**Independent Assessment Management Tool**

Concept Specification

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# Introduction

## Objective

The objective of this document is to define de concept phase of the Independent Assessment Management Tool software.

## Abbreviations

|  |  |
| --- | --- |
| IA\_ORG | Independent Assessment Organization |
| C\_ORG | Client Organization |
| CENELEC | Comité de Normalisation Européenne |
| CSM | EU regulation “Common Safety Method” |
| IEC | International Electrotechnical Commission |
| ISA | Independent Safety Assessor |
| ISO | International Organization for Standardisation |
| KPI | Key Performance Indicators |
| MIL (std) | United States Military Standards |
| MS | MicroSoft |
| OS | Operating System |
| Q&S | Quality & Safety (part of Viattech company name) |
| RAMS | Reliability Availability Maintainability Safety |
| SQL | Structured Query Language |
| SW | Software |
| XML | Extensible Markup Language |

## References

### Internal References

| **Title** | **Reference** | **Revision** |
| --- | --- | --- |
| 1. Viattech Quality Manual | VIAT-QA-MNL-001 | 2.0 |
| 1. Procédure – Audits externes, Inspections & Evaluation de la Sécurité | VIAT-QA-PROC-07 | 2.0 |

# About Viattech Q&S

## Introduction

Viattech is an engineering and consultancy company specialized in the field of system and RAMS services covering the complete project life cycle.

We know that in the current competitive market environment, the only way to stay ahead of the competition is by innovating and developing of team competencies. Therefore -and since several years- Viattech invests heavily in the development of innovative tools and in house training of qualified staff in the domain of system and RAMS engineering.

Viattech company has the following main values and principles:

* Long term client satisfaction;
* Provide real added value to our clients;
* Integrity;
* Target oriented;
* Highest standards of quality on our services and deliverables.

## Structure of the company

### Organisation

The company is structured in 3 operational business offices as illustrated in the figure below (réf. [1]).



* Engineering (RAMS and system consulting and studies, tools development and R&D)
* Audit & Assessment
* Training

### Consulting RAMS and system

This activity, part of the Engineering office, provides engineering and consultancy in the RAMS domain, system/product modeling, system development process and methods, demonstration of standards requirements using a set of technics, best pratices and experience.

As RAMS domain is highly regulated by many different standards and those standards include procedures and methods derived from engineering development best practices not only for RAMS but also for design, verification and tests.

Our engineers have significant experience in the process and methods required to implement complex systems/products developments. They follow internal training cycle and seminaries at Viattech offices by our Training office.

Our engineers expertise are spread throughout all the V cycle phases (concept, system requirements and (semi-)formal modeling, system architecture, implementation, hardware and software design) as well as during the ascending branch of the V cycle (hardware/software tests, hardware/software integration tests, system integration tests and validation tests, acceptance).

Some of our engineers are more system oriented (functional specifications/modeling/ architecture design) and others are more product oriented (hardware & software development).

Our consulting services include the following type of missions:

* **System and RAMS studies:** based on systematic RAMS analysis methods and technics, our consultants carry out the necessary activities to identify and mitigate the hazardous and unavailability risks such that the demonstration of the specified targets can be achieved. The main objective of these studies is to analyse the cause and the consequence of each potential failure mode of the designed system and to assess their criticality based on pre-defined criteria. Our Engineers are able to use (semi-)formal methods and tool for modeling systems and process behaviors so that it can be used for systematic RAMS analysis, detail design, verification and testing purposes.
* **Safety Management:** based on the applicable standards, our experience and the safety assurance program of our clients, our consultants manage the RAMS activities in order to achieve the products and systems certification/homologation (RAMS assurance plan, Hazard Log report, Hazard Analyses, elaboration of Safety Case/ Homologation dossier, interface with integrator).
* **Consulting & support to develop and implement a RAMS assurance program and system development process methods:** we help our clients to put in place an organization, processes, structured methods and tools to achieve their RAMS and development targets including system V cycle approach of working.

### 

### Audit and Assessment

This service includes safety assessment and certification in accordance with the applicable standards (CENELEC EN50126/50128/50129, CSM, MIL, IEC or others).

In addition to reference standards, we base our approach in our experience on real projects and the most important issues affecting RAMS.

Our safety assessments are based on a dual approach (réf. [2]):

Safety Audits (assessment of safety management): this phase consists in interviews with the development team to better identify and understand his competences and the real applied processes, that could be different from the ones referenced in the project documentation. This kind of audit is an useful and efficient way to discuss some open points and to find a way to solve them.

AND

Documentation Review (safety technical assessment): during this phase, a detailed and critical review of the key documents as design specifications, tests specifications, technical procedures, tests reports, RAMS analyses, etc. is performed.

The main differentiation between our approach and the approach of others is that we are able to assess technically if a product and system has reach its intended RAMS targets whereas others will only base their opinions on the full compliancy to standards and full set of documentation (paper work).

### Software tools and products

This activity, part of the Engineering office, is in charge of the development of innovative RAMS methods and software tools. Since several years, our team is involved in the development of a platform of an Integrated RAMS Management System (IRMS).

Used in our client’s premises, the IRMS tool increases substantially the standardization of methods as well as the collaboration between the development team and the RAMS team. The project RAMS analyses are carried out in a consistency basis by sharing common and relevant information between the different IRMS modules.

The available IRMS product (BL2) is composed of the following components/functions

* C0 – This is the core of the IRMS system. This component is responsible to provide all system services to the other components/functions (define project, access right, events log etc)
* C1 – Hazard risk management. This component is responsible to help the safety engineer for managing, controlling and reducing hazardous risk to an acceptable level.
* C2 – Qualitative Hazard Analysis. This component is responsible to help the safety engineer to perform the main qualitative safety analyses (FMECA, FMEA, PHA, SHA, HAZOP, IHA etc).
* C3 – Reliability Prediction of Electronic Equipment. This component is responsible to calculate the reliability values of electronic components, boards and products.

For more details about IRMS® platform, please refer to §**Erreur ! Source du renvoi introuvable.**.

### Training

This service, provided by the Training office, includes the development and maintenance of the training courses and tools. The training courses are carried out continuously for the internal needs of Viattech engineering staff and proposed to the clients as well.

The training program is composed of several modules:

1. Introduction to dependability and safety assurance
2. Risk Management Process through the project lifecycle
3. RAMS analysis methods and techniques
4. Safety demonstration method (safety case)
5. IRMS® platform

The content of the training modules can be adapted based on the specific needs of our clients.

# Independent Assessment Management Tool

## Introduction

Many Standards ISO, IEC, CENELEC, Yellow Book etc. require an Independent Assessment / Certification (Safety or Not) of a given product, system, organization etc.

The objective of the independent assessment is to verify if the assessment target meets the requirements of the related standards.

Regarding safety related standards, commercial operation of products is based on a positive assessment report form an IA\_ORG.

## Independent Assessment Process

Independent Assessment is generally performed using two main techniques:

* Audit: the IA\_ORG interview the project team and verify that organisation, skills, procedures, methods are applied effectively based associated project plans, company procedures and methods;
* Document assessment or Inspection: the IA\_ORG will assess or inspect documentation or technical installations, in order to verify if procedure, methods, technics, design etc. are in conformity with standard requirements.

During Independent Assessment, the IA\_ORG provide observation and sometimes recommendations in order to comply with applicable standards. Each observation is associated to a severity level.

For each observation, the Client Organization (CO)) has to provide detail answers and scheduled action plan to the Independent Assessor (IA) so that deviations from the standards are eliminated or reduced to acceptable level.

Only when all or a specific number of sever deviations are addressed properly, the IA is able to produce a final assessment report and certification.

The assessment activity generally involves the transmission of significant amount of evidence in many type of formats (documentation / photos etc.).

## State of the art

As indicated above, many standards require an IA. Some of those standards have specific requirements regarding the IA procedure and methods.

Currently each assessment body has its own procedures, methods and tools for the implementation of an IA program.

The assessment tools are represented in most cases by basic templates implemented in MS Word or MS Excel.

Based on our independent assessment work experience, the using such tools have significant disadvantages and have significant impact on the quality and productivity both of the IA and CO.

## Objective

Following many years of cumulated experience in independent assessment and RAMS engineering, a significant amount of potential improvements have been identified regarding the implementation of the IA process and methods used in this field.

As existing basic tools couldn’t satisfy those potential improvements, we have therefore identified the opportunity to develop of an innovative tool that would meet our criteria and improve significantly the productivity, the consistency and quality of the IA and CO outputs.

This concept document identifies a number of significant improvements in §3.5.

## 

## Needs & issues and associated Requirements

The table below identifies needs and issues arising from assessment activities which are a target for substantial improvement by implementation in a specialized tool:

| **Id.** | **Issues description** | **Effect** | **Solution** |
| --- | --- | --- | --- |
| 1 | IA\_ORG templates | Bad image of the IA\_ORG, errors of references within IA\_ORG documentation, errors in the format templates => this creates ambiguity and a feeling of amateurism. | Creation of function which allows the IA documentation to follow simple, automated and structured templates including a unambiguous documentation reference management preferably automated or semi-automated. |
| 2 | Storage IA\_ORG documents | IA\_ORG documents are lost;  wrong versions are used;  C\_ORG claim to have sent a document but the document has never been received;  Those issues create situations in which CO delays are produced with loss of confidence between IA and CO.  The findings or observations raised upon obsolete CO documents are interpreted by C\_ORG as useless and with poor quality. Issues that should have been detected have not or have been detected too late. | Storage function which allows for precise and unambiguous storage of CO documents and easy access to this documents anywhere any time.  Real time information on the availability of documents (email, USB etc exchanges is banned).  For each finding, one or more links should be allowed to a document reference, document electronic copy and its version.  Locking mechanism to avoid changes on documents associated to findings when IA as locked the finding state. |
| 3 | Access rights | It is common practice that an IA produces a list of findings/ observations in word or Excel and asks the CO to answer those findings and observations. This is normally performed by sending a file (word or excel) to which the CO has then to input data on it and send back to the IA.  In order to avoid changes in the IA file by the CO on parts which can only be edited by the IA, this last normally insert file protections on part of the documents. When dealing with Excell files, this can be tricky, as sometimes the CO would like to add lines, columns and other details without asking for the IA a new file etc.  For example: IA observation files may be transmitted to unauthorized third party violating clauses of confidentiality.  Excell / Word protections may be bypassed and IA data/text may be intentionally or unintentionally updated, deleted or inserted. | Create a function that limits the rights of the CO to modify parts of the findings/observations forms. This function shall be accessible any time anywhere.  Assign rights to IA such as Project Manager / Lead Assessor (LA) / Assessor.  CO Client role is allocated to the parts of findings which are editable by the CO.  The LA is the only one with rights to close findings or change the severity.  Create independent assessment projects entities so that only IA and CO users associated to a given independent assessment project can access it. |
| 5 | Version management | It is common practice that an IA produces a list of findings/ observations in word or Excel and asks the CO to answer those findings and observations. This is normally performed by sending a file (word or excel) to which the CO has then to input data on it and send back to theIA.  In order to trace the progress of the various interactions Observation (OBS) /Answer (ANSW) between CO and IA, a version is added to the file at each interaction. This is performed by the IA, but as it has to be performed manually.  The manual manipulation of version causes many unexpected errors such as transmittal of an obsolete file with a correct version name, non-update of file statistics with a correct version name, unintentional modification by CO of the file version and file name. | Each interaction between IA / CO should be versioned and this version being incremented.  An event driven function should allow the LA to freeze a finding list and in this event, a version is incremented.  This function should be provided in the same way.  A state machine should define the allowed transitions between states and version increment of findings. |
| 6 | Progress report | It is common practice that an IA to produce a list of findings/ observations in word or excel and ask the CO to answer those findings and observations. To show the progress of the evaluation and the CO answers and document submittal, it is common that the IA produce a progress report, listing the number of open points and their severity.  If this is performed, it has to be done manually. This is a source of many errors and requires some time to get it right each time there is a version release. | Implement a reporting function which allows with the click of a button to provide different types of Key Performances Indicators (KPI).  These KPI should show the amount of evaluated documents, the number of each severity open, the amount closed and the amount not applicable.  An examples of KPI is the amount of evaluated documents; the amount of observations classified by their status (opened/closed) and/or their severity and/or if they are applicable or not.  Provide a table which shows all documents inserted in the tool the delivery date of each version inserted and their status.  Provide facilities to allow the production of a report with additional data based on SQL Queries on any condition required by the IA\_ORG. |
| 7 | Data entry errors | During the findings process is common for the IA and CO to make data entry errors such as:   * Wrong answer date; * Wrong document reference or version; * wrong observation reference id numbering * duplication of findings (copy/paste) issues * omissions and etc. | To implement data entry filters and consistency checks. |
| 8 | Transfer of findings and answers | As indicated before the transfer of findings in performed via files. This can generate a time lag in case of lost of mail, error of address, person in charge of distributing the file being in holidays. | To avoid delays due to inherent multiple failures during transfer of files, a solution must be provided to allow the access of both IA and CO to the findings/observations forms at anytime and anywhere such as with a web browser via a secure network environment. |
| 9 | Activity sequence control | The findings/observation forms are structured in a way that the progress of a finding closure is followed in a precise way. This includes the interactions between IA and CO, the findings closure states, the actions, the corrective actions proposed etc. | To build in the tool a generic process flow for findings with step by step controls and restrictions. |
| 10 | Keep track of changes | When findings/observation forms are used and versions are implemented, it is common that IA has difficulty to trace the changes on their own documents. This is clearly a ISO issue and if implemented, very time consuming | To build an History log function that logs all modifications in findings/ Observations.  Build a function which give to the user each finding which is related to a given document or document version.  Build a function to group findings by topics.  Build a function to track changes between two consecutive versions of findings and record it in an amendment record |
| 11 | COTS compatibility | Many files used in assessment process are built in Excel file using Macros. Microsoft is known to have huge issues with backwards compatibility of Excel files each time there is a new major release. Consequence: updates in the IA or CO versions of MS tools may corrupt the exchange file or make to MACRO unusable causing significant loss of time and energy. | Build the tool in a foundation which ensures backwards compatibility or at least strong support for it. |
| 12 | Report templates | Existing tool templates may not be optimal to CO. Some CO may require different report formats etc.  As the tool can be sold to any assessment body, the reports templates should be configurable as well as the logo etc. | Build a function to customize reports. |
| 13 | State of the art | As the tool can be sold to any assessment body there should be an investigation in common data elements between assessors of different types. | Perform an analysis of assessment standards IEC/ISO to capture requirements related to elements an assessor must log in a finding |
| 14 | Inclusion of photos, or any files produced by C\_ORG during assessment activities | During an audit, a finding may be raised which need to support of evidence produced by the auditor (photo of an item referred in a finding). This is sedum possible using current custom tools. | Build a function which allows the evaluation team to add any type of file produced by IA\_ORG associated to a finding. |
| 15 | Language issues | Templates are language based and sensitive to any language changes. Text entered by the user may be language proof by wrong text corrector or language corrector plugin is absent. | Language selection is provided on real-time and user selectable. Language proving is based on built-in web based agent based on language selection |
| 16 | Issues with how to use templates by C\_ORG | CO has many issues to use IA tools and many times end up by doing unintentionally errors that can cause data loss or transmittal of file version with answers entered in wrong fields, wrong data information, insufficient evidence, wrong timing for answers (answering only part of a file whereas all observation need to be answered) etc. | Provide workflow management and localized help function and well as error reports. |

## IA Tool concept

Based on the analysis of the previous section, the following concepts can be defined:

***Hardware/ Architecture/ Software:***

* The IA tool should be based on a distributed architecture (client / server).
* The Server side should be configured for high availability.
* The tool shall be accessible any time anywhere;
* The client side should be Web interface based.
* The software running on the server side shall be reliable and shall be fault tolerant to any perturbations resulting in data corruption.
* The interface between the server and the client shall be protected against hacking, masquerade.
* Software shall be maintainable, low obsolescence risk, standard and widely used in the industry.

***Functions:***

* As IA activity is process based, the tool shall incorporate business workflow with verification and validation steps
* Versioning at each main step of business workflow
* Access rights based on project and roles
* Logging function with minimal administrator interference
* Possibility to add attachment of any evidence from CO or IA at each step of the workflow and to each observation.
* Baseline management
* Data entry consistency check and filters, to avoid data entry errors or inconsistencies.
* Locking or unlocking parts of data and access to some functions based on the state of the workflow or on user input.
* Customization of reports and specific queries for text and KPI reports with client log etc
* Customization of KPI reports including graphical contents
* Customization of forms and allowed data entry based on specific IA methods such as the number and identity of severity levels, observation reference id etc.
* Include collaboration forum where information between IA and CO can be exchanged outside the formal IA exchange.
* Include calendar function associated to a project where IA and CO can exchange forecasted update dates.
* Grouping of projects by clients.
* Specific logging view depending on CO user rights
* Detail entry history, to recover any data update and the origin of the update (user responsible).
* Search tool which allows to find a string of text in all observations objects for a specific project.
* Real time language support for N languages and user dynamic selectable language.
* Mobile device compatible web interface (Ipad like)
* Help function to support CO users to complete theindependent assessment forms and workflow process.
* Error messages when the user attempt to perform an action that is not allowed as per the workflow or any predefined consistency violation.

## Reuse of existing development

The development of this tool can benefit from Viattech Q&S experience in the development of IRMS C0, C1, C2 and C3 project.

All Hardware/ Architecture/ Software high level requirements specified in §3.6 are already implemented in IRMS tool. Therefore, Viattech Q&S can reuse this basis for IA Tool.

Regarding independent assessment tool functions, some elements from IRMS can be partially reused as the data entry history, project / user /roles allocation, loggin procedure, error message principle (used in C2 and C3) and locking and unlocking principle.

Some functions are completely new as:

* business workflow with verification and validation,
* search engine,
* grouping of projects,
* HMI (completely different using other COTS),
* calendar function,
* collaboration forum,
* customization of reports, database and queries
* management of attachments in an object form etc.

## IA Tool Development Process

Viattech Q&S is committed to deliver good quality products to its customers. The IAMT platform will be developed following a V cycle process and best practices recommended by IS0 9001 §7.1. The main phases of development are the following:

* Research and capture of requirements on the state of the art and relevant standards;
* Requirements specification and functional design;
* Traceability of the relevant standards requirements with the functional design specification;
* Software architecture design and coding;
* Code testing;
* Designer functional tests;
* Formal functional tests and traceability to requirements;
* Release note.

## IA work flow concept

Based on our experience in the IA field, we have identified key generic phase and business workflow when performing IA work.

This generic high level workflow is included in the figure below:



## IA Work Flow supported by IA Tool

IA generic workflow supported or implemented in the IA tool is shown in blue in the figure below.

The activities with the doted rectangle can be repeated N times depending on the project complexity and size.



## IA Tool appeal

***For our clients***

We estimate that the market for this type of tool is quite big if considering ISO, CENELEC, NOBO activities in Europe and elsewhere.

As the tool can be customized by the user, there is a possibility to adapt to a specific workflow, report, KPI used by the IA.

The IA tool would have significant pricing power due to the following reasons:

* No equivalent tool in the market;
* Significant gain quality; standard and professional outputs;
* Significant gain productivity; reduced manual inputs, manual checks, data manipulation errors, versioning errors, transmittal errors, access anytime anywhere etc;
* User experience; data entry is always performed in the same way, help functions guide the user and avoid rework, same data is available real-time to all users etc;
* Reduced risks compared to existing methods data corruption , unintended or intended breach of confidentiality clauses); full redundancy of storage and backup, access rights on users, functions, reports as well as event history with who did what, when and with which computer;

***For our Viattech Q&S IA division***

As per the same reasons as above, we estimate that the gain in man/hours will be equivalent to 20% of the costs of each IA mission (productivity increase, cost of non-quality). This does not include the following indirect gains:

* Client satisfaction and market advantage as the C\_ORG will be provided with a professional tool which will allow them also to reduce costs and increase the assessment speed and quality;
* Viattech Q&S image and reputation;
* IA misson cost reduction increases the competitiveness of Viattech and consequently the maket share.

## IA Tool benefits to Brussels

As for IRMS, IA tool commercialization will require R&D resources as well development resources. But the most important impact to the region is in case IA tool is commercialized in Europe or beyond. In this case, tool evolution, sustaining, maintenance, IT management, will generate 1 to 2 additional full time resources (software and IT).

In addition to this direct gain, Brussels should gain by having a high tech company known beyond Belgium and contributing to Brussels image abroad.