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NASA System Safety Handbook

Volume 1, System Safety Framework and Concepts for Implementation

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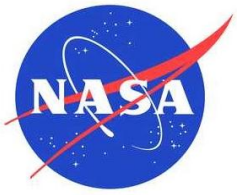

NASA System Safety Handbook

Volume 1, System Safety Framework and Concepts for Implementation

National Aeronautics and Space Administration
NASA Headquarters
Washington, D.C. 20546

November 2011

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Preface

System safety assessment is defined in NPR 8715.3C, *NASA General Safety Program Requirements* [1], as a disciplined, systematic approach to the analysis of risks resulting from hazards that can affect humans, the environment, and mission assets. Achievement of the highest practicable degree of system safety is one of NASA's highest priorities.

Traditionally, system safety assessment at NASA and elsewhere has focused on the application of a set of safety analysis tools to identify safety risks and formulate effective controls.[1] Familiar tools used for this purpose include various forms of hazard analyses, failure modes and effects analyses, and probabilistic safety assessment (commonly also referred to as probabilistic risk assessment (PRA)). In the past, it has been assumed that to show that a system is safe, it is sufficient to provide assurance that the process for identifying the hazards has been as comprehensive as possible and that each identified hazard has one or more associated controls.[2]

While historically this approach has been used reasonably effectively to ensure that known risks are controlled, it has become increasingly apparent that evolution to a more holistic approach is needed as systems become more complex and the cost of designing, building, and operating them become more of an issue. For example, the NASA Aerospace Safety Advisory Panel (ASAP) has made several statements in its annual reports supporting a more holistic approach. In 2006, it recommended that "... a comprehensive risk assessment, communication and acceptance process be implemented to ensure that overall launch risk is considered in an integrated and consistent manner." In 2009, it advocated for "... a process for using a risk-informed design approach to produce a design that is optimally and sufficiently safe." As a rationale for the latter advocacy, it stated that "... the ASAP applauds switching to a performance-based approach because it emphasizes early risk identification to guide designs, thus enabling creative design approaches that might be more efficient, safer, or both."

For purposes of this preface, it is worth mentioning three areas where the handbook emphasizes a more holistic type of thinking. First, the handbook takes the position that it is

[1] Note that while some people consider the term "controls" to refer to active measures and "barriers" to refer to passive measures, we use the term "controls" to embrace both.

[2] Note that while some view hazards as being limited to materials and energy sources that can impair worker safety, we take the more general view of hazards, expressed in NPR 8715.3, to include any "state or set of conditions, internal or external to a system that has the potential to cause harm". Examples of hazards include materials, energy sources, or operational practices that in uncontrolled situations can lead to scenarios that could produce death, injury, illness, equipment loss or damage, or damage to a protected environment.

important to not just focus on risk on an individual basis but to consider measures of aggregate safety risk and to ensure wherever possible that there be quantitative measures for evaluating how effective the controls are in reducing these aggregate risks. The term aggregate risk, when used in this handbook, refers to the accumulation of risks from individual scenarios that lead to a shortfall in safety performance at a high level: e.g., an excessively high probability of loss of crew, loss of mission, planetary contamination, etc. Without aggregated quantitative measures such as these, it is not reasonable to expect that safety has been optimized with respect to other technical and programmatic objectives. At the same time, it is fully recognized that not all sources of risk are amenable to precise quantitative analysis and that the use of qualitative approaches and bounding estimates may be appropriate for those risk sources.

Second, the handbook stresses the necessity of developing confidence that the controls derived for the purpose of achieving system safety not only handle risks that have been identified and properly characterized but also provide a general, more holistic means for protecting against unidentified or uncharacterized risks. For example, while it is not possible to be assured that all credible causes of risk have been identified, there are defenses that can provide protection against broad categories of risks and thereby increase the chances that individual causes are contained.

Third, the handbook strives at all times to treat uncertainties as an integral aspect of risk and as a part of making decisions. The term “uncertainty” here does not refer to an actuarial type of data analysis, but rather to a characterization of our state of knowledge regarding results from logical and physical models that approximate reality. Uncertainty analysis finds how the output parameters of the models are related to plausible variations in the input parameters and in the modeling assumptions. The evaluation of uncertainties represents a method of probabilistic thinking wherein the analyst and decision makers recognize possible outcomes other than the outcome perceived to be “most likely.” Without this type of analysis, it is not possible to determine the worth of an analysis product as a basis for making decisions related to safety and mission success.

In line with these considerations, the handbook does not take a hazard-analysis-centric approach to system safety. Hazard analysis remains a useful tool to facilitate brainstorming but does not substitute for a more holistic approach geared to a comprehensive identification and understanding of individual risk issues and their contributions to aggregate safety risks. The handbook strives to emphasize the importance of identifying the most critical scenarios that contribute to the risk of not meeting the agreed-upon safety objectives and requirements using all appropriate tools (including but not limited to hazard analysis). Thereafter, emphasis shifts to identifying the risk drivers that cause these scenarios to be critical and ensuring that there are controls directed toward preventing or mitigating the risk drivers.

To address these and other areas, the handbook advocates a proactive, analytic-deliberative, risk-informed approach to system safety, enabling the integration of system safety activities with systems engineering and risk management processes. It emphasizes how one can systematically provide the necessary evidence to substantiate the claim that a system is safe to within an acceptable risk tolerance, and that safety has been achieved in a cost-effective manner. The methodology discussed in this handbook is part of a systems engineering process and is intended to be integral to the system safety practices being conducted by the NASA safety and mission assurance and systems engineering organizations.

The handbook posits that to conclude that a system is adequately safe, it is necessary to consider a set of safety claims that derive from the safety objectives of the organization. The safety claims are developed from a hierarchy of safety objectives and are therefore hierarchical themselves. Assurance that all the claims are true within acceptable risk tolerance limits implies that all of the safety objectives have been satisfied, and therefore that the system is safe. The acceptable risk tolerance limits are provided by the authority who must make the decision whether or not to proceed to the next step in the life cycle. These tolerances are therefore referred to as the decision maker's risk tolerances.

In general, the safety claims address two fundamental facets of safety: 1) whether required safety thresholds or goals have been achieved, and 2) whether the safety risk is as low as possible within reasonable impacts on cost, schedule, and performance. The latter facet includes consideration of controls that are collective in nature (i.e., apply generically to broad categories of risks) and thereby provide protection against unidentified or uncharacterized risks.

The demonstration that all the claims are true within the decision maker's risk tolerance comprises what is referred to as a risk-informed safety case, or RISC. The evidence contained within the RISC is of two kinds, one of which may be called direct or demonstrative, the other indirect or validating. Direct or demonstrative evidence refers to the results that have accrued from operational experience, from testing, and from analysis. These results must support the assertion that the design of the system and the controls that have been developed are sufficient to substantiate all the safety claims within the acceptable tolerance. Indirect or validating evidence refers to the factors that show that the operational experience, testing, and analysis are valid and are directly applicable to the mission being evaluated. Such factors include the validity of the assumptions made, the relevance of the environments used or assumed, the degree of verification and validation of the models, the qualifications of the personnel, the robustness of the quality assurance processes, the quality of management oversight, etc.

Evidence is developed through application of technical processes consistent with those in the systems engineering engine of NPR 7123.1A, *NASA Systems Engineering Processes and Requirements* [2], which operate collectively to support the safety case. One purpose of the handbook is to illustrate the types of analyses and methods that are needed to provide the evidence and the manner in which the inputs to and outputs from each process help build the case. Individual organizations may have different systems engineering processes and interfaces, which would result in corresponding differences in the safety case. The technical processes are based on using a graded approach to system safety modeling, where qualitative and quantitative risk analysis techniques are applied in a complementary fashion. The approach adopts scenario-based analysis techniques, and in analyzing each scenario, it recognizes and characterizes the effects of uncertainties.

While discussing technical processes, the handbook does not prescribe any particular procedure and/or specific software tool. The handbook takes the position that there are many procedures and tools that could apply to different situations, and the preferences of the practitioners are not only relevant but important to preserve.

This System Safety handbook is the first of two volumes, the second of which will be published next year. This volume provides a high level view of the concepts and is intended for systems engineers, system safety specialists, and system safety managers. It has been informed by NPR 8715.3C; NPR 7123.1A; NPD 8700.1, *NASA Policy for Safety and Mission Success* [3]; NPR 8705.2B, *Human-Rating Requirements for Space Systems* [4]; NPR 8000.4A, *Agency Risk Management Procedural Requirements* [5]; and NASA/SP-2011-3422, *NASA Risk Management Handbook* [6].

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1 Purpose

The purpose of Volume 1 of the NASA System Safety Handbook is to present the overall framework for System Safety and to provide the general concepts needed to implement the framework. The treatment addresses activities throughout the system life cycle to assure that the system meets safety performance requirements and is as safe as reasonably practicable.

This handbook is intended for project management and engineering teams and for those with review and oversight responsibilities. It can be used both in a forward-thinking mode to promote the development of safe systems, and in a retrospective mode to determine whether desired safety objectives have been achieved.

The topics covered in this volume include general approaches for formulating a hierarchy of safety objectives, generating a corresponding hierarchical set of safety claims, characterizing the system safety activities needed to provide supporting evidence, and presenting a risk-informed safety case that validates the claims. Volume 2, to be completed in 2012, will provide specific guidance on the conduct of the major system safety activities and the development of the evidence.

2 Overview of System Safety

2.1 What is Safety?

NPR 8715.3C and MIL-STD-882D [7] define safety as freedom from those conditions that can cause death, injury, occupational illness, damage to or loss of equipment or property, or damage to the environment. This concept of safety is inclusive of human safety, which includes workers directly involved in system interactions, workers not directly involved in system interactions, as well as members of the general public.

Although this definition is broad, it focuses exclusively on physical, rather than functional, consequences. However, for systems such as non-recoverable spacecraft, damage to or loss of equipment may be meaningful only insofar as it translates into degradation or loss of mission objectives. Therefore, for the purposes of this handbook, freedom from conditions that can cause loss of mission (LOM) is also included in the definition of safety. Figure 2-1 illustrates the scope of potentially impacted populations to which the concept of safety can apply.

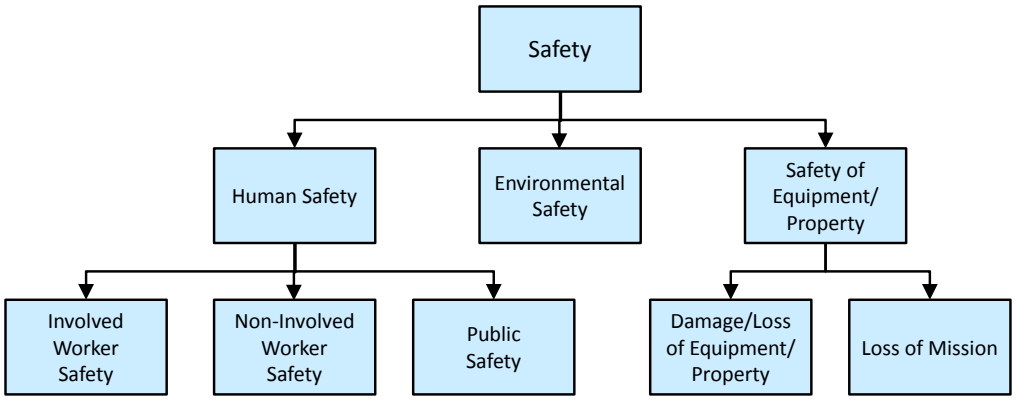


Figure 2-1. Impacted Populations within the Scope of Safety

Safety

Safety is freedom from those conditions that can cause death, injury, occupational illness, damage to or loss of equipment or property, or damage to the environment. In any given application, the specific scope of safety must be clearly defined by the stakeholders in terms of the entities to which it applies and the consequences against which it is assessed. For example, for non-reusable and/or non-recoverable systems, damage to or loss of equipment may be meaningful only insofar as it translates into degradation or loss of mission objectives.

In any case, the population included in the definition of safety is context dependent, and it is up to the involved parties, including stakeholders, to unambiguously define what constitutes safety for a given application in a given environment.

Just as the scope of conditions relevant to safety is application specific, so too is the degree of "safety" that is considered acceptable. We do not expect to attain absolute safety, but we strive to attain a degree of safety that fulfills obligations to the at-risk communities and addresses agency priorities. An adequately safe system is not necessarily one that completely precludes all conditions that can lead to undesirable consequences. Rather, an adequately safe system is one that adheres to the following fundamental safety principles:

- An adequately safe system is assessed as meeting a minimum threshold level of safety, as determined by analysis, operating experience, or a combination of both. Below this level the system is considered unsafe.

  This minimum level of safety is not necessarily fixed over the life of a system. As a system is operated and information is gained as to its strengths and weaknesses, design (hardware and software), and operational modifications are typically made which, over the long run, improve its safety performance.[3] In particular, an initial level of safety performance may be accepted for a developmental system, with the expectation that it will be improved as failure modes are "wrung out" over time. In such cases the level of tolerable safety can be expressed as a *safety threshold* against which current system performance is assessed, and a *safety goal* against which future performance will be assessed.

  This attitude towards safety is now part of NASA's policy for certification of human space flight systems [4] as also reflected in NASA's agency-level safety goals and thresholds for crew transportation system missions to the International Space Station (ISS) [8]. The safety threshold represents the initial minimum level of safety for the system, whereas the safety goal, which is set at a higher level of safety, represents the agency's expectations from continuous safety upgrades and improvements to the system throughout the acquisition life cycle.

- An adequately safe system is as safe as reasonably practicable (ASARP). The ASARP concept is closely related to the "as low as reasonably achievable" (ALARA) and "as low as reasonably practicable" (ALARP) concepts that are common in U.S. nuclear applications and U.K. Health and Safety law, respectively [9, 10]. A determination that a

[3] This is typically the case for production line items where operating experience can inform the design and operation of future units, and for reusable systems that can be modified prior to reuse. It is less the case for one-time, non-recoverable systems where the opportunity to modify the system is limited.

system is ASARP entails weighing its safety performance against the sacrifice needed to further improve it. The system is ASARP if an incremental improvement in safety would require a disproportionate deterioration of system performance in other areas. Thus, a system that is ASARP is one where safety improvement is given the highest priority within the constraints of operational effectiveness, time, and cost, throughout all phases of the system life cycle.

These two principles of adequate safety must be maintained throughout all phases of the system life cycle. Opportunities to impact safety (or correspondingly, threats to safety) exist from concept studies to closeout, and system safety activities must be operative throughout.

> As Safe As Reasonably Practicable (ASARP)
>
> Being as safe as reasonably practicable (ASARP) is a fundamental principle of adequate safety. A determination that a system is ASARP entails weighing its safety performance against the sacrifice needed to further improve it. The system is ASARP if an incremental improvement in safety would require a disproportionate deterioration of system performance in other areas.

Quantitatively, safety can be characterized positively as the probability that undesirable consequences will be avoided, or negatively as the probability that undesirable consequences will be incurred. It is this second characterization that is most common, and which is typically equated with the term 'risk.' Indeed, both the terms "as low as reasonably achievable" (ALARA) and "as low as reasonably practicable" (ALARP) refer to risk. However, the term 'risk' is used in the NASA context as "the potential for performance shortfalls… with respect to achieving explicitly established and stated performance requirements" [5], and that is the definition used in this Handbook. Consequently, the safety of a system is referred to here as its 'safety performance' rather than as its risk.

2.2 What is System Safety?

NPR 8715.3C defines system safety as the "application of engineering and management principles, criteria, and techniques to optimize safety… within the constraints of operational effectiveness, time, and cost throughout all phases of the system life cycle."[4] The term 'system,' as used here, refers to one integrated entity that performs a specified function and includes hardware, software, human elements, and consideration of the environment within which the system operates.

[4] Adapted from [7].

System Safety

System safety is the application of engineering and management principles, criteria, and techniques to optimize safety within the constraints of operational effectiveness, time, and cost throughout all phases of the system life cycle. System safety is to safety as systems engineering is to engineering. When performing appropriate analysis, the evaluation is performed holistically by tying into systems engineering practices and ensuring that system safety has an integrated system-level perspective.

System safety is a rational pursuit of safety within a systems perspective; one in which the system is treated holistically, accounting for interactions among its constituent parts. The need for system safety and the methods it employs are driven by many factors, including:

- The high cost of testing, which limits the ability to rely on test-fail-fix strategies of safe system development and drives reliance on analytical results
- Increasing system complexity, which makes it necessary to go beyond traditional hazard evaluation mechanisms (e.g., FMEA, HAZOP) because they are limited in their ability to identify hazardous system interactions
- The development of systems that operate at the edge of engineering capability, requiring a high degree of discipline in system realization and system operation management and oversight
- The use of unproven technology, requiring engineering conservatism to protect against unknown safety risks while at the same time requiring allowances for novel solutions

System safety has traditionally focused on hazards and controls. NPR 8715.3C defines hazard as "a state or a set of conditions, internal or external to a system, that has the potential to cause harm." However, it is not necessarily desirable to take a hazard-centric approach to system safety, since what is called a "hazard" is often somewhat arbitrary, having more to do with where the blame is placed for undesired consequences, rather than with some specific attribute of the system that can be identified as a hazard a priori. Indeed, in complex systems it is not uncommon to find hazards that are declared only after the potential for undesired consequences is uncovered. This is particularly true for systems whose most critical scenarios involve (combinations of) random hardware failure, rather than explicit loss of control over a quantity of hazardous material or an energy source.

Hazard-centric analysis techniques (e.g., checklists, HAZOP, etc.) are valuable elements of systems safety, but other, non-hazard-centric techniques (e.g., PRA) are also valuable. In all

cases, the technique(s) used should be appropriate to the system being analyzed and the context of the analysis. Regardless of the technique(s) used, the goal of analysis is to develop, to the maximum extent practical, a scenario-based understanding of the system's safety performance in order to:

- Identify the most critical scenarios that can lead to the undesired consequences
- Identify the risk drivers that cause these scenarios to be critical
- Ensure that the controls are directed toward the risk drivers

This Handbook uses the term hazard as a generic reference to the potential causal factors of accident scenarios, whether direct or indirect, primary or contributory. This is in keeping with the NPR 8715.3C definition, and is consistent with the use of the term in some other industries [11].

During system design and realization, system safety activities take place within the context of the systems engineering technical processes enumerated in NPR 7123.1A and shown in Figure 2-2. As such, system safety activities are neither auxiliary to nor duplicative of those systems engineering processes that have the potential to affect safety. Rather, system safety activities are integrated into systems engineering processes in a manner that best assures optimal safety throughout these life cycle phases. During system operation, system safety activities take place within the context of those program control processes that impose operational discipline, such as maintenance, auditing, inspections, etc. These activities are risk informed in the sense that risk information is used to help prioritize specific tasks. Unanticipated events and anomalies occurring during system operation are evaluated to determine whether they could be considered as precursors to accidents, and if so, whether the risk models need to be modified and additional controls need to be implemented[5]. The system safety activities during system operation are coordinated with requirements in NPR 7120.5D, *NASA Space Flight Program and Project Management Requirements* [12], as well as NPR 8715.3C [1] and other related documents and standards.

[5] Note that while the term "controls" often refers to active measures and "barriers" to passive measures, we use the term "controls" to embrace both.

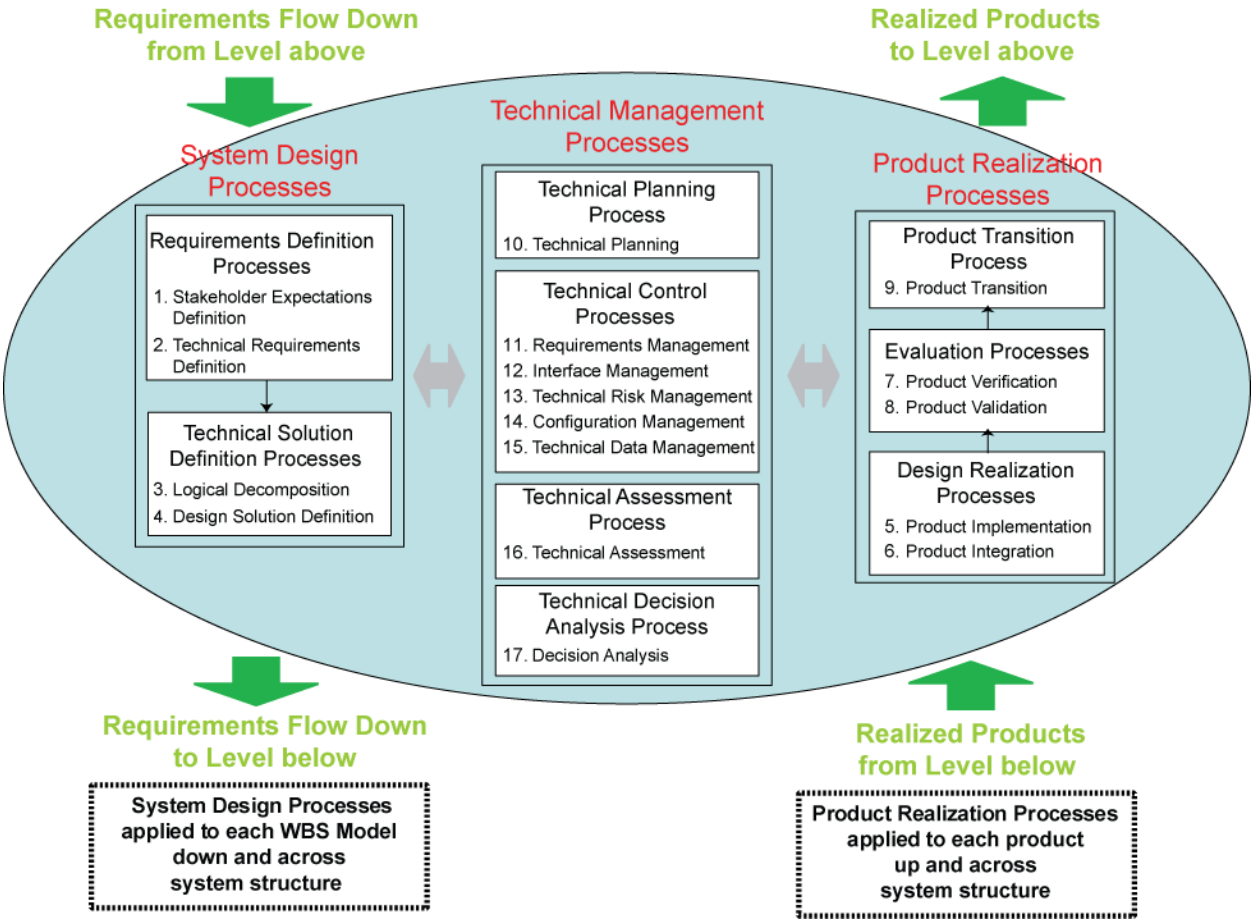


Figure 2-2. Systems Engineering Technical Processes [2]

2.3 The System Safety Framework

System safety at NASA is performed in the context of the *System Safety Framework* that is the principal focus of this volume of the System Safety Handbook. The System Safety Framework guides system safety activities towards the satisfaction of defined safety objectives, and organizes system safety products and activities into a coherent case for safety. The System Safety Framework is illustrated in Figure 2-3. The main elements of the framework and the details associated with them are discussed in the following subsections.

2.3.1 Establishing Safety Objectives

As discussed in NPR 8000.4A, at the outset of a program or project, the set of objectives, deliverables, performance measures, baseline performance requirements, resources, and schedules that define the task to be performed is negotiated between the organizational unit performing the task and the organizational unit responsible for oversight. With respect to

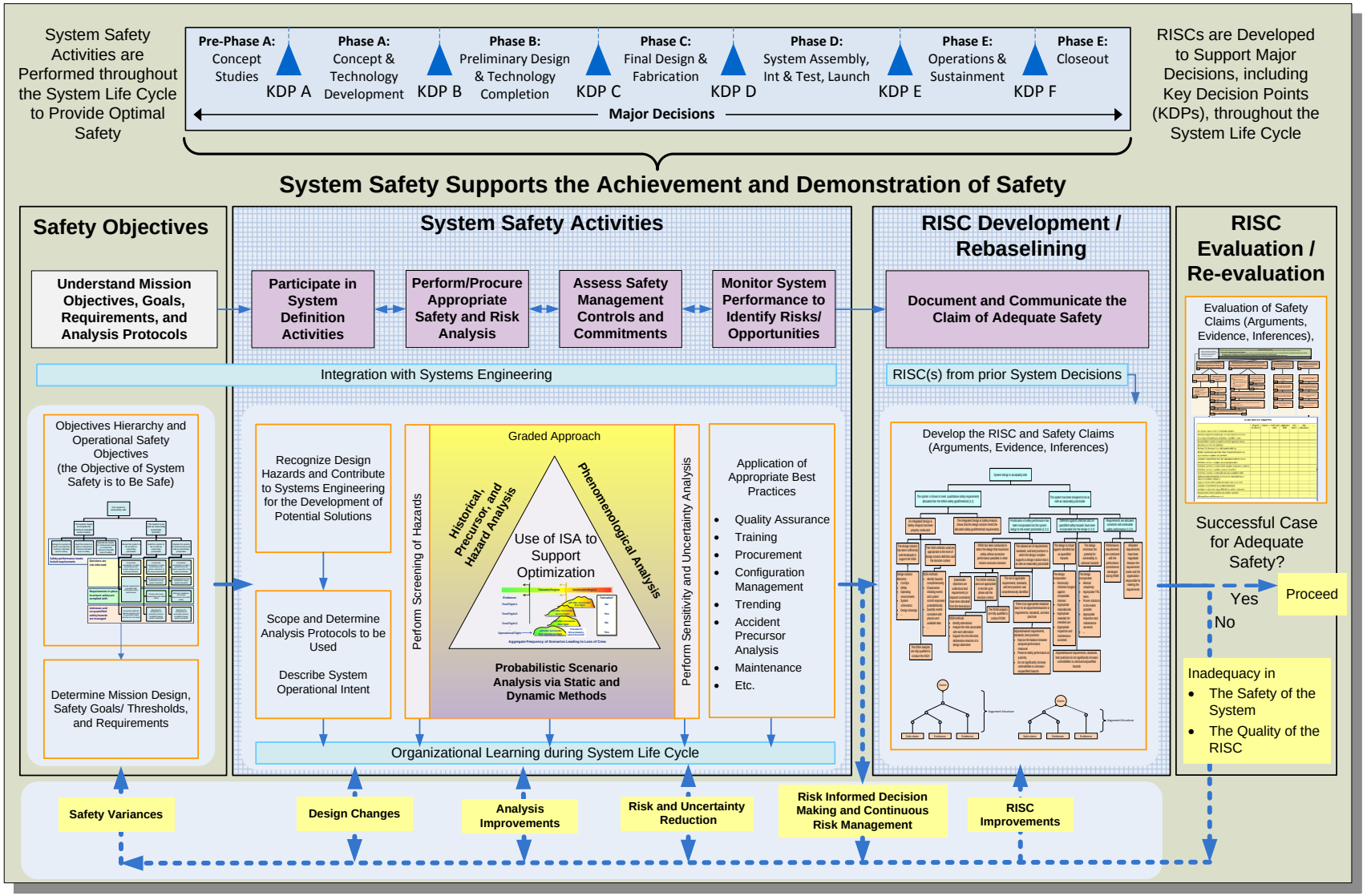


Figure 2-3. The System Safety Framework

safety, a set of safety objectives is negotiated consistent with the two fundamental safety principles discussed previously.

These general principles are further decomposed into specific safety objectives to be met by the system, such as adhering to certain safety codes and standards; implementing provisions against unknown or unanalyzed hazards; assuring responsiveness to new information, whether adverse or beneficial; etc. By specifying safety objectives down to a level where they can be clearly addressed by systems engineering processes, an operational definition of safety is created that enables the processes to be developed and assessed in terms of the safety objectives. If the safety objectives have indeed been met, then, by virtue of their derivation from fundamental safety principles, the system is adequately safe.

2.3.2 Conducting System Safety Activities

System safety activities are conducted as part of overall systems engineering technical process activities, and are focused on the achievement of the stated safety objectives. The specific system safety activities can vary with each application to a given task, but generally fall into the categories of:

- **Conducting an Integrated Safety Analysis (ISA)[6]:** The Integrated Safety Analysis models the safety of the system in the context of its intended application in the intended environment. The ISA must be tailored to the current application, and to the analysis techniques (e.g., qualitative versus quantitative) and the information available at a particular point in the life cycle. As the system design evolves, the ISA is kept current, typically through the use of progressively more rigorous analysis techniques that model the system at progressively finer levels of detail. The ISA is maintained during system realization and is used to inform development decisions related to safety, such as test protocols. During system operation, the ISA is kept current to reflect such things as design modifications and accumulating operational experience, including anomalies.

  The focus of the ISA is on safety; however, in order to risk-inform trade studies and other decisions, the ISA must be integrable with other performance models in the mission execution domain of cost, schedule, and technical performance, as discussed in [6].

[6] The term “integrated safety analysis” and acronym ISA used in this report should not be confused with the term “integrated design and safety analysis”, which has been used elsewhere with reference to the determination of failure tolerance requirements and the required amount of redundancy in design.

Integrated Safety Analysis

Integrated safety analysis (ISA) refers to the development and analysis of scenarios that may lead to undesirable consequences with respect to safety. ISA includes both hazard-centric and non-hazard-centric methods for identifying and characterizing potential accident scenarios. This includes accident causes, contributing factors, effectiveness of controls (both existing and proposed), analysis of physical responses of the system to the environments it encounters, and analysis of the probability that the undesirable consequences will be realized. The analysis of any particular scenario can be either quantitative or qualitative, as appropriate for the scenario being considered and the nature of the undesired consequence.

ISA integrates different types of safety analyses (e.g., FMEA, PRA, phenomenological modeling) to the greatest extent possible. Data developed in any one analysis can be used in the other analyses to some degree. The ISA consolidates these separate analyses to produce a single comprehensive set of safety performance measures, to help guide and influence the design and operation of the system, and to provide a body of objective evidence that the system satisfies applicable safety and mission assurance requirements.

- **Demonstrating Satisfaction of Safety Requirements:** A principal use to which the ISA is put is demonstration of satisfaction of probabilistic safety requirements such as the NASA safety goals and thresholds, satisfaction of requirements allocated from the safety goals and thresholds, or compliance with other safety requirements levied on the system. As such, the ISA must conform to any analysis protocols that have been established as an adequate technical basis for the generation of the applicable safety performance measures.

- **System Design Support:** By far the most effective way that system safety activities advance the cause of safety is through the influence they can have over system design when properly integrated into the system design process. This entails development of an ISA as early as possible in the formulation phase of the system life cycle in order to influence direction-setting design decisions upon which, typically, safety strongly depends. It also entails continuous evolution of the ISA during successive design cycles in order to analyze the safety performance of the various alternative designs considered during design trades and down-selects. The same principle applies during system operation when design and operational modifications are made, e.g., in response to risk management concerns or as part of a process of continuous improvement. In other

words, the ISA must be a living analysis that is kept current and relevant to decision making throughout the entire system life cycle.

- **Requirements Development Support:** System safety supports requirements development in two distinct ways: 1) by supporting the development of alternate means of complying with the intent of the requirements levied upon the organization; and 2) by developing a rational basis for the allocation (flowdown) of safety requirements to subordinate organizations.

- **Performance Monitoring Support:** System safety supports effective performance monitoring, both in the development of monitoring protocols and in the response to performance data. The ISA is used to risk-inform the selection of performance attributes that will be monitored, both to ensure that significant epistemic uncertainties are reduced as experience accumulates, and to ensure that important performance-related assumptions in the ISA remain valid over the life cycle of the system. Anomalous performance data are scrutinized for their potential impact on safety (e.g., via accident precursor analysis) and managed accordingly.[7]

- **Program Control and Commitments Support:** System safety promotes the development of program controls and commitments needed to ensure that the framework for safety is backed by sound administrative and management practices. The importance of this area of safety assurance is highlighted, for example, in the report of the Columbia Accident Investigation Board (CAIB) [14], which mentions the following as being among the most important causative factors for the Space Shuttle Columbia accident:

    - Organizational barriers that prevented effective communication of critical safety information
    - Lack of integrated management across program elements
    - Decision making processes that operated outside the organization's rules

  Other aspects of program controls and commitments covered within the system safety framework include configuration management, quality assurance, training and certification of personnel, use of best practices and lessons learned, and assurance that requirements are being adhered to.

[7] Guidance on accident precursor analysis is provided in NASA/SP-2011-3423, *NASA Accident Precursor Analysis Handbook* [13].

2.3.3 Developing/Evaluating a Risk-Informed Safety Case

The risk-informed safety case (RISC) is the means by which the satisfaction of the system's safety objectives is demonstrated and communicated to decision makers at major milestones such as Key Decision Points (KDPs). It is a structured argument, supported by a body of evidence, that provides a compelling, comprehensible and valid case that a system is or will be adequately safe for a given application in a given environment[8]. A key concept is the idea of a "case," comprising argument and evidence that is convincing with respect to a specific claim of safety. Conversely, an *ad hoc* list of "risks" that have been addressed through a mitigation plan is not a safety case. As noted by Holloway [16], "An argument without adequate supporting evidence is…unconvincing. A body of evidence without an argument is unexplained."

> Risk-Informed Safety Case
>
> A risk-informed safety case (RISC) is a structured argument, supported by a body of evidence, that provides a compelling, comprehensible and valid case that a system is or will be adequately safe for a given application in a given environment. This is accomplished by addressing each of the operational safety objectives that have been negotiated for the system, including articulation of a roadmap for the achievement of safety objectives that are applicable to later phases of the system life cycle.
>
> The term 'risk-informed' is used to emphasize that a determination of adequate safety is the result of a deliberative decision making process that necessarily entails an assessment of risks and tries to achieve a balance between the system's safety performance and its performance in other areas.

The elements of the RISC are [17]:

- An explicit set of *safety claims* about the system(s), for example, the probability of an accident or a group of accidents is low
- Supporting *evidence* for the claim, for example, representative operating history, redundancy in design, or results of analysis
- Structured *safety arguments* that link claims to evidence and which use logically valid rules of inference

The claims made (and defended) by the RISC dovetail with the safety objectives negotiated at the outset of system formulation. In other words, satisfaction of each distinct safety objective is

[8] Adapted from [15].

stated as a corresponding claim in the RISC. By substantiating each claim with appropriate arguments and supporting evidence, the RISC is able to meaningfully argue that the corresponding objective has been met and, thus, that the system is adequately safe.

Evaluation of the RISC is the means by which reasonable assurance of adequate safety of the system can be obtained by the responsible oversight organization. As in a legal case, the "burden of proof" is on the RISC developer to make the case for safety to a critical, and skeptical, approval authority. Deficiencies in either the safety of the system or in the quality of the RISC must be addressed in order for the oversight organization to have reasonable assurance that the system is adequately safe.

The interaction of safety objectives, system safety activities, the RISC, and the RISC evaluation is illustrated in Figure 2-4.

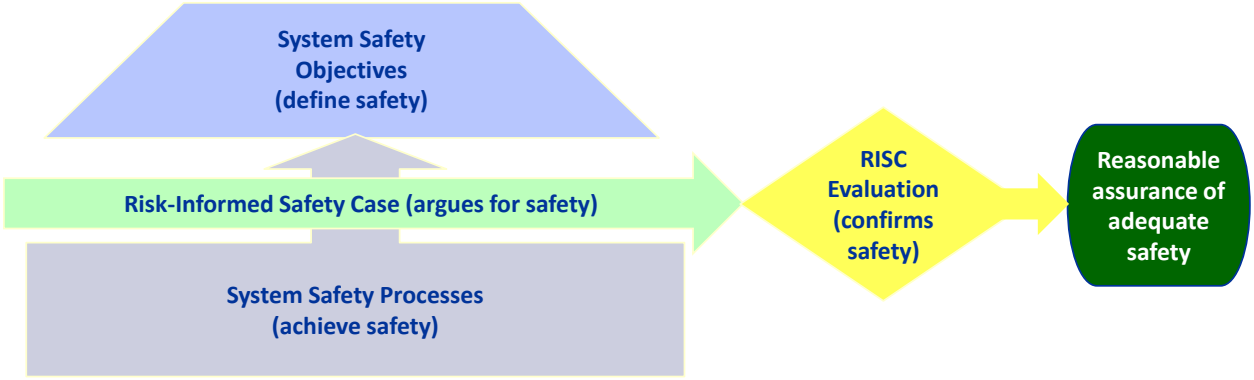


Figure 2-4. Interaction of Safety Objectives, System Safety Activities, the RISC, and RISC Evaluation

3 Safety Objectives

The purpose of Chapter 3 is to describe the fundamental principles of adequate safety in the context of NASA's missions, and to show how a hierarchy of safety objectives can be derived from those principles.

3.1 Fundamental Principles of Adequate Safety

An adequately safe system adheres to the fundamental principles of:

- Meeting or exceeding the minimum tolerable level of safety established by the stakeholders[9]
- Being as safe as reasonably practicable (ASARP)

Both of these principles apply throughout the entire system life cycle, from concept studies to closeout. The fundamental nature of these principles is illustrated in Figure 3-1, which shows a high level objectives hierarchy that decomposes the overall fundamental objective "Achieve an adequately safe system" into its fundamental components, throughout the system life cycle. The resulting six objectives at the bottom of the figure set the stage for the further development of safety objectives on a system-by-system basis, as negotiated by the organizational unit performing the task and the unit overseeing the task.

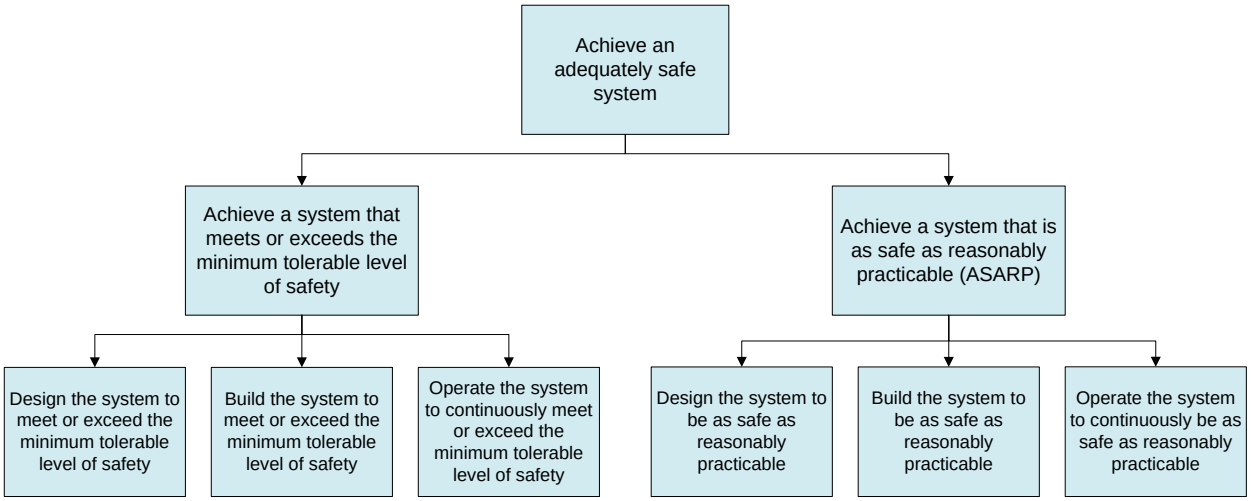


Figure 3-1. Fundamental Principles of Adequate Safety

[9] The minimum tolerable level of safety need not be fixed over the life cycle of the system, as discussed in Section 3.1.1.

Objectives Hierarchies

An objectives hierarchy decomposes an overall fundamental objective (in this case, "Achieve an adequately safe system") into its fundamental components. The upper levels in an objectives hierarchy represent more general objectives, and the lower levels explain or describe important elements of the more general levels. For example, in Figure 3-1, meeting or exceeding the minimum tolerable level of safety is an important element of being adequately safe. In a well-constructed objectives hierarchy, the set of objectives at any level represent a necessary and sufficient decomposition of the objectives at the level above. This enables assessment of the achievement of the top-level objective, whose achievement may be difficult to assess directly, in terms of the achievement of the bottom-level objectives, which ideally are specific enough to confidently assess.

Objectives hierarchies are not necessarily unique, even for a given set of stakeholders. Consequently, they should be developed in a negotiated fashion in order to arrive at consensus as to the set of objectives at the bottom of the hierarchy.

3.1.1 Meeting or Exceeding the Minimum Tolerable Level of Safety

An adequately safe system meets or exceeds a minimum tolerable level of safety. This principle captures the attitude that a system can potentially be too unsafe to justify the benefits it might produce in other areas. If the system cannot meet its mission objectives within the safety tolerance of the decision makers, then acceptance of the safety shortfall requires elevation to the next higher level in the organization.

The definition of safety refers to the potential for a variety of undesirable consequences (e.g., to people, equipment or property, or the environment). Each one of these consequences may have a distinct minimum tolerable level of safety, such that an adequately safe system must meet or exceed all defined minima. A system's inability to meet one minimum implies it is not adequately safe, even if all other safety minima are exceeded.

Minimum tolerable levels of safety can be either explicit or implicit. Section 3.1.1.3 discusses NASA's safety goals and thresholds, which are explicit minimum tolerable levels of safety for transporting astronauts to the ISS. In other cases, such as robotic missions where loss of mission is the dominant concern, a minimum tolerable level of safety might not be explicitly defined. Instead, estimates (whether qualitative or quantitative) of the probability of loss of mission are considered in decision making, with minimum tolerable levels implicit in the decisions.

Operationally, in order to define explicit minimum tolerable levels of safety, each type of potential consequence for which a minimum exists must have a performance measure associated with it that objectively expresses the system's level of safety for that consequence. These performance measures are typically probabilistic, expressing the likelihood, per mission or per unit time, that the undesirable consequences will be experienced. Examples include:

- **Probability of Loss of Crew (P(LOC)):** The probability (typically per a defined reference mission) of death or permanently debilitating injury to one or more crewmembers. This performance measure is commonly used to assess crew safety. It is a sufficient measure for overall crew safety (i.e., freedom from LOC, injury, and illness) for short-duration missions where LOC is the dominant concern. For longer duration missions it may be more useful to explicitly address injury and illness using separate performance measures for each. Additionally, although P(LOC) indicates the probability of crew death, it does not indicate the number of lives lost. For systems with distributed crews that are subject to different conditions, decision support may warrant quantification of the number of lives lost, as well as the probability that lives will be lost.

- **Probability of Loss of Vehicle (P(LOV)):** The probability that the vehicle will be lost during a mission. In the context of expendable vehicles, this P(LOV) has typically been used to quantify the probability that a vehicle will be lost or damaged prior to meeting its mission objectives, such that the objectives are not met. In the context of reusable vehicles, P(LOV) has typically been used to quantify the probability that, during a mission, a vehicle will be rendered unusable for future missions.

- **Probability of Loss of Mission (P(LOM)):** The probability that mission objectives will not be met. For expendable vehicles (e.g., deep-space robotic missions), P(LOM) is closely related to P(LOV) since, in that context, loss of vehicle is only relevant inasmuch as it affects the achievement of mission objectives.

- **Casualty Expectation:** The expected number of deaths (typically per event). Casualty expectation calculations are typically performed in the contexts of range safety and reentry risk assessment.

Although safety performance measures are typically probabilistic, they need not be. This is particularly true for systems that produce undesirable consequences as part of normal operations. For example, pollution limits are imposed on behalf of environmental safety, with the understanding that pollution rates below the limits are considered safe.

In order to meaningfully compare the safety performance of a system to a set of defined criteria (such as safety minima), it is necessary to establish the analysis protocols in accordance

with which the performance measures are calculated.[10] Adherence to prescribed analysis protocols assures consistency of interpretation between the assessed system safety performance and the criteria to which it is compared. For example, a given safety minimum might be defined with the expectation that system performance will be conservatively calculated, so that there is high confidence that actual system performance will exceed the minimum. Alternatively, but more or less equivalently, the safety minimum might be defined with an expectation that a reasonable reserve will be applied to the calculated system performance so as to account for unknown, un-quantified, and under-evaluated risks.[11] Conversely, the minimum might be defined expecting that mean value of system performance will be calculated, so that the minimum will be met on average for risks that are known. In the latter case, it would be expected that the safety minimum would be defined with sufficient conservatism to account for unknown, un-quantified, and under-evaluated risks. These three situations illustrate very different sets of expectations and system safety analysis results for what superficially may be identical safety minima.

3.1.1.1 Safety Growth due to Accumulated Experience

As a system is operated and information is gained as to its strengths and weaknesses, hardware, software and operational modifications are typically made which, over the long run, improve its safety performance. This has been expressed in the context of reliability growth [18]:

> "Time variations of reliability presents [sic] problems only in the early stages of development. Once any specific equipment design has been fully developed and used for some time in service, its reliability stabilizes at a relatively fixed value. However, during test and initial application, deficiencies are often detected which require design changes to improve reliability."

Thus, an initial level of safety performance may be accepted for a developmental system, with the expectation that the safety performance will be improved as failure modes are "wrung out" over time. When this is the case, the minimum tolerable level of safety may not be fixed over the life of a system, but instead may increase over time in concert with expectations of safety growth in the system. The task of demonstrating that the system meets or exceeds the minimum tolerable levels of safety then involves two separate demonstrations:

- Demonstration that the system meets the current minimum tolerable level of safety

[10] Analysis protocols typically address methods and sources of data, and will be addressed further in Volume 2.
[11] The term "under-evaluated" is included here to highlight the fact that unknown risks may include not only risks about which nothing is known, but also risks for which some aspects are known while other aspects are unknown.

- Demonstration that a program of continuous improvement is planned or in place, which has a reasonable expectation of meeting or exceeding future minimum tolerable levels of safety that exceed current levels

For example, in the face of safety growth expectations it is not enough to select a system design that meets current safety minima. Selection decisions also need to be informed by assessment of the ability to mature the safety performance of the system to meet future minima. This requires forward thinking about issues such as technology development, modularity, evolvability, etc., as they relate to safety.

Traditionally, safety growth has been equated with reliability growth, which concerns mainly the reduction of mean times to failure for hardware components. In the safety context of this handbook, however, growth includes incremental improvements over the lifetime of a program/ project in many areas, including the following:

- Hardware reliability (the usual target of reliability growth)
- Software reliability, integrity, and range of applicability
- Human reliability and the ability to respond effectively to unexpected events
- Integrity and applicability of operating policies and procedures
- Effectiveness of management practices

Growth in all these areas is predicated on the idea that the initial design, fabrication, assembly processes, testing programs, training programs, operating procedures, and management practices will contain deficiencies that only become apparent with operating experience [19]. Because of these deficiencies, the initial level of safety may be below the system's safety goal. A safety growth program will incorporate corrective actions each time a problem or deficiency is uncovered so as to progressively increase the level of safety, enabling the safety goal to be satisfied after a reasonable period of time.

3.1.1.2 Safety Degradation due to Aging and Wear-out

For systems that are reused many times (such as a reusable booster or space shuttle) or systems that are subject to very long missions (such as an orbiting space station or a robotic mission to explore outer planets), the possibility of safety degradation with time due to aging and wear-out of materials must be taken into account. Causes of wear-out typically include material degradation (chemistry effects, embrittlement, strain hardening), internal geometry changes (compression, distortion, erosion), and microscopic failures (microcracks, pitting).

Space systems are designed to survive their duty life before wear-out occurs, but nonetheless, concerns are sometimes raised about wear-out risks during ongoing missions.[12] Systems exposed to high radiation, high temperatures, high stresses, and many load cycles will typically be more subject to wear-out effects than systems exposed to more benign environments.

Thus, it is possible for a system to meet the safety goal for most of its life but not meet it toward the end of its life. In such cases, it is necessary to warrant that the late-term degradation in safety is tolerable.

3.1.1.3 NASA Safety Goals and Thresholds

This section discusses the Agency's current safety goal and threshold requirements as applied to human spaceflight to low earth orbit (LEO). A more general *rationale* for formulating safety goals and thresholds will be taken up in Volume 2.

NASA's minimum level of tolerable safety for human spaceflight missions is articulated in NASA's agency-level safety goals and thresholds for crew transportation system missions to the ISS [8]. They represent minimum Agency requirements for any new human spaceflight transportation system acquisition.

The NASA safety goals and thresholds reflect a tolerance for an initial safety performance that is below long-term expectations for safety, as expressed in terms of a design threshold, a requirement for life cycle continuous safety improvement, and a statement of verification protocol:

- "**Design Threshold:** At a minimum, the spaceflight system designed for transport of the crew to the ISS shall be at least as safe for the combined ascent and entry phases as the Space Shuttle was at the end of its operational life, and in the aggregate, for a 210-day mission to ISS, the system shall be at least as safe as the Space Shuttle was at the end of its operational life on a 12-day mission to the ISS.

- "**Life Cycle Continuous Safety Improvement:** For the long term, any acquisition of crew transportation capabilities or services to the ISS shall include a continuous safety upgrade and improvement program throughout the acquisition life cycle. The ultimate goal of the upgrade and improvement program shall be a system that will be an order of magnitude safer for the combined ascent and entry phases than was the Space Shuttle at the end of its operational life, and that in the aggregate, will be substantially safer for a 210-day mission to the ISS than was the Space Shuttle at the end of its operational life.

[12] A real-life example of an issue that became a concern during flight operation for both reusable space vehicles and long-term Earth-orbiting satellites is the premature shorting of electrical equipment due to the growth of metal whiskers [20].

- "**Verification:** [N]umeric criteria shall be used to verify compliance with the design thresholds and long term goals. The criteria are mean values and shall be determined via probabilistic safety analyses using NASA-accepted methods similar to those applied by the Space Shuttle, ISS, and Constellation programs. These evaluations must be an integral part of NASA's overall program of insight and oversight in order to understand, address, and, where necessary, accept the risks associated with the spaceflight system."

The NASA safety goals and thresholds are illustrated notionally in Figure 3-2. In the figure, system safety performance is split into three regions. Below the threshold, safety performance is intolerable, and a system in this region would require additional design or operational development before acquisition would be considered. Between the threshold and the goal, safety performance is tolerable, but vigorous programmatic measures should be in place to improve safety performance towards the goal. Above the goal, safety improvement is still pursued, but the main focus of system safety activities is on the preservation of the existing safety performance over the long term.

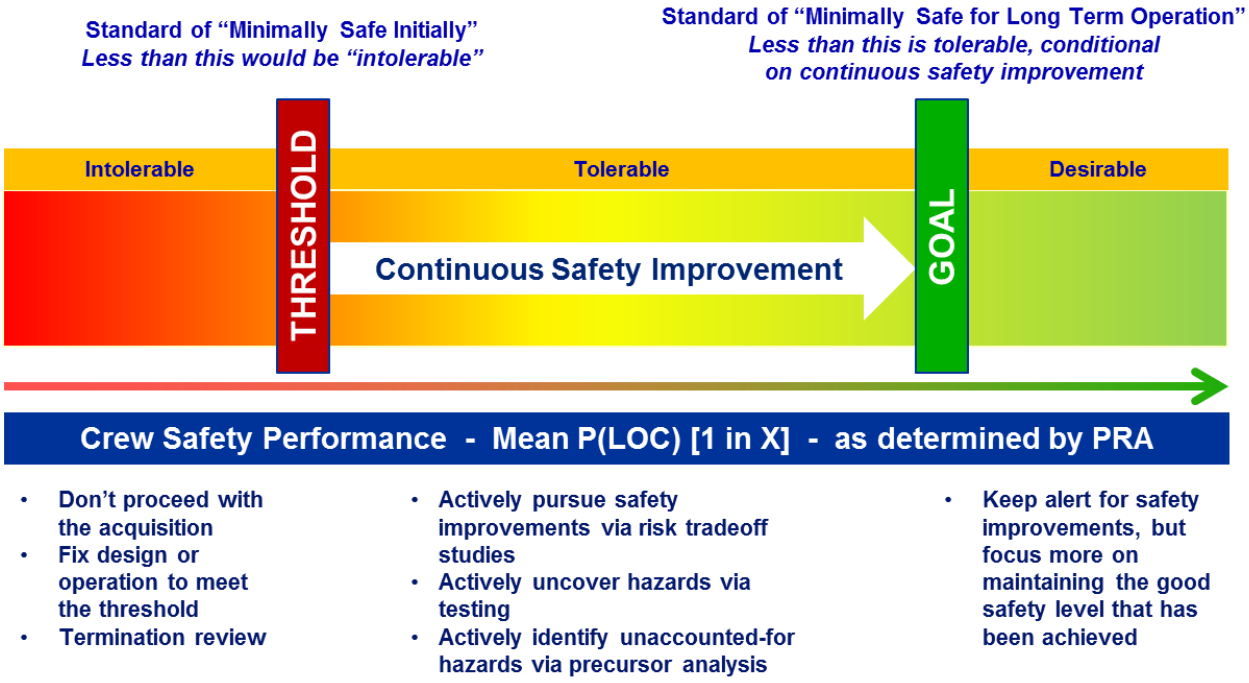


Figure 3-2. NASA Safety Goals and Thresholds

NASA Safety Goals and Thresholds as Defined for Crew Transportation to the ISS

NASA's safety goals and thresholds for crew transportation missions to the International Space Station (ISS) establish minimum tolerable levels of crew safety for acquisition of crew space transportation systems or services.

- Safety thresholds are initial minimum tolerable levels of safety for any crew transportation acquisition. They represent levels of safety considered achievable in light of findings from the Constellation Program, but are set below what is considered safe enough in the long term.
- Safety goals are the levels of crew safety considered safe enough in the long term. As long as these goals are not met, a continuous safety improvement program is required. The acquisition selection process should consider to what extent continuous safety improvement processes will allow progress towards the safety goals. Achievement of the goal could be the basis for a freeze in system design. However, the ASARP objective requires that continuous safety improvement be sought as long as other programmatic impacts are not unreasonable.

The NASA safety goals and thresholds define minimum tolerable levels of safety that change over time, in recognition of the safety growth that crew transportation systems are expected to experience during the operational phases of their system life cycles.

3.1.1.4 Safety Risk Reserves

NASA's agency-level safety goals and thresholds, as stated in the preceding section, do not explicitly address the question of how to account for unknown, un-quantified, and under-evaluated hazards. Yet, the expectation is that the demonstration of safety thresholds and goal satisfaction ought to be based on the actual risk, including both known and unknown sources.

To determine whether or not a system meets the safety goals and thresholds, therefore, it is necessary to consider whether the hazards that are not fully considered in the system's integrated safety analysis because they are not known or fully understood at the time the analysis is being performed are significant compared to those that are considered. In general, it would be expected that the relative importance of unknowns would be much greater for systems that employ fundamentally new technology or are being applied to new operating environments than for systems that are based on heritage design and standard operational envelopes. It would also be expected that for the former case, the importance of the unknowns would diminish as operating experience grows. There are recent analyses and surveys of

operational experience that corroborate these intuitive expectations and that can be used to help bound the magnitude of these effects.[13]

Consequently, as shown in Figure 3-3, it is incumbent to maintain a healthy safety risk reserve between the explicitly-calculated safety risk and the specified safety thresholds and goals, particularly when a program is young.[14] As flight experience accrues, events may occur that cause the calculated risk and the applied reserve to either increase or decrease. As indicated in the figure, the calculated risk will likely increase when additional failure causes are identified but will decrease when modifications are implemented to mitigate these causes. The amount of reserve needed to account for unknowns may either increase or decrease when new design modifications are implemented, depending upon the nature of the modification, but will tend to decrease upon the addition of in-flight recovery capabilities. The reserve needed for unknowns will also decrease as operational experience is gained without unexpected new events occurring.

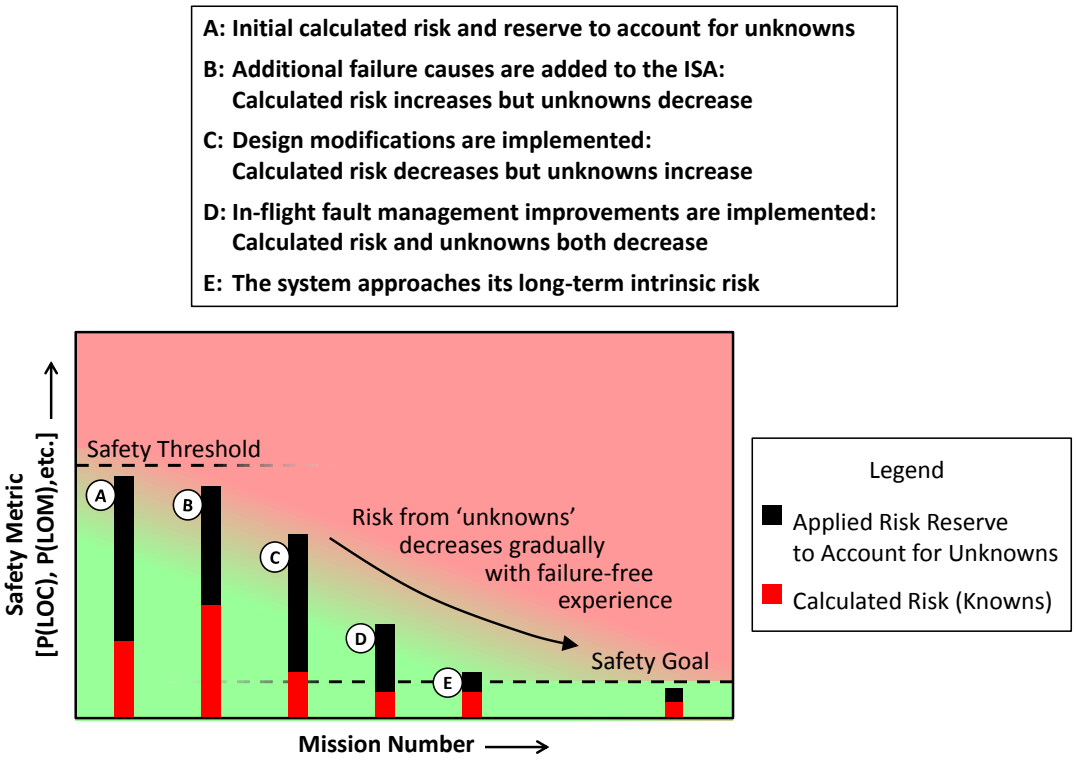


Figure 3-3. Assessing System Safety Performance against the NASA Safety Threshold and Goal

[13] For example, a recently published retrospective analysis of the risk to astronauts in the space shuttle program has shown that the ability to predict the probability of loss of crew was far superior near the end of the 30-year shuttle operational lifetime than near the beginning of it [21]. As another example, surveys have demonstrated that the rate of failures of new launch vehicles during their early operational years tends to be much higher than during their later operational years, and that the ratio of early-time to late-time failure rates was highly dependent upon unanticipated causes [22].

[14] This position is also reflected in the ASAP *Annual Report for 2011* [23].

Volume 2 will further elaborate on the subject of safety risk reserves and will provide guidance on how to implement them with appropriate examples.

3.1.2 Being as Safe as Reasonably Practicable

An adequately safe system is as safe as reasonably practicable (ASARP). At the core of ASARP is the concept of "reasonably practicable." This entails weighing the safety performance of the system against the sacrifice needed to further improve it. The system is ASARP if an incremental improvement in safety would require a disproportionate deterioration of system operational effectiveness, schedule, or cost. Thus, a system that is ASARP is one where safety improvement is given the highest priority within program constraints, throughout all phases of the system life cycle.

The ASARP concept is closely related to the "as low as reasonably achievable" (ALARA) and "as low as reasonably practicable" (ALARP) concepts that are common in U.S. nuclear applications and U.K. Health and Safety law, respectively. The terms ALARA and ALARP refer to 'risk' as that term is used in these contexts, and is therefore something to be minimized. Because the term 'risk' is used in NPR 8000.4A as "the potential for performance shortfalls… with respect to achieving explicitly established and stated performance requirements," which is not the context in which the term is used in the ALARA and ALARP concepts, ASARP refers instead to maximizing safety instead of minimizing risk. Nevertheless, the terms are essentially synonymous.

ALARA is defined in 10 CFR 20 [9] as:

> "…making every reasonable effort to maintain exposures to ionizing radiation as far below the dose limits as practical, consistent with the purpose for which the licensed activity is undertaken, taking into account the state of technology, the economics of improvements in relation to state of technology, the economics of improvements in relation to benefits to the public health and safety, and other societal and socioeconomic considerations, and in relation to utilization of nuclear energy and licensed materials in the public interest."

Similarly, the definition of ALARP set out by the British Court of Appeal [24] is:

> "'Reasonably practicable' is a narrower term than 'physically possible' … a computation must be made by the owner in which the quantum of risk is placed on one scale and the sacrifice involved in the measures necessary for averting the risk (whether in money, time or trouble) is placed in the other, and that, if it be shown that there is a gross disproportion between them – the risk being

insignificant in relation to the sacrifice – the defendants discharge the onus on them."

Thus, the claim that a system is ASARP implies that:

- A comprehensive spectrum of alternative means for achieving operational objectives has been identified.
- The performance of each alternative has been characterized in sufficient detail to support an assessment of the relative gains and losses in performance (operational effectiveness, safety, cost, and schedule) that would result from selecting one alternative over another.
- Safety performance is given priority in the selection of an alternative, insofar as the selection is within operational constraints.

In other words, ASARP is an attitude towards risk-informed decision making (RIDM) [6] that places a high value on safety. It is operative in every systems engineering process where decisions are made that affect the safety performance of the system.

The ASARP concept is illustrated graphically in Figure 3-4. The curve represents the *efficient frontier*[15] of the trade space of identified alternatives, and shows the tradeoff between safety performance and performance in other mission execution domains (cost, schedule, technical). The ASARP region contains those alternatives whose safety performance is as high as can be achieved without resulting in intolerable performance in one or more of the other domains. Figure 3-4 shows that:

- Improvements to cost, schedule, or technical performance beyond minimum tolerable levels are not justifiable if they come at the expense of safety performance.[16]
- The ASARP concept makes no explicit reference to the absolute value of a system's safety performance or the tolerability of that performance. It is strictly concerned with its safety performance relative to that of the other identified alternatives.
- ASARP is a region of the trade space and can contain more than one specific alternative. Moreover, the boundaries of that region are not sharply defined. Consequently, there is

[15] The efficient frontier represents the subset of the trade space containing those alternatives whose performance is not dominated by other alternatives. An alternative is dominated if there another alternative with superior performance in every performance measure. The efficient frontier expresses the limits of the functional relationships among the performance measures. At the efficient frontier, additional gains cannot be made in any performance measure without a concomitant erosion of performance in some other measure.

[16] ASARP does not rule out improvements in cost, schedule, or technical performance that can be made without significant impact on safety.

a subjective element to determining that a system is ASARP that entails the prudent application of engineering and management judgment.

It is sometimes necessary to balance one type of safety performance against another when developing and/or operating a system. For example, range safety and crew safety may be competing objectives to some extent if measures that enhance crew safety, such as abort/destruct protocols, erode the safety of personnel (or the public) on the ground. The ASARP concept does not provide any heuristic for determining how best to balance these concerns, but it does specify that overall safety performance, however determined, should be prioritized.

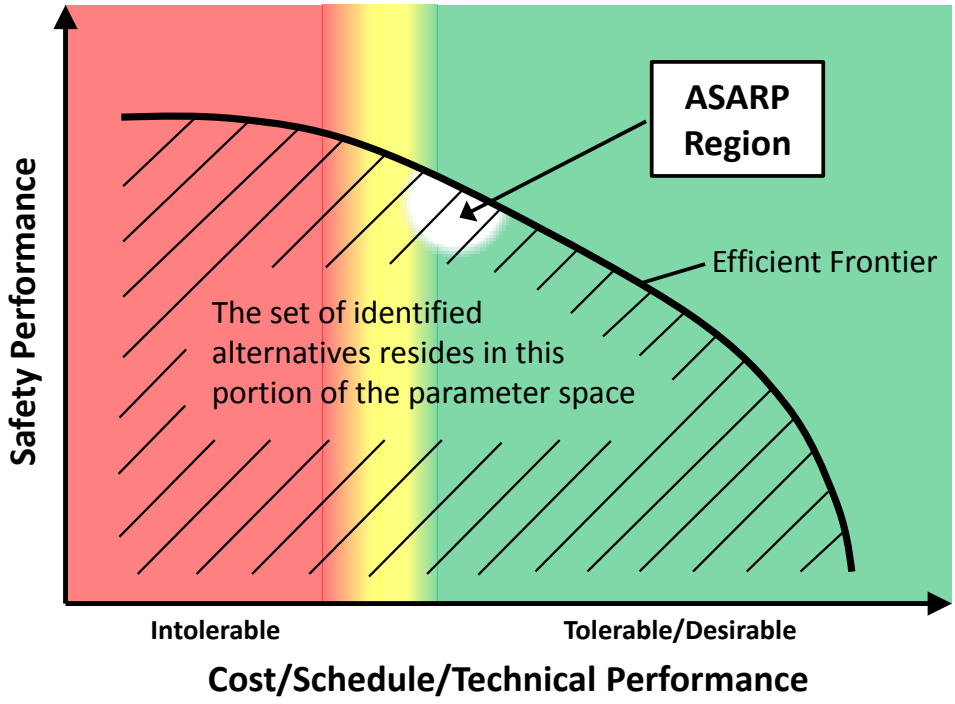


Figure 3-4. As Safe As Reasonably Practicable (ASARP)

3.2 Derivation of Operational Safety Objectives

As discussed in Section 3.1, the six safety objectives at the bottom of Figure 3-1 set the stage for the further development of safety objectives, to be negotiated on a system-by-system basis between the organizational unit performing the task and the unit overseeing the task. By developing safety objectives down to a level where they can be clearly addressed by systems engineering processes, a link is created that enables the processes to be assessed in terms of the degree to which the safety objectives have been met. If the safety objectives have indeed been met, then, by virtue of their derivation from fundamental safety principles, the system is adequately safe. In other words, the derived safety objectives at the bottom level of the

objectives hierarchy represent the *operational* definition of safety for the system under consideration, and are therefore referred to as *operational safety objectives*.[17] As such, they are the starting point for tailoring the systems engineering processes used in design, realization, and operation, to assure that they adequately address safety in every activity that has the potential to affect safety.

Although there is expected to be a high degree of overlap between the operational safety objectives of different aerospace systems, due in part to the application of a common NASA systems engineering framework across the agency, there is no single set of operational safety objectives that is universally applicable to all systems. Factors that influence their development include:

- The presence of members of the public (or lack thereof)
- The presence of crew (or lack thereof)
- The presence and type of environmental hazards (Earth environment, planetary environment)
- Expectations of post-mission system recovery/reuse
- System cost
- System life expectancy
- Mission value
- The level in the product breakdown structure (PBS) under consideration (e.g., vehicle, element, system, sub-system)
- The systems engineering process framework used

In any case, the rationale for a given decomposition from fundamental safety principles to operational safety objectives must be given (e.g., in the System Safety Technical Plan (SSTP) [1]), with specific emphasis on the completeness of the derivation.

Figure 3-5 presents an example derivation of operational safety objectives for a notional space mission. They fall within the four areas illustrated by the shaded boxes, “The quantified safety performance meets requirements,” “Decisions are risk informed,” “Requirements that affect

[17] The term ‘operational’ is used here to indicate that these are the objectives that the system safety activities explicitly address. It is unrelated to the usage of the term ‘operation’ in the context of ‘system design, realization, and operation.’

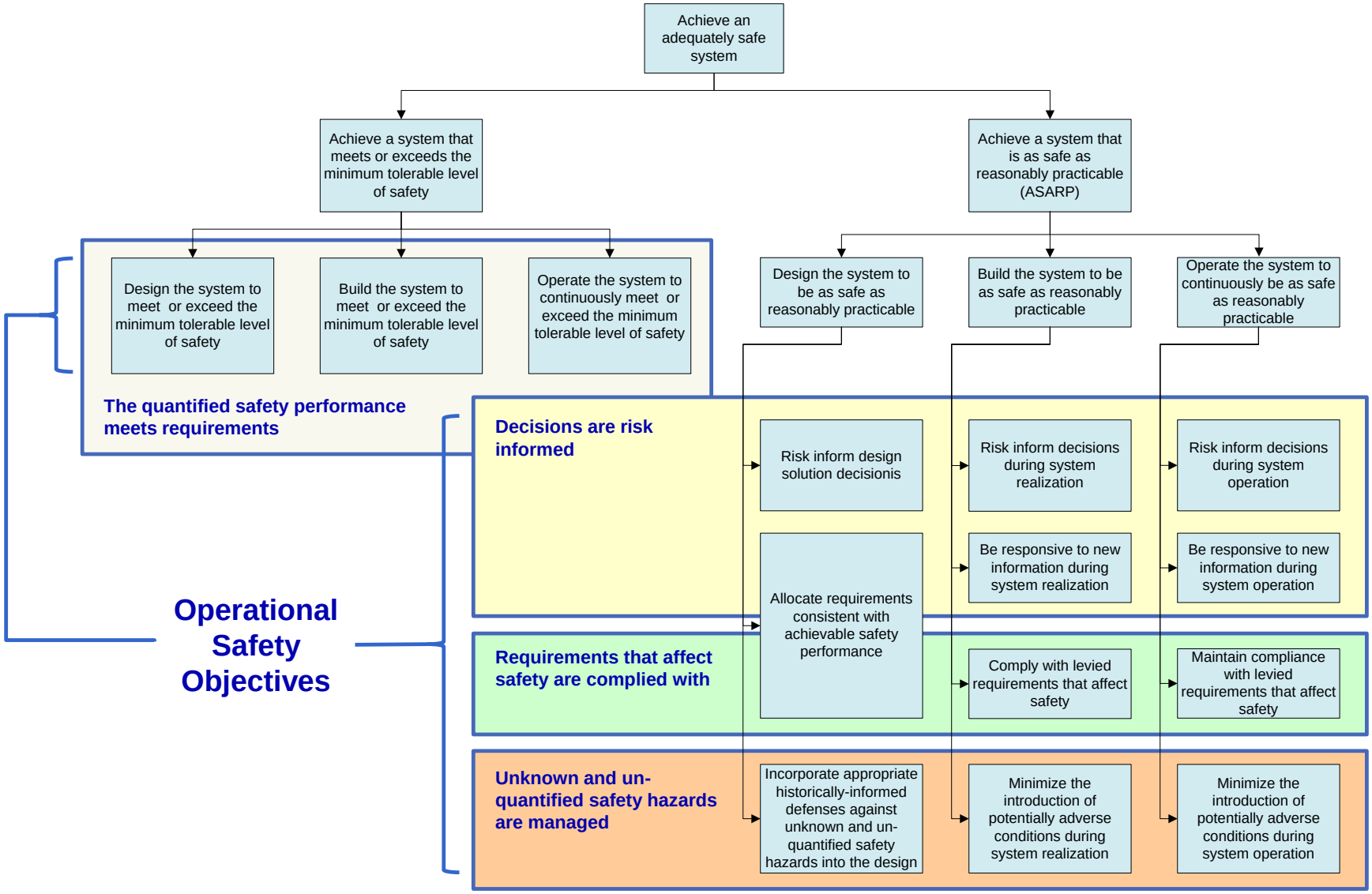


Figure 3-5. Derivation of Operational Safety Objectives for a Notional Space Mission

safety are complied with," and "Unknown and un-quantified safety hazards are managed." The processes used to achieve these objectives is the topic of Section 4, System Safety Activities.

3.2.1 The Quantified Safety Performance Meets Requirements

In practice, the extent to which a system meets minimum tolerable levels of aggregate safety is assessed in terms of meeting levied safety performance requirements that either directly correspond to minimum tolerable levels or are allocated from safety performance requirements from the organizational unit above. No additional decomposition is needed in this area to arrive at the operational objectives of:

- Design the system to meet or exceed the minimum tolerable level of safety.
- Build the system to meet or exceed the minimum tolerable level of safety.
- Operate the system to continuously meet or exceed the minimum tolerable level of safety.

Implicit in these objectives is a safety analysis whose performance measures correspond to the safety performance of interest, and that is conducted in accordance with the analysis protocols that have been agreed on as part of the requirements negotiation process between the responsible organizational units. As such, issues such as the completeness of the set of analyzed accident scenarios, the effectiveness of controls, and the likelihood of adverse safety consequences, are subsumed within the conduct of the safety analysis.

3.2.2 Decisions are Risk Informed

As discussed in Section 3.1.2, the ASARP concept implies risk-informed decision making (RIDM) throughout the system life cycle. RIDM is discussed in detail in [6], and contains the steps enumerated in Figure 3-6. In RIDM, safety analysis is integrated into a risk analysis framework, illustrated in Figure 3-7, in order to supply inputs to other mission execution domain analyses (cost, schedule, technical) whose results are dependent upon the safety analysis results, and to produce the safety performance measures that bear upon stakeholder objectives and are therefore relevant to decision making. This enables decision alternatives to be compared in terms of the full spectrum of performance characteristics that matter to the decision maker, which is a necessary condition for assuring that the system is ASARP.

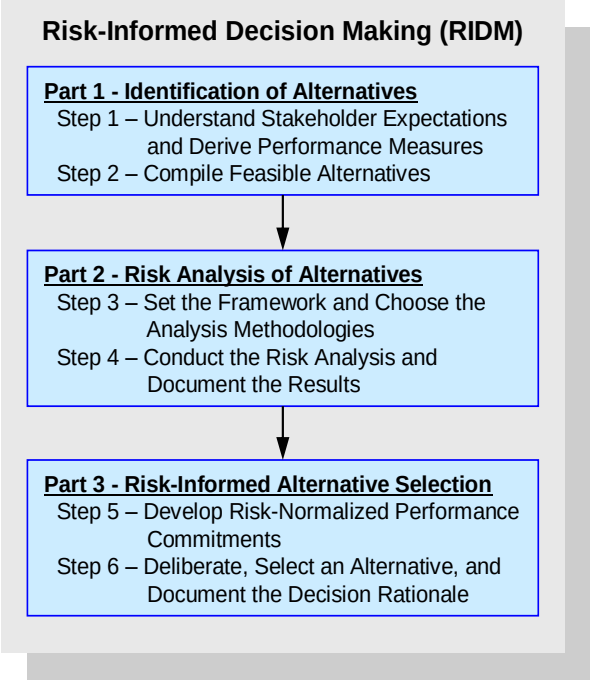


Figure 3-6. RIDM Process Steps

The operational safety objectives in this area are:

- **Risk inform design solution decisions and decisions made during system realization/ operation:** These three objectives refer to the expectation that decision making will be risk informed, and that decision makers align their priorities with the principle of ASARP: i.e., they incorporate prioritization of safety performance to the extent practicable.

- **Allocate requirements consistent with achievable safety performance:** This objective refers to the expectation that the safety performance requirements which are allocated to lower organizational units are achievable by those units. Requirements allocation is addressed by the RIDM process through the development of risk-normalized performance commitments [6], which are the assessed levels of system performance that are achievable within the risk tolerance of the decision maker. Since system development is ultimately driven by requirements, requirements allocation has a major influence over the system that is ultimately produced. Risk informing the requirements allocation process assures that the resulting system is ASARP. Sections 4.2.1.6 and 4.4 provide additional information about risk informed requirements allocation.

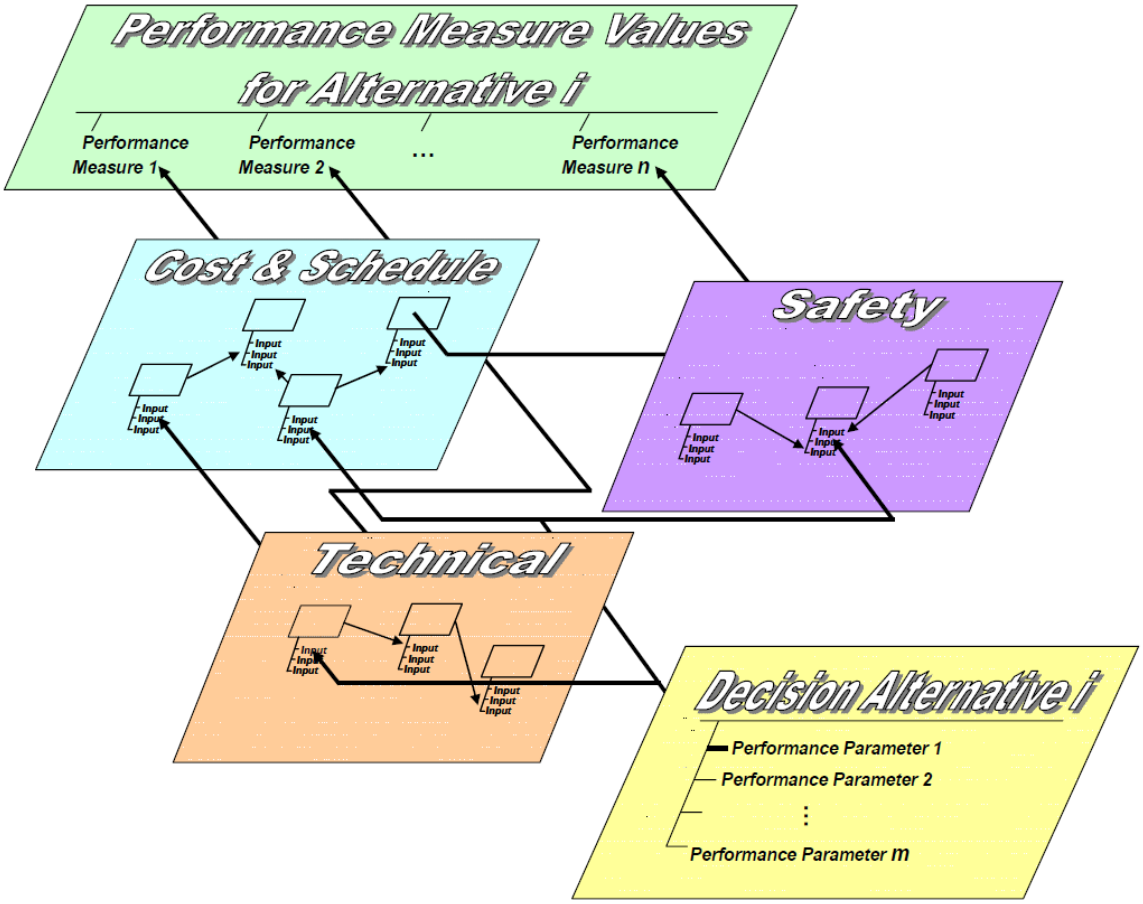


Figure 3-7. Safety Analysis in the Context of the RIDM Risk Analysis Framework

- **Be responsive to new information during system realization/operation:** These objectives refer to the expectation that system management will be responsive to new information that arises post-design. The information itself can be either positive (a potential opportunity) or negative (a potential concern), and can come from within the system (e.g., anomalous system behavior) or from sources external to the system (e.g., investigations of similar systems, changes to the system's operating environment). In any case, the expectation is that a RM capability will be implemented that will enable system design and operational modifications to be considered in light of new information, so that unnecessary deterioration of safety can be averted and that opportunities to improve safety can be exploited.

3.2.3 Requirements that Affect Safety are Complied With

Requirements represent the constraints placed upon the system. In the hierarchical structure of NASA, organizational units generally interact with requirements in two distinct ways: by complying with requirements that have been negotiated with the next higher organizational

unit in the hierarchy; and by overseeing compliance with requirements that have been negotiated with organizational units at lower levels of the hierarchy.

- **Allocate requirements consistent with achievable safety performance:** This objective is in this section, as well as in Section 3.2.2, because the organizational unit that allocates requirements to lower level units is also responsible for overseeing compliance with the allocated requirements.

- **Comply/maintain compliance with levied requirements that affect safety:** These objectives refer to the basic systems engineering expectation that requirements will be complied with, and that compliance will be maintained throughout the system life cycle.

3.2.4 Unknown and Un-quantified Safety Hazards are Managed

The area, 'Decisions are Risk Informed,' addresses those accident scenarios whose impacts on safety performance have been quantified. However, in all safety analysis activities there is the issue of completeness, i.e., there is no way to ensure that all scenarios (above some threshold of significance) have been appropriately identified and analyzed. There is always the possibility of the existence of unknown and un-quantified safety hazards, which are typically managed using a suite of heuristic best practices such as simplicity in design, robust margins, adherence to codes and standards, inclusion of recovery capability, etc.

- **Incorporate appropriate historically-informed defenses against unknown and un-quantified safety hazards into the design:** This objective refers to measures taken to minimize the possibility that an incomplete understanding or analytical characterization of the system will result in a system that may exhibit undesirable safety performance. These measures go beyond those explicitly derived from the ISA, to include measures that have developed historically and are recognized as best practices in their engineering disciplines. Defenses against unknown and un-quantified safety hazards represent a historically-informed conservative stance with respect to incomplete understanding of the system.

- **Minimize the introduction of potentially adverse conditions during system realization/operation:** These objectives refer to the expectation that the system will be built, operated, and maintained in such a way as to minimize the introduction of additional hazards. Such hazards may be introduced as a result of manufacturing or integration processes, life cycle maintenance practices, operational practices, etc. In general, this area relates to adherence to best practices in system realization and operation, and the imposition of engineering discipline to keep system operation within the design intent.

4 System Safety Activities

4.1 Introduction

In Chapter 3, an example safety objective hierarchy was devised with separate derivative objectives applying to each of three phases during the life cycle: design, realization, and operation. When talking about system safety activities and their relationships to the safety objectives, it is convenient to decompose the design phase still further into two sub-phases because the activities during early design tend to be quite different from those during later design. This is to be expected from the fact that early design decisions, which involve choices between basic concepts, are informed by risk-informed decision making (RIDM) processes, whereas later design decisions, which are of a more detailed nature, are informed by continuous risk management (CRM) processes. Thus, this chapter on system safety activities will provide separate examples for each of the following four mission phases:

- Concept development and early system design
- Detailed system design
- System realization
- System operation (including performance monitoring and re-evaluation)

Section 4.2 will deal with the characterization of the system safety activities and the development of the relationships between them and the safety objectives. Sections 4.3 through 4.5 will discuss special topics that are important for the successful execution of the activities within the frameworks provided by NPR 7123.1 and NPR 8000.4A. Section 4.3 will be concerned with topics relevant to integrated safety analysis, Section 4.4 with topics relevant to risk-informed allocations of safety thresholds and goals, and Section 4.5 with topics relevant to the collaborative formulation of controls.

The development of the risk-informed safety case, which provides the arguments that the safety objectives have been met, will be provided in Chapter 5.

4.2 Overview of System Safety Activities and their Relationships to Safety Objectives

4.2.1 Concept Development and Early System Design

The system safety activities needed to support concept development and early system design are presented in Figure 4-1 in purple colored boxes. The operational safety objectives for this

phase, in blue colored boxes, are those listed in Figure 3-5 of Section 3.2 in conjunction with the blocks that start with the phrase “Design the system to ...”.

A bit of orientation is needed to facilitate understanding of Figure 4-1 and the figures that follow. First, note that the activities in several of the purple boxes are nested. For example, the box entitled “Develop Integrated Safety Analysis (ISA)” is wholly contained within a box entitled “Develop Risk Analysis of Alternatives”. This nesting purports to show that integrated safety analyses are part of a risk analysis process that also includes other contributing activities: cost analysis, schedule analysis, and technical performance analysis in particular. These other analysis activities are germane to the system safety formulation because they contribute to the evaluation of whether the system is “As Safe as Reasonably Practicable”, one of the governing safety objectives. Thus, although they are not performed by system safety professionals, they are explicitly shown in a figure entitled “Principal System Safety Activities”. The box entitled “Develop Risk Analysis of Alternatives” is likewise contained within a box entitled “Conduct RIDM”. The RIDM box includes not only risk analysis but also other contributing activities (such as deliberation on decisions; Refer to Figure 3-6). However, since these other contributing activities are not part of the safety framework, they are not explicitly shown in the figure. The nesting format automatically implies an arrow from the smaller activities within the nest to the larger activity surrounding it.

The arrows that are in the form of arcs depict two separate types of interfaces. One is the input-output relationships between the activities, and the other is the principal interfaces between the activities and the objectives. In the interest of avoiding excessive clutter, interfaces between activities and objectives that are considered to be secondary are not shown. Some of the more important interfaces will be discussed in succeeding subsections.

Between the activities and the objectives is a horizontal broad olive-colored arrow labeled “RISC”, within which lies the Risk Informed Safety Case. Although not explicitly shown in this figure and those that follow, the RISC arrow contains the case to be made that the evidence produced by the system safety activities is sufficient to justify that the safety objectives have been met. The contents of the RISC arrow will be the principal topic to be discussed in Chapter 5.

The following subsections will discuss the nature of each of the system safety activities that are depicted in Figure 4-1.

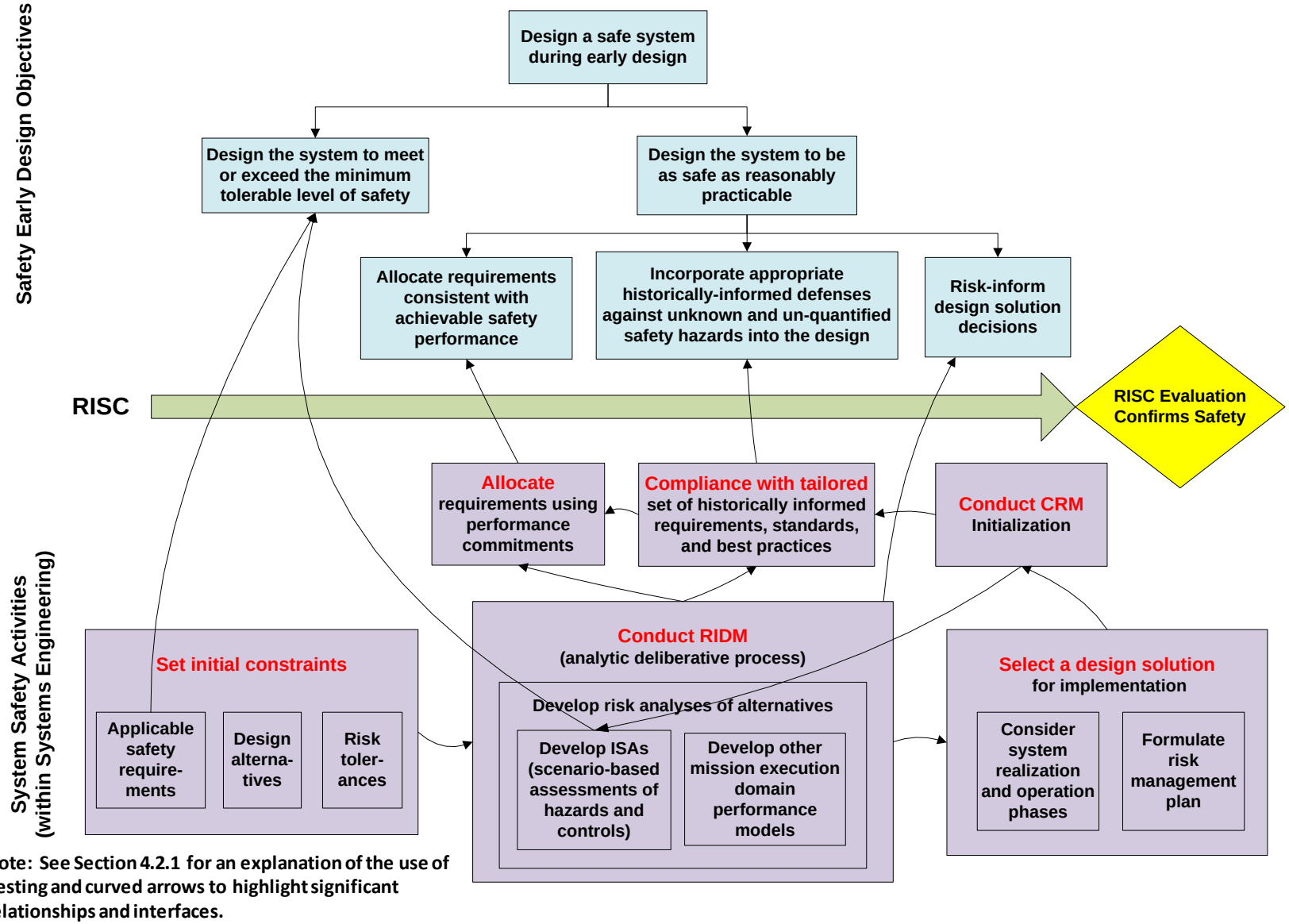


Figure 4-1. Principal System Safety Activities and Related Processes during Concept Development and Early System Design, and their Interfaces with the Safety Objectives

4.2.1.1 Set Initial Constraints

The initial constraints are developed within the system safety function in collaboration with the systems engineering function and the project stakeholders and decision makers. At the beginning of a project during concept development, the requisite constraints include the following:

- Conceptual characterization of the design alternatives being considered.
- Applicable requirements and standards developed or adopted for the project by the system engineering function. Initially the emphasis is on requirements that pertain to safety, but because one of the high level objectives is to develop a system that is as safe as reasonably practicable (ASARP), the safety analysts also have to be aware of the key requirements that pertain to cost, schedule and technical performance.
- The decision makers' risk tolerance levels for not meeting the requirements. Risk tolerance is usually expressed as the amount of uncertainty that the decision maker is willing to tolerate pursuant to meeting the requirement. Since requirements are specified by systems engineering and risk tolerances by decision makers, the two are considered separate entities.
- Other mission-relevant constraints, including concept of operations, design reference missions, and operating environments.

The constraints affect many of the activities, although the arrow in Figure 4-1 indicates that the principal effect is on the activities contained within the general context of risk informed decision making.

4.2.1.2 Conduct Risk-Informed Decision Making

The principal objectives of RIDM are as follows:

- Provide and explain risk results to decision makers in order to facilitate their decisions about which of several major design alternatives to select for further development.
- Provide performance commitments and associated risk tolerances to the system engineering function to facilitate the development of performance requirements for the selected design alternative.
- Assist in the allocation of safety-related performance requirements from higher to lower levels in the organization.

In addition to these general objectives, there are specific products and information that RIDM provides to support the system safety activities:

- Models and results that the system safety team can use to evaluate trade-offs in the search for a final design that is "as safe as reasonably practicable"

The general RIDM process includes risk-informed decision making spanning all four mission execution domains: safety, technical, cost, and schedule. Although the integration of risk models from these four domains is the responsibility of the risk management (RM) function, the development of individual models that support this integration effort requires interaction of the RM analysts with the analysts that are dedicated to modeling system safety, technical performance, cost, and schedule. Therefore, although RIDM has its own framework and processes (as summarized in [6]), there are strong interfaces with the system safety framework and, correspondingly, the results pertaining to safety, technical, cost, and schedule risks are shared.

4.2.1.2.1 Develop Integrated Safety Analyses

The integrated safety analysis (ISA) during concept development and early design occurs under the RIDM process, and in later phases occurs under the CRM process.[18] ISA is a proactive investigation into the ways that the system can fail, the likelihood of such failures, and their consequences. ISA includes both hazard-centric and non-hazard-centric methods for identifying and characterizing potential accident scenarios. This includes accident causes, contributing factors, effectiveness of controls (both existing and proposed), analysis of physical responses of the system to the environments it encounters, and analysis of the probability that the undesirable consequences will be realized. Both quantitative and qualitative analyses can be performed as part of an ISA, as appropriate for the scenario being considered and the nature of the undesired consequence. Principal outputs from ISA are as follows:

- A set of accident scenarios that can produce undesirable safety performance (see Appendix B and Section 4.3.1 for a definition and discussion of the term "scenario")
- Identification and evaluation of the potential causes of these accident scenarios
- Identification and evaluation of existing controls associated with the scenarios
- Probability density functions (PDFs) for safety metrics when appropriate (e.g., PDFs for the probability of LOC, LOV, LOM.)

[18] As mentioned in an earlier footnote, ISA is different from the Integrated Design and Safety Analysis function referred to in other documents with reference to failure tolerance and redundancy requirements.

- Safety margins (e.g., structural and thermal safety margins, radiation margins, etc.)
- Sensitivity of safety metric PDFs and safety margins to parameter variations
- Credibility assessment of the models used

The safety analysis should have the following characteristics (which will be elaborated upon further in Section 4.3):

- PDFs for safety metrics and safety margins should be obtained for all key decision points (KDPs) during the project, including those that have not yet occurred. In other words, the safety analyses should consider time to be a variable and should clarify how the risk is anticipated to increase or decrease between the present time and the completion of the project.
- The analysis models should be scenario based. It is not sufficient simply to identify hazards and formulate controls. Rather, a set of possible accident scenarios should be developed wherein each scenario starts from an initiating event, proceeds with the occurrence of enabling events, and terminates with consequences that pertain to not meeting safety requirements.
- A graded analysis approach should be used. That is to say, the amount of effort spent in evaluating each scenario (i.e., formulating the models, obtaining supporting data, and performing calculations) should be proportional to the risk-importance of the scenario.
- Uncertainties should be explicitly considered. The risk evaluation should include both aleatory uncertainty (pertaining to random or stochastic behavior) and epistemic uncertainty (pertaining to lack of knowledge). Where possible, these two types of uncertainty should be analyzed separately from one another. Uncertainties to be addressed should include both uncertainties in input parameters to the models and uncertainties in the models used.
- There should be evidence, per NASA-STD-7009, *Standard for Models and Simulations* [25], that the models and the data used as input to them are technically credible and appropriate for the conditions under which they are assumed to apply.

4.2.1.2.2 Develop Other Mission Execution Domain Performance Models

Because of the “reasonably practicable” part of the ASARP objective, it is necessary to consider the cost, schedule, and technical performance impacts of various options being considered to optimize safety. Modeling of cost, schedule, and technical performance per se is not a responsibility of the system safety function, but is rather under the jurisdiction of other

organizational units within the project. However, under the ASARP objective, the system safety function requires involvement in the systems engineering trade studies that consider how variations in design, test plans, sustainment, and other facets of the project might affect not only safety but also the other mission execution domains. This requires that the safety team work closely with the costing, scheduling, and engineering units within the project.

4.2.1.3 Select a Design Solution for Implementation

The process of down-selecting from the design alternatives to one particular design concept is conducted through a risk-informed deliberation by the decision makers. The safety team collaborates in ensuring that results from the integrated safety analysis are understood and properly interpreted by the decision makers.

Although the integrated safety analysis and overarching RIDM activities described in this section are conducted during the concept development and early design phase, the risks being considered must include not only design risks but also risks during the system realization and operation phases that may be instigated or promoted by the design being considered. Therefore, the risk information provided to the decision makers includes risks that may come to realization in future mission phases, not just the present mission phase.

The selection of a design concept is documented in a Risk Informed Selection Report and is incorporated into the project's Risk Management Plan (RMP).

4.2.1.4 Conduct CRM Initialization

As discussed in the RM Handbook [6], the role of CRM early in the project, before most design details have been developed, is to complete the risk modeling started during RIDM to include all scenarios that affect the magnitude of the performance risks (as opposed to emphasizing just those that are needed to differentiate between the candidate design alternatives).

Therefore, the CRM initialization activity provides improved models and results that the system safety team can use to better evaluate ASARP trade-offs and tailor the safety requirements.

Another outcome from CRM initialization is a more complete identification of the scenarios that are driving the risk. Once known, it may be decided that a more detailed and robust treatment of these risk-driving scenarios is needed in order to ensure the accuracy and completeness of the analysis. Similarly, it may be possible to lessen the amount of robustness applied to scenarios that are not contributing significantly to risk, or even to drop them from the model altogether, so as to reduce downstream analysis costs. This is the essence of a graded approach, which allows for the integrated safety analysis to be tailored so that effort is

dedicated foremost to the scenarios that matter. The feedback path from CRM initialization to Integrated Safety Analysis in Figure 4-1 provides this mechanism.

4.2.1.5 Comply with a Tailored Set of Historically Informed Requirements, Standards, and Best Practices

Requirements that have developed historically and are recognized as best practices in their engineering disciplines tend to provide protection against potential accident scenarios that may not have been uncovered during the risk assessment or that may have been uncovered but are not easily quantified. Therefore, compliance with such requirements helps to achieve the objective of incorporating defenses against unknown or un-quantified safety hazards.

At the same time, as part of the risk-informed process for decision making, requirements levied upon an organizational unit may be appealed if it can be shown that they impede the achievement of optimal safety rather than facilitate it. Justification for appealing requirements is provided in NASA Policy Directive NPD 1000.0A, *Governance and Strategic Management Handbook* [26], from which the following is a direct quotation:

> "Good requirements that are properly managed are essential to any successful undertaking. Part of establishing the proper set of requirements is the adjustment of prescribed requirements to the specific task (e.g., a program or project).
>
> "Principals that govern processes of tailoring requirements are:
>
> 1. "The organization at the level that established the requirement must approve the request for tailoring of that requirement unless this authority has been formally delegated elsewhere. The organization approving the tailoring disposition consults with the other organizations that were involved in the establishment of the specific requirement and obtains concurrence of those organizations having a material interest.
> 2. "The involved management at the next higher level is to be informed in a timely manner of the request for tailoring of the prescribed requirements."

In the process for tailoring the set of requirements that is deemed to be applicable to a program or project, individual requirements are either waived or adjusted. Waiving of a requirement involves an excision of the requirement in its entirety from the set that applies to the program/project. Adjustment of a requirement implies that the requirement remains in place but in an altered form. For example, if the requirement specifies a threshold value that must be achieved within a given risk tolerance, the adjustment may involve a change to the threshold value, the associated risk tolerance, or both.

System safety enters into the deliberation of whether or not a requirement should be waived or adjusted by providing the risk information that supports the decision. For example, either of the following two arguments could be used in favor of waiving a requirement:

- The requirement clearly has a negative impact on safety (e.g., increases the probability of LOC), and removing it would not have any negative impacts on other mission execution domains (i.e., would not increase cost, cause schedule slippages, or degrade technical performance).
- The requirement has only a negligible positive effect on safety and removing it would have a clearly significant positive effect on or more other mission execution domains.

An argument that might be used to support adjustment of a requirement, rather than waiving it, might be as follows:

- Making a prescribed adjustment to the requirement would have a clearly significant net positive effect on safety and clearly would not have a significant negative impact on the other mission execution domains.

The use of the term “clearly” in each of these arguments states a desire that the decision to waive or adjust a requirement be made judiciously and only when clearly indicated as beneficial. The reason for this caution is that the requirements, when initially formulated, may have been based on best practices derived from historical experience, or on other considerations that go beyond safety. Discarding or adjusting requirements should not be undertaken without careful deliberation of the concomitant effects, which might include the following:

- Impacts on the overall safety defense strategy (e.g., a degradation of a defense-in-depth strategy)
- Impacts on the Agency’s strategic goals
- Impacts on perceptions outside the Agency

In other words, the decision to waive or adjust requirements, like any key decision, should be risk-informed but not risk-based.

4.2.1.6 Allocate Requirements using Performance Commitments

In order for a design team at any level of the organization to complete its work, it is necessary for it to have requirements for the performance of the assets that it is responsible for. The process for determining the required asset performance parameters involves an allocation, e.g.,

from system to subsystem or component level. (Note that although allocation is most commonly thought of in terms of reliabilities, any quantitative performance requirement can be allocated.)

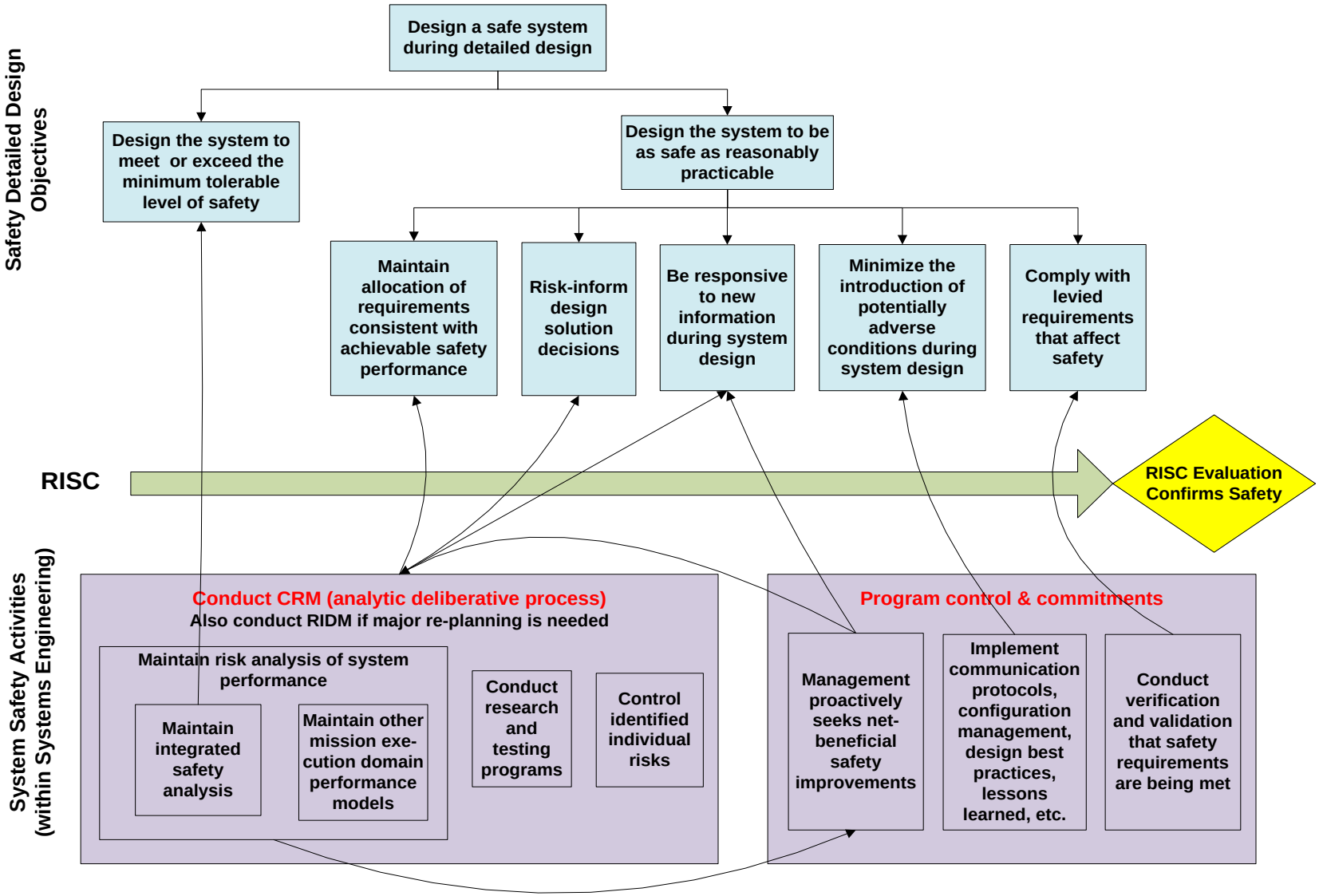
In theory, the required performance at subsystem or component level should result in the performance of the system being at least as high as its required value. For example, allocated mean failure rates at subsystem or component levels should be both practical and consistent with achieving the thresholds and goals for the probabilities of LOC, LOV, and LOM at the system level. The problem is that there is a high risk of not meeting these criteria and of not achieving the ASARP objective if the allocation is performed in an ad-hoc manner, where historical experience is the only guide. For this reason, it is important that the allocation process be model based and risk informed. The RIDM and CRM initialization processes provide a basis for accomplishing this since, taken together, they provide support for the development of performance commitments and risk tolerances that relate to the performance objectives of each organizational unit.

More on this subject will be provided in Section 4.4.

4.2.2 Detailed System Design

The system safety activities needed to support detailed system design are presented in Figure 4-2. This phase is different from the concept development and early design phase because the length of time required to complete the detailed design makes it likely that new risk issues requiring resolution will surface as design details are being developed. These new risks often involve the necessity of having to reallocate subsystem masses while ensuring that allocated safety requirements, codes, and standards continue to be satisfied.

The lower level safety objectives for this phase consist of a combination of objectives listed in Figure 3-5 of Section 3.2 under the phrases “Design the system to ...” and “Build the system to ...”. This results in an expansion lower-level objectives under the ASARP objective to five, as shown in Figure 4-2. The broadening of the early design safety objectives reflects the fact that during detailed design, new information, both positive and negative in character, is being generated. Sometimes this information takes the form of new risks and challenges. Other times the new information takes the form of new opportunities to improve safety.



Note: See Section 4.2.1 for an explanation of the use of nesting and curved arrows to highlight significant relationships and interfaces.

Figure 4-2. Principal System Safety Activities and Related Processes during Detailed System Design, and their Interfaces with the Safety Objectives

4.2.2.1 Conduct Continuous Risk Management (CRM) during Detailed System Design

The gathering of new information that affects the risks in any of the mission execution domains (safety, technical, schedule, and cost) is a role of CRM that is maintained throughout the entire project timeline. This type of new information is used to update the risk models and supporting databases. Consonant with these updates, the role of CRM evolves to include the development and implementation of new controls when needed to counteract any new or changed risks. As appropriate, the CRM activity includes research and testing in order to improve the understanding of the risks and to assist the development of controls.

As is discussed in the RM Handbook [6], the activities conducted as part of CRM comprise the following steps:

- **Identify:** The purpose of the *Identify* step is to capture stakeholders' concerns regarding the achievement of safety requirements as well as performance requirements in other mission execution domains. These concerns are recorded as individual risks in a *risk database*. Each individual risk is articulated as a *risk statement* that contains a *condition*, a *departure*, an *asset*, and a *consequence*.

- **Analyze:** The objectives of the *Analyze* step are to estimate the likelihoods of the departure and the magnitudes of the consequence for each individual risk, to evaluate the timeframe available for preventive or mitigative action, to characterize the uncertainties, to calculate the aggregate risks of not meeting specified thresholds and goals at different project milestones (as well as the aggregate risks within other mission execution domains), and to determine which departure events and parameters within the models are the most important contributors to each aggregate risk (i.e., the drivers for the risk of not meeting the requirement for P(LOC), P(LOV), P(LOM), and each other levied safety requirement).

- **Plan:** The objective of the *Plan* step is to decide what action, if any, should be taken to reduce the safety risks and other mission execution domain risks that are caused by the aggregation of identified individual risks. The possible actions are: *Accept*, *Mitigate*, *Watch*, *Research*, *Elevate*, and *Close*.

- **Track:** The objective of the *Track* step is to acquire, compile, and report observable data to follow the progress of the implementation of risk management decisions, and their effectiveness once implemented. The tracking task of CRM serves as a clearing house for new information that could lead to a new risk item, a change in risk analysis, a change in a previously agreed-to plan, or the need to implement a previously agreed-to contingency.

- **Control:** When tracking data indicates that a risk management decision is not impacting risk as expected, it may be necessary to implement a *control* action. Control actions are intended to assure that the planned action is effective. If the planned action becomes unviable, due either to an inability to implement it or a lack of effectiveness, then the Plan step is revisited and a different action is chosen

- **Communicate and Document:** Well-defined, documented communication tools, formats, and protocols assure that individual risks are identified in a manner that supports the evaluation of their impacts on performance risk and that those that impact multiple organizational units (i.e., crosscutting risks) are identified, enabling the coordination of risk management efforts. Risk management decisions and their rationales are captured as part of the institutional knowledge of the organization.

As was discussed with regard to the RIDM process, the development of individual models that support the risk integration and management effort requires interaction of the RM analysts with the analysts that are dedicated to modeling system safety, technical performance, cost, and schedule. Therefore, although CRM, like RIDM, has its own processes (as summarized in [6]), there are strong interfaces with the system safety framework. For example, any controls developed within CRM to prevent or mitigate a new risk must support the following general safety objectives:

- Assure that the overall probabilistic safety threshold requirement continues to be satisfied

- Assure that safety performance continues to be the most important priority as long as the impacts to cost, schedule, and technical performance remain acceptable

- Assure that the approach to safety is holistic, such that the overall control strategy promotes protection against unknown or un-quantified risks

4.2.2.2 Maintain a Robust Set of Program Controls and Commitments during Detailed System Design

Program controls and commitments play an important role in ensuring that safety objectives are met. During the detailed design phase, some of the more important elements of this activity include the following:

- Management actively promotes an environment within which design opportunities for improving safety without incurring unreasonable cost, schedule, and technical impacts are sought out and implemented.

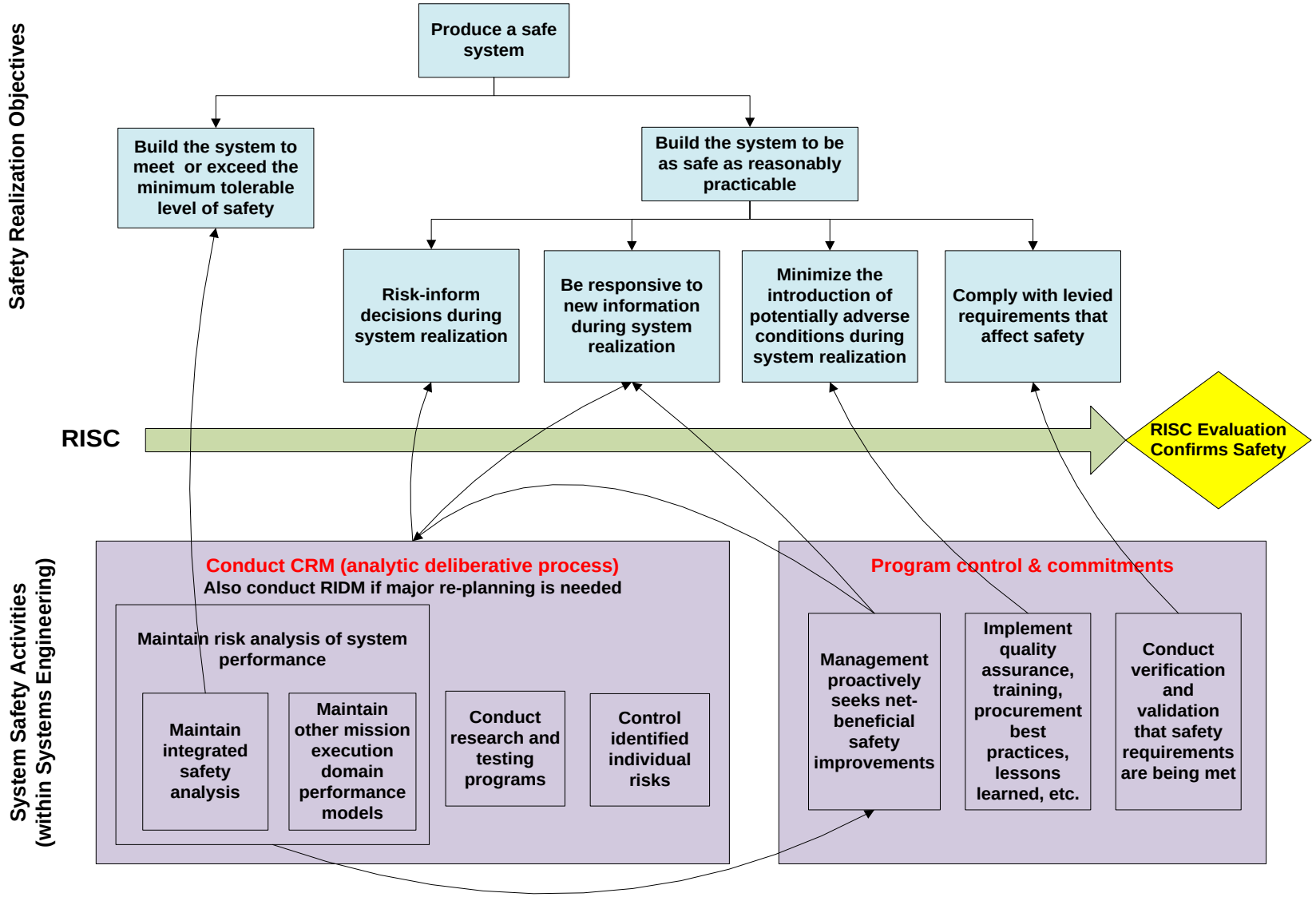
- Protocols are in place that promote effective and timely communication among design teams from different organizations working on different parts of the system.
- Configuration management processes are in place to ensure that modifications to the design are kept up to date and that everyone is working from the same drawings and specifications.
- There is a process for ensuring that decisions relating to design choices are informed by best practices and by lessons learned from previous projects; for example, mass margins and safety margins are adequate and appropriate for each project milestone.
- There is a process for verifying that all requirements, codes, and standards related to system design that have been designated as being important to safety are satisfied, and continue to be satisfied as changes occur.

Because of the ASARP principle that puts a premium on improving safety, there is a feedback loop in Figure 4-2 from the block labeled “Management proactively seeks net-beneficial safety improvements” to the block labeled “Conduct CRM”. The feedback involves tradeoffs wherein variations in design variables and/or controls are explored. Sensitivity studies using the integrated safety analysis models together with cost, schedule and technical performance models are performed to determine how these variations affect the ability to meet performance requirements in each mission execution domain. The ASARP process in general is a collaborative effort involving deliberation between the system safety team and the teams responsible for cost, schedule, and mission assurance.

Finally, just as the safety requirements for a program/project are tailored during early design by using a risk-informed process, the formulation of program controls and commitments during detailed design and subsequent phases similarly need to be tailored using a risk-informed process. The intent is to focus attention and resources on risk-significant issues and on items that are critical to safety, while defocusing attention and resources from insignificant issues and noncritical items. The process is a deliberative one involving management and system safety personnel.

4.2.3 System Realization

The system safety activities needed to support system realization are presented in Figure 4-3. The safety objectives for this phase are those listed in Figure 3-5 of Section 3.2 in conjunction with the blocks that start with the phrase “Build the system to ...”.



Note: See Section 4.2.1 for an explanation of the use of nesting and curved arrows to highlight significant relationships and interfaces.

Figure 4-3. Principal System Safety Activities and Related Processes during System Realization, and their Interfaces with the Safety Objectives

4.2.3.1 Conduct Continuous Risk Management during System Realization

The activities under Continuous Risk Management and their interfaces with the safety objectives during the system realization phase are similar to those in Section 4.2.2.1 and Figure 4-2.

4.2.3.2 Maintain a Robust Set of Program Controls and Commitments during System Realization

During the system realization phase, some of the more important elements of program controls and commitments include the following:

- During the process of building the subsystems and integrating them into a completed system, management actively promotes an environment within which opportunities are sought out and implemented for improving safety without incurring unreasonable cost, schedule, and technical impacts.
- Quality assurance plans and processes are in compliance with SAE Aerospace Standard (AS) 9100 [27], and audits and reviews are conducted to ensure that actual practice is in compliance with the plans.
- Training programs are in place where needed to help employees at NASA and NASA's suppliers to gain the necessary knowledge and skill to fulfill the mission. Where appropriate, the personnel assigned to each task are certified to perform that task.
- Best practices and lessons learned from previous programs and projects are implemented into the activities conducted during the system realization phase.
- The procurement process utilizes a risk-informed decision methodology to select between supplier alternatives.
- There is a process for verifying that all requirements, codes, and standards related to system realization that have been designated as being important to safety are satisfied, and continue to be satisfied as changes occur.
- Effective processes for configuration management and change control are implemented and maintained throughout the system realization phase.

Other aspects of program controls and commitments are discussed in Section 4.2.2.2.

4.2.4 System Operation

The system safety activities needed to support system operation are presented in Figure 4-4. The safety objectives for this phase are those listed in Figure 3-5 of Section 3.2 in conjunction with the blocks that start with the phrase “Operate the system to ...”.

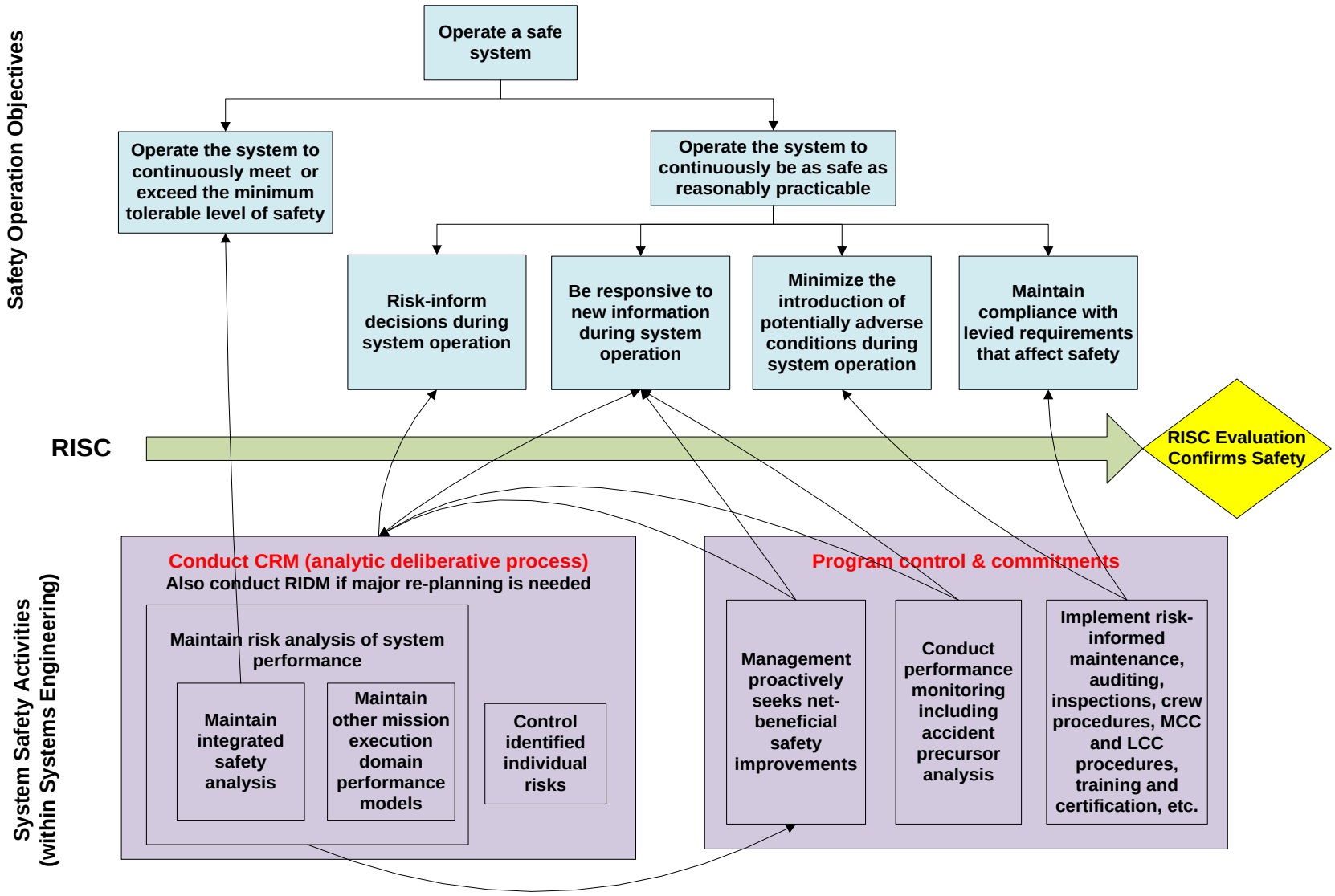
4.2.4.1 Conduct Continuous Risk Management during System Operation

The activities under Continuous Risk Management and their interfaces with the safety objectives during the system operation phase are similar to those in Section 4.2.2.1 and Figure 4-2. The exception is the deletion of the block entitled “Conduct Research and Testing Programs”. Most research and testing to support a better understanding of the risks and development of controls would have been completed prior to operation.

4.2.4.2 Maintain a Robust Set of Program Controls and Commitments during System Operation

During the system operation phase, some of the more important elements of program controls and commitments include the following:

- During system operation, management actively promotes an environment within which opportunities are sought out and implemented for improving safety without incurring unreasonable cost, schedule, and technical impacts.
- Unanticipated events and anomalies occurring during system operation are evaluated to determine whether they could be considered as precursors to an accident. If so, this information is fed back to the CRM process to determine whether the risk models need to be modified and whether additional controls are needed.
- A risk-informed approach to maintenance, inspections, and audits is implemented. The ordering of activities in these areas is prioritized so that actions that are important to safety risk are conducted first and most thoroughly.
- Similarly, a risk-informed approach to training and certification of crew, mission control personnel, and launch control personnel is implemented. Operating procedures, training, and certification are prioritized to emphasize areas and skills that are needed to minimize safety risks.
- Best practices and lessons learned from previous programs and projects are implemented into the activities conducted during the system operation phase.



Note: See Section 4.2.1 for an explanation of the use of nesting and curved arrows to highlight significant relationships and interfaces.

Figure 4-4. Principal System Safety Activities and Related Processes during System Operation, and their Interfaces with the Safety Objectives

- There is a process for verifying that all requirements, codes, and standards related to system operation that have been designated as being important to safety are satisfied, and continue to be satisfied as changes occur.

- Effective processes for configuration management and change control are implemented and maintained throughout the operational phase.

Other aspects of program controls and commitments are discussed in Section 4.2.2.2.

4.3 Special Topics Pertaining to Integrated Safety Analysis

This section provides a broader perspective and, in some cases, more detailed information on themes that are discussed in Section 4.2 with regard to integrated safety analysis.

4.3.1 Scenario Orientation of System Safety Analysis

In realistic engineering situations, scenario-based modeling within ISA is central to building a strong safety case, because it is necessary to understand what scenario elements need to be prevented or mitigated, in order to formulate, justify, implement, and (for purposes of the safety case) defend the strategies needed to prevent or mitigate those events. Moreover, in typical system safety applications, besides identifying scenarios, it is necessary to quantify scenario likelihoods, and to address uncertainty. This is true in the context of safety prioritization and safety tradeoff exercises, or as part of addressing safety requirements, goals, or thresholds.

In Figure 4-5, the concept of a "scenario" is used to define the safety context that will be described in the RISC. As indicated in that figure, a scenario begins with an initiating event that perturbs the system away from its nominal condition. Subsequent pivotal events that are relevant to the evolution of the scenario may (or may not) occur, and may have either a mitigating or exacerbating effect on the accident progression. The successful functioning of controls will in general have a mitigating effect, whereas the failure of controls to function, the defeating of controls due to overwhelming stresses, or the involvement of hazardous material will tend to exacerbate the scenario. The spectrum of possibilities for the evolution of the accident is represented by the multiple pathways that can be followed and the multiple end states that can be produced.

As discussed in Section 2.2, both hazard-centric and non-hazard-centric analysis techniques may be used to develop scenarios, identify risk drivers, and evaluate the effectiveness of controls. Hazard analysis as traditionally practiced by NASA has focused specifically on the worst-case credible consequences of identified scenarios, which generally occurs under bounding stresses and/or significant control set failure. Although this scope of analysis is

valuable, it is insufficient to support the calculation of probabilistic safety metrics such as P(LOC), P(LOV), and P(LOM). ISA needs to go beyond the examination of worst-case end states to also systematically address less severe end states. Scenario development requires systematic analysis of complex interactions, dependencies and combinatorial effects. NASA/SP-2011-3421, *Probabilistic Risk assessment Procedures Guide for NASA Managers and Practitioners* [28], contains additional guidance on scenario development.

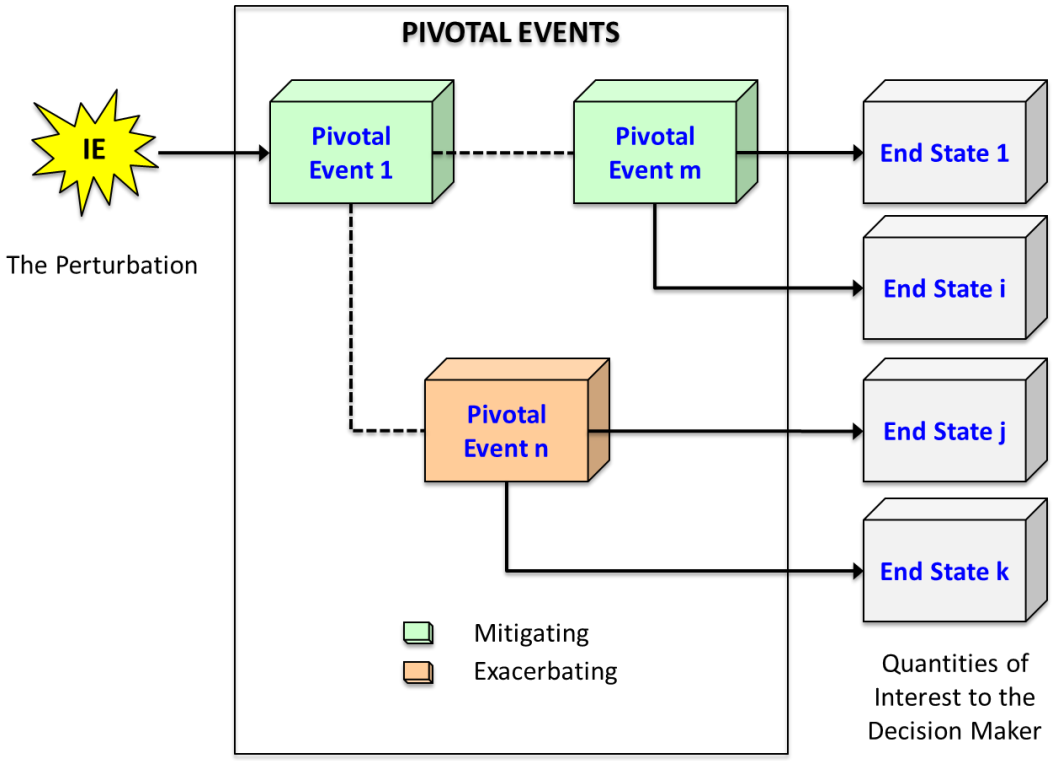


Figure 4-5. The Concept of a Scenario

4.3.2 Probabilistic Thinking as Applied to Sensitivity and Uncertainty Analysis

Probabilistic thinking is the process of explicitly factoring the quality of our state-of-knowledge, as reflected by the limits and uncertainties in our knowledge, into models, analysis, and decision-making. This process recognizes limits and uncertainties in all areas of the system safety assessment, including: completeness of risk issue identification, understanding of the phenomenology, the caliber of evidence supporting the RISC, and weighing the possibility of adverse outcomes in decision-making.

Probabilistic thinking is important because it affects our modeling of System Safety. It forces us to have an understanding of possible implications of both internalized information and unwritten assumptions. Further, it is used to express internalized information via written and verbal communications as part of the RISC.

Why Do We Use Probabilistic Thinking?

Probabilistic thinking is a concept pervasive to the successful implementation of the system safety framework

The Safety Performance Measure

We cannot observe (being able to ascertain) a probabilistic safety claim, but we can evaluate our degree of certainty (confidence) in meeting the claim *probabilistically*.

Application of Risk Analysis

When developing risk models (including logic-, simulation-, and phenomena-based), we describe scenario likelihoods and consequences *probabilistically*.

Claims Contained in the RISC

Within a RISC a portion of the evidence and arguments justifying a safety claim is *probabilistic*.

Organizational Learning

When determining the applicability of an accident precursor, we need to consider the *probability* of events that must occur or conditions that need to change to result in significant consequences.

Key elements to the probabilistic thinking process include:

- Identifying and clearly describing questions and concerns that need to be described in a probabilistic manner—i.e., clearly formulate the problem
- Obtaining and evaluating relevant data and information on system performance and risk issues
- Evaluating internal assumptions and biases and describing them in a probabilistic manner

Sensitivity and uncertainty approaches suggest where better performance would help, where there are weaknesses and vulnerabilities in the system, the degree of margin, areas of the

"unexpected," and where to focus resources to improve the system and reduce uncertainty. Sensitivity analysis is a technique used to determine how different values (or data) or a particular parameter impact a model and the effect the specific system or mission change has on the analysis result. By performing sensitivity analysis, we build confidence in our System Safety models by studying uncertainties that are inherently a part of data. This technique also helps to understand the system response envelope by experimenting with a wide range of data and assumptions: for example exploring how the system will behave during extreme situations—i.e., not just sensitivity on data.

Uncertainty approaches rely heavily on probabilistic models and are intrinsically associated with probabilistic thinking. Sensitivity analyses also rely on probabilistic models, but the main reason is to establish a reasonable range for the parameters being varied.

Additional guidance on probabilistic thinking as applied to risk analysis can be found in [28].

4.3.3 Life cycle Aspects of Integrated Safety Analysis and Testing

Depending on project scale, life cycle phase, etc., different modeling rigor is appropriate in integrated safety analysis. As a general rule of thumb, the rigor of modeling should increase with successive program/project life cycle phases. In addition for a given phase, parametric, engineering, and logic modeling can commence at a low level of detail; the level of detail can be increased in an iterative fashion based on the requirement to reach a robust decision.

It is important to differentiate between model rigor and the concept of graded analysis. Model rigor pertains to the level of detail that is included in a model and is proportional to the maturity of the design. It would not make sense, for example, to include modeling of components in an integrated safety analysis if the components had not yet been specified in the design. On the other hand, graded analysis pertains more to the breadth of the modeling. In a graded analysis, the effort devoted to analyzing a particular risk issue or scenario is proportional to the importance of the issue or scenario being considered and whether it affects the ability to make an informed decision. It would not be necessary, for example, to analyze all the possible scenarios associated with an initiating event if the probability of the initiating event were vanishingly small. Further discussion of the graded approach philosophy is provided in Section 4.3.4.

The following approaches to modeling rigor are discussed as well in [6]. They are applicable to different phases of the life cycle as indicated below.

4.3.3.1 Pre-Design Trade Studies

During pre-design trade studies, estimates can be made based on first-order simulation methods and/or similarity estimating methods.

- First-order simulation methods involve the use of closed-form or simple differential equations that can be solved given appropriate initial and/or bounding conditions without the need for control-volume based computational methods. The equations may be standard physics equations of state or empirically-derived relationships from operation of similar systems or components.

- Similarity estimate methods are based on comparison and extrapolation to like items or efforts. Reliability and operational data from one past program that is technically representative of the program to be estimated can serve as the basis of estimate. These data are then subjectively adjusted upward or downward, depending upon whether the subject system is believed to be more or less complex than the analogous program.

4.3.3.2 Concept Development and Early Design

During concept development and early design, first-order simulation methods, semi-detailed simulation estimation methods, and first-order parametric estimation methods may be appropriate.

- Semi-detailed simulation methods require the construction of a model that represents the physical states of interest in a virtual manner using control-volume based computational methods or methods of a similar nature. During conceptual development, the amount of design detail in the models will be limited to what is available and the virtual models may use computation approximations such as lumped elements rather than finite elements.

- First-order parametric estimation methods are based on historical data and mathematical expressions that relate safety, reliability, and/or operational estimates as the dependent variable to selected, independent, driving variables. Regression analysis or first-order technical equations may be used.

4.3.3.3 Detailed Design

During *detailed design*, detailed simulation estimation methods and detailed logic modeling estimation methods are appropriate.

- Detailed simulation methods are an extension of the semi-detailed simulation methods described above. These simulations typically require systems and conditions to be modeled to a high-level of fidelity, including the use of "meshes" or network diagrams to represent the system, its environment (either internal, external, or both), and/or processes acting on the system or environment. Examples are computational fluid dynamics (CFD) and finite-element modeling.

- Detailed logic modeling estimation methods involve "top-down" developed but "bottom-up" quantified scenario-based or discrete-event logic models that segregate the system or processes to be evaluated into discrete segments. These segments are then quantified and mathematically integrated through Boolean logic to produce the top-level safety estimate. Detailed technical simulation and/or testing, as well as operational data, can be used to assist in developing pdfs for quantification of the model.

4.3.3.4 System/Component Testing and System Operation

System and component testing should be risk-informed, in that the choice of tests to be performed and parameters to be varied should be tailored toward reducing uncertainties pertaining to the risk drivers. The use of risk information to help with prioritization of testing follows the same principles as its use for prioritizing program controls, commitments, and safety related activities such as maintenance, audits, inspections, training, and certification (see Section 4.2.4.2).

During system/component testing and system operation, various testing and operational methodologies can be used and statistical methods can be applied.

- Testing can encompass the use of table-top experiments all the way up to full-scale prototypes operated under real-world conditions. The objective of a test is to measure how the system or its constituent components may perform within actual mission conditions. Testing could be used for assessing the expected performance of competing concepts or for evaluating whether the system or components will meet flight specifications.

- Once the system is deployed, data gathered during operation can be analyzed to provide empirically accurate representations of how the system will respond to different conditions and how it will operate throughout its lifetime. This information can serve as the basis for applicable changes, such as software uploads or procedural changes, that may improve the overall performance of the system. Testing and detailed simulation

may be combined with operating experience to extrapolate from known operating conditions.

- Statistic methods can be applied to data collected during testing or from system operation during an actual mission. In addition, patterns in the data may be modeled in a way that accounts for randomness and uncertainty in the observations, and then serve as the basis for design or procedural changes that may improve the overall safety of the system. These methods are useful for answering yes/no questions about the data (hypothesis testing), describing associations within the data (correlation), modeling relationships within the data (regression), extrapolation, interpolation, or simply for data mining activities.

Care must be taken during system/component testing to ensure that differences between the test environment and the conditions the system will experience during operation are accounted for in the models that are developed. For example, the effects of zero gravity must be considered in deriving models from the data if the tests are conducted in a non-zero gravity environment. Accounting for differences between test and operating environments may be especially important when new technologies and/or new applications of existing technologies are used.

4.3.4 Graded Approach Philosophy

The concept of a "graded approach" is discussed briefly in Section 4.2.1.2.1 and in more detail in [6]. The point of a graded approach to analysis is to match analysis effort to the needs driving the current decision process. Suppose that in the context of a key decision, an initial analysis shows an unacceptably high upper bound of the probability of some accident scenario leading to a high consequence, thus requiring a costly mitigation be incorporated in the design. However, a more detailed analysis has the potential to narrow the uncertainty bounds on the scenario's probability of occurrence, potentially to the point where the mitigation can be omitted (because the detailed analysis shows the probability is very low). If the more detailed analysis is not too expensive (relative to the cost of the mitigation), then it is worth doing.

Graded Approach

A graded approach to analysis requires that the resources and depth of analysis be commensurate with the stakes and the complexity of the decision situations being addressed.

4.3.5 Use of Operating Experience and Precursor Analysis

As part of an integrated safety analysis, an update process takes place at any time during the system life cycle when relevant new information becomes available. During the operational phase, the information frequently involves the recognition that a precursor to an accident has occurred. A precursor can be considered to be a transition in an accident scenario that could lead to a full-blown accident if other events were to occur. Precursor analysis is akin to continuous improvement based on root cause analysis, where the event that triggers the analysis is the precursor.

Ordinarily, accidents are prevented by a combination of barriers (human and hardware or software system features to prevent accidents). Failure of particular combinations of barriers corresponds to an accident. A precursor is a scenario in which some barriers are at least partially degraded. Attributes of precursors include:

- Observation indicates some failure mechanism
- Same mechanism could occur again
- The consequences could be more severe than what has been experienced

While a precursor is an indication of a problem that could recur with more severe consequences, it is also an opportunity to learn. Precursor analysis is unique in that it explicitly assesses risk implications of occurring events. Events that are analyzed include not only failures, but also the more general class of anomalies and issues. To assess risk implications of an event, two general questions are asked:

1. What events were needed to occur or what conditions were needed to change to result in significant consequences?
2. What is the likelihood of these additional events or conditions that were needed?

Since precursors are “pre-accidents,” they could represent a variety of events such as a near-miss because of an opportune mitigation; faults that can become failure conditions without correction; unexpected trends in test, operation, or maintenance; or common causes of faults or deteriorations.

An active and effective precursor analysis program can lead to changes in the design or operating practice before an accident ever occurs. Learning will often require relinquishing or admitting to a previous misunderstanding or analysis error, or revising the assessment of uncertainty in a particular area of modeling.

Ultimately, organizational learning through precursor analysis helps to couple operational data and practices (the reality) to the models used for System Safety (the prediction of reality) as shown in Figure 4-6.

Additional guidance on precursor analysis can be found in [13].

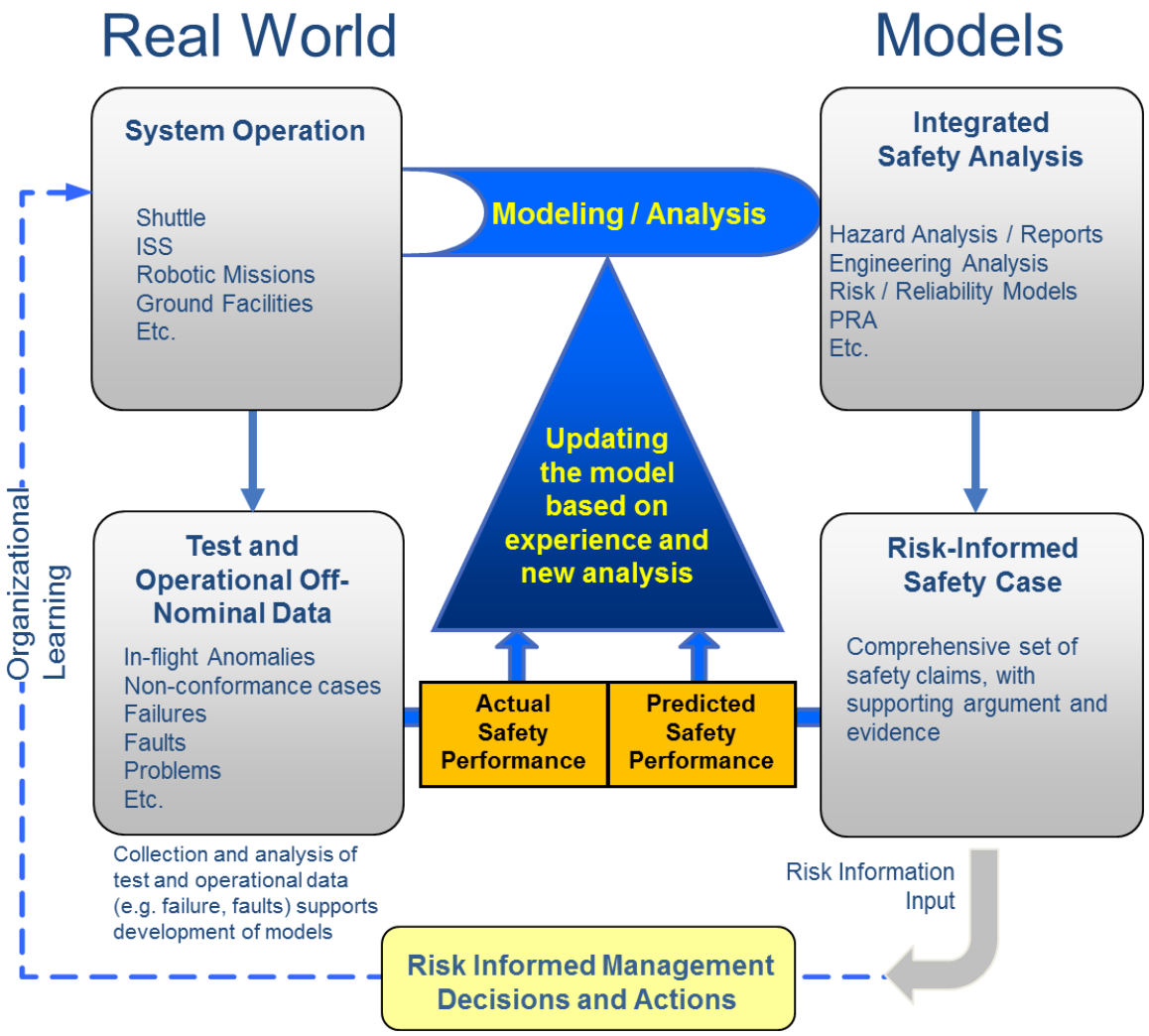


Figure 4-6. Example of how Learning Informs Decisions and Models in the Mission Life Cycle

4.4 Special Topics Pertaining to Risk-Informed Allocations of Safety Thresholds and Goals

Safety performance measures such as P(LOC) or P(LOV) are integral metrics and are very closely related to fundamental safety objectives of a program/project at the highest level. Depending upon the characteristics of the mission, P(LOC) is generally the metric of principal interest for

crewed missions, P(LOV) for robotic missions with recoverable and reusable elements, and P(LOM) for robotic missions with all elements expendable.

In order to facilitate the achievement of the high level probabilistic requirements without requiring multiple design iterations, it is common practice for probabilistic allocations to be made from the top level down to the lower elements of the system. In this way, the ownership of the safety requirements similarly is allocated from program/project level down to the lower organizational units supporting the program/project.

For illustration purposes, it is convenient to discuss allocation as occurring in three tiers, although in practice, the tiers may often be conducted in unison. The first tier involves allocating reliabilities to lower level operational elements in the system. Such elements would include normally operating hardware components, the associated software that controls the operation of the hardware, and the human operators in the launch and mission control centers who send commands from Earth to the spacecraft. Because the top requirements are expressed in failure space (e.g., loss of vehicle rather than survival of the vehicle), the lower level requirements are also expressed in failure space (i.e., failure probabilities on demand, mean failure rates, or unreliabilities rather than success probabilities, mean success rates, or reliabilities).

The second tier in the allocation process expands upon the items mentioned above to include consideration of the logic for recovery from faults, along with the associated probabilities that the fault is detected, that it is within the coverage of the fault management system, and that the actions to recover from the fault are successful. Coverage probabilities refer to the probability that each fault that is encountered is one from which the system can recover through the actions of control personnel on the ground and/or on-board control logic. Because we are still dealing with failure space in the definition of the top-level safety performance measures, the allocations pertain to the probabilities of lack of detection, lack of coverage, and lack of successful execution.

The third tier of the allocation process is really a special subset of the second tier (fault management) that applies specifically to crewed missions. It further expands upon the elements listed above to include the control logic for crew abort and the corresponding effectiveness of abort actions. Abort effectiveness depends upon the range of environments that the abort system may experience during an abort, as well as the relative likelihoods of encountering each environment. In turn, the nature of the environments that the abort vehicle will encounter depends upon the particular system failure that necessitates the abort and the amount of time it takes to initiate the abort. In failure space, the allocation concerns the probabilities that abort will be unsuccessful for each environment that may be encountered.

Once failure probabilities or failure rates have been allocated, the designers, with the help of reliability experts, have to determine a design approach that meets those allocations. Designers have several means for increasing the reliability of a system:

- They can add redundancy, such that multiple failures are required before a critical function is lost. Redundancy can be applied not only for hardware elements but also for software elements and for tasks performed by humans. The failure probability/rate of the redundant system can be determined mathematically from the failure probabilities/rates of the components within it (e.g., [29,30]). If there are similar components that are subject to failure from a common source or mechanism, the mathematical formulation must account for these common-cause failure possibilities.

- They can replace less reliable components with more reliable components. There are many sources of information to assist the designer in making replacements to improve reliabilities for all three elements (hardware, software, and human). These include the use of hardware and software reliability data from vendors to assist in the selection of the replacement component, use of ground test and operational flight data, and use of handbooks that provide reliability shaping factors as a function of environmental stressors (e.g., [31-33]) .

- They can add design margin for hardware components whose failure probabilities/rates are sensitive to physical stressors such as temperature, mechanical loads, and radiation levels. The relationship between design margin and failure probabilities/rates can be estimated from phenomenological models (e.g., [34]).

Of course, the implications of adding reliability on other system requirements, such as vehicle mass, schedule, and cost, have to be taken into consideration through the risk management processes described in Section 4.2.

The following subsections describe the development and application of logic models to allocate safety thresholds and goals for each of the three tiers of allocation mentioned above.

4.4.1 Use of Risk Logic Modeling to Allocate Failure Probabilities/ Rates for Normally Operating Components of the System

The process of risk informing the allocation of failure probabilities/rates to lower levels starts from developing logic models (such as fault trees or reliability block diagrams) and continues with applying them in a quantitative fashion. As illustrated in Figure 4-7, the “top event” for a logic model used in a safety analysis may be LOC, LOV, or LOM, the midlevel events represent failures of subsystems, and the lowest level events are failures of the hardware, software, and human components of the system or failures at their interfaces. The combinations of failure

events that propagate through the trees represent the set of credible accident scenarios that can lead to LOC, LOV, or LOM. A PDF, or probability density function, for P(LOC), L(LOV), or P(LOM) is calculated by performing a "bottom-up" analysis, wherein available failure data or failure models are used to estimate PDFs for the failure rates or probabilities at the lowest level of the tree and the failure PDFs are quantitatively propagated up through the logic model. On the right-hand-side of the figure, the top-level PDF has been numerically integrated to obtain a CCDF, or complementary cumulative distribution function. (The CCDF is one minus the integral of the PDF.) The value of the CCDF representation is that it allows a direct reading from the vertical scale of the likelihood that the P(LOC), P(LOM), or P(LOM) is greater than the requirement. The objective is for this likelihood to be within the risk tolerance provided by the decision maker.

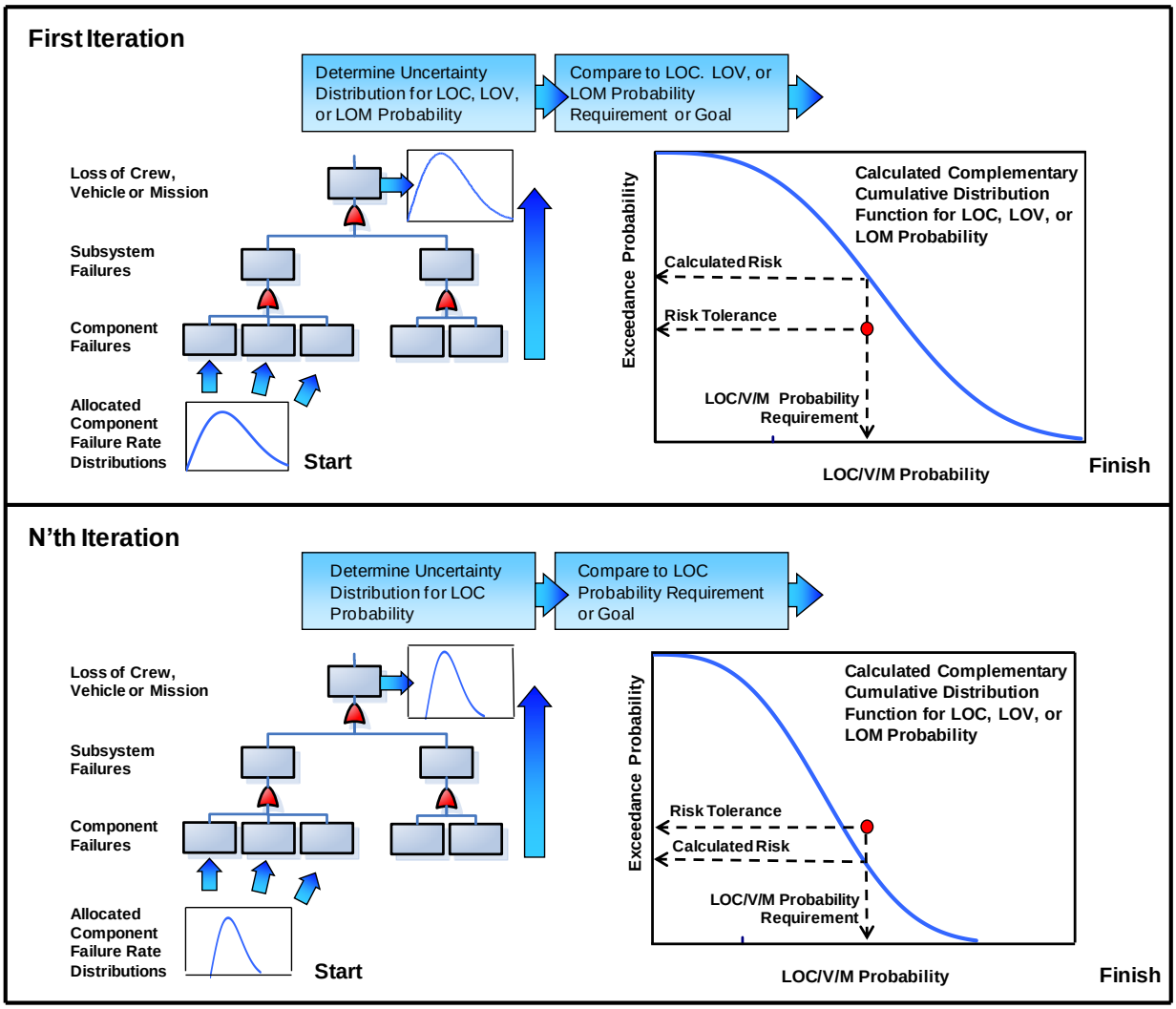


Figure 4-7. Schematic of Process for Allocating Failure Probability Requirements to Lower Levels

The need to allocate lower level failure probabilities that are different from those obtained from failure data and models occurs when the calculation indicates that the LOC, LOV, or LOM probability requirement cannot be met within the decision maker's risk tolerance. In that case, the reliabilities of the components must be increased beyond their usual or typical values. As shown in Figure 4-7, several iterations may be necessary before settling upon a set of allocated component reliabilities that achieves the overall safety requirement and is practicable.

There are several methods in the literature that are used for determining how much to increase the reliability of each component (hardware, software, or human) and the reliabilities of their interfaces. One method is based on developing cost functions that relate how much it would cost to increase the reliability of each component by a given amount [35]. When this information is propagated through the logic model, the result is a map of how increases in the reliability of each component affect both the probability of LOC, LOV, or LOM and the cost to the program/project. This method has the potential for achieving the desired probability of LOC LOV, or LOM at minimum cost.

Many times, the minimum cost solution may have to be modified to take account of other factors that come into play (e.g., availability of parts, fabrication questions, operation aspects, maintenance, and sustainability). For this reason, the allocation process is deliberative, involving a collaborative interaction between the designers and the safety analysts.

4.4.2 Special Considerations to Account for Fault Management Capabilities

The allocation process discussed in the preceding subsection can be extended to include fault management capabilities. Often this extension can be accomplished simply by adding recovery paths in the logic model (e.g. fault tree) that has already been developed to allocate failure probabilities/rates for normally operating components (e.g., Figure 4-8). These recovery paths include events that pertain to whether the fault is detected, whether it is covered by the fault management logic, and whether the recovery system operates successfully. In the simplest cases, probability distributions for these events are generated offline and are treated as inputs to the logic model.

If the recovery process is complex and is dependent upon the timing and ordering of actions taken, however, it may be necessary to develop more complex logic models. These could include Markov chains and/or dynamic fault trees [36] in place of the simpler construct shown in Figure 4-8. These time-dependent logic models are typically solved in a time-marching fashion and may require the use of a Monte-Carlo sampling process. More information on this subject will be provided in Volume 2.

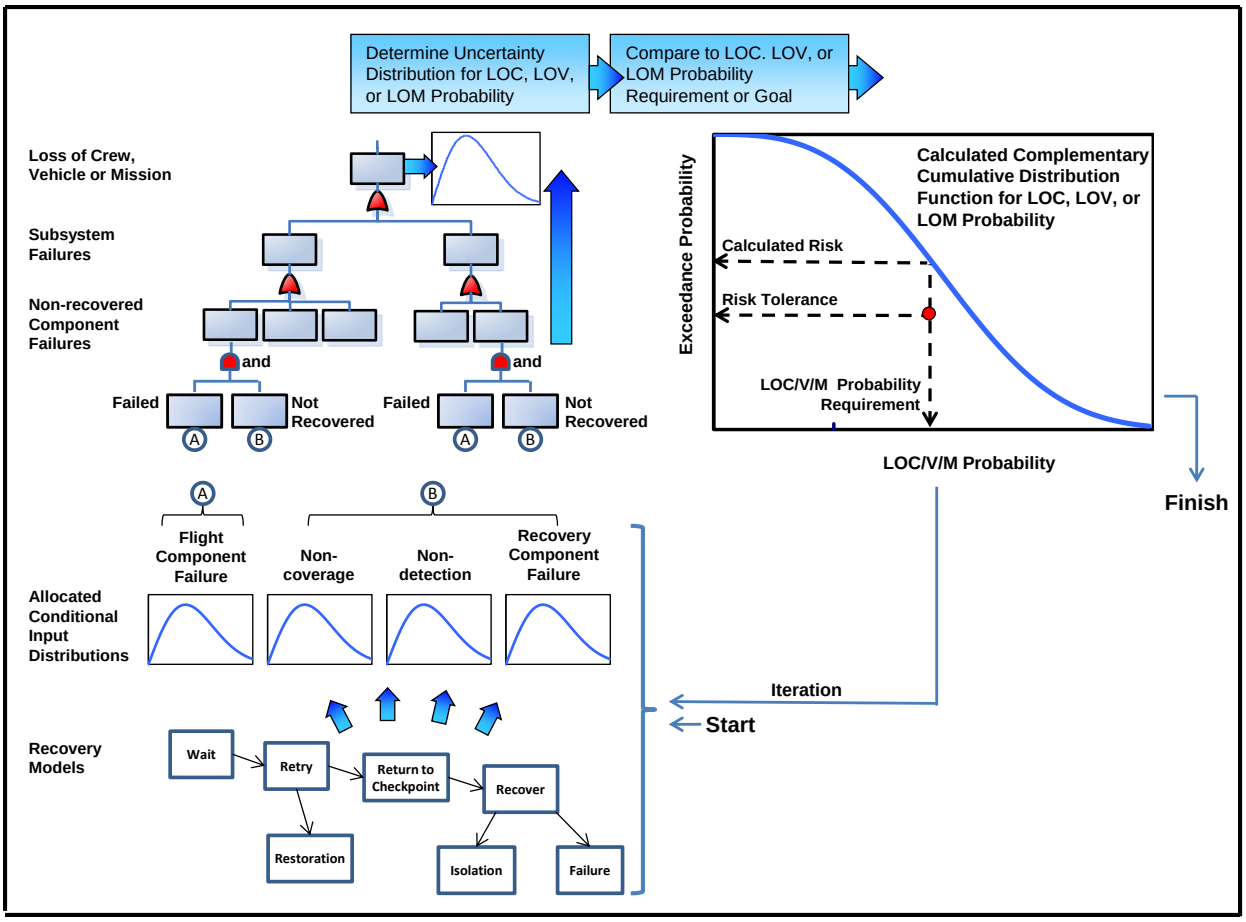


Figure 4-8. Schematic Modification of Process for Allocating Failure Probability Requirements to Lower Levels to Include Fault Management Provisions

4.4.3 Special Considerations for Crewed Systems with Abort Capability

As stated previously, NASA has established a set of agency-level safety goals and thresholds for crewed missions to the ISS that, given the reliabilities of the current generation of state-of-the-art launch vehicles, will require robust launch abort capability in order to protect the crew in the face of mission-ending launch vehicle failure. The allocation process for P(LOC) therefore naturally decomposes into reliability constraints on the launch vehicle and abort effectiveness constraints on the aborting crew vehicle.[19] However, abort effectiveness is highly dependent on launch vehicle failure mode, specifically:

- The ability to detect the launch vehicle failure in a timely manner

[19] The reliability of the crew vehicle during nominal mission operations also factors in to the vehicle-level safety performance, but is not directly relevant to a discussion of abort.

- The abort conditions created by the failing launch vehicle while the aborting vehicle is mated to it, and as it is leaving the launch vehicle vicinity
- The time into flight at which launch vehicle failure occurs

Therefore, it is not necessarily constructive to allocate a single reliability to the launch vehicle, irrespective of failure mode; nor is it necessarily meaningful to allocate a single abort effectiveness to the abort vehicle, irrespective of the environments from which it must abort. Instead, the contribution to P(LOC) from each launch vehicle failure mode should be separately evaluated in terms of the probability of occurrence of the failure mode and the effectiveness of the abort system against it. Within the logic model, the contribution to P(LOC) from abort is the disjunction of the contributions to P(LOC) from each of the individually-analyzed launch vehicle failure modes, as shown in Figure 4-9.

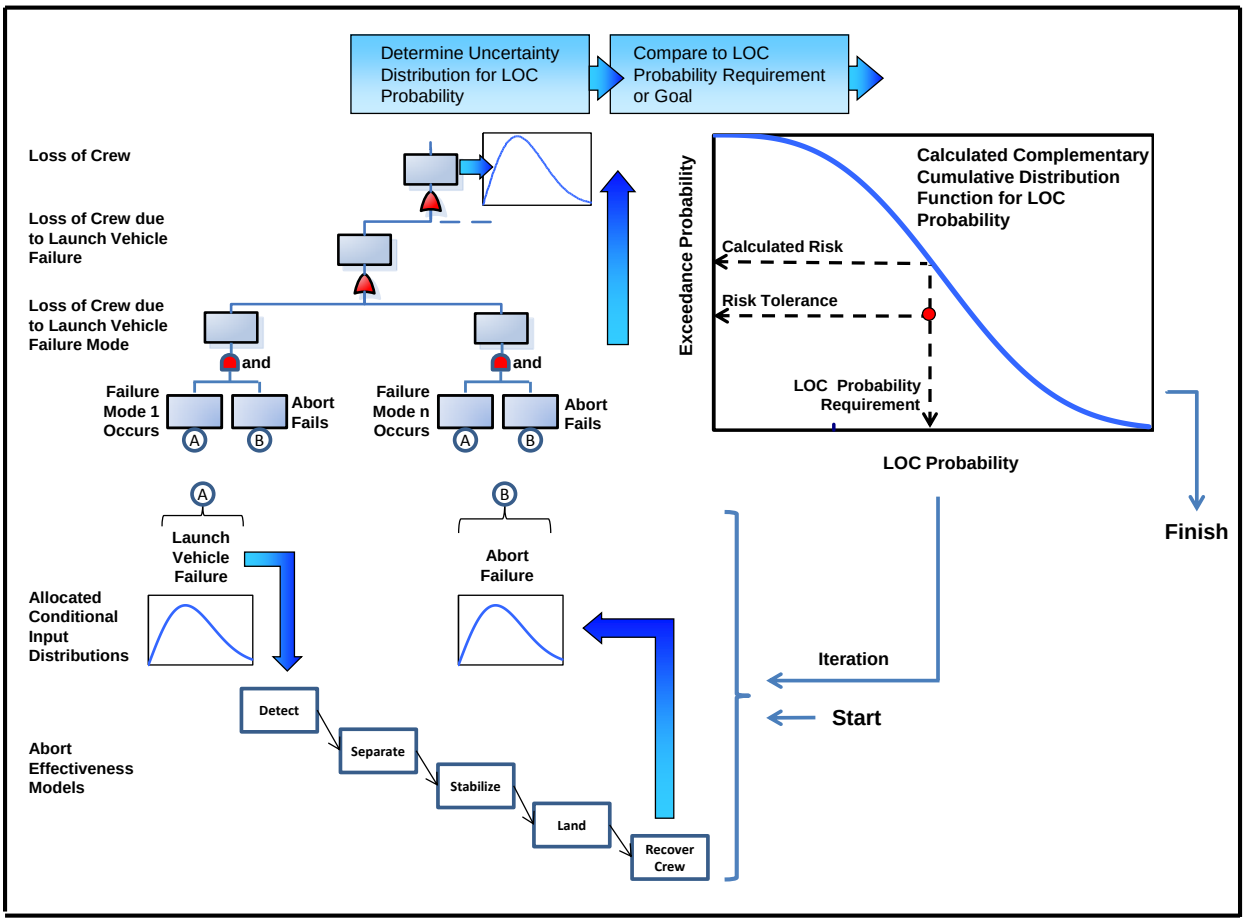


Figure 4-9. Schematic Modification of Process for Allocating Failure Probability Requirements to Lower Levels to Include Launch Abort Capability

Abort is a complex and dynamic operation. Consequently, abort modeling typically involves modeling of the physical phenomena associated with the aerodynamic loads on the abort

vehicle, the overpressures and debris fields produced by the launch vehicle should it explode, the ability of crew vehicle to withstand the abort environment, etc. A Monte-Carlo sampling process is typically used to quantify abort effectiveness, either as a function of mission time or integrated over the ascent.

An additional issue with respect to crewed systems with abort capability is the fact that abort systems are only demanded during crew-threatening launch vehicle failures, and therefore do not generate a flight history that can be used to significantly reduce epistemic uncertainties and gain confidence in system performance. This situation increases reliance on analysis, particularly in the form of simulation, as well as testing, to demonstrate compliance with allocated abort effectiveness probabilities. More information on crewed systems with abort capability will be provided in Volume 2.

4.5 Collaborative Development of Controls

Controls are developed through collaboration between the system safety and design disciplines. Development of controls in a complicated system is difficult and there are many considerations to be addressed:

- Budget, mass, and other performance measures.

- The need not to introduce new hazards in the course of changing the system to mitigate a given hazard. (For example, adding a sensor to more quickly/accurately detect a failure condition may introduce a new weakness stemming from having to make yet another penetration in a pressure vessel.)

- The need to consider the controls as a portfolio. A given control may address multiple hazards, and may be net-beneficial considering all of the hazards mitigated, even though it would be too expensive in money or mass to be justified for any one hazard. Conversely, a control that is very effective at reducing a single hazard may be found to be superfluous in the context of the entire set of controls. This is an illustration of the benefits of “holistic thinking” this guidebook strives to encourage. Further elaboration on this point will be provided in Section 4.5.1.

- The need to consider the interactions among controls. One control may counteract another control. For example, two controls may each reduce the risk substantially if applied individually, but if applied jointly might only reduce risk by an insignificant amount. Alternatively, they may collectively result in a slight reduction of the probability of LOC but a substantial increase in the probability of injury, or loss of assets.

Some risks may be controllable up to a point without resorting to design modifications, through changes to operating practice or mission profile. A prominent example is measures taken in space shuttle operation to avoid damage from micrometeoroids and orbital debris (MMOD).

In general, since scenarios and risks frequently involve interfaces between different parts of a system, a holistic, integrated analysis on complex systems can only be done correctly in a collaborative environment. Figure 4-10 illustrates conceptually how causal factors, controls, and models may be correlated.

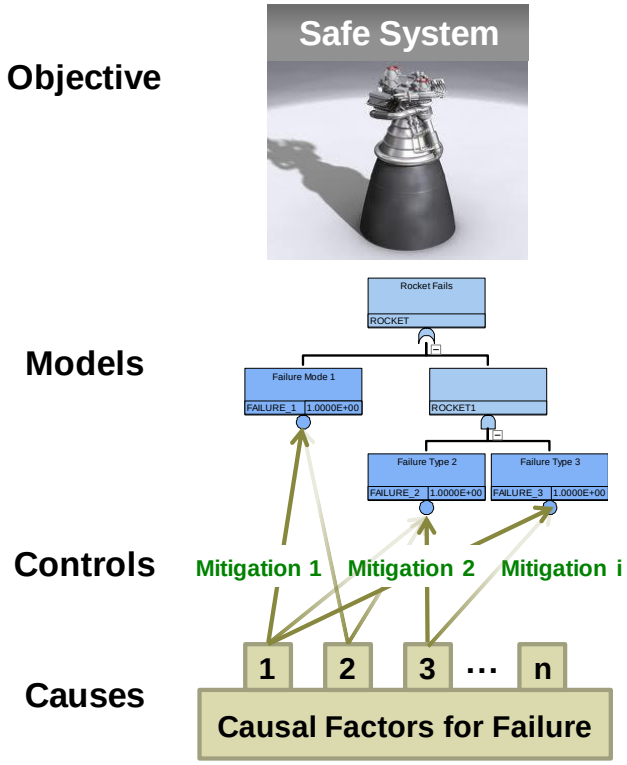


Figure 4-10. Development of Controls must be Performed in a Collaborative Environment due to the Interactions of Causal Factors, Controls, and Models

4.5.1 Cause-Specific versus Generic Controls

It is convenient to think of controls in terms of two types: cause specific and generic. A cause specific control is one that acts on only one specific underlying controllable cause, whereas a generic control is one that acts on many. For example, replacement of a specific unreliable component with a different component is a cause-specific control, whereas controls to increase overall due diligence with respect to quality assurance are generic controls. Within the category of generic, one can also speak in terms of controls that apply to the whole project or to different phases of the project.

Examples of controls that are generic for all mission phases include:

- Provisions to ensure that all safety-related issues raised at any level of the organization are aired and resolved
- Provisions to ensure independence and authority of the safety organization to address all safety-related issues
- Provisions to ensure that adequate procedures are in place for all safety-related activities
- Provisions to ensure that employees and contractors are adequately and frequently trained in procedures that relate to safety

Examples of controls that are design generic include:

- Controls to ensure functional redundancy in the design wherever possible
- Controls to ensure single points of failure and common cause failures are adequately addressed

Examples of controls that are testing generic include:

- Controls to ensure that all critical components are tested as-flown
- Controls to ensure that all testing activities that have potential safety implications are adequately monitored

Examples of controls that are flight operations generic include:

- Controls to ensure that emergency procedures are carried out correctly
- Controls to ensure that ad-hoc procedures are monitored by ground personnel

Controls that are cause-specific focus attention on risks that are known. They have the potential to prevent or mitigate particular risks at less cost and with less overall impact to the program/project at large than generic controls. However, generic controls have the potential for controlling a broader swath of risks at lower overall cost than a collection of cause-specific controls. Generic controls increase the potential for reducing the cumulative impact of risks that are unknown. Their greatest potential is realized when the generic controls, taken as a whole, cover all phases within the program/project, all activities within each phase, and all organizational units contributing to the program/project.

A strong set of controls will include both cause-specific and generic controls.

5 The Risk-Informed Safety Case (RISC)

5.1 Introduction

System safety has existed for many years. However, system safety practice is continuing to evolve. A key concept that has proven its value in other application areas is the concept of the "safety case." This chapter discusses the elements for producing a risk-informed safety case, presents an example of the structure of a RISC, and provides further examples of how the decision maker might choose to use the RISC to evaluate whether the system is adequately safe.

Historically, safety cases have a heritage tracing back to the 1960's in the United Kingdom, and have been widely adopted in high-profile safety critical industries in Europe and Australia, including nuclear installations, industrial plants, defense procurement and transportation. The safety case concept has also been extended to apply to additional system attributes beyond just safety, resulting in "Assurance Cases" and "Dependability Cases".

For purposes of NASA system safety practice, the term 'risk-informed safety case' (RISC) is used, to emphasize that a determination of adequate safety is the result of a deliberative decision making process that necessarily entails an assessment of risks and tries to achieve a balance between the system's safety performance and its performance in other areas.

The risk-informed safety case (RISC) is the means by which an organization manifestly takes ownership of a system's safety and which makes the case to decision makers, at major milestones such as Key Decision Points (KDPs), that the system's safety objectives have been achieved. It is a structured argument, supported by a body of evidence, that provides a compelling, comprehensible and valid case that a system is or will be adequately safe for a given application in a given environment.[20]

The validity of the RISC is conditional on a specified application of the system within a specified environment; hence the RISC must clearly define the operational envelope within which the system is claimed to be safe. If this envelope is penetrated, then one or more claims may no longer be valid and the system may no longer be adequately safe.

The RISC is specific to the decision context (e.g., milestone review) for which it is constructed. Therefore, a system may have a number of RISCs over the course of its development and operational life, corresponding to the various points in its life cycle where it is necessary to show that the safety objectives have been, or will be, met. Of course, it is to be expected that the RISC developed for a particular decision context will make maximum use of any RISCs for

[20] Adapted from [15].

that system that were developed for prior decision contexts, updated with new analysis, data, plans, etc., as needed to show that the safety objectives of the current context have been met. As such, the RISC can be viewed as a single product that evolves, and is periodically rebaselined, over the system life cycle, as opposed to a set of individual products developed for a sequence of milestones. The distinction is purely semantic, and this handbook adopts the convention that a separate RISC is developed for each decision context requiring one.

Developing a RISC involves [17]:

- Making an explicit set of claims about the system(s), for example, the probability of an accident or a group of accidents is low compared to some standard or constraint
- Producing evidence that supports the claims, for example, representative operating history, redundancy in design, or results of analysis
- Providing a set of safety arguments that link the claims to the evidence
- Making clear the assumptions and judgments underlying the arguments

The claims made (and defended) by the RISC are the safety objectives negotiated at the outset of system formulation. In other words, each distinct safety objective is stated as a corresponding distinct claim in the RISC. By successfully substantiating each claim, the RISC shows that the corresponding objective has been met and, thus, that the system is adequately safe.

Each organizational unit that participates in a program/ project can be considered to have its own objectives that derive, basically, from the allocation of safety requirements from higher levels. (The allocation of safety performance requirements has been discussed in Sections 2.3.2, 3.2.2, 4.2.1.6, and 4.4.) Thus, each organizational unit can produce its own RISC purporting to show that its objectives have been satisfied with sufficient confidence. The overall RISC for the system incorporates the RISCs from each organizational unit.

The RISC does not need to include exhaustive details – it may refer to supporting evidence tied to key claims contained in other documents. Furthermore, the RISC is not an analysis, although it typically contains results of analyses. It is not, for example, an ISA, although it may include an ISA. Rather, it is the marshaling of available evidence into an argument to support a decision regarding the adequacy of safety of a system.

5.2 Elements of the RISC[21]

The main elements of the RISC are:

- A set of *safety claims* about the safety of the system. Taken together, the safety claims should substantiate the overarching claim that the operational safety objectives defined for the system have been met (*ipso facto* that the system is adequately safe). The most straightforward way to structure the claims is for each operational safety objective to be rephrased as a claim that the objective has been met.

- *Evidence* that is used as the basis of the safety argument. This can be either facts (e.g., established scientific principles or empirical data), explicit assumptions, or sub-claims.

- Structured *safety arguments* that link the evidence to the safety claims, and which use logically valid rules of inference. Safety arguments can be deterministic, probabilistic, or qualitative.

The use of these elements is illustrated in Figure 5-1 and Figure 5-2. These figures show a step in the argument in which a claim is subdivided into a mix of evidence and sub-claims, which illustrates the hierarchical structure of the RISC. Each sub-claim is a claim in its own right, which the RISC elaborates with further steps in the argument. This makes it easier to understand the overall argument and to partition the RISC activities. In particular, RISCs produced by subordinate organizational units (e.g., sub-system-level units) can be used as sub-claims of the RISC at the next higher level of the NASA hierarchy. This allows demonstration of sub-claims to propagate upward, as RISCs are evaluated and accepted at successively higher levels of the organizational hierarchy. Conversely, it means that the RISC at a given level can at best be considered provisional until all subordinate RISCs have been accepted. The approach can be applied recursively, so that substantiated claims about a subsystem can be used as evidence in a parent case [37].

Figure 5-2 illustrates a situation where two independent arguments support the same safety claim. The first argument is supported by a single piece of evidence, whereas the second argument is supported by the combination of a different piece of evidence along with a pre-existing sub-claim. Both arguments support the claim without depending on the other argument. By using independent evidence and arguments, the claim is made more robust, i.e., it can tolerate flaws in a single argument.

[21] Adapted from [17].

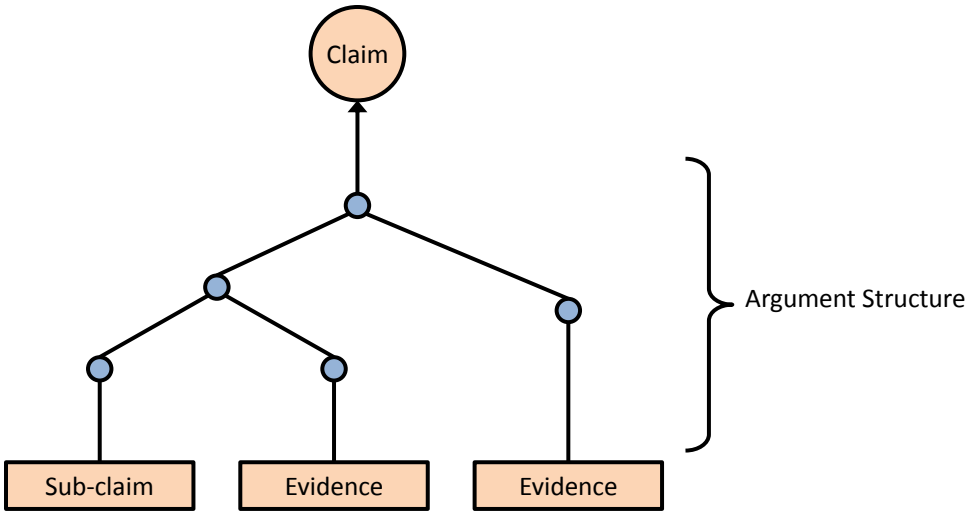


Figure 5-1. Use of RISC Elements to Support a Safety Claim[22]

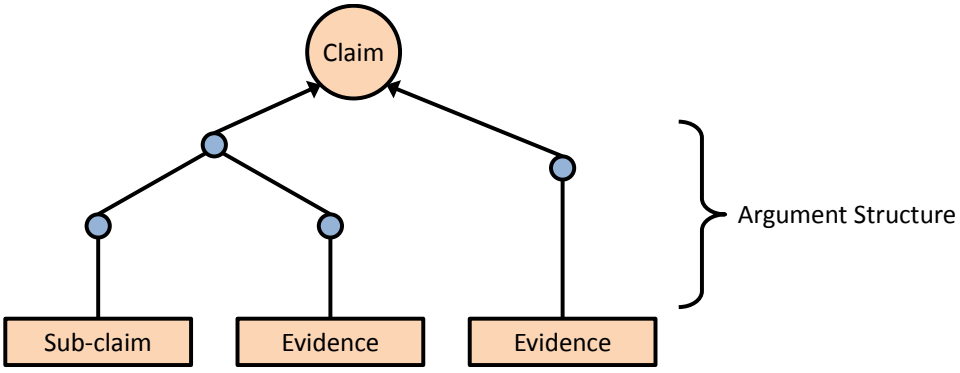


Figure 5-2. A Safety Claim Supported by Two Independent Arguments[23]

5.2.1 Sources of Evidence

The arguments are supported by evidence from the following main sources:

- The design
- The development processes, including processes for system realization and operation
- Test results
- Validated models and simulations

[22] Adapted from [17].
[23] Ibid.

- System operational data
- Historical data
- Documented management and quality assurance plans
- Documented procedures including verification and validation procedures
- Documented training material
- Other documented program/project controls

5.2.2 Types of Safety Argument

Different types of safety arguments can be used to support safety claims:

- **Deterministic arguments:** The application of predetermined rules to derive a true/false claim, given some initial assumptions (e.g., demonstration of compliance to a specification or safety requirement, assertion of known physical attributes such as physical laws and material properties, etc.).
- **Probabilistic arguments:** Quantitative statistical reasoning that establishes a probabilistic claim. For example, to substantiate a claim that the probability of loss of mission P(LOM) for some system is X, a probabilistic argument would reason statistically from evidence to quantify P(LOM).
- **Qualitative arguments:** Compliance with rules that have an indirect link to the desired attributes (e.g. compliance with industry standards, crediting of staff skill and experience, etc.).

The choice of argument will depend on the available evidence and the type of claim. For example, claims for reliability would normally be supported by statistical arguments, while other claims (e.g. for maintainability) might rely on more qualitative arguments such as adherence to codes of practice.

Additionally, safety arguments can be classified in terms of their role in supporting a safety claim:

- A direct or demonstrative argument uses evidence to show that a particular objective has been achieved. A direct argument has the general structure, “Given the evidence, the objective has been met.”

- An indirect, backing, or validating argument shows that the evidence used in a direct argument is trustworthy. The evidence brought to bear in a backing argument typically addresses issues such as the quality or applicability of data and the capabilities of practitioners. A backing argument has the general structure, "Given the (backing argument's) evidence, the direct argument's evidence can be relied on."

5.3 RISC Life Cycle Considerations

As discussed in Section 2.1, the concept of adequate safety requires that safety is addressed throughout all phases of the system life cycle. This translates into the development of safety objectives that span the full life of the system, from concept studies to closeout. Correspondingly, the RISC must also address the full system life cycle, regardless of the particular point in the life cycle at which the RISC is developed. This manifests in the RISC as two distinct types of safety claims:

- Claims related to the safety objectives of the current or previous phases argue that the objectives have been met.

- Claims related to the safety objectives of future phases argue that a 'roadmap' has been established for the satisfaction of objectives yet to be met, i.e., that necessary planning and preparation have been conducted and that commitments are in place to meet the objectives at the appropriate time.

The form of the RISC arguments for accomplished objectives vs. upcoming objectives is shown in Figure 5-3 for the point in time at which design has completed and realization is about to commence. As the system proceeds in the life cycle and RISCs are developed for successive milestones, arguments demonstrating an ability and commitment to meeting objectives are replaced by arguments demonstrating accomplishment of objectives.

5.3.1 Transitioning from Safety Thresholds to Safety Goals

In the case of a system for which the initial minimum tolerable level of safety is defined by a safety threshold, but which is expected to undergo safety growth during operation and ultimately meet a stricter safety goal, the RISC must make a case that a program of continuous improvement is planned or in place that has a reasonable expectation of producing the requisite safety improvement. In other words, the RISC must provide a roadmap towards the satisfaction of the safety goal in terms of the plans, and commitments necessary for making that level of safety come true. The form of argument for safety improvement is likely to be probabilistic and/or qualitative, since such improvements typically depend on activities, such as testing, whose outcomes cannot be predicted with certainty beforehand.

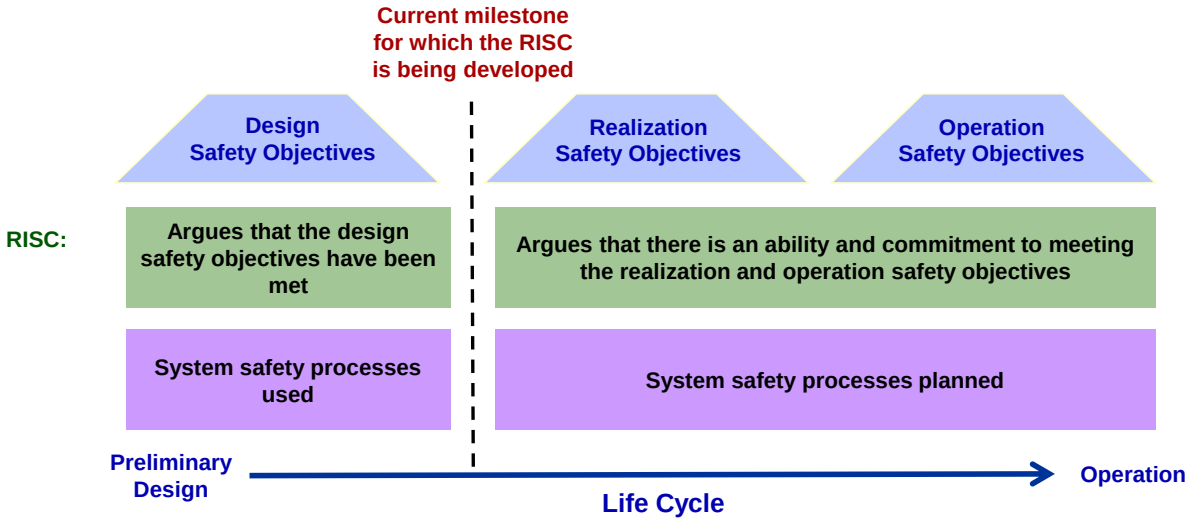


Figure 5-3. Coverage of the System Life Cycle in the RISC

5.3.2 Maintaining a High Level of Safety throughout the Mission Life

In cases where life limiting factors and reliability degradation due to wear-out are areas of concern (e.g., for robotic missions of long duration), it is necessary to show as part of the RISC that the reliability of the system will remain adequately high throughout its design life.

5.4 An Example RISC Structure

The high-level structure of the RISC is determined by the safety objectives negotiated at the outset of system formulation. The most straightforward relationship between the safety objectives and the RISC is for each claim in the RISC to correspond to an operational safety objective of the task. This situation is shown in Figure 5-4, which restates the objectives of Figure 3-5 as claims about the safety of the system. Because the operational safety objectives have been derived from the top-level objective, “The system is adequately safe,” the burden of the RISC is to substantiate them, in which case the top-level objective is also substantiated.

The figures in this section are intended to illustrate the overall structure that a particular safety case might have. They are not meant to prescribe a general safety case structure, nor are they meant to suggest a limit to the depth or complexity of an actual safety case. Volume 2 will provide specific safety case examples and present formats such as Goal Structuring Notation (GSN) for structuring claims [38].

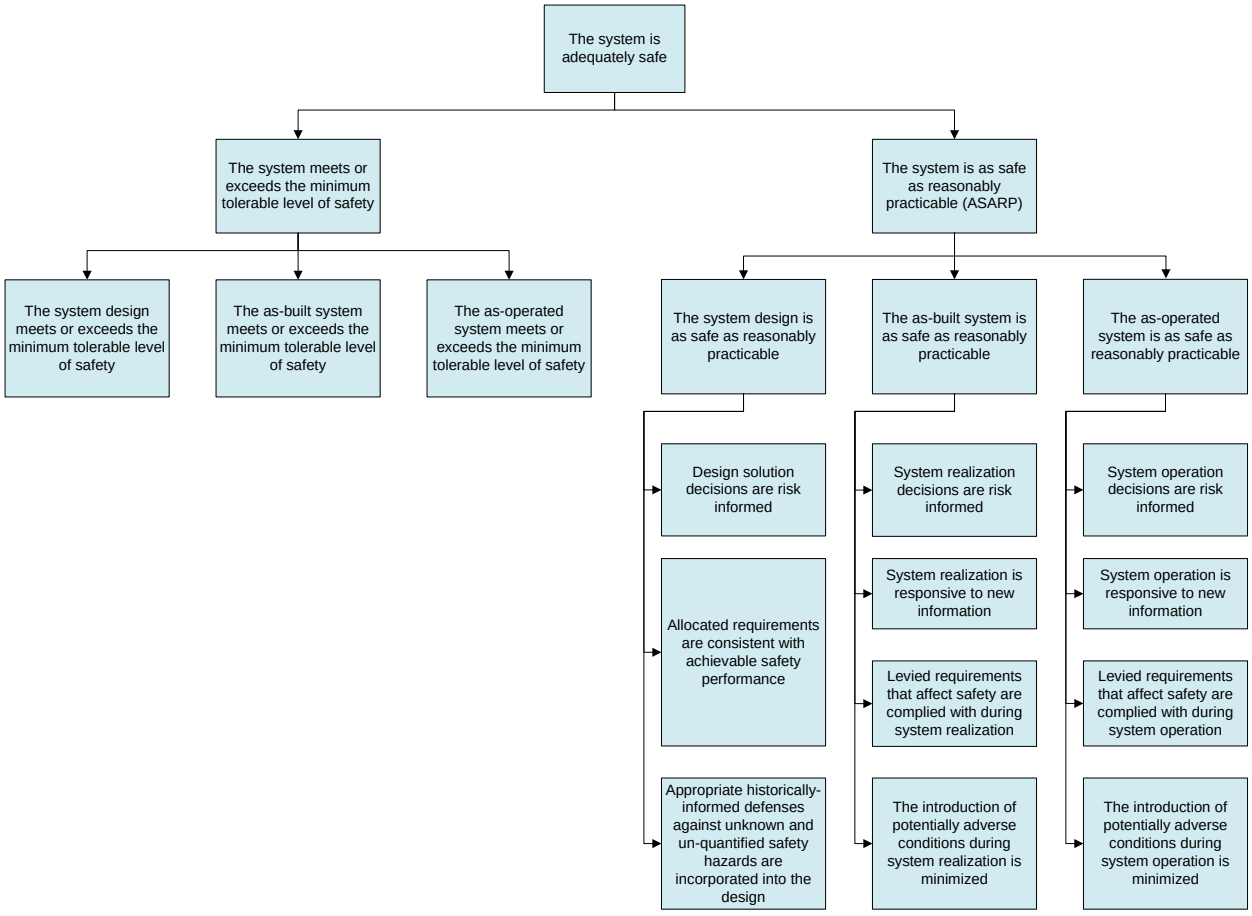


Figure 5-4. Top-Level Claims of the Example RISC

5.4.1 RISC Design Claims

Figure 5-5 shows that part of Figure 5-4 pertaining to system design, including the four operational design safety claims at the leaves of the tree. These are the design claims that the RISC must substantiate.

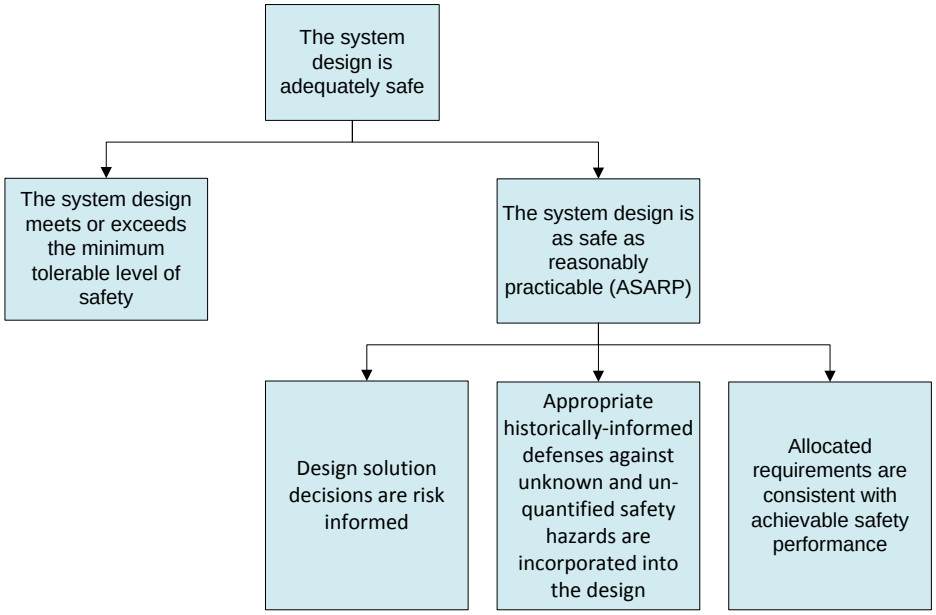


Figure 5-5. RISC Design Claims Derived from Design Objectives

- **RISC Design Claim, "The system design meets or exceeds the minimum tolerable level of safety."**

  Figure 5-6 shows an example RISC structure for the claim, "The system design meets or exceeds the minimum tolerable level of safety."

  At the first level of decomposition, this claim makes the two sub-claims:

  - The results of the ISA show that the system design exceeds the tolerable level of safety. This is a direct argument for the higher-level claim.
  - The ISA has been properly conducted. This is a backing claim for the first sub-claim. It argues that the evidence supporting the first sub-claim, namely the ISA, is trustworthy.

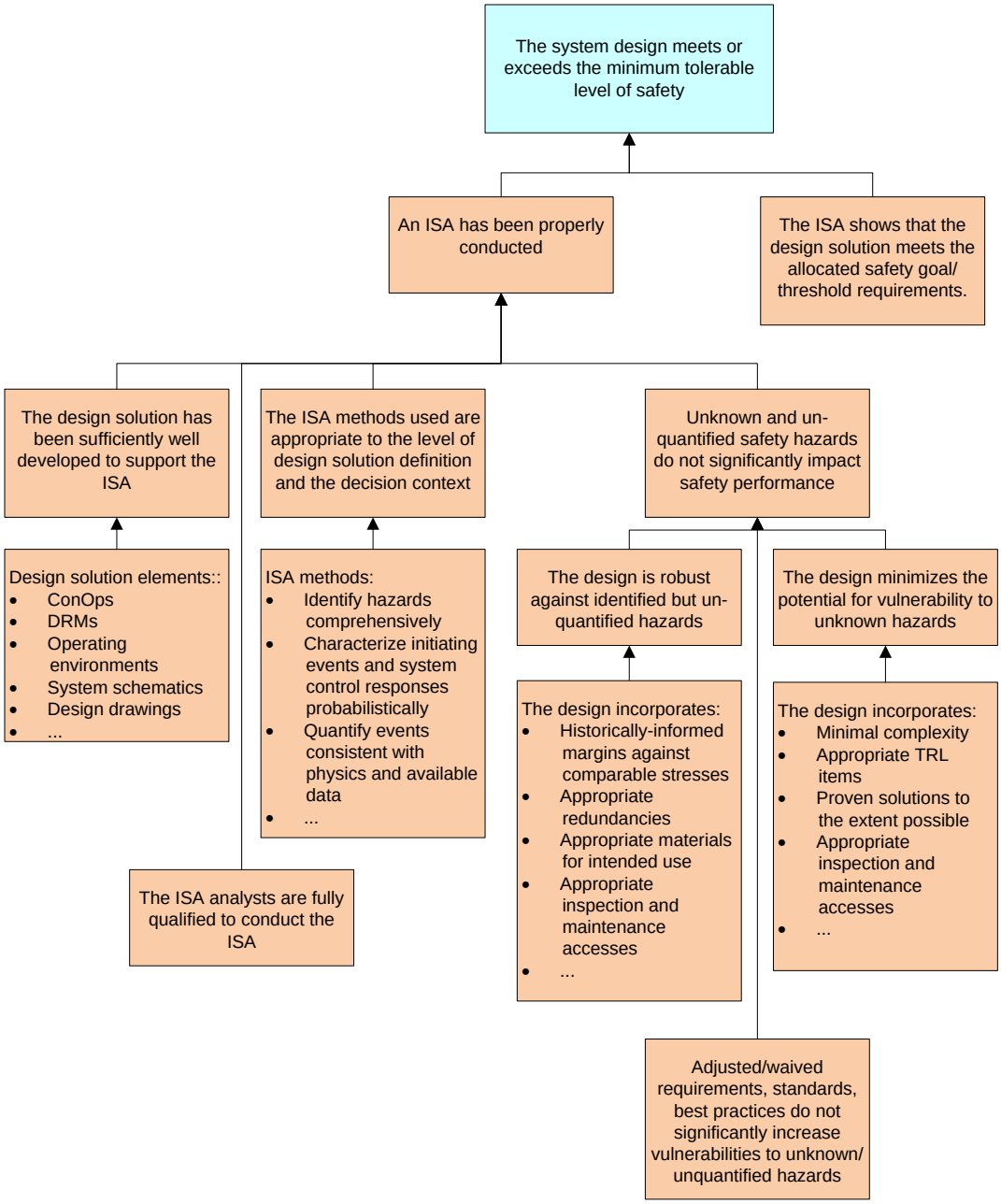


Figure 5-6. RISC Design Claim, "The System design meets or exceeds the minimum tolerable level of safety."

The claim that the ISA has been properly conducted is further decomposed into the claims that the design solution is sufficiently well developed to support the ISA; that the analysts are qualified to conduct the ISA; that the ISA methods used are appropriate to the level of design solution definition and the decision context; and that unknown and un-quantified safety hazards do not significantly impact safety performance. These are the attributes of the ISA that the sub-claim argues are necessary and sufficient to find

the ISA trustworthy to use in the manner that it is being used, i.e., for comparison against the minimum tolerable level of safety.

The depth of argument and extent of evidence needed to support the claims ultimately depends on decision maker needs, and expectations are negotiated up front in the form of evaluation protocols. The terminal boxes containing bulleted items notionally indicate the expectation that:

- Each of the major design solution elements would be documented, and an argument would be made that this level of definition is adequate for the decision context to which the RISC is applied.
- The ISA methods suit the level of design definition and adequately accomplish the necessary system safety function of identifying and characterizing potential accident scenarios in terms of accident causes, contributing factors, effectiveness of controls, the probabilities of the potential end states, etc.
- The design is suitably robust against un-quantified hazards by virtue of appropriate margins, redundancies, materials, accesses, etc.
- The design minimizes the potential for vulnerability to unknown hazards by virtue of simplicity, technological maturity, the use of proven solutions, appropriate accesses, etc.

- **RISC Design Claim, "Design solution decisions are risk informed."**

  Figure 5-7 shows an example RISC structure for the claim, "Design solution decisions are risk informed."

  At the first level of decomposition, this claim makes the two sub-claims:

  - RIDM has been conducted to select a design that is ASARP.
  - Requirements have been tailored, and standards and best practices have been adopted, which supports the selected design.

  These are direct claims, both of which are necessary for substantiating the higher level claim. The first claim is supported by argument and evidence related to the proper conduct of RIDM, i.e., that stakeholder objectives have been properly understood and that requirements have been allocated from the next higher organizational unit. The second claim is supported by argument and evidence related to the acceptable tailoring of requirements, standards, and best practices, i.e., that a comprehensive initial set has been identified, and that there is an appropriate analytical basis for each

adjustment/waiver from that initial set that demonstrates adherence to the ASARP principle.

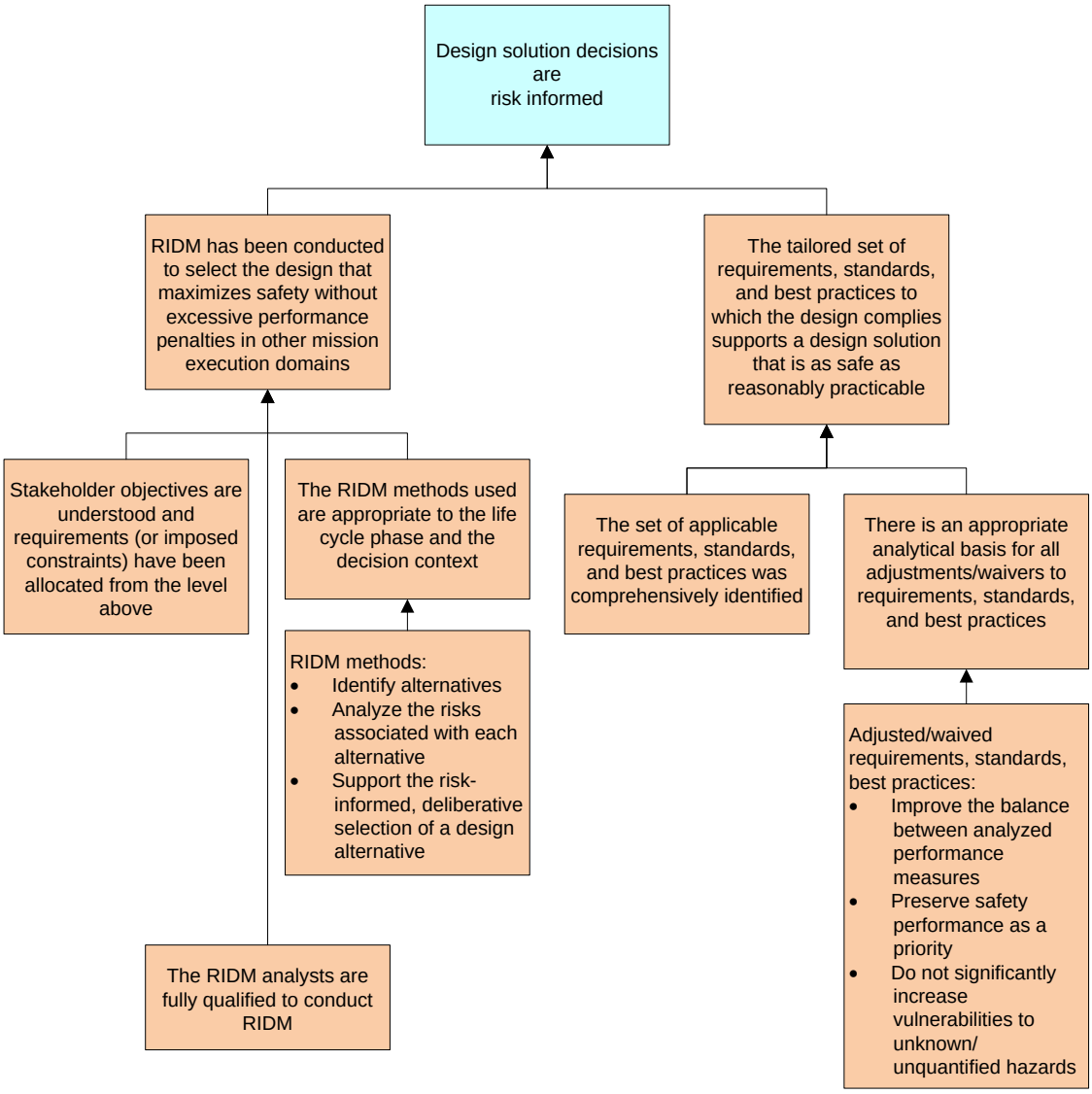


Figure 5-7. RISC Design Claim, "Design solution decisions are risk informed."

- **RISC Design Claim, "Allocated requirements are consistent with achievable safety performance."**

  Figure 5-8 shows an example RISC structure for the claim, "Minimum tolerable levels of safety have been allocated consistent with achievable safety performance."

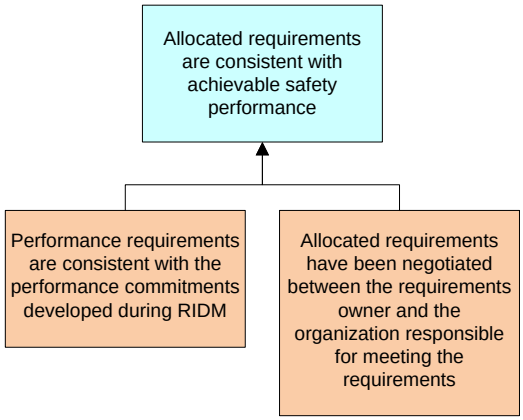


Figure 5-8. RISC Design Claim, "Allocated requirements are consistent with achievable safety performance."

This sub-claim is substantiated by argument and evidence related to the development of performance commitments as part of the RIDM process, consistency between the performance commitments and the allocated requirements, and the mutual negotiated acceptance of the allocated requirements by the organization levying the requirements and the organization responsible for meeting them.

- **RISC Design Claim, "Appropriate historically-informed defenses against unknown and un-quantified safety hazards are incorporated into the design."**

  Figure 5-9 shows an example RISC structure for the claim, "Appropriate historically-informed defenses against unknown and un-quantified safety hazards are incorporated into the design."

  This sub-claim addresses the fundamental issue that scenario identification and characterization can never be shown to be complete, and that adherence to historically based design principles and best practices is a necessary component of the ASARP principle. In this case, the claim that appropriate defenses against such hazards have been incorporated into the design is decomposed into argument and evidence that the design is robust against hazards that may be present, i.e., it incorporates appropriate margins, redundancies, materials, etc.; and argument and evidence that the presence of hazards has been minimized, i.e., the design is minimally complex, it uses proven technologies and design solutions, etc.

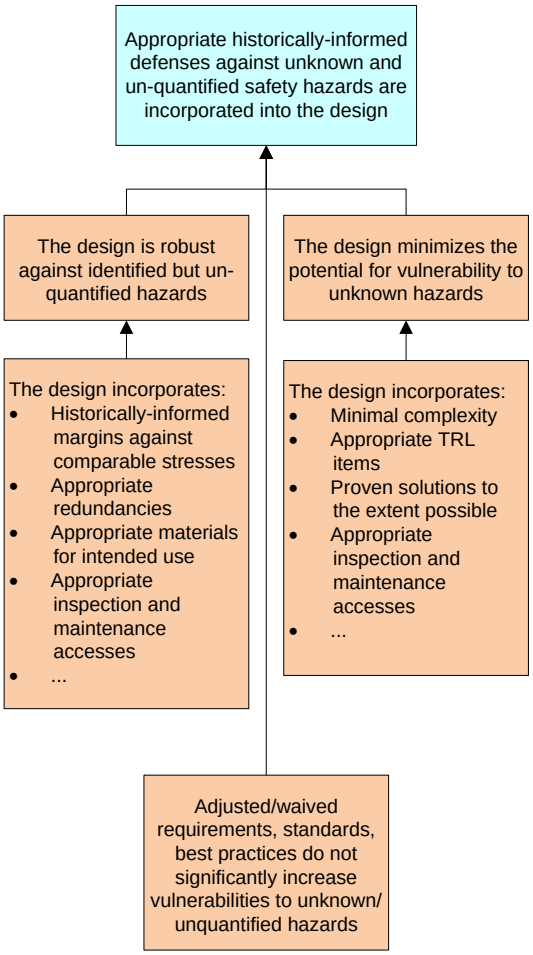


Figure 5-9. RISC Design Claim, "Appropriate historically-informed defenses against unknown and un-quantified safety hazards are incorporated into the design."

Figure 5-10 shows the complete structure of the RISC design claims discussed above. Taken as a whole, this claims structure supports the case that the system design is safe.

5.4.2 RISC Realization and Operation Claims

The RISC realization and operation claims are shown in Figure 5-11 and Figure 5-12. Like the RISC design claims, the RISC realization and operation claims are developed from the operational safety objectives that have been negotiated up front, in accordance with the RISC expectations contained in the evaluation protocols that have also been negotiated up front.

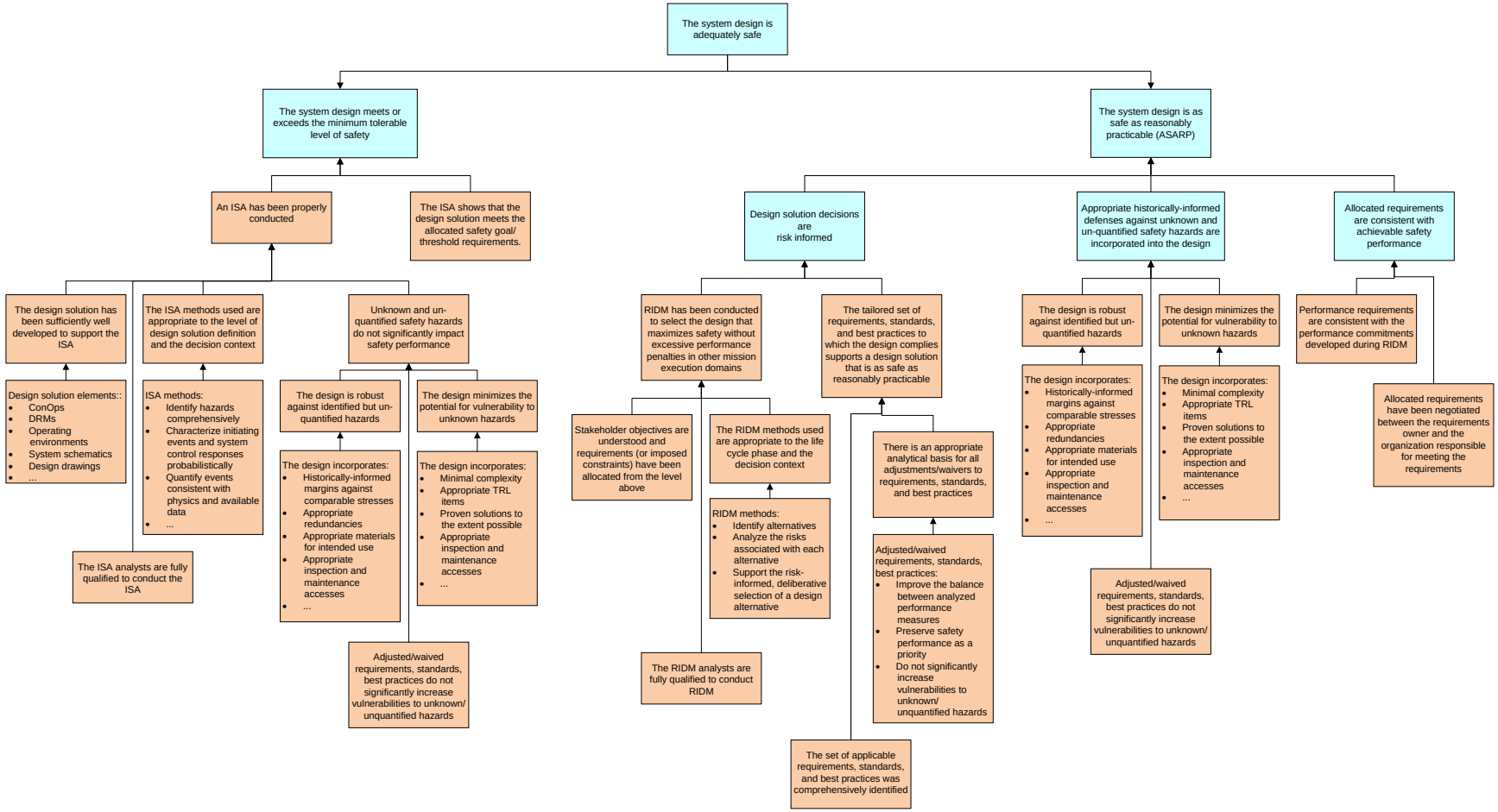


Figure 5-10. Complete Structure of the RISC System Design Claim

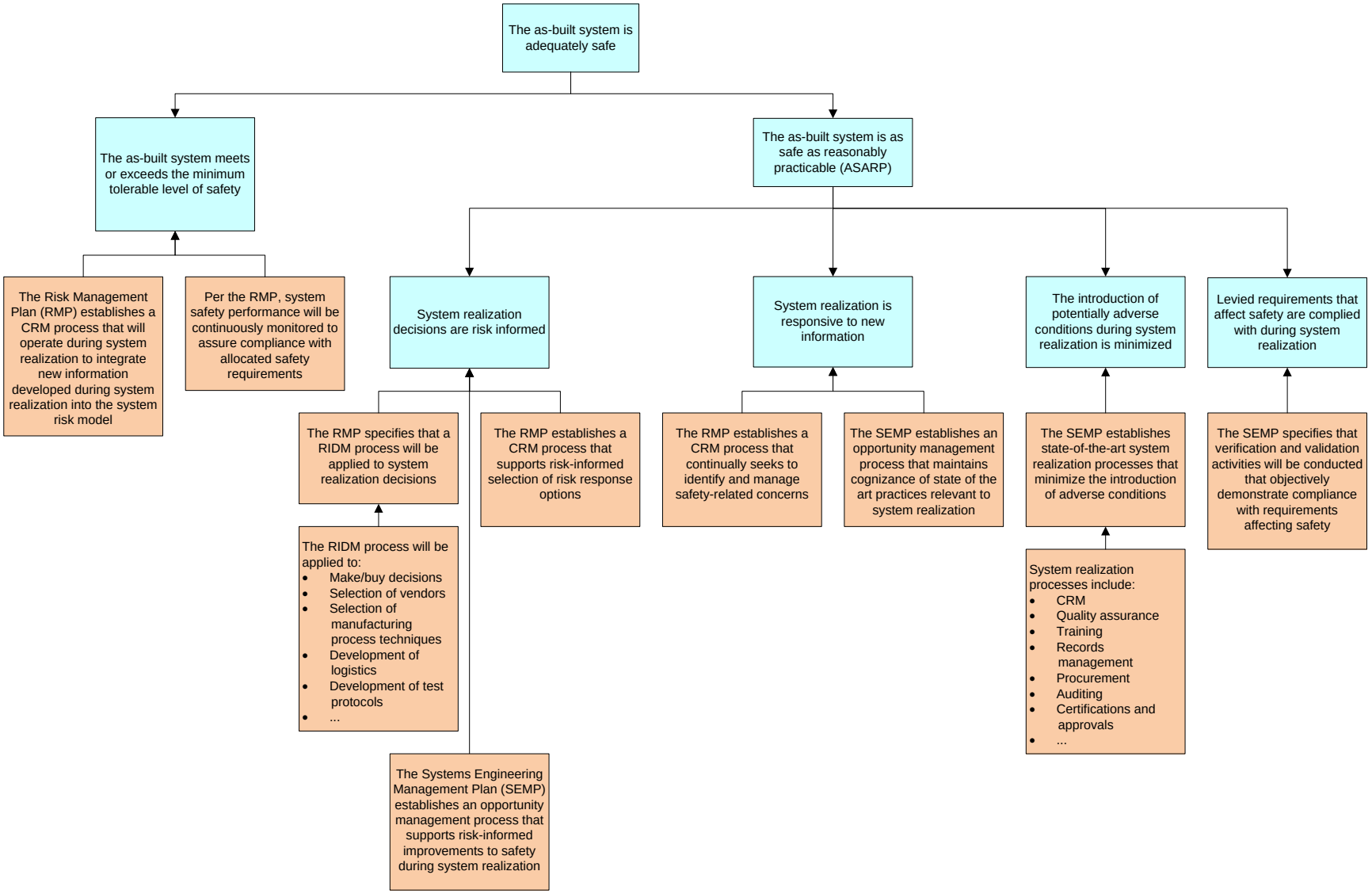


Figure 5-11. Complete Structure of the RISC System Realization Claim

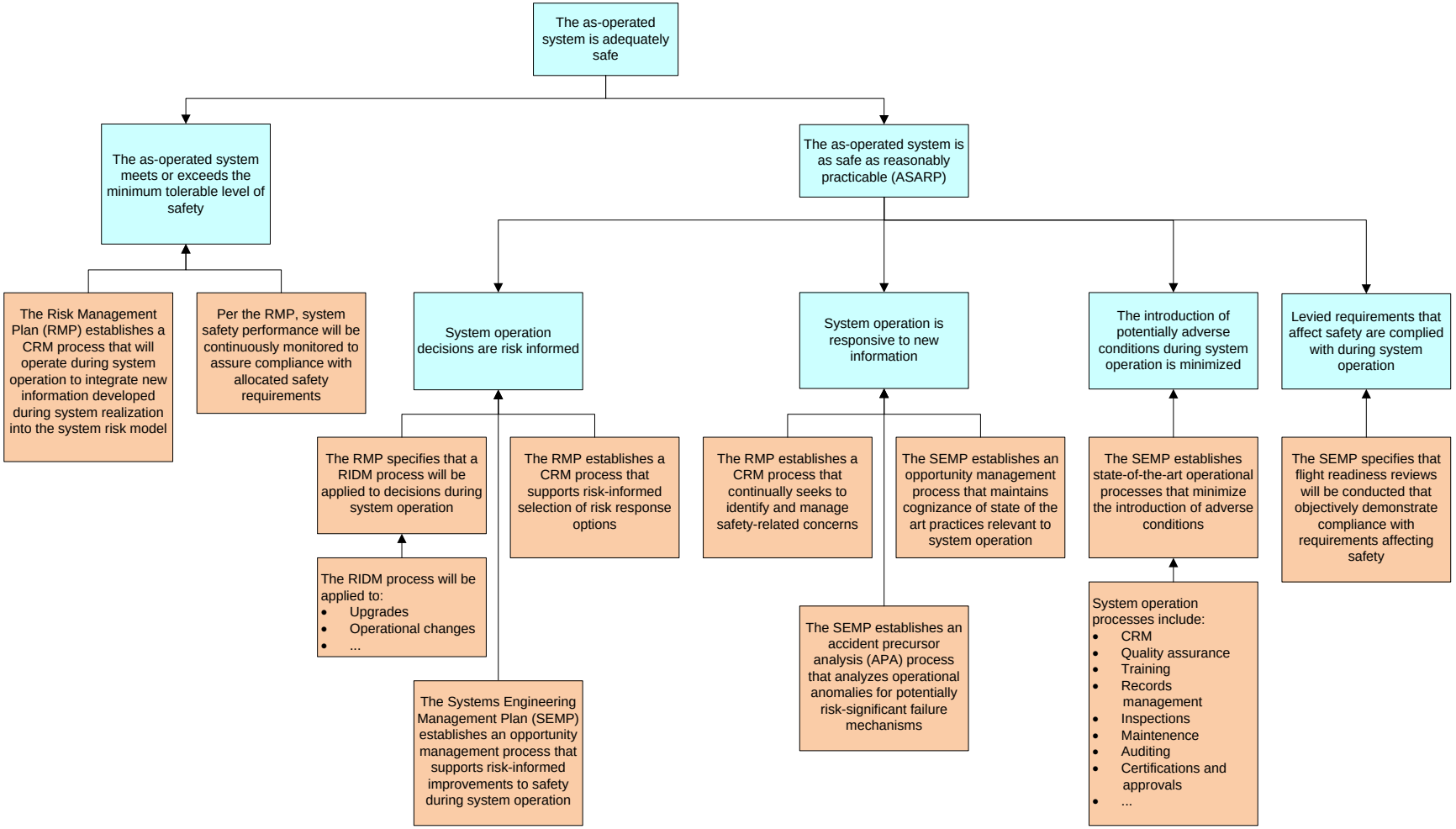


Figure 5-12. Complete Structure of the RISC System Operation Claim

5.5 Evaluating the RISC

Presentation of the RISC to the decision-maker is not a stopping point. The decision-maker needs to consciously accept or reject the claims made by the RISC. This needs to be carried out based on *evaluation protocols*. For each claim in the RISC, it is the task of the decision-maker to:

1. Understand the technical basis (i.e., evidence) behind the claim.
2. Question the technical basis of the claim to determine its validity.
3. Provide judgment as to adequacy of the claim.

In other words, to evaluate the RISC, the claims in the RISC are critically reviewed, thereby making use of the collected evidence related to the safety of the system.

In questioning the technical basis of the RISC and judging its adequacy, it is important for the reviewer to evaluate the RISC from a critical/skeptical viewpoint. The assumptions underlying the RISC and the effectiveness of the processes implemented in accordance with the RISC should be continually reviewed throughout every phase of the project.

It is a common and good practice for an evaluator to have one or more checklists for determining whether the evidence is sufficient to support a claim. The checklist should not mimic the structure of the RISC. Rather, it should be organized independently from the RISC so as not to be constrained by the preconceptions and assumptions of the RISC provider. An independent checklist will also tend to be generically applicable, as opposed to a RISC which tends to be more application specific.

Two example checklists that would be appropriate for RISCs that pertain to NASA projects are shown in Table 5-1 and Table 5-2. Each empty box in the checklists provides room for a grade and for the evaluator's comments.[24] The grade is a means for ranking the degree to which each item in the checklist has been addressed successfully by the safety case being evaluated. In keeping with the general categories of activities depicted in Figure 4-1 through Figure 4-4, Table 5-1 applies to analyses and Table 5-2 to program controls. In the terminology of Section 5.2.2, Table 5-1 provides an evaluation of direct or demonstrative arguments that a claim is satisfied, whereas Table 5-2 provides backing or validating arguments.

Another example checklist that could be very useful to an evaluator of RISCs for NASA projects is shown in Figure 5-13. This checklist is presented in a flow-down fashion starting from the top-level claim (the system is safe). It has the advantage of explicitly showing how arguments based on evidence support claims.

[24] The format of the table can be changed to suit the reviewer's needs. For example, it may be sufficient for some reviewers to enter one comment per row in Table 5-1 rather than one per cell.

Table 5-1. Example Checklist for Grading and Commenting on Direct (Demonstrative) Arguments Made in the RISC

	ANALYSIS TYPE						
	Physical Responses	Hazards	Individual Risks	Aggregate Risks	Risk Drivers	Risk Allocations	...
Important issues are identified and evaluated	Grade: Comment:	Grade: Comment:	Grade: Comment:	Grade: Comment:	Grade: Comment:	Grade: Comment:	
Models are graded according to the importance of the issue	Grade: Comment:	Grade: Comment:	Grade: Comment:	Grade: Comment:	Grade: Comment:	Grade: Comment:	
Tests support models and analysis of important issues	Grade: Comment:	Grade: Comment:	Grade: Comment:	Grade: Comment:	Grade: Comment:	Grade: Comment:	
Best available models are used for all risk significant issues	Grade: Comment:	Grade: Comment:	Grade: Comment:	Grade: Comment:	Grade: Comment:	Grade: Comment:	
Models are verified & validated	Grade: Comment:	Grade: Comment:	Grade: Comment:	Grade: Comment:	Grade: Comment:	Grade: Comment:	
Makes effective use of scenario based modeling	Grade: Comment:	Grade: Comment:	Grade: Comment:	Grade: Comment:	Grade: Comment:	Grade: Comment:	
Design, mission, & environment are characterized correctly	Grade: Comment:	Grade: Comment:	Grade: Comment:	Grade: Comment:	Grade: Comment:	Grade: Comment:	
Inputs and assumptions are justified	Grade: Comment:	Grade: Comment:	Grade: Comment:	Grade: Comment:	Grade: Comment:	Grade: Comment:	
Analyses are performed for each appropriate mission phase	Grade: Comment:	Grade: Comment:	Grade: Comment:	Grade: Comment:	Grade: Comment:	Grade: Comment:	
Interfaces between analyses are properly handled	Grade: Comment:	Grade: Comment:	Grade: Comment:	Grade: Comment:	Grade: Comment:	Grade: Comment:	
Interfaces between models within analyses are properly handled	Grade: Comment:	Grade: Comment:	Grade: Comment:	Grade: Comment:	Grade: Comment:	Grade: Comment:	
Interfaces between assets are properly handled	Grade: Comment:	Grade: Comment:	Grade: Comment:	Grade: Comment:	Grade: Comment:	Grade: Comment:	
Interfaces between mission phases are properly handled	Grade: Comment:	Grade: Comment:	Grade: Comment:	Grade: Comment:	Grade: Comment:	Grade: Comment:	
All known potentially important sources of uncertainty are characterized and evaluated	Grade: Comment:	Grade: Comment:	Grade: Comment:	Grade: Comment:	Grade: Comment:	Grade: Comment:	
Appropriate sensitivity and trade studies are performed	Grade: Comment:	Grade: Comment:	Grade: Comment:	Grade: Comment:	Grade: Comment:	Grade: Comment:	
Analyses are performed by qualified personnel	Grade: Comment:	Grade: Comment:	Grade: Comment:	Grade: Comment:	Grade: Comment:	Grade: Comment:	
Analyses are reviewed by qualified independent reviewers	Grade: Comment:	Grade: Comment:	Grade: Comment:	Grade: Comment:	Grade: Comment:	Grade: Comment:	
Review comments are acted upon and/or resolved	Grade: Comment:	Grade: Comment:	Grade: Comment:	Grade: Comment:	Grade: Comment:	Grade: Comment:	
All aspects are well documented	Grade: Comment:	Grade: Comment:	Grade: Comment:	Grade: Comment:	Grade: Comment:	Grade: Comment:	

Table 5-2. Example Checklist for Grading and Commenting on Backing (Validating) Arguments Made in the RISC

PROGRAMMATIC CONTROL	
Plans related to programmatic controls are comprehensively and clearly documented.	Grade: Comment:
Management will actively promote an environment within which design opportunities for improving safety without incurring unreasonable cost, schedule, and technical impacts are sought out and implemented during each project phase.	Grade: Comment:
Protocols are in place that will promote effective and timely communication among design teams from different organizations working on different parts of the system.	Grade: Comment:
Configuration management processes will be in place to ensure that modifications to the design are kept up to date and that everyone is working from the same drawings and specifications.	Grade: Comment:
There is a process for ensuring that decisions relating to design, realization, and operation will be informed by best practices and by lessons learned from previous projects.	Grade: Comment:
There is a process for verifying that all requirements, codes, and standards related to system design, realization, and operation that have been designated as being important to safety will be satisfied, and continue to be satisfied as changes occur.	Grade: Comment:
Quality assurance plans and processes are in compliance with SAE Aerospace Standard (AS) 9100 and audits and reviews will be conducted to ensure that actual practice is in compliance with the plans.	Grade: Comment:
Training programs will be in place where needed to help employees at NASA and NASA's suppliers to gain the necessary knowledge and skill to fulfill the mission. Where appropriate, the personnel assigned to each task will be certified to perform that task.	Grade: Comment:
The procurement process will utilize a risk-informed decision methodology to select between supplier alternatives.	Grade: Comment:
Unanticipated events and anomalies occurring during system operation will be evaluated to determine whether they could be considered as precursors to an accident. If so, this information will be used to determine whether the risk models need to be modified and whether additional controls are needed.	Grade: Comment:
A risk-informed approach to maintenance, inspections, and audits will be implemented. The ordering of activities in these areas will be prioritized so that actions that are important to safety risk are conducted first and most thoroughly.	Grade: Comment:
A risk-informed approach to training and certification of crew, mission control personnel, and launch control personnel will be implemented. Operating procedures, training, and certification will be prioritized to emphasize areas and skills that are needed to minimize safety risks	Grade: Comment:

The example checklists provided herein are for illustration purposes only. They are not intended to replace the evaluator's judgment in formulating questions to be addressed during the evaluation process.

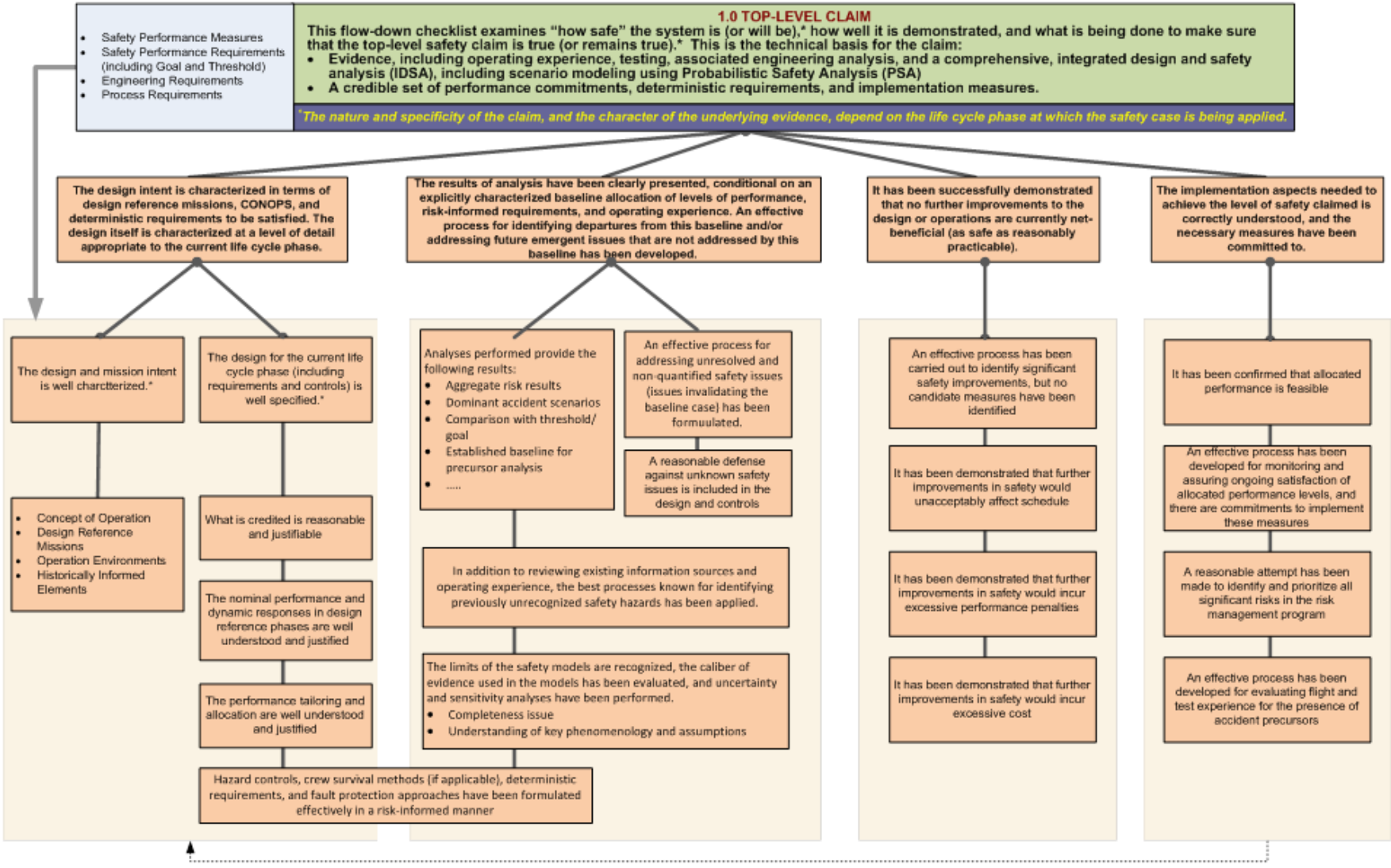


Figure 5-13. Flow-Down Checklist for Evaluating The RISC

6 Conclusions

This volume of the NASA System Safety Handbook presents a System Safety Framework that provides a coherent structure for organizing system safety activities towards the achievement and demonstration of safety throughout the system life cycle. Within the framework, system safety activities are organized around the accomplishment of clearly stated safety objectives that collectively define adequate safety for the system, and are communicated to decision makers via a risk-informed safety case that provides a compelling, comprehensible and valid argument, supported by evidence, that the system is or will be adequately safe for a given application in a given environment.

System safety, which traditionally has focused on the conduct of safety analyses such as hazard analysis and PRA, is broadened in this handbook to entail more than just analysis; it is a holistic, integrated discipline that informs decision making throughout the system life cycle. It brings together qualitative and quantitative analysis, historical experience, adherence to standards and best practices, and compliance with requirements to ensure that safety is properly considered whenever decisions are made that affect safety. As such, system safety personnel must actively collaborate with systems engineering and program control organizations to influence decision making during concept development, design, system realization, and system operation, with the objective that the system meets or exceeds the minimum tolerable level of safety, that it is as safe as reasonably practicable, and for systems that will be reused, that a plausible plan is in place for continuous safety improvement in accordance with increasing minimum tolerable levels of safety over time.

The assurance argument that the system is safe is documented in the risk-informed safety case (RISC), which brings together all of the key pieces of system safety into a single reviewable document. At major milestones such as Key Decision Points (KDPs), the RISC provides decision makers with a coherent means of evaluating the safety of the system. Informed by this evaluation, a decision can be made to either proceed in the system life cycle or not. If safety is found lacking in one or more particulars, the risk-informed safety case supports the identification of additional measures that must be implemented before the system continues to the next life cycle phase.

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Appendix A: Acronyms

ALARA	As Low as Reasonably Achievable
ALARP	As Low as Reasonably Practicable
APA	Accident Precursor Analysis
AS	Aerospace Standard
ASAP	Aerospace Safety Advisory Panel
ASARP	As Safe as Reasonably Practicable
CAIB	Columbia Accident Investigation Board
CALCE	Center for Advanced Life Cycle Engineering
CCDF	Complementary Cumulative Distribution Function
CDR	Critical Design Review
CFD	Computational Fluid Dynamics
ConOps	Concept of operations
CRM	Continuous Risk Management
DoD	Department of Defense
FAA	Federal Aviation Administration
FM	Fault Management
FMEA	Failure Modes and Effects Analysis
GSN	Goal Structuring Notation
HAZOP	Hazard and Operability Study
ISA	Integrated Safety Analysis
ISS	International Space Station
KDP	Key Decision Point

LEO	Low Earth Orbit
LOC	Loss of Crew
LOM	Loss of Mission
LOV	Loss of Vehicle
MMOD	Micro-Meteoroid and Orbital Debris
NASA	National Aeronautics and Space Administration
NPD	NASA Policy Directive
NPR	NASA Procedural Requirement
PBS	Product Breakdown Structure
PDF	Probability Density Function
PDR	Preliminary Design Review
PRA	Probabilistic Risk Assessment
PSA	Probabilistic Safety Analysis
QA	Quality Assurance
RIDM	Risk-Informed Decision Making
RISC	Risk-Informed Safety Case
RM	Risk Management
RMP	Risk Management Plan
SAE	Society of Automotive Engineers
SE	Systems Engineering
SEMP	Systems Engineering Management Plan
SIR	System Integration Review
SSTP	System Safety Technical Plan
STI	Scientific and Technical Information

Appendix B: Definitions

Aleatory – Pertaining to stochastic (non-deterministic) events, the outcome of which is described by a probability density function. From the Latin alea (game of chance, die).

As Safe as Reasonably Practicable – A philosophy that states that safety should be increased as opportunities arise if the impact on cost, schedule, technical performance, or any other domain of interest to NASA is reasonable and acceptable.

Condition – A current fact-based situation or environment that is causing concern, doubt, anxiety, or uneasiness.

Consequence – The foreseeable, credible negative impact(s) on the organizational unit's ability to meet its performance requirements.

Continuous Risk Management (CRM) - A specific process for the management of risks associated with implementation of designs, plans, and processes. The CRM functions of identify, analyze, plan, track, control, and communicate and document provide a disciplined environment for continuously assessing what could go wrong, determining which issues are important to deal with, and implementing strategies for dealing with them.

Control – In the safety context, any provision taken to reduce the likelihood and/or severity of an accident. Controls can include design modifications to address specific risks, improvements in quality assurance, modification of procedures, improvements in personnel training, provisions to improve management oversight where needed, etc.

Departure – An undesired event that might occur at a future time representing a change from the current plan and leading potentially to a consequence. It is the uncertainty in the occurrence or non-occurrence of the DEPARTURE that is the initially identified source of risk.

Enabling Event – A condition that provides the opportunity to challenge system safety, potentially leading to an accident.

Epistemic – Pertaining to the degree of knowledge. From the Greek episteme (knowledge)

Evaluation Protocol – A set of techniques, standards, and practices to be applied in demonstrating the level of satisfaction of a performance requirement (e.g., a safety goal). An evaluation protocol may include mandated assumptions, may specify a particular process of analysis, and may limit the degree of credit that can be taken for a particular design feature.

Hazard – A state or a set of conditions, internal or external to a system, that has the potential to cause harm. Examples of hazards include materials, energy sources, or operational practices that in uncontrolled situations can lead to scenarios that could produce death, injury, illness, equipment loss or damage, or damage to a protected environment.

Hazards Analysis – An application of systematic and replicable methods to identify and understand hazards, and to characterize the risk of mishaps that involve hazards. Risks originate from hazards – the absence of a hazard implies a freedom from the associated risk.

Initiating Event – A departure from a desired operational envelope to a system state where a control response is required either by human, software, or machine intervention.

Key Decision Point – The event at which the Decision Authority determines the readiness of a program/project to progress to the next phase of the life cycle (or to the next KDP)

Model – A description or representation of a system, entity, phenomenon, or process.

Objectives Hierarchy – An arrangement where objectives are decomposed into a set of quantifiable sub-objectives, each of which is implied by the top-level objective

Performance Measure – A quantifiable attribute of a decision alternative, used to support decision-making. Performance measures are typically defined for all mission execution domains and for institutional performance. For purposes of System Safety at NASA, performance measures include metrics related to human safety, asset protection, and environmental protection.

Performance Requirements – A value of a performance measure to be achieved by an organizational unit's work that has been agreed-upon to satisfy the needs of the next higher organizational level. [NPR 8000.4A]

Probabilistic Safety Analysis – A structured, probabilistic treatment of scenarios, likelihoods, consequences using a graded approach. Within this approach, the word "probabilistic" refers explicitly to a Bayesian treatment of uncertainty.

Probabilistic Thinking – A process of explicitly factoring in the quality of our state-of-knowledge into models, analysis, and decision-making. This process recognizes limits in all areas of the System Safety assessment, including: completeness of hazard identification, understanding of the phenomenology, the caliber of evidence supporting the RISC, and weighing the possibility of adverse outcomes in decision-making.

Risk – The potential for shortfalls, which may be realized in the future, with respect to achieving explicitly stated performance requirements. Risk is characterized by a set of triplets: 1) the

scenario(s) leading to degraded performance in one or more performance measures, 2) the likelihood(s) of those scenarios. and 3) the consequence(s) of the impact on performance that would result if those scenarios were to occur.

Risk-Informed Decision Making – A decision making approach that uses a diverse set of performance measures (some of which are model-based risk metrics) along with other considerations within a deliberative process to inform decision making.

Risk-Informed Safety Case – A documented body of evidence that provides a convincing and valid argument that: (1) applicable safety standards and requirements are met, (2) a given system is adequately safe for a given application in a given environment, and (3) a process of system optimization has been carried out to identify and implement net-beneficial improvements.

Risk Management – A process that includes risk-informed decision making and continuous risk management in an integrated framework. This integration is done in order to foster proactive risk management, to better inform decision-making through better use of risk information, and then to more effectively control implementation risks by focusing the continuous risk management process on the baseline performance requirements emerging from the RIDM process. [NPR 8000.4A]

Risk Statement – A statement of a concern or issue that could affect the ability to achieve one or more safety requirements. Each risk statement contains a *condition*, a *departure*, an *asset*, and a *consequence*.

Safety – Freedom from those hazards that can cause death, injury, or illness in humans, adversely affect the environment, or cause damage to or loss of equipment or property.

Safety Case – A documented body of evidence that provides a convincing and valid argument that a system is adequately safe for a given application in a given environment.

Safety Claim – A statement asserting the level of safety of a system or subsystem.

Safety Goal – A target level of safety that is not a threshold of acceptability, but to whose accomplishment design work should aspire.

Safety Margin – Extra performance allocated to systems, structures, and components to preserve safety over the range of credible variations in the loads (stresses, temperatures, etc.) to which they will be subjected.

Safety Risk Reserve – An incremental risk added to the evaluated risk to account for the estimated total effects of unknown, un-quantified, and under-evaluated risks. It is estimated

from analysis of historical experience with similar technologies taking into account the complexity of the system, the degree to which new technology is being used, and the degree to which new operating environments are being introduced.

Safety Threshold – Criteria for risk acceptance decisions; acceptance of risks exceeding threshold values requires elevation of the risk to the next higher level in the organization.

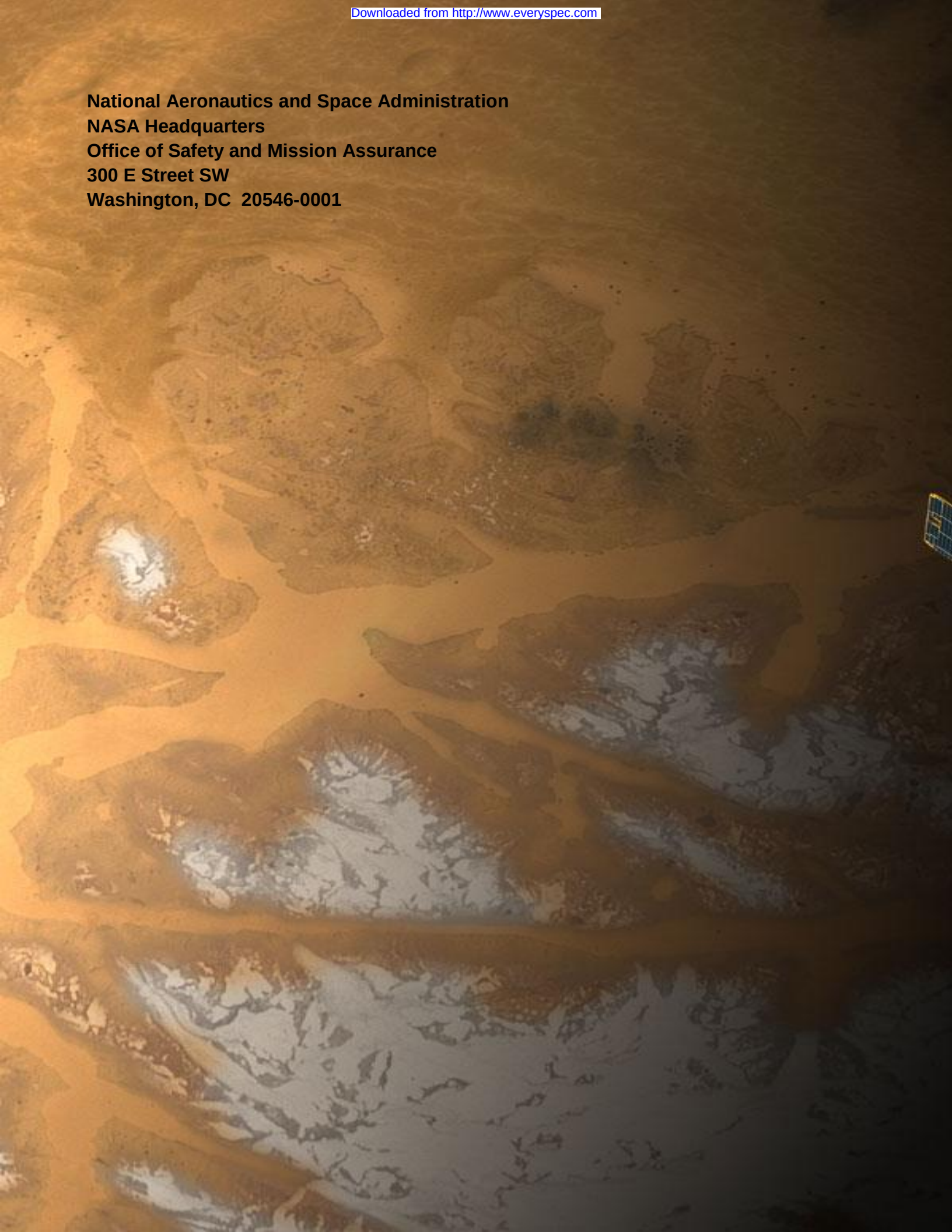
Scenario – A sequence of credible events that specifies the evolution of a system or process from a given state to a future state. In the context of risk management, scenarios are used to identify the ways in which a system or process in its current state can evolve to an undesirable state.

Sensitivity Study – The study of how the variation in the output of a model can be apportioned to different sources of variation in the model input and parameters.

Success Path – A scenario wherein the chain of events leads to an acceptable outcome, and is based upon the complement of system design attributes that work together to do a particular job.

System Safety – A disciplined, systematic process for the consideration of risks resulting from hazards that can affect humans, the environment, or mission assets. Per NPR 8715.3C, System Safety is the rational pursuit of safety within a systems perspective, where the degree of "safety" is to be understood in the context of a particular application. The system safety process does not expect to attain absolute safety, but strives to attain a degree of safety that fulfills obligations to the at-risk communities and addresses Agency priorities.

Uncertainty – An imperfect state of knowledge or a physical variability resulting from a variety of factors including, but not limited to, lack of knowledge, applicability of information, physical variation, randomness or stochastic behavior, indeterminacy, judgment, and approximation.



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