

Handling an ISO/IEC 15504 SPICE Assessment Wave, an Unique Incident

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What was this wave all about?

- An administrative action which leads to the ISO/IEC 15504 SPICE Organizational Maturity certification of a large amount of companies
- Goes on since late 2015 & 2016
- Originated from a joint agreement between Turkish Standards Institution (TSE) and Turkish Ministry of Health.
- Can be considered as a Turkish equivalent of QuaSAR II initiative of Balearic Islands, or TickIT Plus certification scheme of EU

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The motivation of TSE and Ministry of Health behind this wave:

- Necessity of advanced cyber security, project management and process management measures in the medical IT companies
- Some incidents of large scale data theft

Some Medical IT companies were far from any understanding of

- Privacy: Meaning that the data could be unofficially shared with non-relevant parties
- Quality: Data could be corrupted
- Project based documentation: Existing ISO 9000 QMS, but not effective

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Through its regulations, Ministry of Health of Turkey declared that all software developing companies of medical softwares such as:

- HMS (Hospital Information Management System)
- LIMS (Laboratory Information Management System)
- Radiology IT Management Systems

must obtain a ISO/IEC 15504-7 certificate on a scope of at least OMM Level-2 and alongside ISO 27001 certification.

No consideration of organisation scale of the companies.

ISO/IEC 15504 SPICE Standard



PRIMARY Life Cycle Processes

Acquisition Process Group (ACQ)

- ACQ.1 Acquisition preparation
- ACQ.2 Supplier selection
- ACQ.3 Contract agreement
- ACQ.4 Supplier monitoring
- ACQ.5 Customer acceptance

Supply Process Group (SPL)

- SPL.1 Supplier tendering
- SPL.2 Product release
- SPL.3 Product acceptance support

Engineering Process Group (ENG)

- ENG.1 Requirements elicitation
- ENG.2 System requirements analysis
- ENG.3 System architectural design
- ENG.4 Software requirements analysis
- ENG.5 Software design
- ENG.6 Software construction
- ENG.7 Software integration
- ENG.8 Software testing
- ENG.9 System integration
- ENG.10 System testing
- ENG.11 Software installation
- ENG.12 Software and system maintenance

Operation Process Group (OPE)

- OPE.1 Operational use
- OPE.2 Customer support

ORGANIZATIONAL Life Cycle Processes

Management Process Group (MAN)

- MAN.1 Organizational alignment
- MAN.2 Organizational management
- MAN.3 Project management
- MAN.4 Quality management
- MAN.5 Risk management
- MAN.6 Measurement

Process Improvement Process Group (PIM)

- PIM.1 Process establishment
- PIM.2 Process assessment
- PIM.3 Process improvement

Resource and Infrastructure Process Group (RIN)

- RIN.1 Human resource management
- RIN.2 Training
- RIN.3 Knowledge management
- RIN.4 Infrastructure

Reuse Process Group (REU)

- REU.1 Asset management
- REU.2 Reuse program management
- REU.3 Domain engineering

The standard aims to assess the quality of the software life cycle processes and supporting processes. It also defines an Organizational Maturity Model which may be considered as a competence level for a company/organizational unit.
(min:0 - max:5)

Names and codes of the processes are defined in ISO/IEC 15504-5:2006.

SUPPORTING Life Cycle Processes

Support Process Group (SUP)

- | | |
|-------------------------|-------------------------------------|
| SUP.1 Quality assurance | SUP.6 Product evaluation |
| SUP.2 Verification | SUP.7 Documentation |
| SUP.3 Validation | SUP.8 Configuration management |
| SUP.4 Joint review | SUP.9 Problem resolution management |
| SUP.5 Audit | SUP.10 Change request management |

ISO/IEC 15504 SPICE Standard OMM Definition



Organizational Maturity Model Level	Minimum Set	Additional Processes	Regular Assessment Duration
1	ENG.1, ENG.4, ENG.5, ENG.6, ENG.7, ENG.8, SPL.2	ENG.2, ENG.3, ENG.9, ENG.10, ENG.11, ENG.12,	1 day
2	SUP.1, SUP.2, SUP.7, SUP.8, SUP.9, SUP.10, MAN.3, MAN.5	ACQ.3, ACQ.4, ACQ.5, SUP.3, SUP.4, SPL.3	4 days
3	RIN.1, RIN.2, RIN.3, RIN.4, PIM.1, PIM.2, PIM.3, MAN.2, MAN.4, MAN.6, SUP.5	REU.1, REU.2, REU.3	11 days
4	QNT.1 Quantitative Performance Management		Not happened yet
5	QNT.2 Quantitative Process Improvement		Not happened yet

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After obtaining the application and performing the assessment in scope, the assessment team agrees upon one of two possible outcomes which might be either:

- The company/organization achieved the relevant level of OMM and has fulfilled the necessary conditions for a certificate or
- The company/organization failed to achieve the applied OMM level due to various shortcomings such as lack of quality understanding, documentation, performance management (for level 2 or above), punctuality, competence or any other non-conformity

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In case of successful certification of the organisation; TSE also conducts periodic surveillance audits to all certified companies/organizations to prevent them from abandoning their newly gained skills, quality assurance and management experiences.

- Period is set to 18 months
- Consists of the collection of updated or contemporary evidence
- May use new projects for surveillance, but not necessary
- After this audit, TSE may suspend the previously granted certificate until any detected major non-conformity is corrected. In case of prolonged suspension, the certificate of company may be revoked.

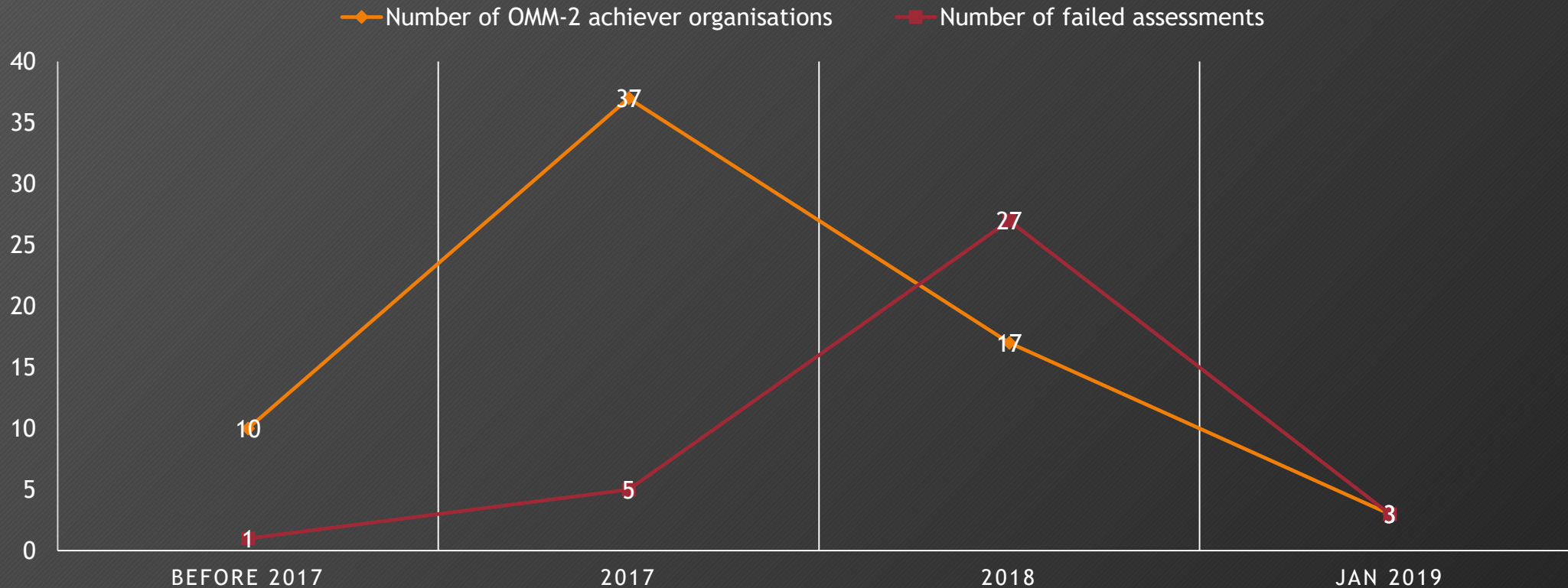
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Since it had inputs, tasks, expectations and outcomes; it was possible to consider the «SPICE Wave» as some kind of macro-process on its own.

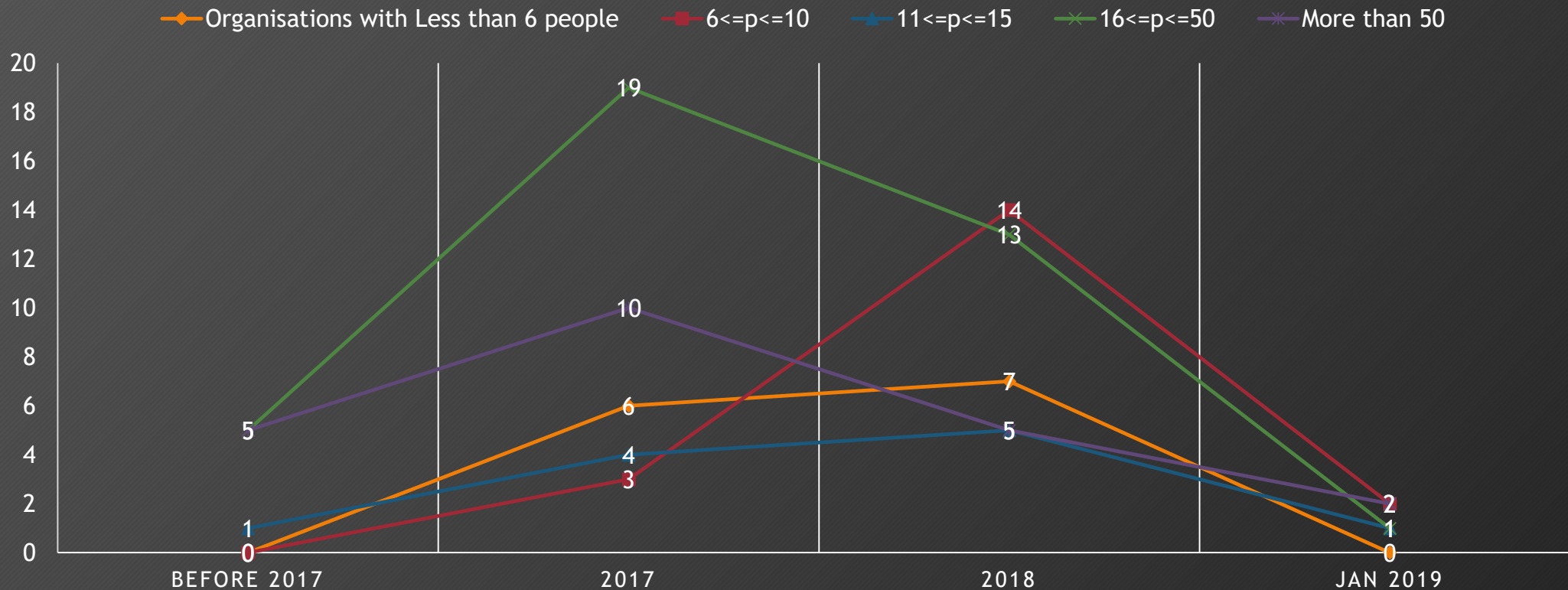
Inputs	Tasks	Expectations
Software Developing Companies and Organizations <ul style="list-style-type: none">• VSE (less than 25 people)• Non-VSE/regular	<ul style="list-style-type: none">• Apply for the certification	<ul style="list-style-type: none">• Obtain the certificate• Gain experience• Acknowledgement and prestige
Company Personnel	<ul style="list-style-type: none">• Work in accord to the standard	<ul style="list-style-type: none">• Gain experience and learn the standard• Complete the projects• Acknowledgement and prestige
TSE and its assessors	<ul style="list-style-type: none">• Train the companies• Plan the assessments• Perform the assessment	<ul style="list-style-type: none">• Gain experience• Develop the personnel• Improve the Certification Quality System of TSE
Projects		
Quality Systems		
Regulations of Ministry and TSE		

Assessment results for each year (OMM-2 assessments only)



*Relevant data obtained from Assessment Logs and Records of Turkish Standards Institution

Assessed organisations with the consideration of personnel numbers (OMM-2 only)

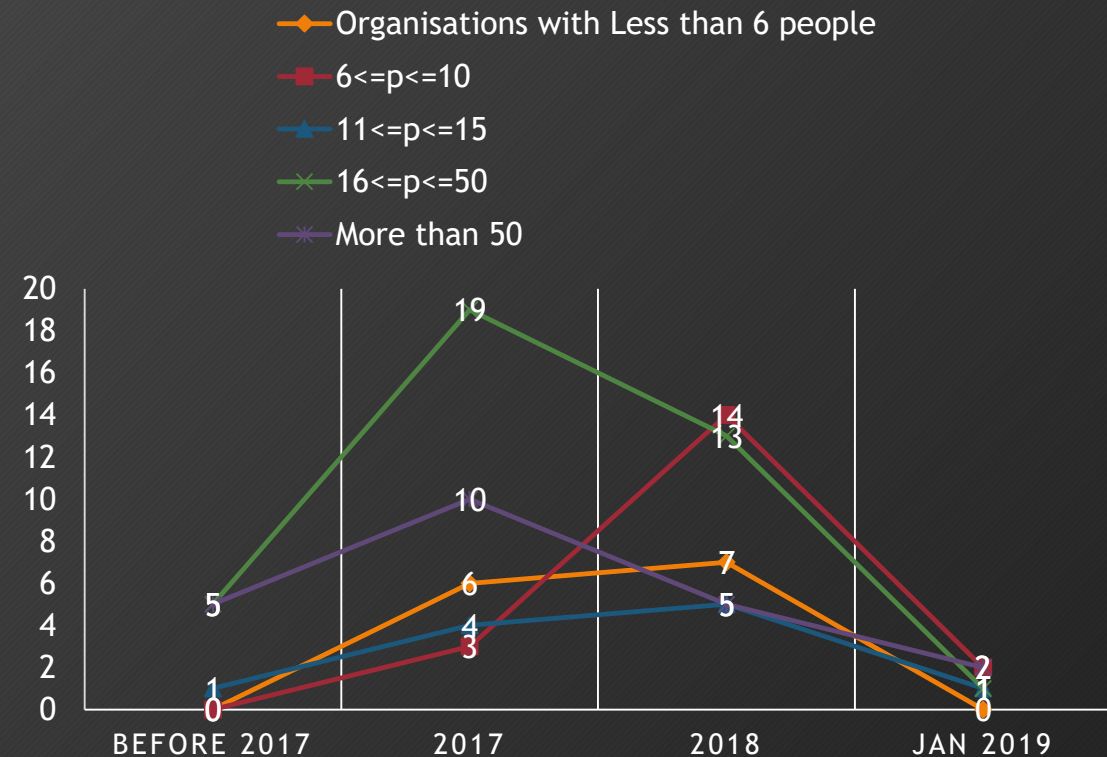
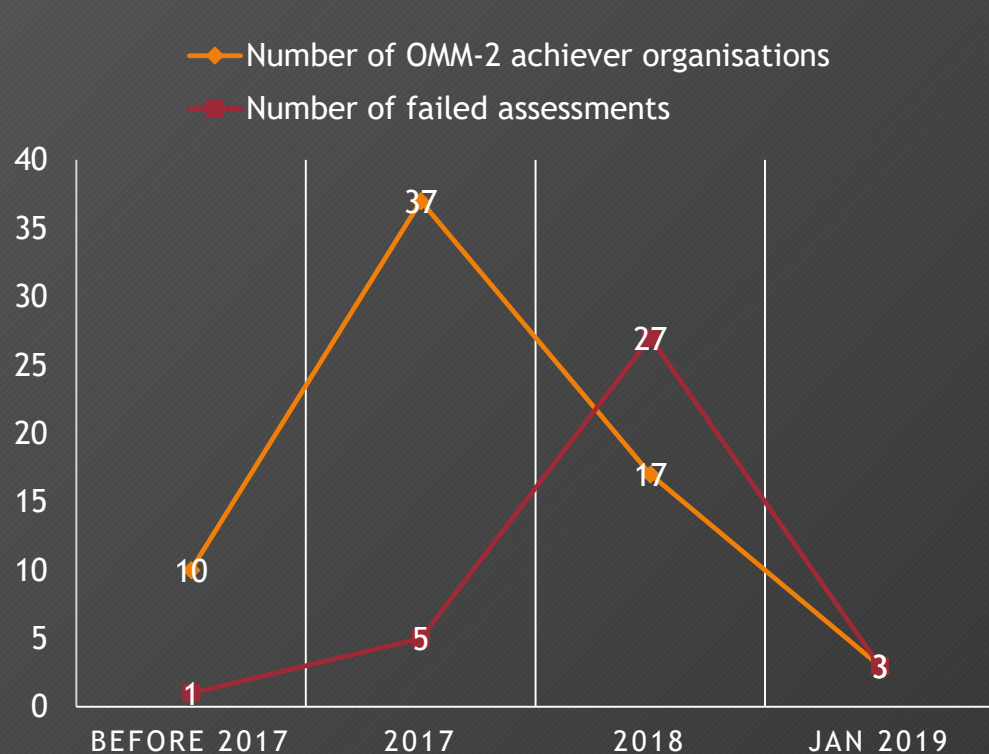


*Relevant data obtained from Assessment Logs and Records of Turkish Standards Institution

Success status of assessed organisations with the consideration of personnel numbers (OMM-2 only)



Any similarity between charts?



*Relevant data obtained from Assessment Logs and Records of Turkish Standards Institution

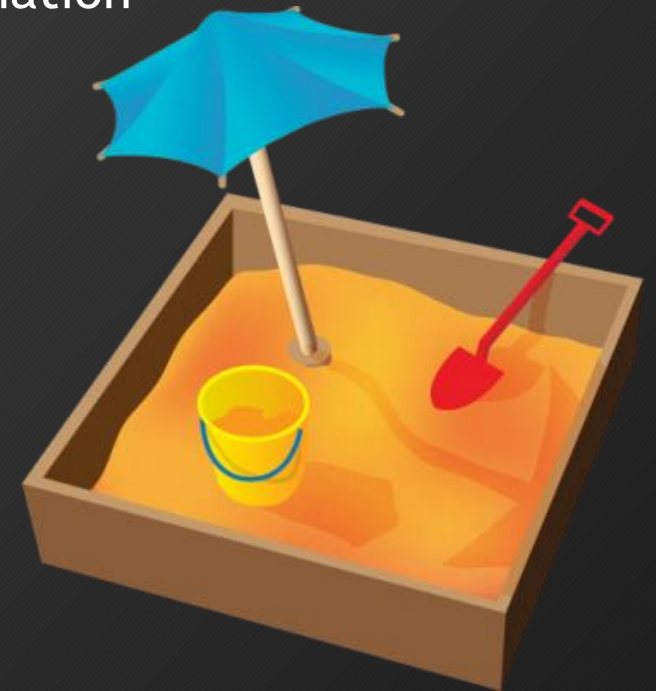
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Some key factors that affected the success of organisations in audits are:

- No prior experience of process management and formal documentation
- Lack of accreditation of related certification bodies in the previous quality certifications such as ISO 9000 and ISO 27001 leading of an underestimation
- Usage of an artificial or a inherited quality system, of which that the company is not really familiar with, and don't really use in their regular lives.

Like a "Sandbox"



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Some key factors that affected the success of organisations in audits are:

- The reliance to the consultancy services
- Lack of competence in the consultant companies
- The communication between the assessed companies and organizations

Frequently encountered weaknesses and flaws during OMM level-2 assessments of the Turkish SPICE wave



Reported Weakness (reported in more than 30 different organisations)	Process
Inadequate or misplanned periodization of project review and/or progression reports,	MAN.3
Risk management strategy defined are incompatible with the risk identification and analysis activities performed.	MAN.5
The production of internal/external audit reports that have no satisfactory knowledge inside. As the responses to most of the questions found in internal audit reports were simple exclamations like “yes”, “no”, “adequate”, ”done”; but contained no detail regarding the observation of the internal assessor or any descriptions, which is not appropriate considering the generic effective documentation recommendations stated by Doheny-Farina [15], indicating that an effective documentation should enforce the writer to more active participation.	SUP.1

Frequently encountered weaknesses and flaws during OMM level-2 assessments of the Turkish SPICE wave



Reported Weakness (reported in more than 30 different organisations)	Process
<p>For Verification, the unclear definition of scope for verification evidence, failing to provide an understanding of how profound the verification controls were. It was also not possible to understand what was the reason behind the positive or negative judgement of personnel who performed the verification.</p>	SUP.2
<p>For the Documentation process, having an impression that it is not possible to achieve organizational maturity without the documentation set provided by consultants. This also hinders the creativity, originality and consideration of a possible e-tracking system such as JIRA, Redmine, Microsoft TFS or another similar system; as recommended by Akman [16].</p> <p>Also some of the consultant companies influenced applicants to the usage of traditional e-documentation such as .doc files and .xls files. Through many audits, it was observed that the documents used in various non-related companies were similar or sometimes exactly same, minus the elementary definition data such as company name, project name and dates. This was due to the fact that the resource was the same consultant company, or as a consequence of plagiarism.</p>	SUP.7

Frequently encountered weaknesses and flaws during OMM level-2 assessments of the Turkish SPICE wave



Reported Weakness (reported in more than 30 different organisations)	Process
For Config. Management, a considerable amount of the applicant companies failed to distinguish Documentation tasks with Configuration. Thus when it is asked from them to describe their configuration strategy they tend to explain their documentation system. Some various important configuration elements used throughout the projects such as external libraries, database structure models, third party applications were not mentioned in configuration related work products.	SUP.8
The applicants structured their configuration items, backups and baselines influenced by this false impression which caused a great weakness in the process ratings.	SUP.8
When assessing testing related processes, it was observed that testing evidence displayed no detailed information regarding the test conditions, inputs and outputs of each test step.	ENG.7 ENG.8 SUP.7
Most of the companies couldn't manage to define a consistent numbering system for their products and the lack of distinction in "major" release, "minor" release or "patch" release definitions. Further interview with personnel didn't help to clarification.	SPL.2

Frequently encountered weaknesses and flaws during OMM level-2 assessments of the Turkish SPICE wave



Reported Weakness (reported in more than 30 different organisations)	Process
<p>The company failed to plan</p> <ul style="list-style-type: none">• The timing• The scope• The frequency of their performance objectives. <p>Reporting performance objective measurement result just once through the entire life-cycle, or evaluating it too early/too late.</p> <p>It was also a major issue for the companies to define performance objectives properly, as some of them were defined in a way to ask for a very elementary thing to be done or demanded a task which was more related to another process (like as an example ENG.8 Software Testing performance objective would be more related to SUP.7 Documentation).</p>	<p>OMM -2 Generic Practices</p>

Positive Outcomes of the Wave



- 67 out of 103 organisations (65%) have achieved OMM level-2 in their first attempt and managed to set up a common ground in terms of standardization, quality and quality terminology
- The rapid growth of certified medical IT companies has also influenced other IT companies that exist in various other sectors such as
 - geographical information systems (GIS)
 - IT technical service and assistance
 - enterprise resource planning (ERP)
 - forestation and husbandry IT management.
- For the ones successful in the assessments, certification led to an advantage in terms of competition.

Lessons to be learned...



Whole wave could have been planned and handled by all responsible parties in better ways; such as:

- Considering the approach of applicant companies, it would be better to carefully study the standard and not see it as a spinoff of ISO 9001. Even at the conclusion meetings, some companies implied that they see the standard as a plain documentation guideline, some of them didn't even bother reading the standard.
- The lack of attention is again, obvious, considering the results of surveillance audits of previously certified companies. 13 out of 28 ISO/IEC 15504 surveillance audits performed between December 2016 and March 2019 have negative results, indicating that the learned practices of SPICE standard were already forgotten or abandoned.

Lessons to be learned...



- Lack of experience and professionalism in some consultancy companies leads to questioning the adequacy of consultant companies and hint towards the necessity of a system for the consultancy competence certification for ISO/IEC 15504 or SPI.
- Possible summit meetings could have been organised by TSE to explain the requirements of the standard to most of the applicant organisations before their applications and assessments.
- Due to the unique role of TSE in Turkey, the institution could also have investigated the implementation and popularization of “serious games” prior the SPICE wave. It could have been helpful to improve the skills of company personnel. Serious games provide great learning opportunities for the participants so that they can experiment, learn from their own mistakes and acquire experience; without causing any considerable damage to the organizational resources or properties.

Lessons to be learned...



- The benefit of the regulation decreed by the Ministry of Health of Turkey is open to dispute. To provide an initial step towards formal and organizational quality in small scale companies, a standard that focuses on to the process quality in Very Small Entities such as ISO/IEC 29110 [21] could be a more useful alternative instead of ISO/IEC 15504 SPICE, as in most of its profile definitions it has less processes instead of minimum 15 processes in ISO/IEC 15504-7 OMM level-2, which makes it easier to understand and adapt by the small-scale organizations.
- The selection of large-scale standards was possibly due to the fact that ISO/IEC 29110 is mostly unknown in Turkey. This issue can be considered as a problem derived by the neglect of research by the relevant parties such as Ministry of Health.

ISO 29110

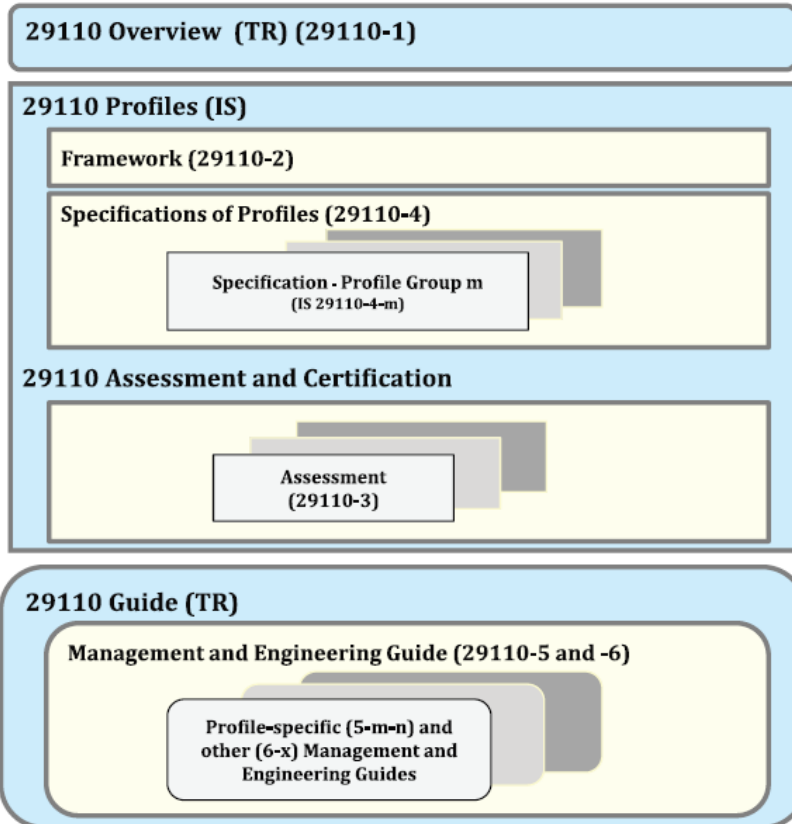
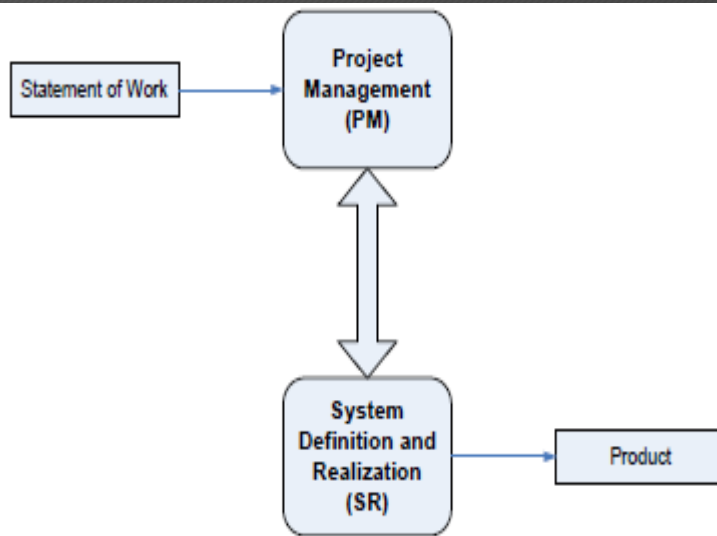


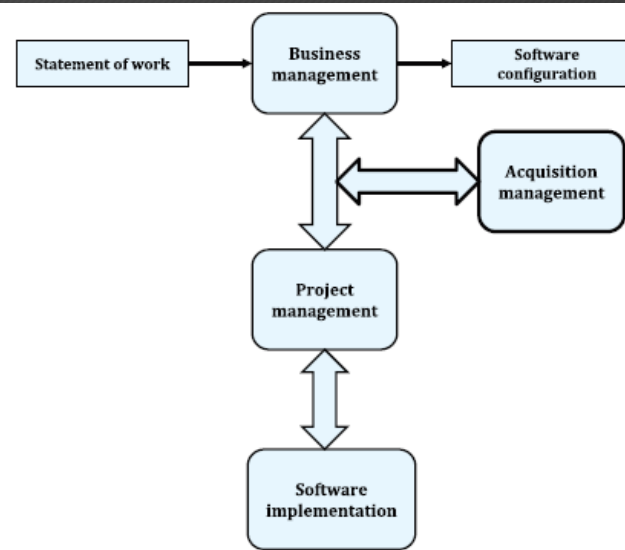
Figure 1 — ISO/IEC 29110 series

A standard with a different approach to maturity, with various process profiles defined which can be aligned to organisations with different sizes.

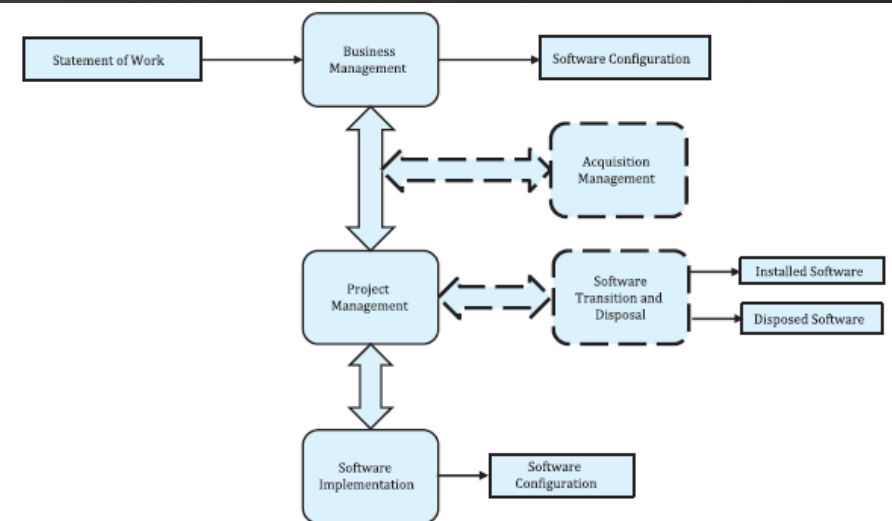
ISO 29110



Entry Profile Processes



Intermediate profile processes



Advanced profile processes

Thank you all for listening 😊



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