# SAFETY CASE (PROJECT AND UNIT)



## QualaTech Aero Consulting Ltd. An international aviation consultancy group, providing services in:

Safety Management Systems (SMS), Management, Training, Change Management, Fatigue Management, Hazard Ident. & Risk Assessment, Safety Case, Harbour and Water Airport/Aerodrome Procedures, Emergency Response Procedures, Airports, Flight Operations, Compliance & Safety, Audits, Aircraft Maintenance Organisations (AMO), Human Factors, Manufacturing, Quality Assurance (implementation, design and audit), Training (QA, SMS, HF, ERP/AEP, Haz. & Risk Assessment).

The services offered by QualaTech-Aero Consulting Ltd. are focused on the aviation industry. However, the principles of Human Factors, Safety, and Quality, apply equally to any industry by reducing human error leading to personal injury and loss.

Safety Management is Business Management!

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### **QualaTech Aero Consulting Ltd.**

The documented result of Safety Assurance is often known as a Safety Case – particularly for <u>new</u> systems and procedures. It is a documented body of evidence that provides a demonstrable and valid argument that a system is adequately safe for a given application and environment over its lifetime. A Safety Case can also be envisioned as an extension of a truly effective Safety Management System (SMS).

A 3rd. Party proactive approach to a Safety Case whether a 'Unit' or 'Project' will significantly help reduce error and loss, which includes: incidents, liability, injury, accidents, death and loss of profit.

### The Safety Case:

It is imperative that an adequate and comprehensive Safety Case is produced specific to a system and or a process to demonstrate the overall safety of that particular system. A Safety Case is a "living document" which evolves over time in association with the safety life-cycle of the operation. The Safety Case records the safety argument, the basic structure of which will remain similar throughout the Safety Case's evolution – regardless of how much the status of the evidence changes and evolves over time. A Safety Case can be divided into several documents (e.g. covering specific subsystems) which would in turn refer to supporting documents such as: design documents, operating procedures, audit reports, corrective actions and other quality documents, reports and tests, etc.

Typically there are many variants of a Safety Case, but most, if not all, fall into one of two categories as follows: those which are used to demonstrate the safety of an on-going service – are known as a <u>Unit Safety Cases</u>; and, those which are used to demonstrate the safety of a substantial change to that service (and/or underlying system) – are known as <u>Project Safety Cases</u>.

**Unit Safety Case (USC):** An organisation may decide to produce or maintain a Unit Safety Case in order to show that the on-going, day-to-day operations are safe and that they will remain so indefinitely. A Unit Safety Case would include typically a prior safety assessment (to show that a service and/or system is predicted to be safe), together with the results of safety audits, surveys and operational monitoring (to show that up to that point in time, it actually has been safe). It should also demonstrate that processes are in place to ensure that all future changes to the system and/or processes etc. will be managed safely through (*inter alia*) a Project Safety Case.

**Project Safety Case (PSC):** An organisation may also decide to produce a Project Safety Case when a particular substantial change to an existing safety-related service and/or system (including the introduction of a new service and/or system) is to be undertaken. A Project Safety Case would normally consider only those risks created or modified by the change and rely on an assumption (or <u>evidence from the corresponding Unit Safety Case</u>) that the pre-change situation is at least tolerably safe. A Project Safety Case is normally used to update and is usually subsumed into a Unit Safety Case.

A Safety Case simply stated, is the documented assurance (i.e. argument and supporting evidence) of the achievement and maintenance of safety. It is the primarily means by which those who are accountable for service provision or projects assure themselves that those services or projects are delivering (or will deliver) and will continue to deliver, an acceptable level of safety.

In the context of a SMS, the Safety Case can also be employed as a means of documenting and recording the 'effective safety' of a service and/or system. Conversely, the implementation of a SMS provides evidence to support a Safety Case. Although many Canadian Certificate Holders have a functional SMS in addition to a competent and comprehensive Quality Management System (QMS) as mandated under the Canadian Aviation Regulations (CAR), a Safety Case is nevertheless, a critical sub-component of those systems. However, in Canada the Safety Case has only recently become common practice since it was endorsed by the former Minister of Transport – The Honourable Denis Lebel P.C., M.P..

Since a primary objective of safety regulation is to ensure that those who are accountable for safety discharge their responsibilities properly, then it follows that a Safety Case - which also serves the above purpose, should moreover assist as a means for verifying safety requirements. Nevertheless, the development of a Safety Case is not an alternative for a Safety Management System or conducting a rigorous 'Safety Assessment', rather, it is a means of structuring and documenting a summary of the results of the Safety Assessment process along with other activities (e.g. simulations, surveys, etc.), in a way that a reader can readily follow the logical reasoning as to why a change (or on-going service) can be considered safe.

#### **Principles of a Safety Case:**

A Safety Case is built upon the following three principles:

- 1. Those who create risks are responsible for controlling those risks.
- 2. Safe operations are achieved by setting and achieving goals rather than by following prescriptive rules.
- 3. All risks must be reduced such that they are below a threshold of acceptability.