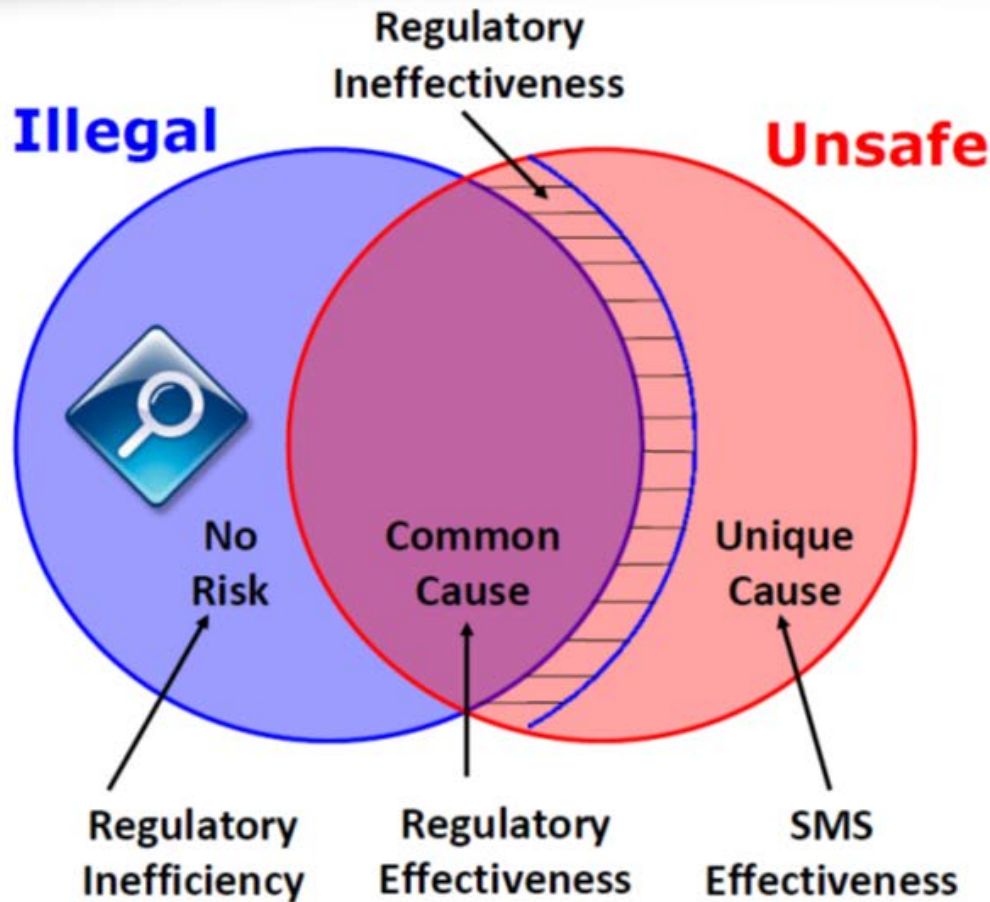




ICAO QMS WORKSHOP

Module 8 – Interface with Safety Management

REGULATORY INEFFECTIVENESS

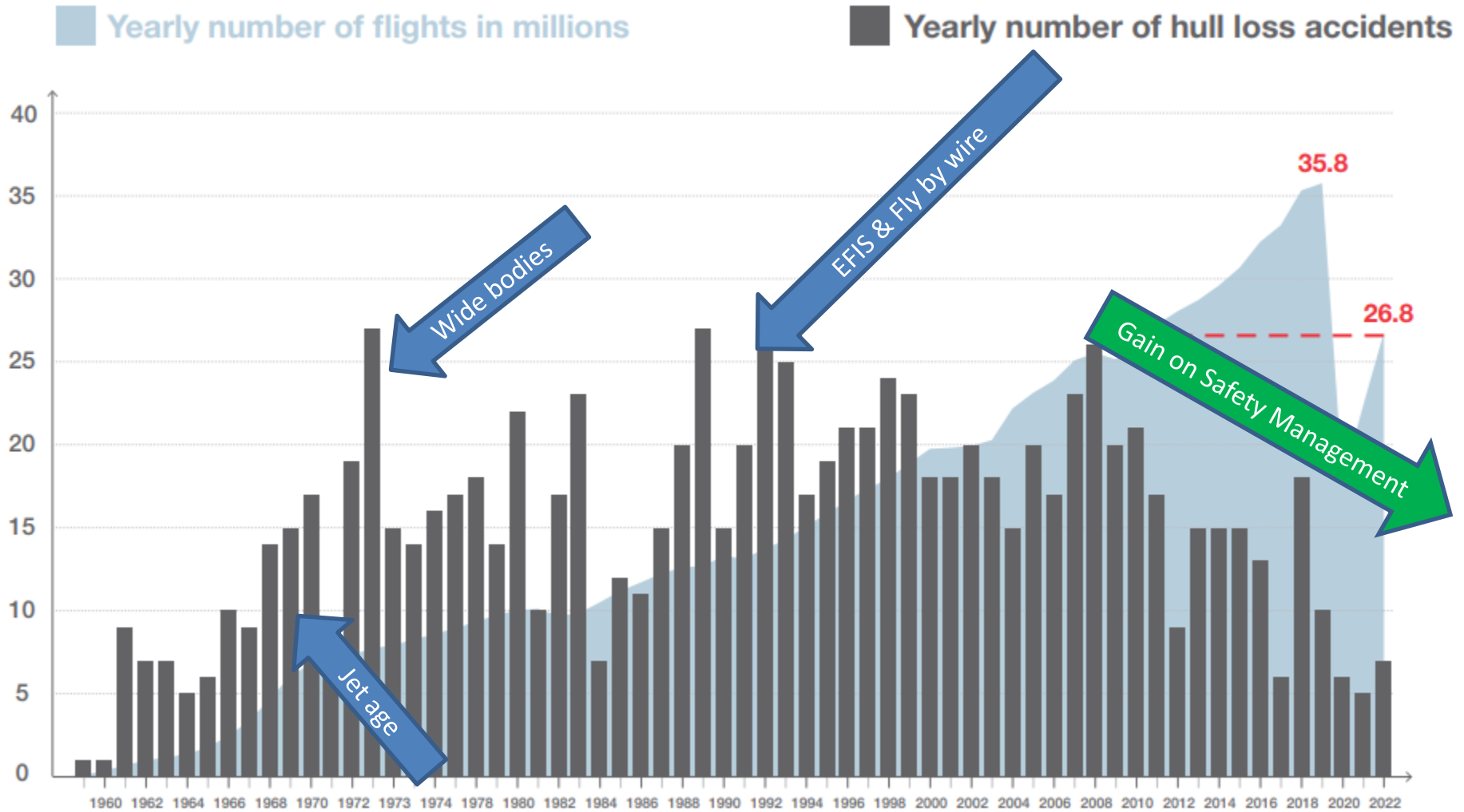


Regulation and standards are intended to enhance safety (or quality) of a product or service.

However, there might be regulated areas, which do not provide benefit (overregulation) and other areas, which are not covered.

For those areas an effective SMS/QMS will ensure safety/quality through its management processes.

GAIN ON MANAGEMENT SYSTEMS



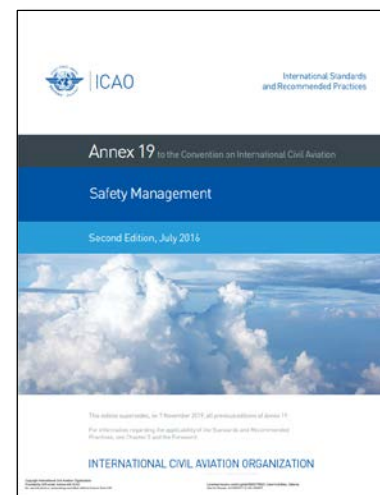
Source: Airbus

ICAO APPROACH TO SAFETY

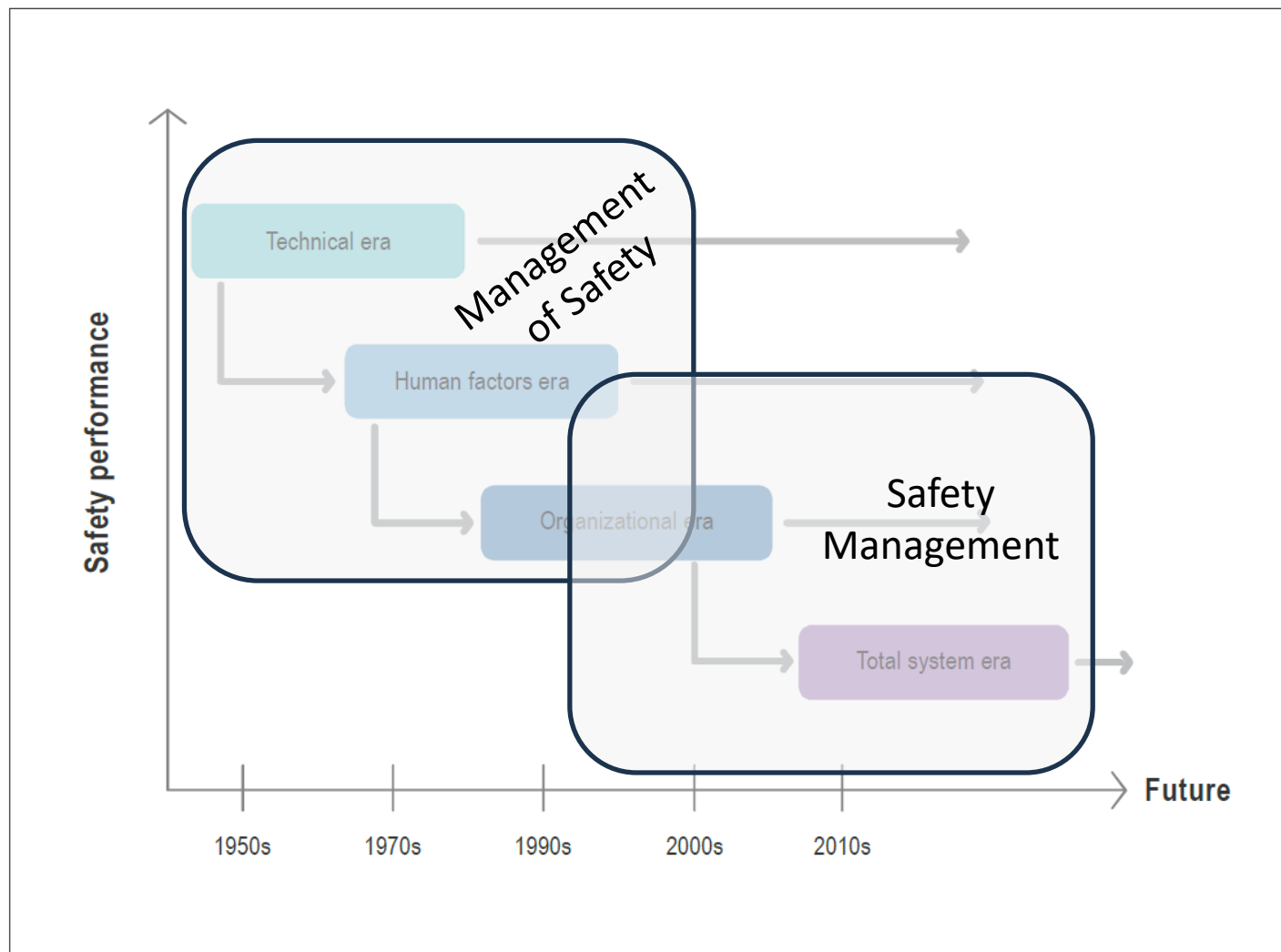
Safety is a core value-offering of rapid and dependable air services, and international cooperation on aviation safety by governments and industry groups, through ICAO, has helped to make commercial aircraft the safest way to travel.

The 193 countries who cooperate through ICAO are currently working toward their agreed **global safety target of zero fatalities by 2030**, in tandem with the strengthening of their regulatory capacities, while pursuing a range of programmes and targets relevant to current core areas of **global aviation safety planning**, oversight, and risk mitigation.

They are also working to enable the safety standardization needed to integrate today's exciting innovations in aircraft propulsion, design, autonomous control, and personal mobility, while still maintaining or improving overall network performance.



THE EVOLUTION OF SAFETY



© ICAO, Doc 9859

ANNEX 19

CHAPTER 4. SAFETY MANAGEMENT SYSTEM (SMS)

Note 1.— Guidance on implementation of an SMS is contained in the Safety Management Manual (SMM) (Doc 9859).

Note 2.— An organization may elect to extend one SMS across multiple service provider activities.

- ▶ Transposed through European regulations
- ▶ Implemented by organisations
- ▶ Oversight by national authorities (except DOA)

4.1 General

4.1.1 The SMS of a service provider shall:

- a) be established in accordance with the framework elements contained in Appendix 2; and
- b) be commensurate with the size of the service provider and the complexity of its aviation products or services.

4.1.2 The State shall ensure that the service provider develops a plan to facilitate SMS implementation.

4.1.3 The SMS of an approved training organization, in accordance with Annex 1, that is exposed to safety risks related to aircraft operations during the provision of its services shall be made acceptable to the State(s) responsible for the organization's approval.

4.1.4 The SMS of a certified operator of aeroplanes or helicopters authorized to conduct international commercial air transport, in accordance with Annex 6, Part I or Part III, Section II, respectively, shall be made acceptable to the State of the Operator.

Note.— When maintenance activities are not conducted by an approved maintenance organization in accordance with Annex 6, Part I, 8.7, but under an equivalent system as in Annex 6, Part I, 8.1.2, or Part III, Section II, 6.1.2, they are included in the scope of the operator's SMS.

4.1.5 The SMS of an approved maintenance organization providing services to operators of aeroplanes or helicopters engaged in international commercial air transport, in accordance with Annex 6, Part I or Part III, Section II, respectively, shall be made acceptable to the State(s) responsible for the organization's approval.

4.1.6 The SMS of an organization responsible for the type design of aircraft, engines or propellers, in accordance with Annex 8, shall be made acceptable to the State of Design.

4.1.7 The SMS of an organization responsible for the manufacture of aircraft, engines or propellers, in accordance with Annex 8, shall be made acceptable to the State of Manufacture.

4.1.8 The SMS of an ATS provider, in accordance with Annex 11, shall be made acceptable to the State responsible for the provider's designation.

4.1.9 The SMS of an operator of a certified aerodrome, in accordance with Annex 14, Volume I, shall be made acceptable to the State responsible for the aerodrome's certification.

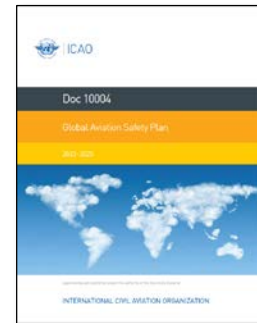
SAFETY AS A SPECIFICATION?

Those two aspects stated as a contrast between the two systems have the potential to enable a strong linkage between the system.

In the view, that quality and safety are NOT contradicting, but safety in an inherent feature of all products and services, will induce the common understanding of safety management into a QMS, and vice versa. The hook for this idea “safety as a feature” lays in ISO9001:2015 8.3.2.1 b) “**the requirements not specified by the customer, but which are necessary for the specified or intended use, to the extent known**”, which covers those features, which are not explicitly specified, but expected by the customer or necessary to ensure the acceptance of the product or service.

E. g. when booking a flight, the customer selects on criteria as price, comfort, routing, benefits, etc. Only if safety gets infringed (e. g. B737MaXX), customers tend to avoid a possible safety hazard.

As soon this understanding is implemented in the management system, the QMS can act as an “umbrella” to cover also future aspects, like information security

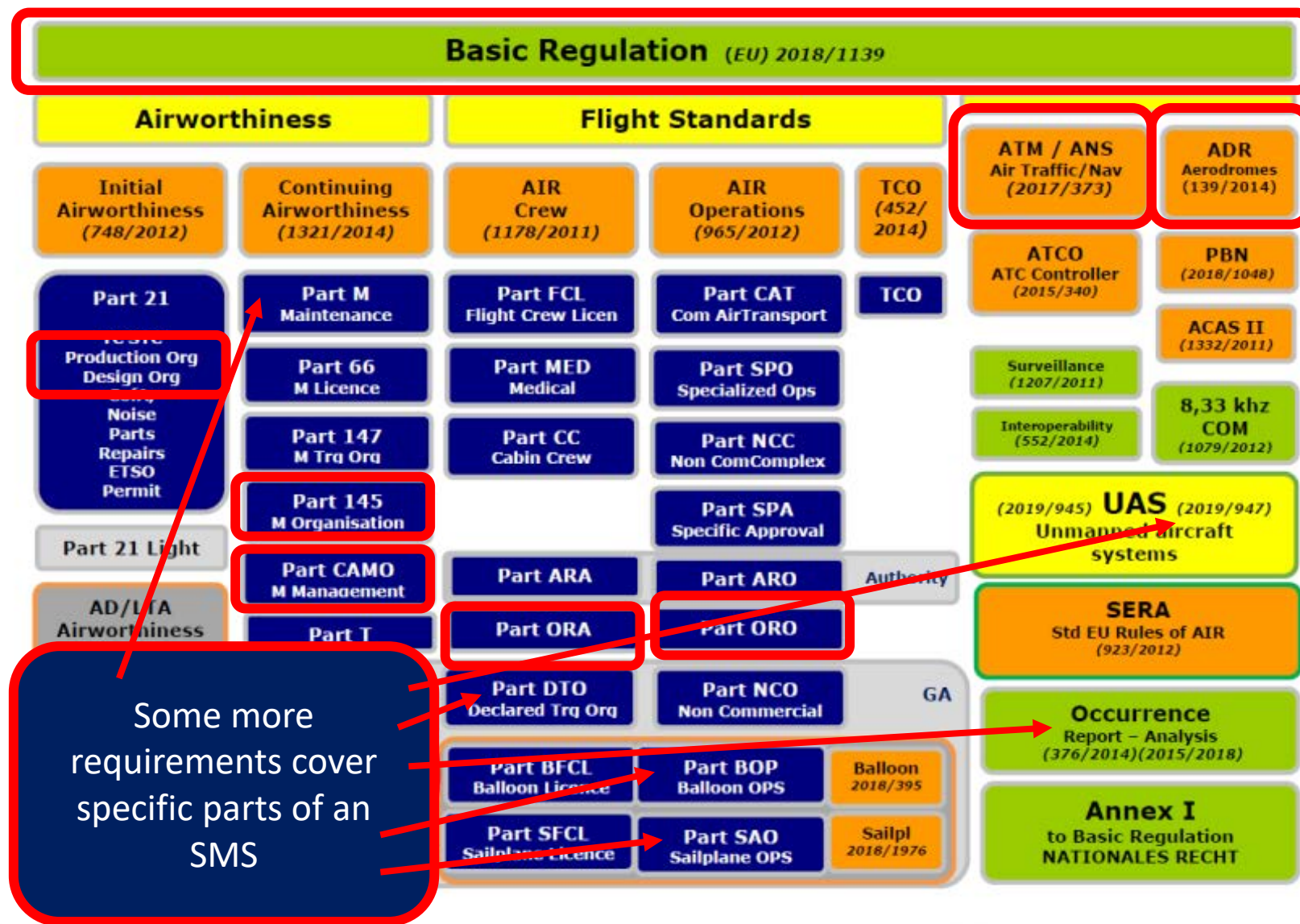


SYNERGIES BETWEEN QMS AND SMS

The synergistic relationship between both systems can be summarized as follows:

- An SMS is supported and informed by QMS “umbrella” processes such as auditing, inspection, investigation, root-cause/causal analysis, process design, statistical trending analysis, preventive measures, documentation, and training.
- SMS may anticipate safety issues that exist despite the organization’s compliance with standards and specifications (see picture below).
- With its focus on compliance with customer requirements and applicable statutory and regulatory requirements, a QMS may constitute a solid foundation upon which to build the SMS; and in return.
- QMS activities may be leveraged through consideration of risks for all planning activities, in particular for the planning and performance of internal audits.

EU REGULATIONS FOR MS



EU SMS + QMS REQUIREMENTS

21.A.139 Production management system

Regulation (EU) 2022/201

- (a) The production organisation shall establish, implement and maintain a production management system that includes a safety management element and a quality management element, with clearly defined accountability and lines of responsibility throughout the organisation.

21.A.239 Design management system

Regulation (EU) 2022/201

- (a) The design organisation shall establish, implement and maintain a design management system that includes a safety management element and a design assurance element with clearly defined accountability and lines of responsibility throughout the organisation.