

Az IATF 16949:2016 szerinti tanúsításra való felkészülés tapasztalatai

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Rendszer felelős
Knorr-Bremse Fékrendszerek Kft.

2017. November

EOQ MNB
EOQ Magyar Nemzeti Bizottság
Közhasznú Egyesület

**EUROPEAN
ORGANIZATION
FOR
QUALITY** 
Az Európai Minőségügyi Szervezet (EOQ) nemzeti képviselője

**„A minőség-innovációs pályázatok 2017 ismertetése és a
gépjárműipari minőségmenedzsment-rendszer
aktuális változásai”**



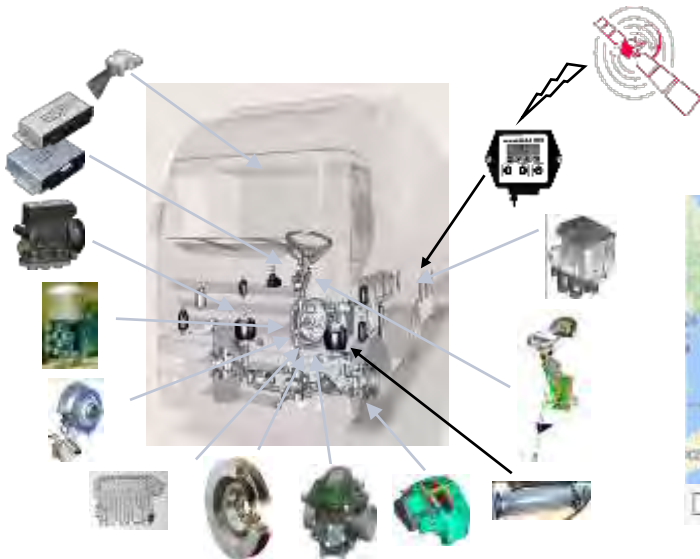
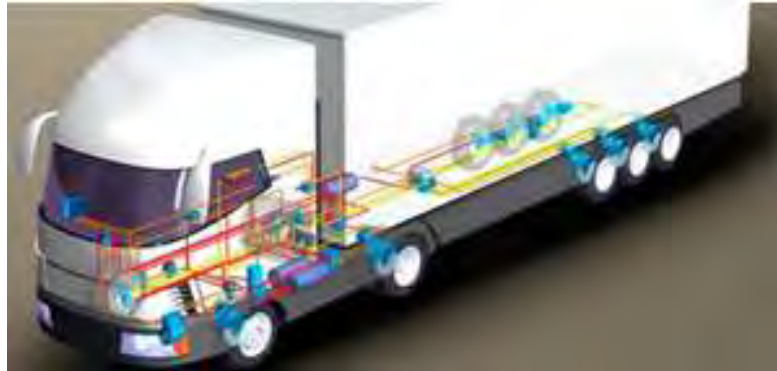
We make mobility safe!

Vasúti és haszongépjármű divízió

Vasúti és haszongép járművek fék- és vezérlő rendszerei

Fejlesztő, gyártó, értékesítő és szerviz tevékenységek a világszerte több, mint 20 országban

Vevők: a világ összes vezető vasúti- és haszongépjármű gyártója

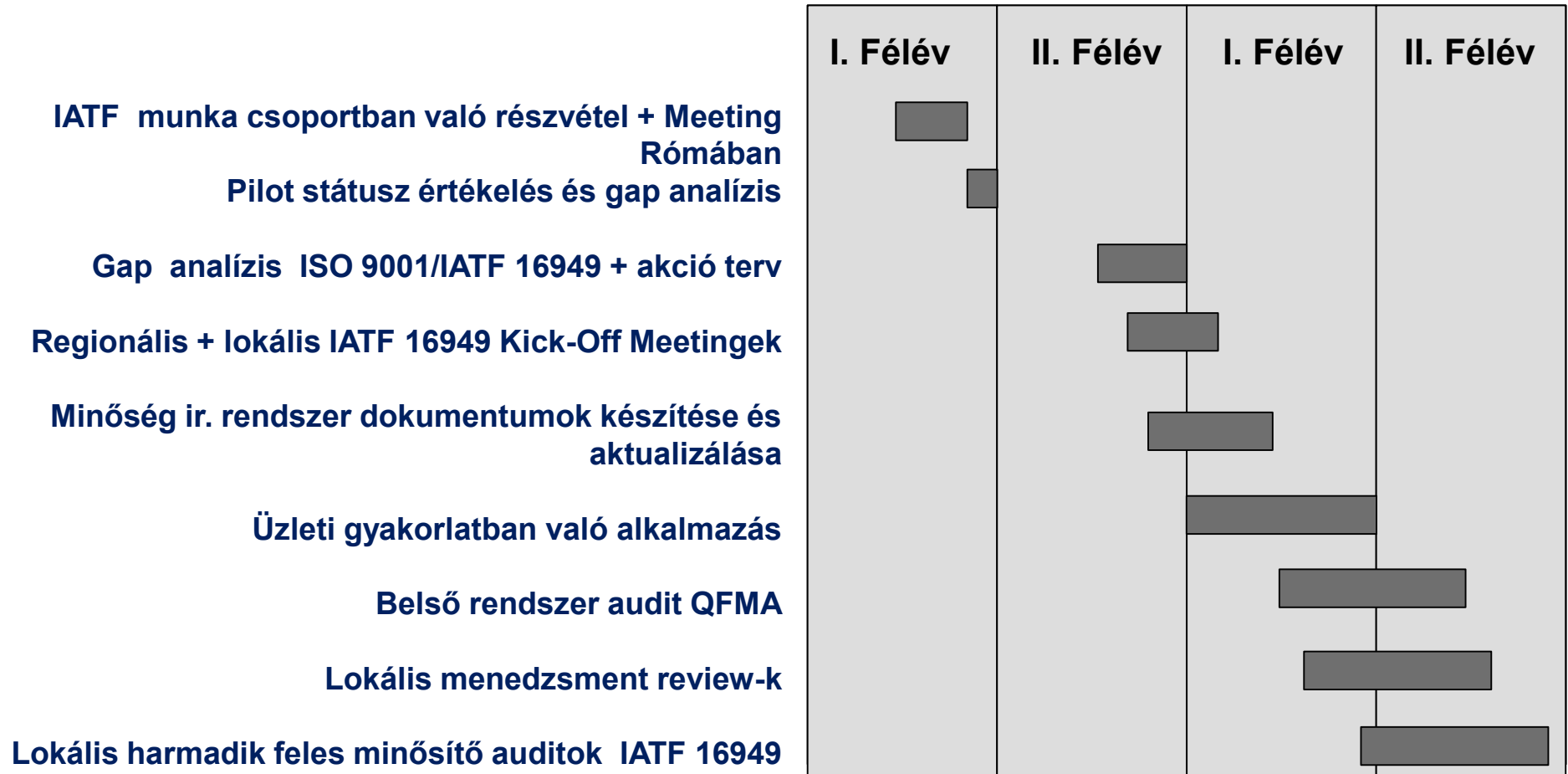


Knorr-Bremse Group	2016
	Euro million
Sales	5,494
Income before taxation	829
Net income	550
Number of employees (at December 31)	24,565

IATF 16949 bevezetési ütemterv

2016

2017



Cél: 2017-ben az új IATF 16949 szabvány alkalmazása minden 3. feles minősítő auditokon!

Új követelmények azonosítása-státuszfelmérés, gap analízis

Új követelmények lebontása hat menedzsment területre

Management

Company Context & Stakeholders	<ul style="list-style-type: none"> - identification of stakeholders and their requirements (4.1 + 4.2) - definition of internal and external strategies (4.1) - strategic planning (including risk & opportunities) (5.1.1)
Product Safety Management	<ul style="list-style-type: none"> - identification and control of product safety relevant characteristics (4.4.1.2) - definition of responsibilities and escalation process (4.4.1.2) - control of product safety in the supply chain and traceability (4.4.1.2)
Corporate Responsibility Policies	<ul style="list-style-type: none"> - definition of corporate responsibility and impact on the society (3.1.1.1) - anti-bribery policy (5.1.1.1) - code of conduct (code escalation policy (e.g. whistle-blowing policy)) (5.1.1.1)
Leadership Responsibility & Internal Audits	<ul style="list-style-type: none"> - Top Management responsibility for effectiveness of the quality system (5.1.1.2) - definition of organizational roles, responsibilities, authorities (5.2/5.3, 5.2.2.2) - definition of an audit program
Risk & Opportunity Management	<ul style="list-style-type: none"> - identification of risks & opportunities - risk reduction actions and avoidance - lessons learned from recalls, etc.

Supplier

Supplier Selection Process	<ul style="list-style-type: none"> - identification of risks of a supplier considering the quality performance (6.4.1.2) - definition of criteria for the supplier identification and selection (6.4.1.2) - evaluation of the supplier's quality management system (6.4.1.2)
Production Service Suppliers	<ul style="list-style-type: none"> - include all production service suppliers in the same supplier processes (6.4.1.1) - production service providers as self-warranty, sorting and calibration (6.4.1.1) - generating data, supplier selection, monitoring, quality system, audits (6.4.1.1)
Software Development Suppliers	<ul style="list-style-type: none"> - assessment of software development capabilities (e.g. ASPICE) (6.4.2.3.1) - use of statistical methodology like APQP for the supplier team (6.4.2.3.1) - software development capability self-assessment by the supplier (6.4.2.3.1)
Supplier Audits & Monitoring	<ul style="list-style-type: none"> - audits for time assessment, monitoring and QM system development (6.4.2.4.1) - product audits and process audits, prioritized based on the risks (6.4.2.4.1) - documented criteria to determine the type, frequency and scope (6.4.2.4.1)
Supplier Quality System Development	<ul style="list-style-type: none"> - compliance to ISO 9001 through supplier of certification audits (6.4.2.3) - obtain objective to achieve certification according to IATF 16949 (6.4.2.3) - develop, implement and improve the quality system according to IATF 16949 (6.4.2.3)

People

Process Owners Competency	<ul style="list-style-type: none"> - top management support other process owners are responsible - shall understand their role and responsibilities
Product Safety Procedures	<ul style="list-style-type: none"> - definition of responsibilities for definition of information flow - definition of responsibilities for
Operational Environment & Safety	<ul style="list-style-type: none"> - maintain environment record for consideration of social, psychosocial - maintain order and cleanliness
Knowledge & Competency Management	<ul style="list-style-type: none"> - determination of necessary knowledge - identification of the available knowledge - determination how to acquire knowledge
Internal & Supplier Audits (Management)	<ul style="list-style-type: none"> - understanding process independence - understanding of applicable standards - understanding of the applicable

Production

Production Performance Monitoring	<ul style="list-style-type: none"> - process capability studies for all manufacturing processes (7.1.1.1) - setting objectives and define actions to achieve them (6.1.1) - process performance as input for the Management Review (6.3.2 + 6.3.3.1)
Final Piece Approval	<ul style="list-style-type: none"> - perform final piece validation and retain records (8.5.1.3) - retain the final piece approval parts for comparison with last piece (8.5.1.3) - define actions to ensure product compliance after milestone period (8.5.1.4)
FMEA & Control Plan Updates	<ul style="list-style-type: none"> - definition of a Control Plan based risk analysis (PFMEA + DFMEA) (6.6.1.1) - including manufacturing controls and reaction plans (6.6.1.1) - update of Control Plan after changes, claims and new risk analysis (6.6.1.1)
Backup Process Controls & Product Repairs	<ul style="list-style-type: none"> - maintain a list of primary process controls and approved back-ups (6.6.1.1) - define work instructions for the back-up manufacturing processes (6.6.1.1) - risk analysis for rework and repair and instruction for re-inspection (6.7.1.4/4.6)
Contingency Planning Details	<ul style="list-style-type: none"> - identification of internal and external risks for the manufacturing (6.1.2.3) - definition of contingency plans avoid production stops at customer (6.1.2.3) - implement continuity system by multi-disciplinary team and management (6.1.2.3)

Design

Product Development Process	<ul style="list-style-type: none"> - documentation of the design process - identification of development phases - output: 3D models and geometries
Process Development Details	<ul style="list-style-type: none"> - assess requirements and structure - capacity analysis during the design - consideration of design for manufacturing and design for assembly (6.3.2.2)
Software Development Details	<ul style="list-style-type: none"> - use of a software development assessment methodology (e.g. ASPICE) (6.3.2.3) - identification of requirements on the embedded software (6.3.3.1) - validation of the embedded software (6.3.4.2) + software process audit (6.3.2.1)
Change & Concession Management	<ul style="list-style-type: none"> - validation of changes against customer requirements before production (6.3.6.1) - document approval from the customer, if required from the customer (6.3.6.1) - documentation of minimum level of embedded software (6.3.6.1)
Traceability Management Planning	<ul style="list-style-type: none"> - analysis of internal, customer and regulatory traceability requirements (6.5.2.1) - documentation of traceability plans based on risk and failure severity (6.5.3.1) - provide data in a format that required response time can be assured (6.5.3.1)

Customer

Customer Service/Relationship	<ul style="list-style-type: none"> - consideration at the defined scope of the management system (4.3.2) - completion of reviews should be done within 10 days (7.3.3.2.2) - consider customer specific requirements in internal and supplier audits (7.3.3.4)
Recycling & Environmental Aspects	<ul style="list-style-type: none"> - product requirements shall include recycling and environmental aspects (8.2.2) - shall include all applicable government and safety regulations (8.2.2.1) - consideration of aspects of storage, handling, elimination and disposal (8.2.2.1)
Customer Specified NC Control	<ul style="list-style-type: none"> - use of the customer defined format for the claim management (10.2.3) - identification of root-causes and corrective actions (10.2.3) - use of re-qualifying methods and update of PFMEA and Control Plan (10.2.3)
Warranty Claim Management	<ul style="list-style-type: none"> - implementation of a warranty management system (10.2.5) - definition of a process for the warranty claim analysis (10.2.5) - consideration of a process for the no-trouble-found cases (10.2.5)
Customer Performance Monitoring	<ul style="list-style-type: none"> - monitoring of customer performance based on data from web portals (9.1.2.1) - consideration as input for the Management Review (9.1.2.1) - definition of action plans when customer performance targets did not meet (9.1.2.1)

Management	People	Design	Supplier	Production	Customer
Company Context & Stakeholders	Process Owner Competency	Product Development Process	Supplier Selection Process	Production Performance Monitoring	Customer Specific Requirements
Product Safety Management	Product Safety Responsible	Process Development Methods	Production Service Suppliers	First/Last Piece Approval	Recycling & Environmental Aspects
Corporate Responsibility Policies	Occupational Environment & Safety	Software Development Process	Software Development Suppliers	FMEA & Control Plan Updates	Customer Specified NC Control
Leadership Responsibility & Internal Audits	Knowledge & Competency Management	Change & Concession Management	Supplier Audits & Monitoring	Backup Process Controls & Product Repairs	Warranty Claim Management
Risk & Opportunity Management	Internal & Supplier Auditor Qualification	Traceability Management Planning	Supplier Quality System Development	Contingency Planning Details	Customer Performance Improvement

Státuszfelmérés, gap analízis, akció terv (példa)

ISO	ISO 9001 + IATF 16949 Requirements	OLD	Knorr-Bremse/Bendix Approach	NO GAP	Group Action	Location Action	Who	When	Done
IATF		NEW		GAP					
	5 Leadership								
	5.1 Leadership and commitment								
	5.1.1 General								
	Top management shall demonstrate leadership and commitment with respect to the quality management system by:		Quality Review + F-Review						
	a) taking accountability for the effectiveness of the quality management system;		Quality Review + F-Review + Power Center Reviews + Management Review						
	b) ensuring that the quality policy and quality objectives are established for the quality management system and are compatible with the context and strategic direction of the organization;		Quality Review + F-Review		check whether the				
	c) ensuring the integration of the quality management system requirements into the organization's business processes;		Quality Review + F-Review		determine how e.g. resource				
	d) promoting the use of the process approach and risk-based thinking;		Quality Review + F-Review + STRAP		review "risk based				
	e) ensuring that the resources needed for the quality management system are available;		Quality Review + F-Review + Budget						
	f) communicating the importance of effective quality management and of conforming to the quality management system requirements;		Quality Review + F-Review						
	g) ensuring that the quality management system achieves its intended results;		Quality Review + F-Review		secure Process Driver Reviews about their processes	conduct reviews with local process Drivers about their processes			
	h) engaging, directing and supporting persons to contribute to the effectiveness of the quality management system;		Quality Review + F-Review + Process Drivers + Power Centers						
	i) promoting improvement;		Quality Review + F-Review + Quick Kaizen + improvement suggestion systems						
	j) supporting other relevant management roles to demonstrate their leadership as it applies to their areas of responsibility.		Quality + F-Review + Process Drivers						
	NOTE Reference to "business" in this International Standard can be interpreted broadly to mean those activities that are core to the purposes of the organization's existence, whether the organization is public, private, for profit or not for profit.		Quality Review + F-Review						
	5.1.1.1 Corporate responsibility								
	The organization shall define and implement corporate responsibility policies, including at a minimum an anti-bribery policy, an employee code of conduct, and an ethics escalation policy ("whistle-blowing policy").		CSR + Values + Code of Conduct		reference at TEX Manual with to Code-of Conduct	communicate Code-of Conduct			
	5.1.1.2 Process effectiveness and efficiency								
	Top management shall review the product realization processes and support processes to evaluate and improve their effectiveness and efficiency. The results of the process review activities shall be included as input to the management review (see Section 9.3.2.1.).		Quality Performance + Process KPIs + Power Center + Power Bases		identify the "support processes" and check it's review	review the identified support processes			
	5.1.1.3 Process owners								
	Top management shall identify process owners who are responsible for managing the organization's processes and related outputs. Process owners shall understand their roles and be competent to perform those roles (see ISO 9001, Section 7.2).		Process Drivers		review PD list and "managing" role	train PD about their roles and tasks			
	5.1.2 Customer focus								
	Top management shall demonstrate leadership and commitment with respect to customer focus by ensuring that:		Customer Contacts and projects						
	a) customer and applicable statutory and regulatory requirements are determined, understood and consistently met;		Customer Contacts and projects		check where the customer and statutory requirements are reviewed	check where the customer and statutory requirements are reviewed			
	b) the risks and opportunities that can affect conformity of products and services and the ability to enhance customer satisfaction are determined and addressed;		Customer Contacts and projects						
	c) the focus on enhancing customer satisfaction is maintained.		Customer Contacts and projects						
	5.2 Policy								
	5.2.1 Establishing the quality policy								
	Top management shall establish, implement and maintain a quality policy that:		Quality First Policy		review the quality policy whether aspects are covered				
	a) is appropriate to the purpose and context of the organization and supports its strategic direction;		Quality First Policy						
	b) provides a framework for setting quality objectives;		Quality First Policy						
	c) includes a commitment to satisfy applicable requirements;		Quality First Policy		check consideration of interested parties				
	d) includes a commitment to continual improvement of the quality management system.		Quality First Policy						

**Összesen:
185 db. csoport szintű akció
138 db lokális szintű akció**

Az analízis alapján csoport szintű és lokális akciók kerültek meghatározásra

Irányítási rendszer dokumentumok készítése és aktualizálása

Egyik legnagyobb kihívás:

7.1.5.2.1 Calibration/verification records

....

g) verification that the software version used for product and process control is as specified

....

i) production-related software verification used for product and process control

Ahhoz hogy valamit verifikáljunk tudnunk kell, hogy mi pontosan az előírás !

„ is as specified”

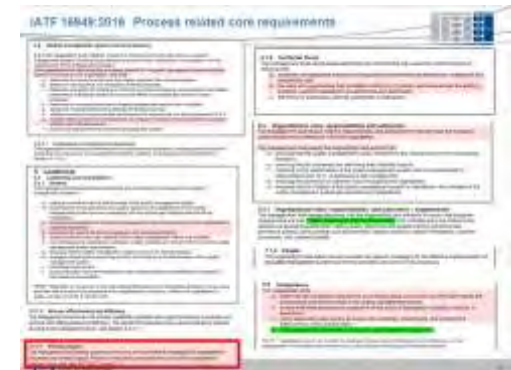
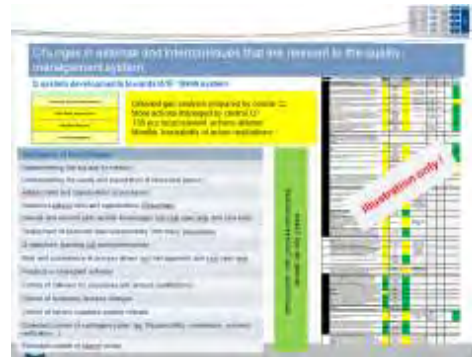
- **Ki írja elő, hogy mit kell használni, ha eddig ez nem volt specifikálva ?**
- **Hol a határ (mit tekintünk úgy hogy befolyással bír a folyamat kontrolljára)?**
- **Milyen mélységig kell (ésszerű) kibontani / feljegyezni az információkat?**
- **Software és/vagy program ?**
- **Hogyan kezeljük, ha nincs verziója az adott software-nek / programnak ?**
- **Hogyan verifikáljuk ?**
- **Milyen időközönként ?**

Üzleti gyakorlatban való alkalmazás

Oktatások:

- menedzsment
- folyamat felelősök
- alkalmazottak kulcs pozíciókban
- Belső auditorok

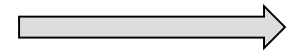
Támogatás



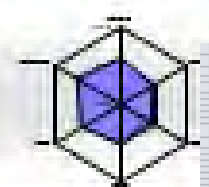
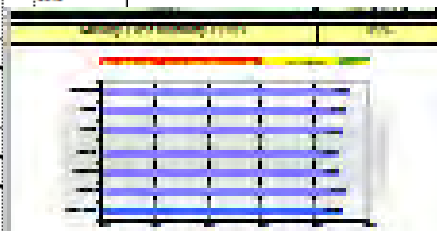
Rekordok létrehozása Változtatása Oktatása

Belső rendszer audit QFMA

Folyamat térkép alapján fő – folyamatok



Process	Requirement	Current State	Target State	Gap	Priority
Management
People
Design
Supplier
Production
Customer



Megvalósulás szempontjai:

Deployment – rendszer dokumentáció, bevezetés, oktatás

Review – Átvizsgálások, ön-értékelések, akciómenedzsment

Performance – folyamat teljesítmények, rekordok megfelelése

Szükséges korrekciók, javítások megtervezése, végrehajtása és hatásosság ellenőrzése

(A tanúsító Audit előtt)

Process	Requirement	Current State	Target State	Gap	Priority
Management
People
Design
Supplier
Production
Customer

Tapasztalatok

- Több követelmény részben vagy egészében már teljesítve vevői kezdeményezésre

- Szisztematikus , multi nacionális team munka

Globális projekt menedzsment
Csoport szintű egyszemélyi felelősség
Lokális szintű egyszemélyi felelősség

- Bevonás

Oktatások minden szinten

Folyamat felelősök: felelősség kommunikálás + motiválás

- Rendszeres, következetes előrehaladás review-k (helyi és csoportszintű)
- Menedzsment elkötelezettsége (Csoport és lokális szinten)

Tapasztalatok - tartalmi súlypontok:

- Szervezet és környezete megértése és kezelése
- Érdekeltek szükségleteinek és elvárásainak megértése és kezelése
- Folyamat kockázatok és lehetőségek meghatározása és kezelése
- Termék minőség tapasztalatok kezelése
- Auditor kompetenciák dokumentálása
- Vevő specifikus követelmények folyamatokhoz rendelése
- Minőségcélok: következetes tervezés akciókkal és erőforrásokkal +hatásosság / hatékonyság értékelés
- Folyamat felelősök kibővített felelőssége
- Termékek beágyazott szoftverekkel
- Folyamat vezérlő és termékminősítő szoftverek verifikálása
- Átmeneti folyamat változások szabályozása
- Szolgáltató beszállítók szabályozása
- Vészhelyzet terv bővítés
- Nyomon követhetőségi terv
- Menedzsment review tartalom bővítés
- Új, specifikus kulcs teljesítmény mutatók alkalmazása

A felkészülés eredménye :

ZERTIFIKAT ■ CERTIFICATE ■ 合格證書 ■ CERTIFICADO ■ CERTIFICAT ■ CERTIFICAT



TANÚSÍTVÁNY

A TÜV SÜD Management Service GmbH
tanúsító helye

ezúton igazolja, hogy a / az

Knorr-Bremse Fékrendszerek Kft.
6000 Kecskemét
Georg Knorr utca 8.
Magyarország

az alábbi érvényességi területen

Haszongépjármű fékrendszerek,
aktív jármű biztonsági rendszerek, integrált jármű modulok és a
haszongépjármű ipar részére egyéb vonatkozó
feltüggesztési rendszer komponensek tervezése és gyártása
(0.3 -szakasz szerinti termékfejlesztéssel egybekötve)

minőségirányítási rendszert
vezeteli be és működtet

A tanúsító audit során bizonyítást nyert,
hogy a rendszer megfelel a / az

IATF 16949

első kiadás, 2016.10.01

szabvány követelményének.

Kiállítás dátum: 2017.09.21.

Lejárat dátum: 2020.09.20.

Tanúsítvány nyilvántartási száma: 12 111 36858/05 TMS

IATF tanúsítvány száma: 0274198

A tanúsítvány részlet képezi a melléklet.

Prüfer/Constatante Management
München, 2017.09.21

1/2 oldal

Köszönöm a figyelmüket!