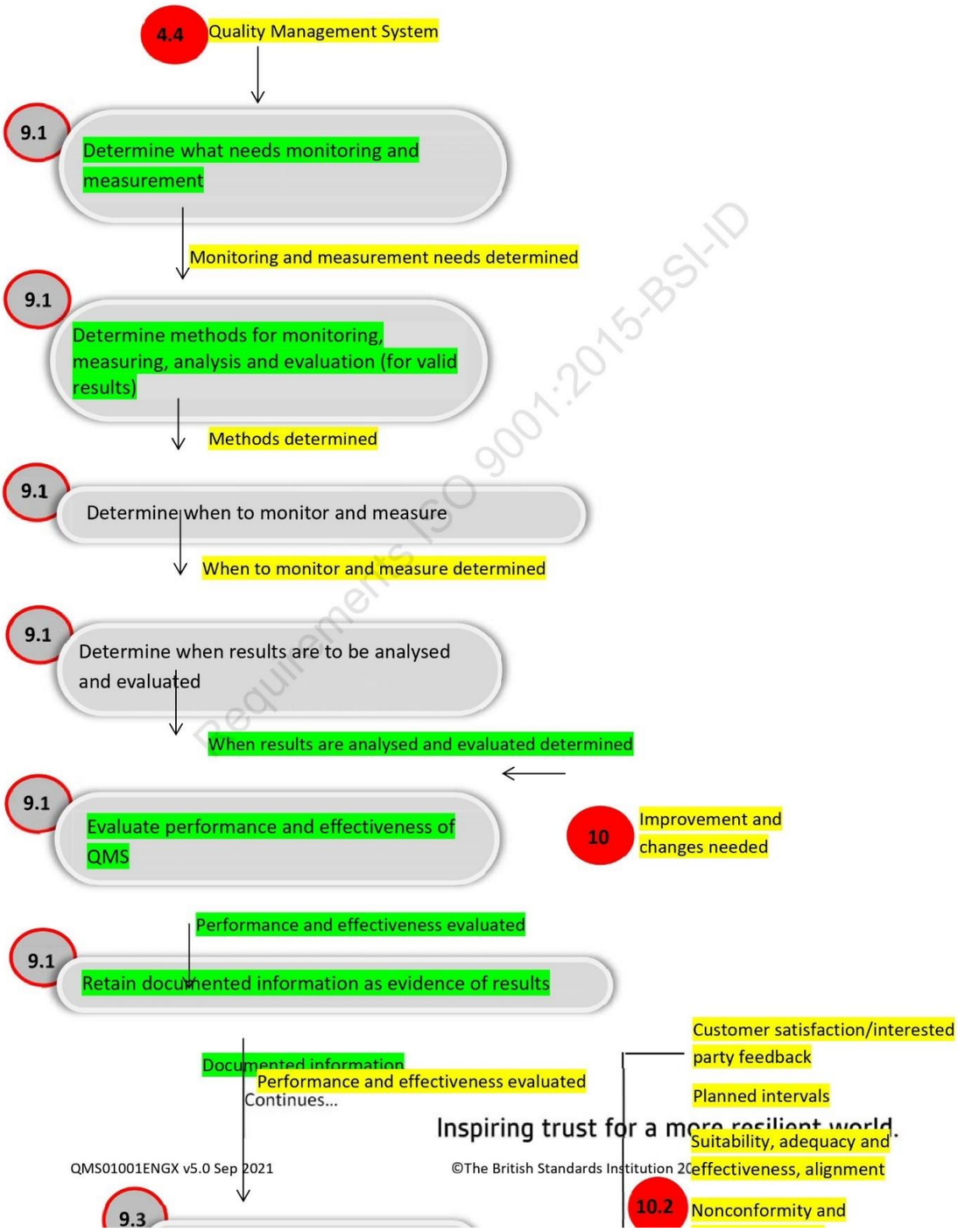
Requirements ISO 9001:2015-BSI-ID

#	ISO 9001 Clause	STATEMENT	True/ False
28	8.7	Preventive action is always required based on the nature of the nonconformity and its effects.	F
29	8.7	There are multiple ways of dealing with nonconforming outputs.	T
30	8.7	Only documented information on the actions taken, on nonconforming outputs, is required.	F

(As the statements above cover each clause requirements, no further notes/slides are needed.)

Requirements ISO 9001:2015-BSI-ID

Activity 7: **Performance evaluation**



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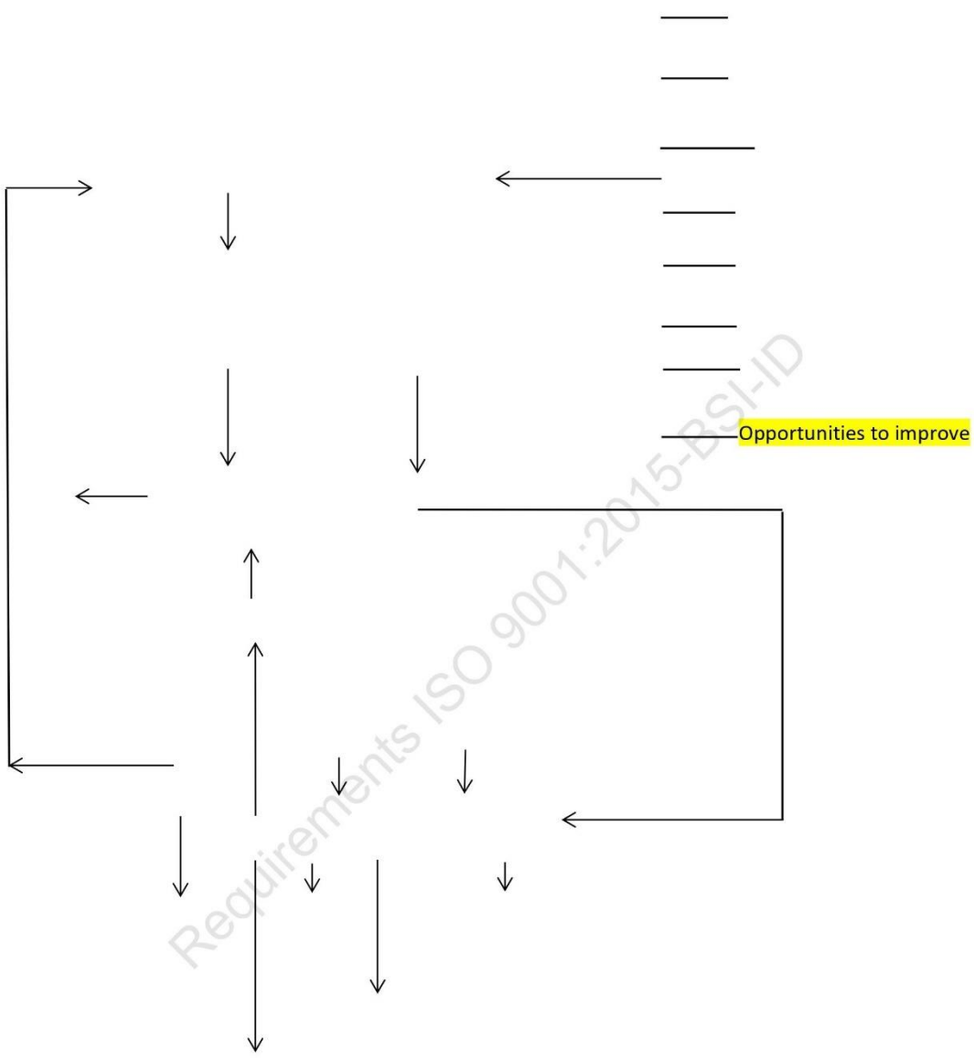

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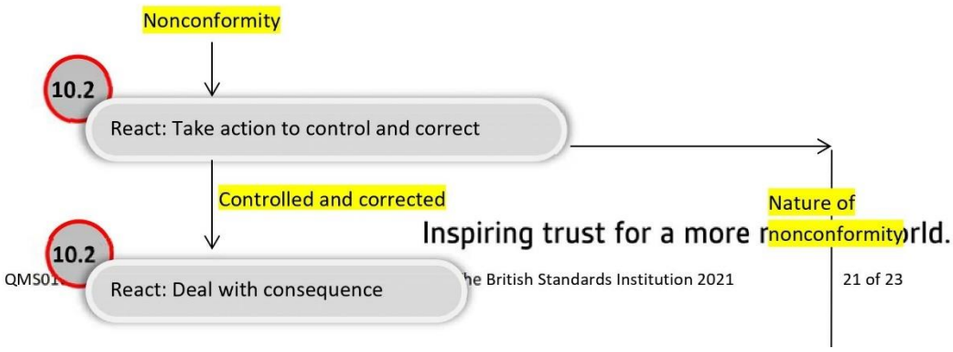
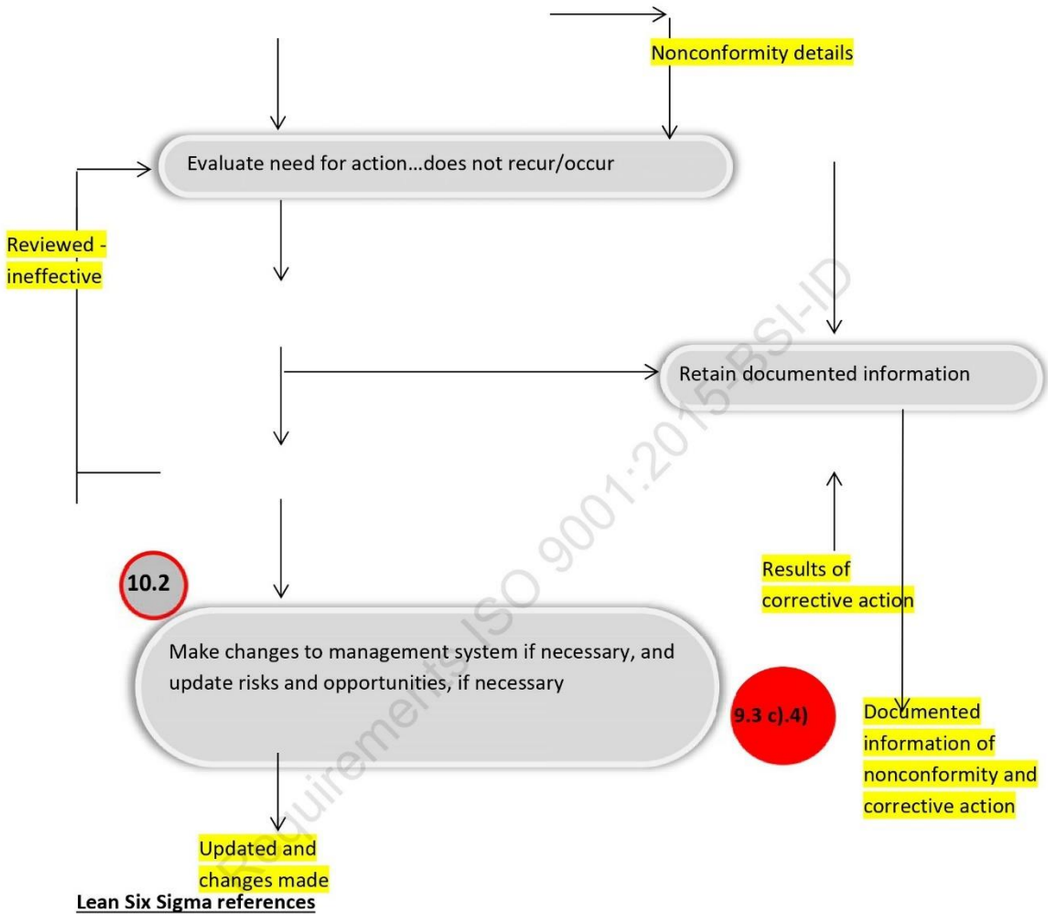
Activity 8: **Nonconformity and corrective action**





Requirements ISO 9001:2015 BSI-ID

Lean Six Sigma references

1. Belt Structure
In some organizations, when using the Lean Six Sigma approach, a leadership and role structure is introduced based on the martial arts. For example, a Green Belt may be a part-time leader of improvement projects whose primary role is functional, whereas a Black Belt may be a full-time specialist in improvement.

2. DMAIC Process
The DMAIC process, used in Lean Six Sigma as a project and improvement methodology, is analogous to the Plan, Do, Check, Act process popularized by Deming which many people involved in quality management and QMS systems will already be familiar with. DMAIC stands for Define, Measure, Analyse, Improve, Control.

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3. The Principles of Lean

- Define value from the customer's perspective
- Identify the value stream (process activities) needed to take a product or service from customer request to completed delivery
- Ensure product or service based activity flows through the value stream without delays
- Use pull systems, so that the product or a service is provided only when the customer wants it
- Strive continuously to eliminate all forms of waste (non-value adding activity) from the processes involved

4. The Principles of Six Sigma

- Gather information to understand the customer's voice
- Convert this understanding to targets and specifications for process performance
- Use data to analyse current state process variability, and relate this to the customer driven targets and specifications that are now established
- Understand the factors that are the root causes of process variability and work to eliminate or reduce their impact for an improved state process
- Establish long term control procedures to maintain the gains

5. Lean Six Sigma Standards

For those interested in the standards associated with Lean Six Sigma there are a number available, which can help guide the practitioners' organization:

- ISO13053 Part 1 Quantitative methods in process improvement – Six Sigma – DMAIC Methodology
- ISO13053 Part 2 Quantitative methods in process improvement – Six Sigma – Tools and Techniques
- ISO17258 Statistical methods – Six Sigma – Basic criteria underlying benchmarking for Six Sigma in organisations
- ISO18404 Quantitative methods in process improvement – Six Sigma – Competencies for key personnel and their organizations in relation to Six Sigma and Lean implementation

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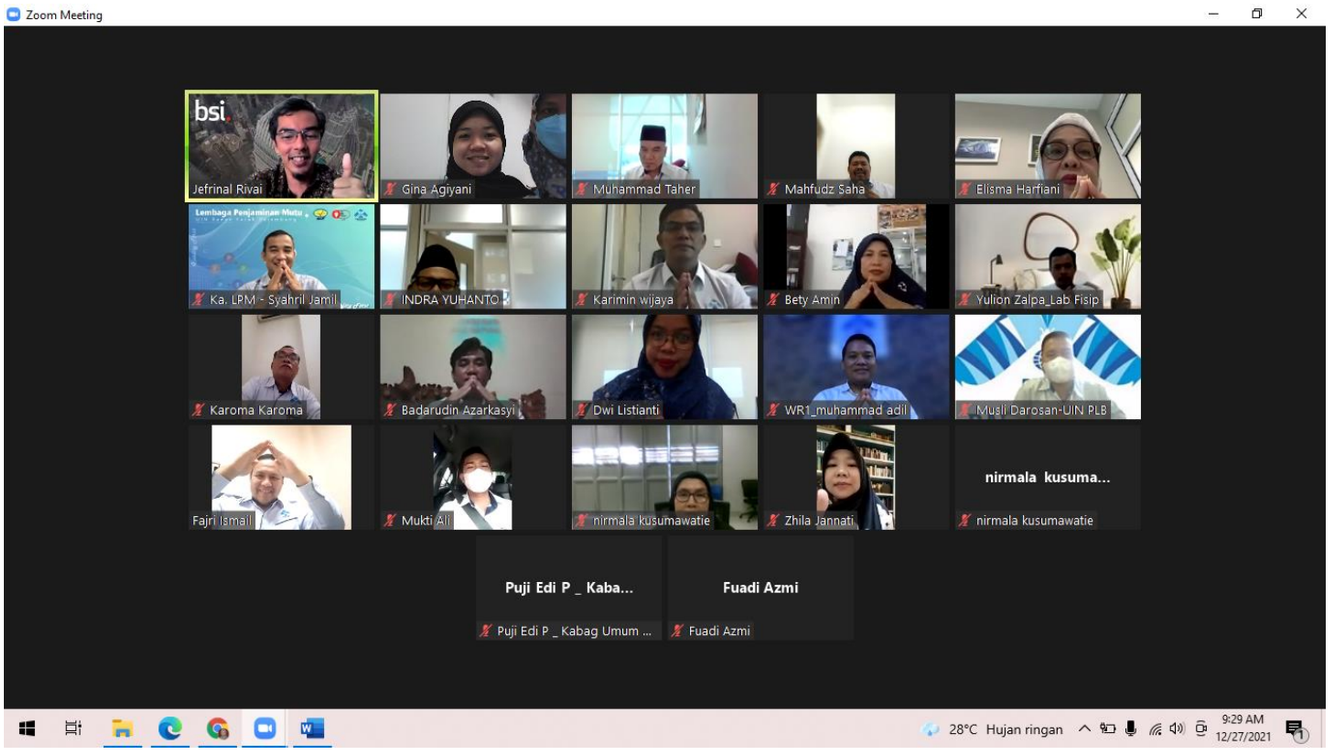
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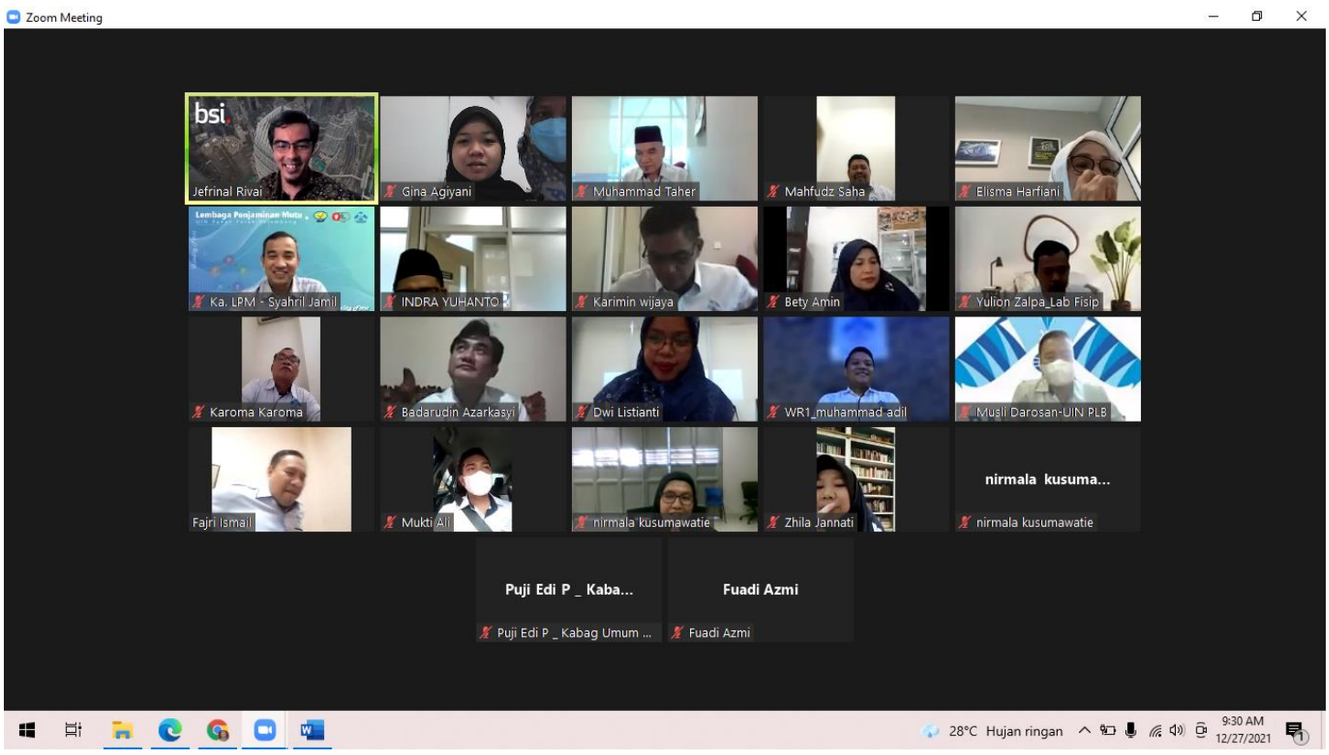
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Bety Amin
Yulion Zalpa_Lab Fisip
Karoma Karoma
Badarudin Azarkasyi
Dwi Listianti
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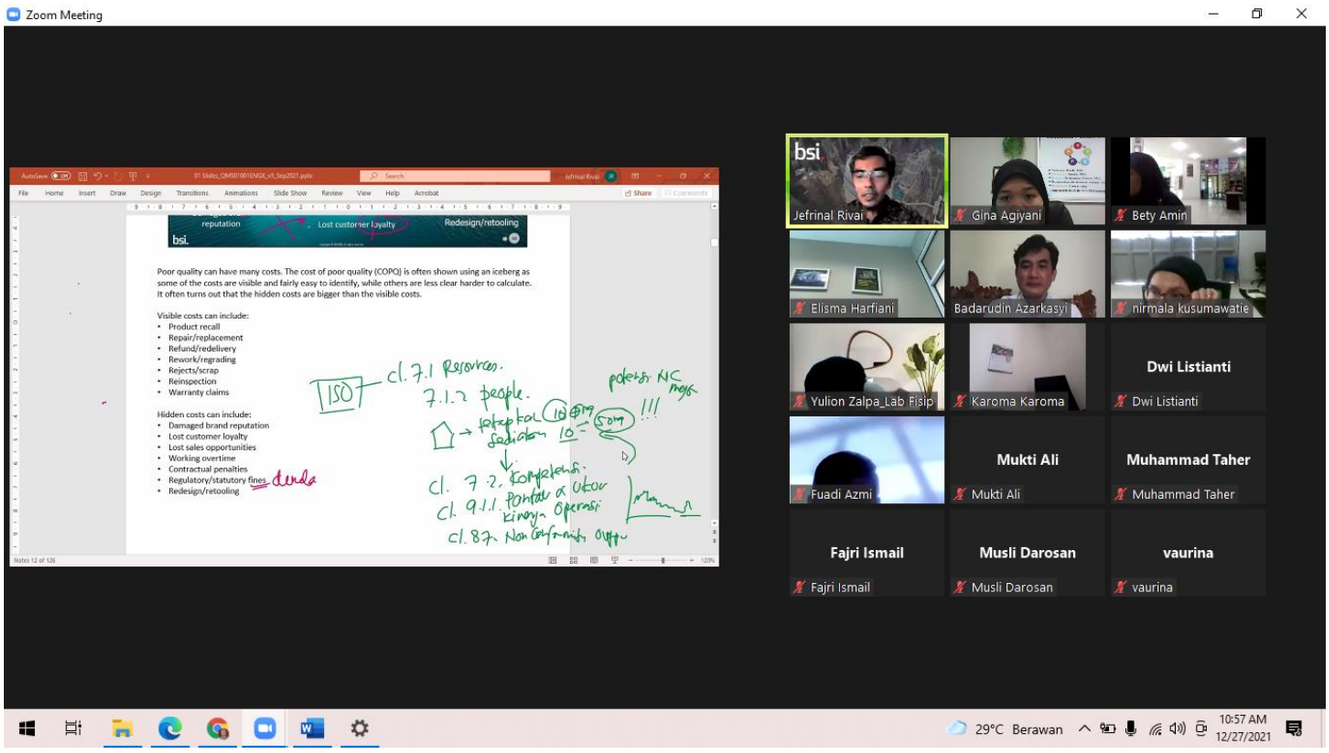
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reputation
Lost customer loyalty
Redesign/retooling
Poor quality can have many costs. The cost of poor quality (COPQ) is often shown using an iceberg as some of the costs are visible and fairly easy to identify, while others are less clear harder to calculate. It often turns out that the hidden costs are bigger than the visible costs.
Visible costs can include:
Product recall
Repair/replacement
Refund/redelivery
Rework/regrading
Rejects/scrap
Reinspection
Warranty claims
Hidden costs can include:
Damaged brand reputation
Lost customer loyalty
Lost sales opportunities
Working overtime
Contractual penalties
Regulatory/statutory fines
Redesign/retooling
Jefrinal Rivai
Gina Agiyani
Bety Amin
Elisma Harfiani
Badarudin Azarkasyi
nirmala kusumawatie
Yulion Zalpa_Lab Fisip
Karoma Karoma
Dwi Listianti
Fuadi Azmi
Mukti Ali
Muhammad Taher
Fajri Ismail
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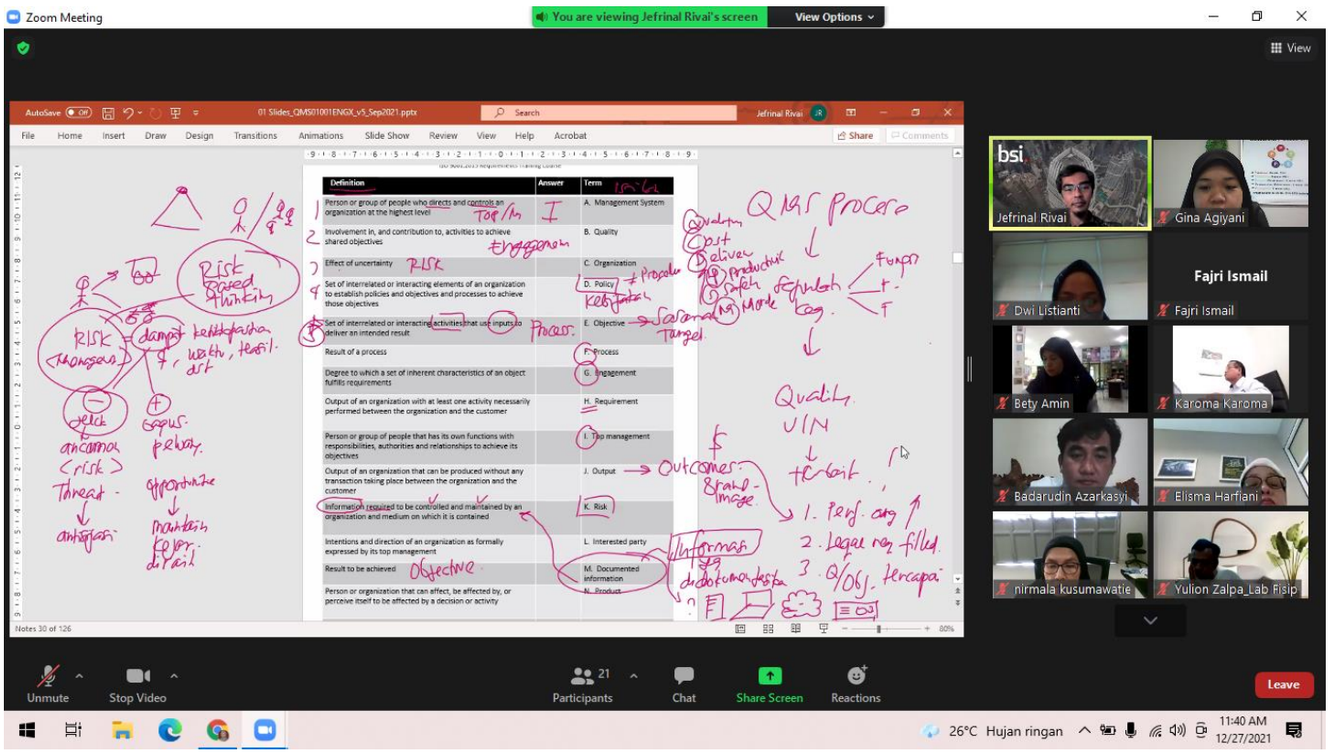
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Definition
Answer
Term
Person or group of people who directs and controls an organization at the highest level
Involvement in, and contribution to, activities to achieve shared objectives
Effect of uncertainty
Set of interrelated or interacting elements of an organization to establish policies and objectives and processes to achieve those objectives
Set of interrelated or interacting activities that use inputs to deliver an intended result
Result of a process
Degree to which a set of inherent characteristics of an object fulfils requirements
Output of an organization with at least one activity necessarily performed between the organization and the customer
Person or group of people that has its own functions with responsibilities, authorities and relationships to achieve its objectives
Output of an organization that can be produced without any transaction taking place between the organization and the customer
Information required to be controlled and maintained by an organization and medium on which it is contained
Intentions and direction of an organization as formally expressed by its top management
Result to be achieved
Person or organization that can affect, be affected by, or perceive itself to be affected by a decision or activity
A. Management System
B. Quality
C. Organization
D. Policy
E. Objective
F. Process
G. Engagement
H. Requirement
I. Top management
J. Output
K. Risk
L. Interested party
M. Documented information
N. Product
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Dwi Listianti
Fajri Ismail
Bety Amin
Karoma Karoma
Badarudin Azarkasyi
Elisma Harfiani
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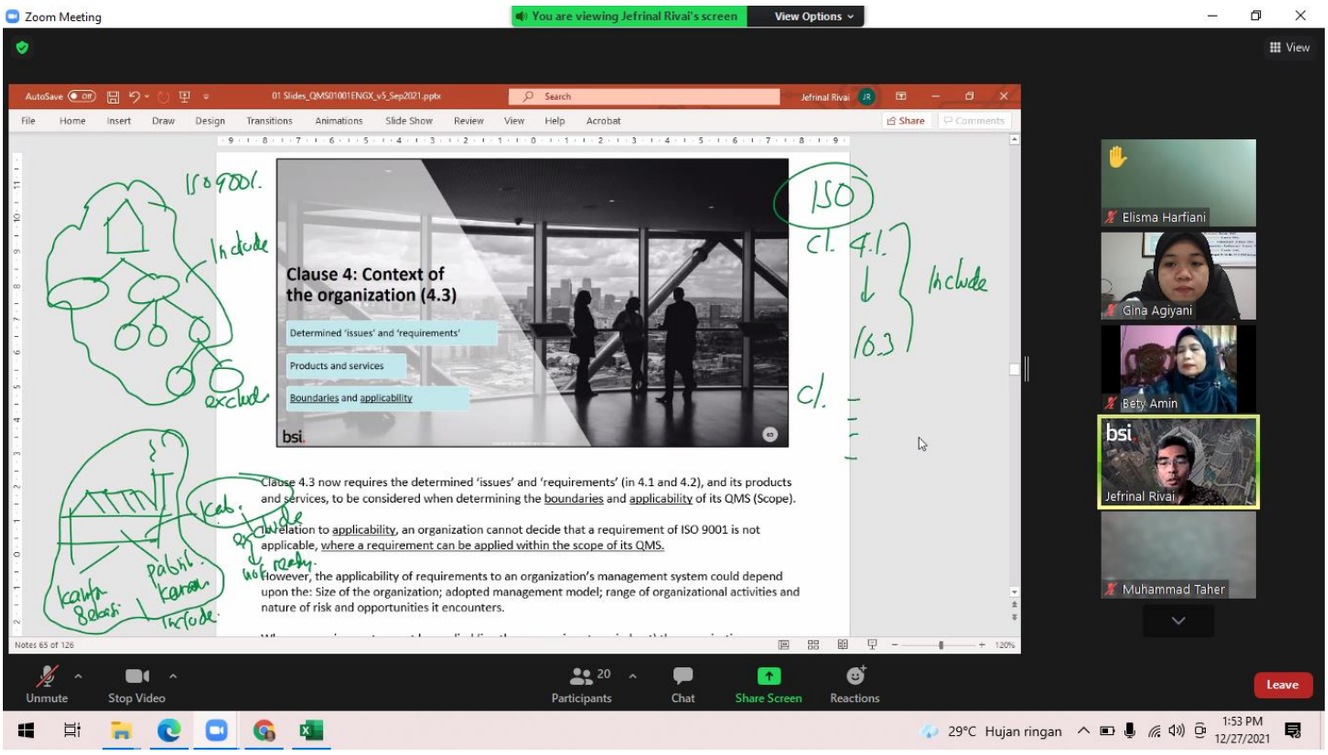
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01 Slides_QMS01001ENGX_v5_Sep2021.pptx
Clause 4: Context of the organization (4.3)
Determined 'issues' and 'requirements'
Products and services
Boundaries and applicability
Clause 4.3 now requires the determined 'issues' and 'requirements' (in 4.1 and 4.2), and its products and services, to be considered when determining the boundaries and applicability of its QMS (Scope).
In relation to applicability, an organization cannot decide that a requirement of ISO 9001 is not applicable, where a requirement can be applied within the scope of its QMS.
However, the applicability of requirements to an organization's management system could depend upon the: Size of the organization; adopted management model; range of organizational activities and nature of risk and opportunities it encounters.
Elisma Harfiani
Gina Agiyani
Bety Amin
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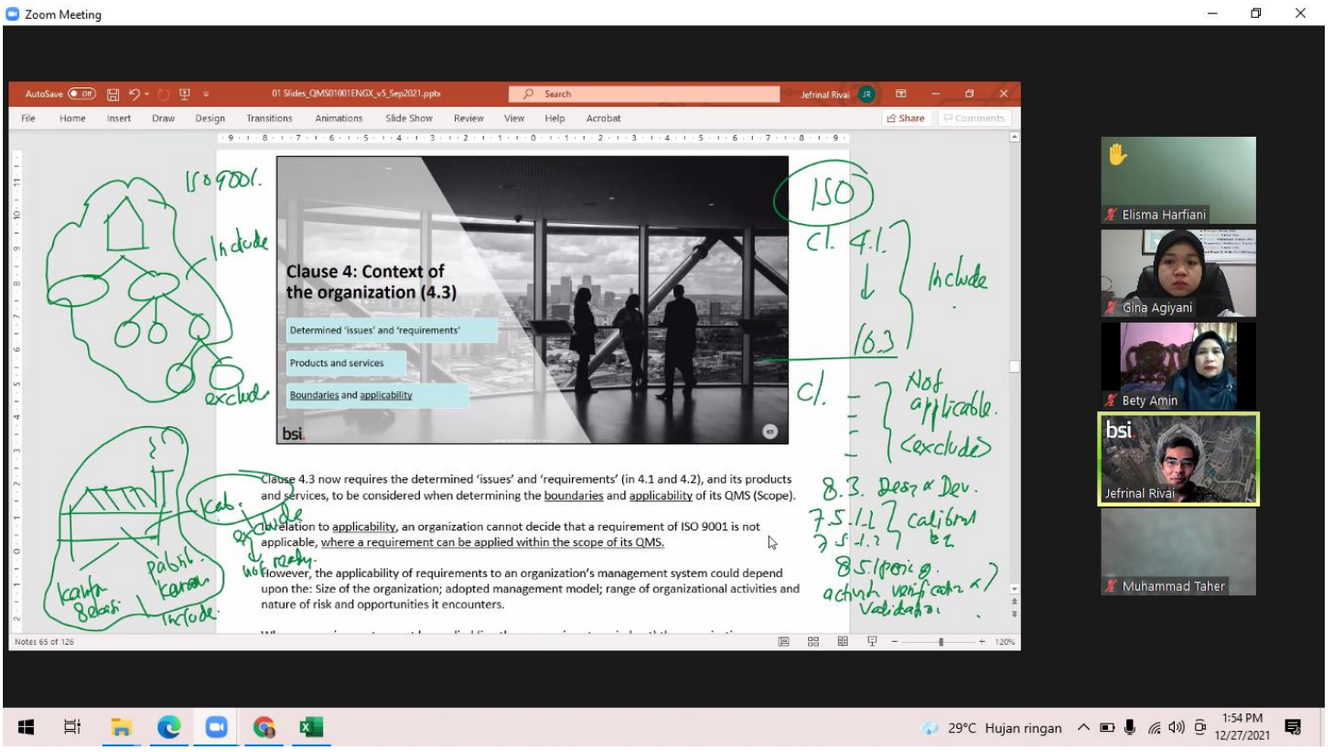
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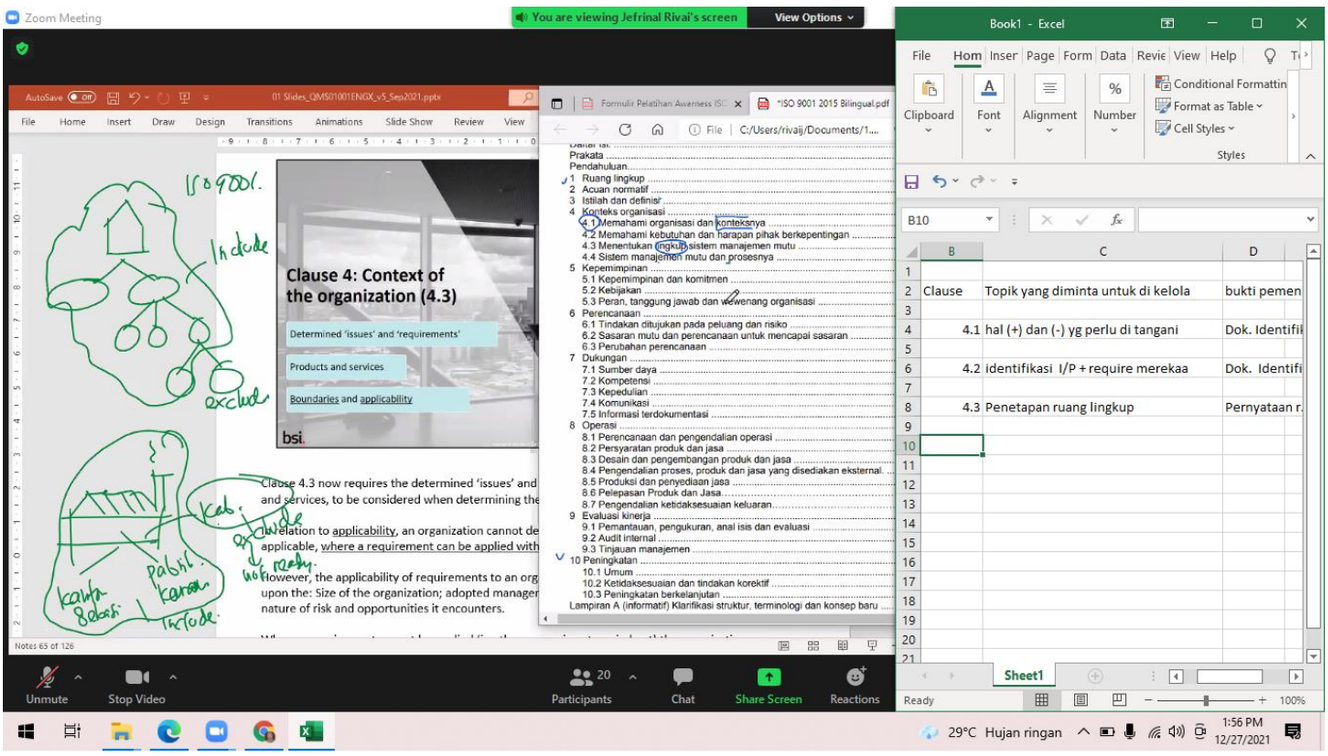
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Book1 - Excel
Clause
Topik yang diminta untuk di kelola
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4.1 hal (+) dan (-) yg perlu di tangani
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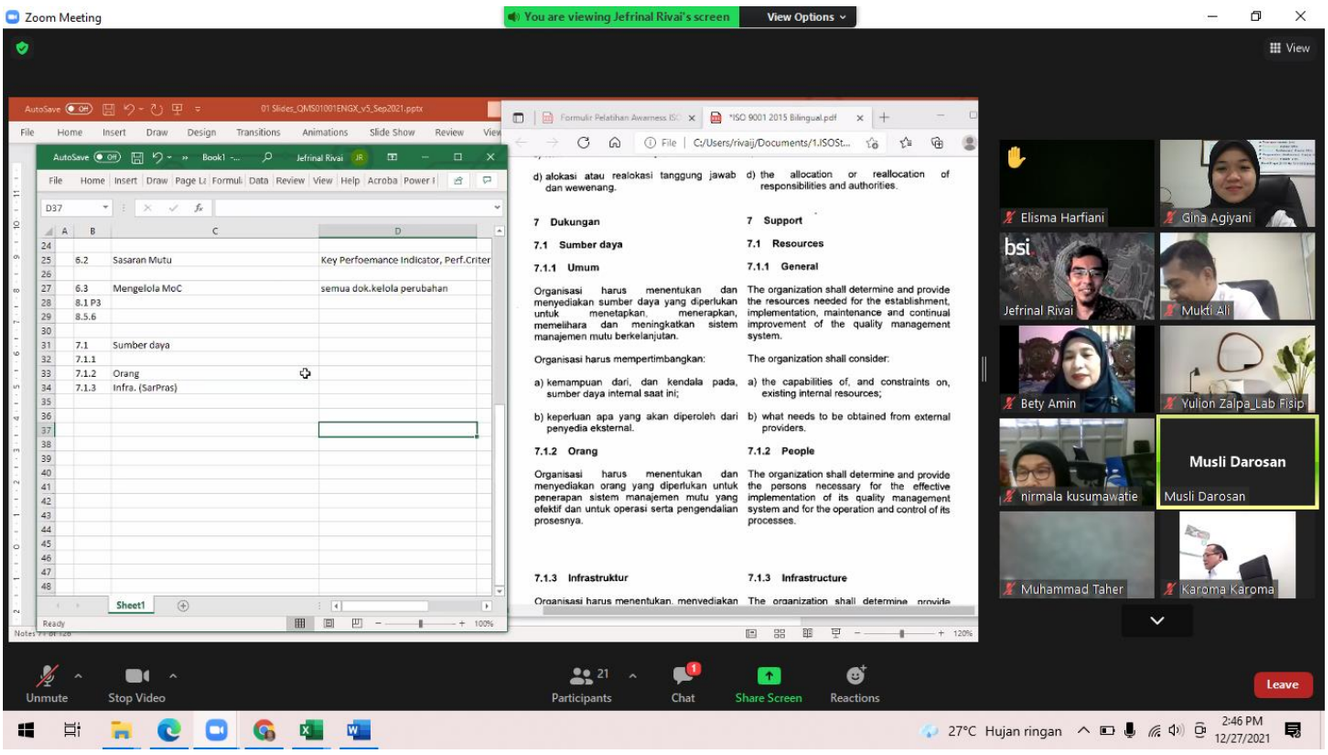
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7 Dukungan
7.1 Sumber daya
7.1.1 Umum
7.1 Resources
7.1.1 General
7.1.2 Orang
7.1.2 People
7.1.3 Infrastruktur
7.1.3 Infrastructure
Elisma Harfiani
Gina Agiyani
Jefrinal Rivai
Mukti Ali
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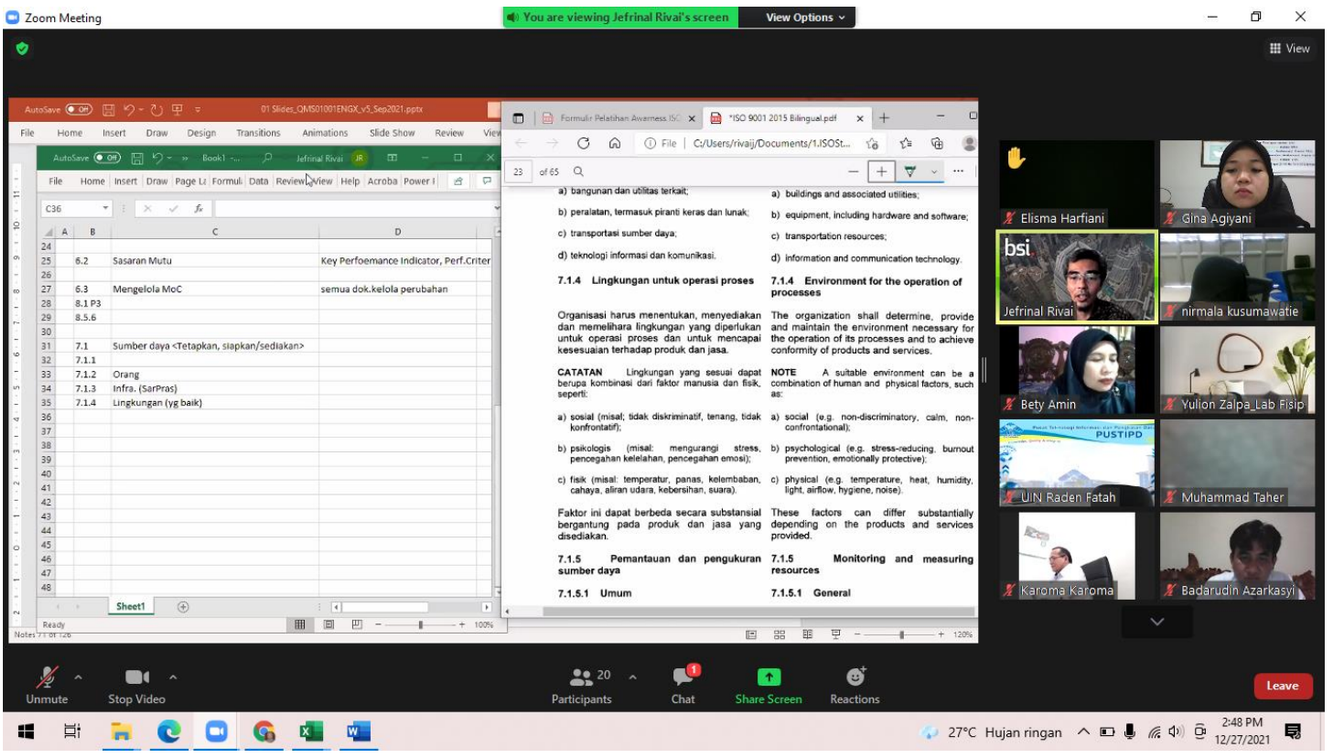
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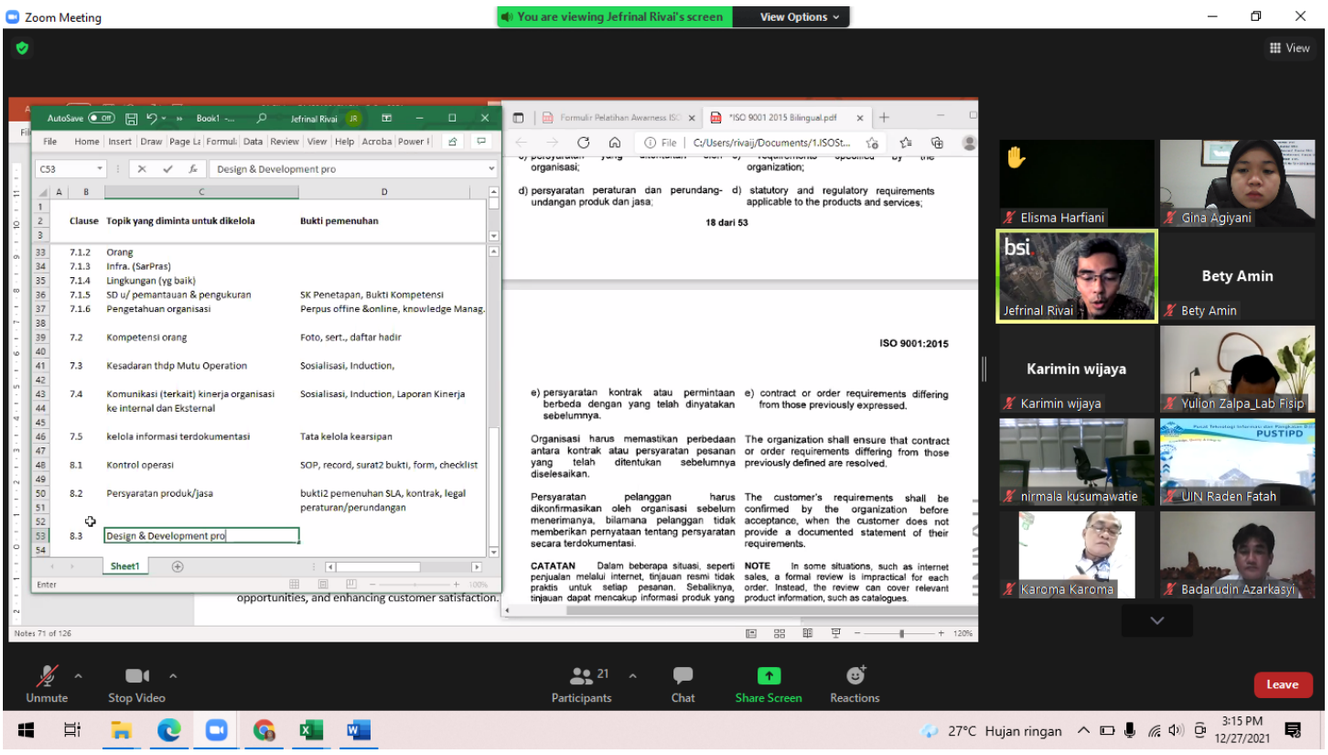
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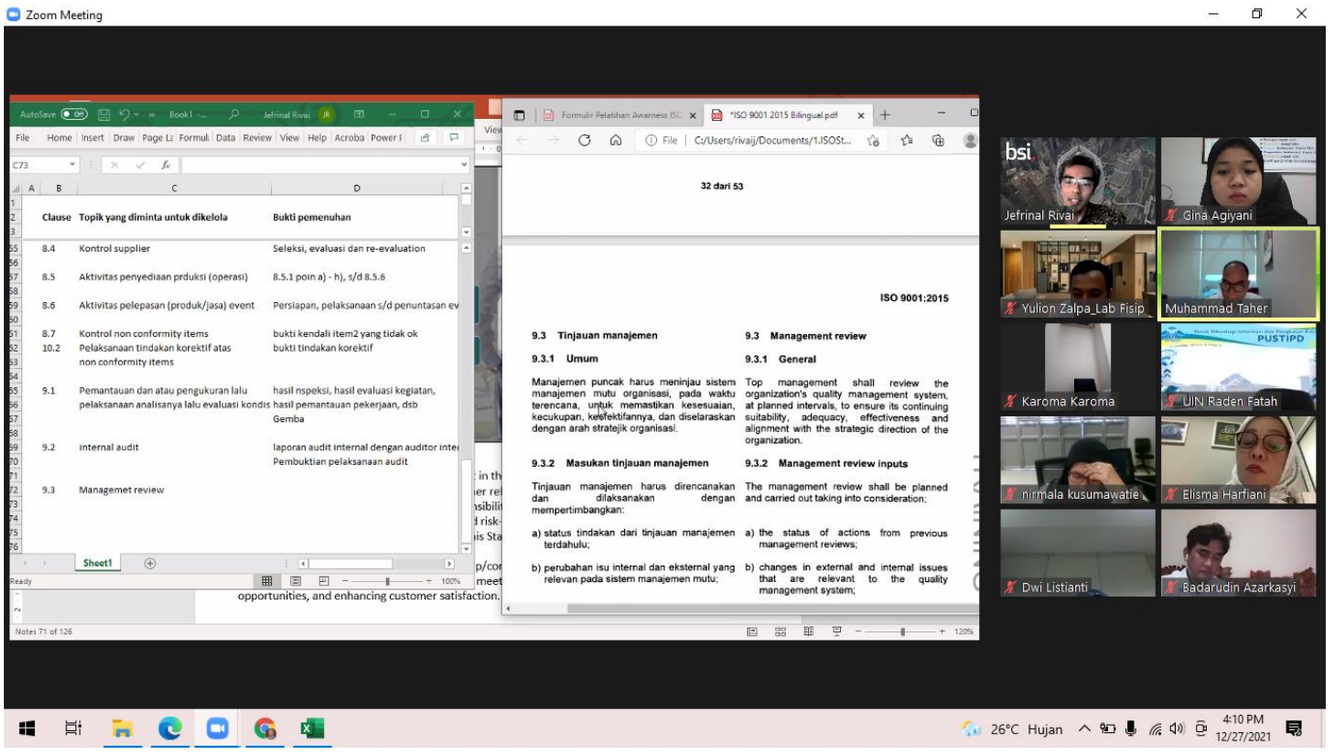
Zoom Meeting
Clause Topik yang diminta untuk dikelola Bukti pemenuhan
8.4 Kontrol supplier Seleksi, evaluasi dan re-evaluation
8.5 Aktivitas penyediaan prduksi (operasi) 8.5.1 poin a) - h), s/d 8.5.6
8.6 Aktivitas pelepasan (produk/jasa) event Persiapan, pelaksanaan s/d penuntasan ev
8.7 Kontrol non conformity items bukti kendali item2 yang tidak ok
10.2 Pelaksanaan tindakan korektif atas bukti tindakan korektif
non conformity items
9.1 Pemantauan dan atau pengukuran lalu hasil nspeksi, hasil evaluasi kegiatan,
pelaksanaan analisanya lalu evaluasi kondis hasil pemantauan pekerjaan, dsb
Gemba
9.2 internal audit laporan audit internal dengan auditor inte
Pembuktian pelaksanaan audit
9.3 Managemet review
Sheet1
32 dari 53
ISO 9001:2015
9.3 Tinjauan manajemen
9.3.1 Umum
Manajemen puncak harus meninjau sistem manajemen mutu organisasi, pada waktu terencana, untuk memastikan kesesuaian, kecukupan, keefektifannya, dan diselaraskan dengan arah strategik organisasi.
9.3.2 Masukan tinjauan manajemen
Tinjauan manajemen harus direncanakan dan dilaksanakan dengan mempertimbangkan:
a) status tindakan dari tinjauan manajemen terdahulu;
b) perubahan isu internal dan eksternal yang relevan pada sistem manajemen mutu;
9.3 Management review
9.3.1 General
Top management shall review the organization's quality management system, at planned intervals, to ensure its continuing suitability, adequacy, effectiveness and alignment with the strategic direction of the organization.
9.3.2 Management review inputs
The management review shall be planned and carried out taking into consideration:
a) the status of actions from previous management reviews;
b) changes in external and internal issues that are relevant to the quality management system;
opportunities, and enhancing customer satisfaction.
Jefrinal Rivai
Gina Agiyani
Yulion Zalpa_Lab Fisip
Muhammad Taher
Karoma Karoma
UIN Raden Fatah
nirmala kusumawatie
Elisma Harfiani
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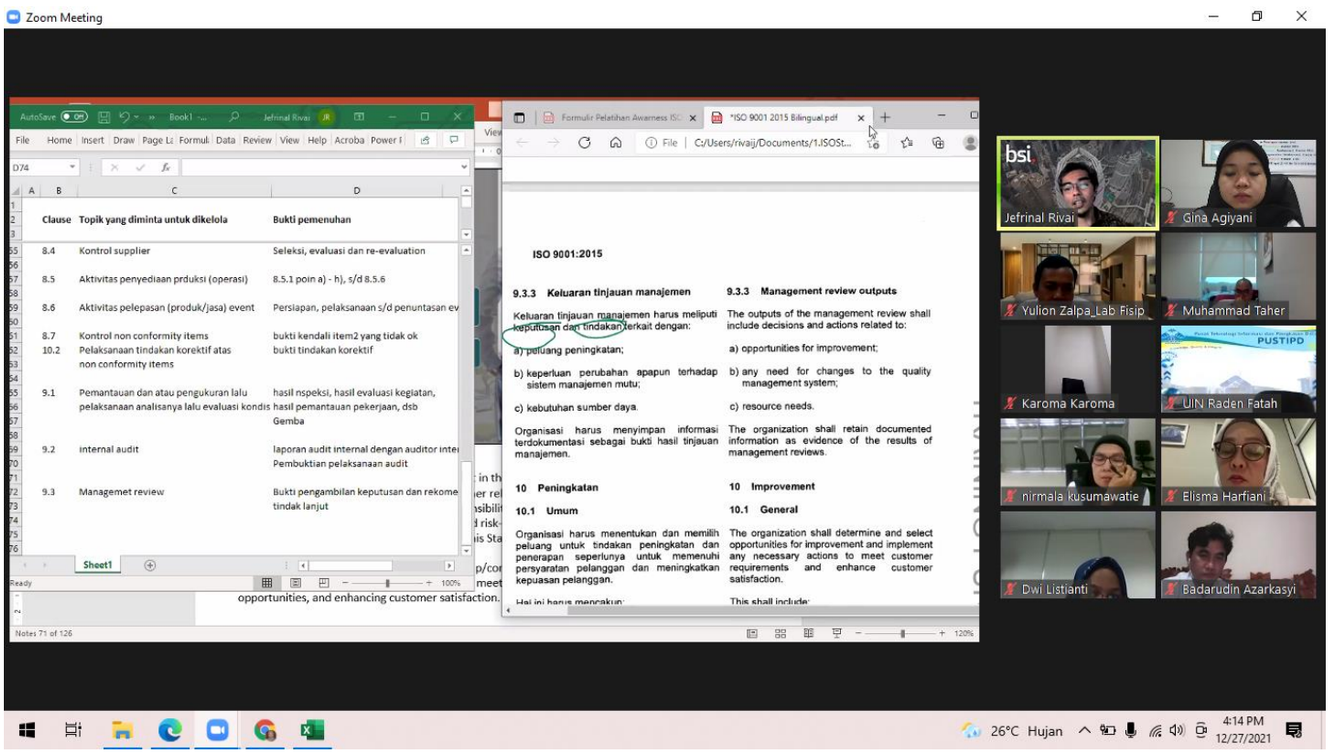
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Pembuktian pelaksanaan audit
9.3 Managemet review Bukti pengambilan keputusan dan rekome
tindak lanjut
Sheet1
ISO 9001:2015
9.3.3 Keluaran tinjauan manajemen
Keluaran tinjauan manajemen harus meliputi keputusan dan tindakan terkait dengan:
a) peluang peningkatan;
b) keperluan perubahan apapun terhadap sistem manajemen mutu;
c) kebutuhan sumber daya.
Organisasi harus menyimpan informasi terdokumentasi sebagai bukti hasil tinjauan manajemen.
10 Peningkatan
10.1 Umum
Organisasi harus menentukan dan memilih peluang untuk tindakan peningkatan dan penerapan seperlunya untuk memenuhi persyaratan pelanggan dan meningkatkan kepuasan pelanggan.
9.3.3 Management review outputs
The outputs of the management review shall include decisions and actions related to:
a) opportunities for improvement;
b) any need for changes to the quality management system;
c) resource needs.
The organization shall retain documented information as evidence of the results of management reviews.
10 Improvement
10.1 General
The organization shall determine and select opportunities for improvement and implement any necessary actions to meet customer requirements and enhance customer satisfaction.
opportunities, and enhancing customer satisfaction.
Jefrinal Rivai
Gina Agiyani
Yulion Zalpa_Lab Fisip
Muhammad Taher
Karoma Karoma
UIN Raden Fatah
nirmala kusumawatie
Elisma Harfiani
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Badarudin Azarkasyi
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