**MCT (multiple choice test) D 28v18 in class**

**ISO 19443: 2018 quality and safety management system readiness**

First and last name: ………………………………..

Date: …………………………

Please tick **all** correct answers (one or more correct answers per question are possible)

**A Quality approach**

**A.1 The first edition of the ISO 9000 family of standards appeared in:**

1947

1980

1987

**A.2 The standard ISO 19443 determines for a quality and safety management system:**

The requirements

The fundamentals

Guidelines for auditing management systems

The automotive production requirements

**A.3 The 7 quality management principles include:**

The quality approach

The process approach

The engagement of people

The quality policy

Risk-based thinking

**A.4 The core booklets of the ISO 9000 family of standards include:**

ISO 9000

ISO 14001

ISO/TS 16949

ISO 9001

ISO 9004

**A.5 In the PDCA cycle, the A stands for:**

Analyze data

Act

Bring support

Adapt

**A.6 The process is:**

Any support allowing the treatment of information

An entity that provides a product

Anyone who receives a product

Activities that transform inputs into outputs

**A.7 ISO stands for:**

International Standard Organization

International Superior Organization

International Organization for Standardization

**A.8 Only one of the following statements is correct. Which one?**

A product can be certified ISO 19443

A service can be certified ISO 19443

A company's quality and safety management system can be certified ISO 19443

Any company with more than 100 persons shall be certified ISO 19443

**B Process approach**

**B.1 A process creates, among other things:**

Added value

Potential nuisances

Quality

Continual improvement

**B.2 A process is determined, among other things, by its:**

Inputs

Strategy

Purpose

Owner

**B.3 The sell and purchase processes are:**

Management processes

Realization processes

Support processes

**B.4 The realization processes include:**

Design

Sell

Acquire resources

Maintain infrastructure

Inspect

**B.5 The process mapping allows us, among other things, to:**

Identify the beneficiary

Identify the interactions

Plan the QSMS

Manage inspection means

Obtain a global vision

**B.6 The process approach, among other things:**

Relies on process management

Allows roles and responsibilities to be clarified

Focuses on the priority to investments

**C Context of the company**

**C.1 External issues that may affect the company's performance are, among others:**

Social environment

Regulatory environment

Corporate culture

Products and services

**C.2 Internal issues that may affect the company's performance are, among others:**

Technology environment

Economic environment

Products and services

Corporate culture

**C.3 Examples of stakeholders:**

Laws and regulations

Customers

Stockholders

Neighbors

**C.4 To understand the needs and expectations of stakeholders means to:**

Meet the product requirements

Meet service requirements

Review product and service requirements

**C.5 The review of product and service requirements:**

Is part of the process negotiate the contract

Requires a feasibility study

Addresses gap situations

Is performed before acceptance of the order

Ensures statutory and regulatory requirements are met

**C.6 The scope of the QSMS takes into account:**

The quality policy

The issues that may affect the performance of the company

The requirements of stakeholders

The products and services

The obligation to maintain documented information

**C.7 The quality and safety management system is:**

Established

Documented

Implemented

Simplified

Improved

**C.8 The number of the requirements of ISO 19443 version 2018 is:**

Less than 200

 Over 200

Over 300

Less than 300

**D Leadership**

**D.1 Leadership of top management should:**

Manage the company’s processes

Fully assume responsibility for the effectiveness of the QSMS

Define the purpose of the company

Lead by example in the field

Support continual improvement

**D.2 Top management commitment is:**

Communicated at all levels

To define the policy

To ensure the availability of manpower and technical resources to achieve the objectives

To support the process approach

Formalized in a written statement

**D.3 Top management shows its commitment:**

By everyday acts

By participating and expressing its opinion at all quality meetings

By determining risks and opportunities that can influence the conformity of products and services

**D.4 A quality policy is:**

Adapted to the purpose of the company

Adapted to the corporate culture

Adequate to the importance of risks in the company

An assurance of the availability of manpower and technical resources

Available to stakeholders

**D.5 The quality policy includes:**

The involvement of staff to achieve expected results

The framework for defining objectives

A commitment to continual improvement of performance

**D.6 A person is appointed to:**

Define the responsibilities and authorities of the QSMS

Ensure that the QSMS meets the requirements of the ISO 19443 standard

Report on the performance of the QSMS

Encourage innovations

**D.7 The responsibilities and authorities of the QSMS:**

Are defined by top management

Are freely available internally

Are listed in the quality policy

Allow controlling changes

**E Planning**

**E.1 Planning the QSMS means taking into account:**

The commitment of top management

External and internal issues

The requirements of stakeholders

The QSMS processes

**E.2 Any threat that can disrupt the company’s activities is:**

Determined

Analyzed

Evaluated

Retained as documented information

**E.3 Actions to reduce side effects are inputs of activities such as:**

Support

Realization

Management review

Evaluation of performance

Improvement

**E.4 The actions to address risks include, among other things:**

Quality objectives and indicators

Roles and responsibilities

Needed resources

A deadline for completion

**E.5 The quality objectives are:**

Measurable

Realistic

Monitored through indicators

Established by top management

**E.6 Documented information on quality objectives:**

Is retained

Is maintained

Is not mandatory

**E.7 Before the introduction of any change, the following is taken into account:**

The necessity

The objective

The documented information retention

Beneficial impacts (opportunities for improvement)

Risk of potential harm

**F Support**

**F.1 Top management provides staff:**

For obtaining conformity of products

For the proper functioning of the QSMS

For the proper functioning of processes including the inspection process

Who have the necessary knowledge

Who have the appropriate competence to address risks

**F.2 The staff is aware, *inter alia*, of:**

The importance of respect for the quality policy

The importance of compliance with the QSMS requirements

The positive effects of everyone’s performance

Everyone's participation in the identification of risks and opportunities

Nonconformities and corrective actions

**F.3 External and internal communication covers:**

How

When

Why

With whom

Who

What topics

**F.4 The QSMS documentation system:**

Follows the structure of the ISO 19443 standard

Focuses on the processes

Includes documented information to maintain

Includes documented information to retain

Includes the quality and safety manual

**F.5 Internal documented information that are commonly used include:**

QSMS scope

Internal audit

Contingency plan

The Labor Code

Action plan

**F.6 Documented information to maintain is identified by its:**

Title

Coding

Approval

Retention time

Distribution

**F.7 Control of the documented information allows one:**

To update information simply and clearly

To group several documented information requirements in one

To react quickly to any nonconformity

To perpetuate know-how

**F.8 Documented information is managed by:**

The owner and actors of every process

The quality and safety department

Repair operators

**G Operation**

**G.1 Operational control is present wherever a risk is identified:**

The design of workstations

The maintenance of equipment and machines

The operation of the equipment

The prevention plan

**G.2 A review of the product and service is a way to check the requirements:**

Given orally by the customer

Specified by the customer

That are implicit

That are statutory and regulatory

**G.3 The design and development of the product and service are ensured when:**

Each stage is planned and controlled

The responsibilities and authorities are determined

The required verifications and validations are determined

Frequent reviews with the customer are being held

**G.4 The design and development inputs:**

Include acceptance criteria

Are complete, unambiguous and non-contradictory

Take into account the legislation and regulations

Take into account the specific functional and performance requirements

**G.5 The design and development outputs:**

Satisfy input design and development requirements

Take into account the resource needs

Contain acceptance criteria or a reference to them

Are verified or validated

**G.6 External providers are evaluated on criteria such as:**

Percentage of compliant products

Costs not changed during the year

Time frames always met



Controls applied at all levels of the supply chain

Lowest prices

**G.7 The information requirements communicated to external providers include:**

The inspection of the process

The product sold and service provided

Approval of product and service

Approval of equipment

Staff competence

**G.8 Product identification is:**

A mandatory requirement

A way to distinguish a product and its status

The aptitude to memorize or restore all or part of a trace of executed functions

**H Performance evaluation**

**H.1 The process inspect:**Allows the treatment of nonconformities

Uses easily reproducible methods

Uses methods appropriate to the specifics of the company  
Uses inspection equipment with valid status

Uses appropriate inspection equipment   
  
**H.2 Arrangements are applied to measure the performance of:**

The control of products and services

The satisfaction of external providers

Conformity of the QSMS

Process control

**H.3 Data analysis helps the company to:**

Increase customer satisfaction

Evaluate process performance

Evaluate the performance of external providers

Find opportunities for continual improvement

Evaluate the effectiveness of the QSMS

**H.4 The internal audit:**

Verifies the competence of the personnel

Allows the effectiveness of the QSMS to be evaluated

Helps improve the effectiveness of the QSMS

**H.5 The audit program takes into account:**

The results of previous audits

The importance of processes

The risks and opportunities related to the processes

The quality objectives

The competency of auditors

**H.6 The management review is:**

A planned meeting to review whether the QSMS is relevant, adequate and effective

A monthly meeting of the executives

A meeting to evaluate external providers

Carried out by top management

Carried out by the quality and safety manager

**H.7 The management review evaluates:**

The promotion of department managers

The pertinence of the QSMS

The effectiveness of the QSMS

The opportunities to improve the QSMS

**H.8 Examples of management review inputs:**

Results from internal audits

Decisions on improving QSMS effectiveness

Stakeholders’ feedback

**H.9 Examples of management review outputs:**

Results of inspection

Decisions on the improvement of a product related to customer requirements and other stakeholders

Decisions on resource needs

**I Improvement**

**I.1 An improvement can be carried out on:**

The staff

The process

Products and services

The quality and safety management system

**I.2 Improvement opportunities exist in cases like:**

Customer complaint rate

Meeting deadlines

Cost reduction

Corrective actions

**I.3 The treatment of nonconformities includes activities such as:**

Identifying nonconformities

Analyzing nonconformities

Seeking opportunities for improvement

Isolating nonconformities

Evaluating the need for corrective actions

**I.4 The purpose of a corrective action is to:**

Correct the nonconformity at once

Eliminate the cause of the nonconformity

Eliminate a detected undesirable event

Prevent the recurrence of the nonconformity

Find out who caused the nonconformity

**I.5 The continual improvement of the QSMS relies, among other things, on:**

Stable processes

Documented information to maintain

Internal audit results

Analysis of data

The search for and justification of solutions

**I.6 Each nonconformity is communicated to the persons concerned:**

To understand what did not work well

To understand why a requirement has not been met

So the leader may punish the culprit

So everyone can have a good laugh

**I.7 Documented information on nonconformities and actions taken:**

Is maintained

Is retained

Is not mandatory

**I.8 Kaizen is:**

A continual improvement approach

Substantial investment costs

Small improvements all the time

A tool against waste

A radical change by rupture

Correct answers: …….. out of 69.

Note: ……. out of 20

Result: very good / good / insufficient

**MCT 28**

**ISO 19443 readiness version 2018**

(Correct answer in blue, wrong answer in red, comment in pink)

**A – Quality approach**

**A.1 D1 F1 The first edition of the ISO 9000 family of standards appeared in:**

1947 Creation of ISO

1980 Creation of ISO/TC 176

1987

**A.2 The standard ISO 19443 determines for a quality and safety management system:**

The requirements

The fundamentals It’s ISO 9000: Fundamentals and vocabulary

Guidelines for auditing management systems It’s ISO 19011: Guidelines for auditing management systems

The automotive production requirements It's ISO/TS 16949: Particular requirements for the application of ISO 9001: 2008 for automotive production and relevant service part organizations

**A.3 The 7 quality management principles include:**

The quality approach This is a broader notion than a principle

The process approach

The engagement of people

The quality policy The policy is consistent with the 7 principles and provides a framework for setting the quality objectives

Risk-based thinking Risk-based thinking is not included in the 7 quality management principles

**A.4 The core booklets of the ISO 9000 family of standards include:**

ISO 9000

ISO 14001 That's a standard related to the environment

ISO/TS 16949 That's a specification related to automotive manufacturers

ISO 9001

ISO 9004

**A.5 D2 F2 In the PDCA cycle, the A stands for:**

Analyze data It’s in Check

Act

Bring support It’s in Do

Adapt

**A.6 The process is:**

Any support allowing the treatment of information This is documented information

An entity that provides a product This is the external provider

Anyone who receives a product This is the customer

Activities that transform inputs into outputs

**A.7 ISO stands for:**

International Standard Organization ISO comes from the Greek prefix "iso" (equal). The correct answer is International Organization for Standardization

International Superior Organization ISO comes from the Greek prefix "iso" (equal). The correct answer is International Organization for Standardization

International Organization for Standardization

**A.8 Only one of the following statements is correct. Which one?**

A product can be certified ISO 19443 The quality and safety management system of a company can be certified ISO 19443

A service can be certified ISO 19443 The quality and safety management system of a company can be certified ISO 19443

A company's quality and safety management system can be certified ISO 19443

Any company with more than 100 persons shall be certified ISO 19443 ISO 19443 certification is voluntary for the quality and safety management system of a company, large or small

**B – Process approach**

**B.1 F3 A process creates, among other things:**

Added value

Potential nuisances

Quality That's not always the case

Continual improvement That's not always the case

**B.2 D3 A process is determined, among other things, by its:**

Inputs

Strategy This is a management process

Purpose

Owner

**B.3 The sell and purchase processes are:**

Management processes They are realization processes

Realization processes

Support processes They are realization processes

**B.4 The realization processes include:**

Design

Sell

Acquire resources It's a management process

Maintain infrastructure It's a support process

Inspect

**B.5 The process mapping allows us, among other things, to:**

Identify the beneficiary

Identify the interactions

Plan the QSMS It's a management process

Manage inspection means It's a support process

Obtain a global vision

**B.6 F4 The process approach, among other things:**

Relies on process management

Allows roles and responsibilities to be clarified

Focuses on the priority to investments It’s the contrary. “Use your brain, not your money.” – Taiichi Ohno

**C – Context of the company**

**C.1 D4 External issues that may affect the company's performance are, among others:**

Social environment

Regulatory environment

Corporate culture This is an internal issue

Products and services This is an internal issue

**C.2 F5 Internal issues that may affect the company's performance are, among others:**

Technology environment This is an external issue

Economic environment This is an external issue

Products and services

Corporate culture

**C.3 Examples of stakeholders:**

Laws and regulations They have no needs or expectations: therefore, cannot be interested in the performance of the QSMS

Customers

Stockholders

Neighbors

**C.4 To understand the needs and expectations of stakeholders means to:**

Meet the product requirements

Meet service requirements

Review product and service requirements This is to ensure the feasibility of the order

**C.5 The review of product and service requirements:**

Is part of the process negotiate the contract

Requires a feasibility study It is not mandatory

Addresses gap situations

Is performed before acceptance of the order

Ensures statutory and regulatory requirements are met

**C.6 The scope of the QSMS takes into account:**

The quality policy It’s the opposite (the quality policy takes into account the scope)

The issues that may affect the performance of the company

The requirements of stakeholders

The products and services

The obligation to maintain documented information

**C.7 The quality and safety management system is:**

Established

Documented

Implemented

Simplified The document system can be simplified, not the management system

Improved

**C.8 F6 The number of the requirements of ISO 19443 version 2018 is:**

Less than 200 The exact number is 444 requirements

Over 200

Over 300

Less than 300 The exact number is 444 requirements

**D - Leadership**

**D.1 D5 Leadership of top management should:**

Manage the company’s processes It's the process owners who are doing it

Fully assume responsibility for the effectiveness of the QSMS

Define the purpose of the company

Lead by example in the field

Support continual improvement

**D.2 F7 Top management commitment is:**

Communicated at all levels That’s true mostly for the quality policy

To define the policy

To ensure the availability of manpower and technical resources to achieve the objectives

To support the process approach

Formalized in a written statement That’s not mandatory anymore

**D.3 Top management shows its commitment:**

By everyday acts

By participating and expressing its opinion at all quality meetings The result can be very mixed

By determining risks and opportunities that can influence the conformity of products and services

**D.4 A quality policy is:**

Adapted to the purpose of the company

Adapted to the corporate culture

Adequate to the importance of risks in the company

An assurance of the availability of manpower and technical resources This is a top management commitment

Available to stakeholders

**D.5 The quality policy includes:**

The involvement of staff to achieve expected results This is a top management commitment

The framework for defining objectives

A commitment to continual improvement of performance

**D.6 A person is appointed to:**

Define the responsibilities and authorities of the QSMS This is done by top management

Ensure that the QSMS meets the requirements of the ISO 19443 standard

Report on the performance of the QSMS

Encourage innovations

**D.7 F8 The responsibilities and authorities of the QSMS:**

Are defined by top management

Are freely available internally

Are listed in the quality policy This is not included in the quality policy as it is available to stakeholders

Allow controlling changes

**E - Planning**

**E.1 D6 Planning the QSMS means taking into account:**

The commitment of top management QSMS planning and management commitment are separate activities

External and internal issues

The requirements of stakeholders

The QSMS processes

**E.2 F9 Any threat that can disrupt the company’s activities is:**

Determined

Analyzed

Evaluated

Retained as documented information This is not a requirement of the standard but it is good practice

**E.3 Actions to reduce side effects are inputs of activities such as:**

Support

Realization

Management review Results and follow-up of actions are inputs of the management review

Evaluation of performance

Improvement

**E.4 The actions to address risks include, among other things:**

Quality objectives and indicators Objectives and indicators are in place to plan actions

Roles and responsibilities

Needed resources

A deadline for completion

**E.5 The quality objectives are:**

Measurable

Realistic

Monitored through indicators

Established by top management Top management determines the quality policy, which provides a framework to determine the objectives

**E.6 Documented information on quality objectives:**

Is retained It must be maintained because it is information that changes – previous term procedure

Is maintained

Is not mandatory It must be maintained because it is information that changes – previous term procedure

**E.7 F10 Before the introduction of any change, the following is taken into account:**

The necessity

The objective

The documented information retention Documented information is changed during or after the application of the change but it is not to be considered upstream

Beneficial impacts (opportunities for improvement)

Risks of potential harm

**F - Support**

**F.1 D7 Top management provides staff:**

For obtaining conformity of products Conformity of services, infrastructure, technology, natural and financial resources must be added

For the proper functioning of the QSMS

For the proper functioning of processes including the inspection process

Who have the necessary knowledge

Who have the appropriate competence to address risks

**F.2 F11 The staff is aware, *inter alia*, of:**

The importance of respect for the quality policy

The importance of compliance with the QSMS requirements

The positive effects of everyone’s performance

Everyone's participation in the identification of risks and opportunities

Nonconformities and corrective actions This is an effect of non-compliance with the QSMS requirements

**F.3 External and internal communication covers:**

How

When

Why It's mandatory to inform stakeholders and address feedback

With whom

Who

What topics

**F.4 The QSMS documentation system:**

Follows the structure of the ISO 19443 standard It is possible but it is easier to use the pyramid: quality and safety manual, processes, procedures (documented information to maintain) and records (documented information to retain)

Focuses on the processes

Includes documented information to maintain

Includes documented information to retain

Includes the quality and safety manual

**F.5 Internal documented information that are commonly used include:**

QSMS scope

Internal audit

Contingency plan

The Labor Code This is an external document

Action plan

**F.6 Documented information to maintain is identified by its:**

Title

Coding

Approval

Retention time This is valid for records (documented information to retain)

Distribution This is valid for records (documented information to retain)

**F.7 F12 Control of the documented information allows one:**

To update information simply and clearly

To group several documented information requirements in one

To react quickly to any nonconformity This is not the role of a documented information

To perpetuate know-how

**F.8 Documented information is managed by:**

The owner and actors of every process

The quality and safety department The quality and safety manager handles certain mandatory documented information but only brings his/her advice and recommendations for other processes

Repair operators It is not their role but they can propose improvements

**G - Operation**

**G.1 D8 Operational control is present wherever a risk is identified:**

The design of workstations

The maintenance of equipment and machines

The operation of the equipment

The prevention plan This is a documented information and not an activity, but if the prevention plan is not regularly tested and updated, a risk can occur

**G.2 F13 A review of the product and service is a way to check the requirements:**

Given orally by the customer Only after customer written transcript and acceptance

Specified by the customer

That are implicit

That are statutory and regulatory

**G.3 The design and development of the product and service are ensured when:**

Each stage is planned and controlled

The responsibilities and authorities are determined

The required verifications and validations are determined

Frequent reviews with the customer are being held This is not mandatory but it can be done at certain stages

**G.4 F14 The design and development inputs:**

Include acceptance criteria That's for outputs

Are complete, unambiguous and non-contradictory

Take into account the legislation and regulations

Take into account the specific functional and performance requirements

**G.5 The design and development outputs:**

Satisfy input design and development requirements

Take into account the resource needs That's for input requirements

Contain acceptance criteria or a reference to them

Are verified or validated

**G.6 External providers are evaluated on criteria such as:**

Percentage of compliant products

Costs not changed during the year

Time frames always met

Controls applied at all levels of the supply chain

Lowest prices – If you buy quality, you only cry once. English proverb

**G.7 The information requirements communicated to external providers include:**

The inspection of the process This is linked to specific internal requirements

The product sold and service provided

Approval of product and service

Approval of equipment

Staff competence

**G.8 F15 Product identification is:**

A mandatory requirement It is mandatory only when appropriate

A way to distinguish a product and its status

The aptitude to memorize or restore all or part of a trace of executed functions This is the definition of traceability

**H – Performance evaluation**

**H.1 D9 The process inspect:**Allows the treatment of nonconformities The treatment of nonconformities is another activity

Uses easily reproducible methods

Uses methods appropriate to the specifics of the company  
Uses inspection equipment with valid status

Uses appropriate inspection equipment   
  
**H.2 F16 Arrangements are applied to measure the performance of:**

The control of products and services

The satisfaction of external providers External providers are evaluated and selected

Conformity of the QSMS

Process control

**H.3 Data analysis helps the company to:**

Increase customer satisfaction

Evaluate process performance

Evaluate the performance of external providers

Find opportunities for continual improvement

Evaluate the effectiveness of the QSMS This is the purpose of internal audit

**H.4 The internal audit:**

Verifies the competence of the personnel It is neither an objective nor a right of the audit

Allows the effectiveness of the QSMS to be evaluated

Helps improve the effectiveness of the QSMS

**H.5 The audit program takes into account:**

The results of previous audits

The importance of processes

The risks and opportunities related to the processes

The quality objectives

The competency of auditors Every auditor is trained prior to auditing

**H.6 F17 The management review is:**

A planned meeting to review whether the QSMS is relevant, adequate and effective

A monthly meeting of the executives A meeting of executives does not change the policy and the objectives

A meeting to evaluate external providers This is not the place for this activity

Carried out by top management

Carried out by the quality and safety manager He/she can prepare but not conduct the review

**H.7 The management review evaluates:**

The promotion of department managers It’s neither the time nor the place for this

The pertinence of the QSMS

The effectiveness of the QSMS

The opportunities to improve the QSMS

**H.8 Examples of management review inputs:**

Results from internal audits

Decisions on improving QSMS effectiveness That’s a management review output

Stakeholders’ feedback

**H.9 F18 Examples of management review outputs:**

Results of inspection That’s a management review input

Decisions on the improvement of a product related to customer requirements and other stakeholders

Decisions on resource needs

**I - Improvement**

**I.1 D10 An improvement can be carried out on:**

The staff Only on the knowledge and competence of staff

The process

Products and services

The quality and safety management system

**I.2 F19 Improvement opportunities exist in cases like:**

Customer complaint rate

Meeting deadlines

Cost reduction

Corrective actions This is an effect: it is better to attack the root cause

**I.3 The treatment of nonconformities includes activities such as:**

Identifying nonconformities

Analyzing nonconformities

Seeking opportunities for improvement Only after the disappearance of nonconformities and their cause can we think of improving

Isolating nonconformities

Evaluating the need for corrective actions

**I.4 The purpose of a corrective action is to:**

Correct the nonconformity at once That's a curative action

Eliminate the cause of the nonconformity

Eliminate a detected undesirable event

Prevent the recurrence of the nonconformity

Find out who caused the nonconformity That's not the purpose of a corrective action at all

**I.5 F20 The continual improvement of the QSMS relies, among other things, on:**

Stable processes

Documented information to maintain That's linked to conformity cf. ISO 9001 version 1994

Internal audit results

Analysis of data

The search for and justification of solutions

**I.6 Each nonconformity is communicated to the persons concerned:**

To understand what did not work well

To understand why a requirement has not been met

So the leader may punish the culprit It’s mainly so the nonconformity could not reappear

So everyone can have a good laugh Laughter is good, but be careful not to hurt your colleague’s feelings

**I.7 Documented information on nonconformities and actions taken:**

Is maintained It must be retained - previous term record

Is retained

Is not mandatory It must be retained - previous term record

**I.8 Kaizen is:**

A continual improvement approach

Substantial investment costs On the contrary, they are minimal

Small improvements all the time

A tool against waste

A radical change by rupture On the contrary, it is a gradual change