

Dokumentation über die Übernahme von
"GS-R-3"
(The Management System for Facilities and Activities)

in die
"Sicherheitskriterien für Kernkraftwerke"

REVISION D

APRIL 2009

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1.	INTRODUCTION				
	BACKGROUND				
1.1	<p>This Safety Requirements publication defines the requirements for establishing, implementing, assessing and continually improving a management system. A management system designed to fulfil these requirements integrates safety, health, environmental, security¹, quality² and economic³ related elements. Safety is the fundamental principle upon which the management system is based. These requirements must be met to ensure the protection of people and the environment and are governed by the objectives, concepts and principles of the IAEA Safety Fundamentals publication [1].</p> <p>¹ This publication covers the security of facilities, nuclear material and sources of radiation only to the extent that security measures for physical protection are essential to safety and the failure of such measures has consequences for safety.</p> <p>² Quality refers to the degree to which a product, process or service satisfies specified requirements.</p> <p>³ Economic objectives are included in the list of elements that have to be integrated, as it is recognized that economic decisions and actions may introduce or may mitigate potential risks.</p>	8	b	M8) 2.3	Der Bezug auf die IAEA Regeln wird nicht explizit gemacht, obwohl auch in M8 die Safety Fundamentals berücksichtigt werden.
1.2.	The standards of the International Organization for Standardization on environmental management systems [2] and on quality management systems [3] were considered in developing this publication. The experience of Member States in developing, implementing and improving management systems was also taken into account.				Keine Anforderung
1.3.	The content of this publication supports the achievement of the two general aims of the management system, as stated by the International Nuclear Safety Group (INSAG) [4]: – “To improve the safety performance of the organization through the planning, control and supervision of safety related activities in normal, transient and emergency situations; and – “To foster and support a strong safety culture through the development and reinforcement of good safety attitudes and behaviour in individuals and teams so as to allow them to carry out their tasks safely.”				Keine Anforderung, die angegebenen Punkte aus INSAG-4 werden in M8 Kap. 2.2 erfasst.
1.4.	This Safety Requirements publication supersedes the Code on Quality Assurance for Safety in Nuclear Power Plants and other Nuclear Installations [5]. It uses the term ‘management system’ rather than ‘quality assurance’. The term management system reflects and includes the initial concept of ‘quality control’ (controlling the quality of products) and its evolution through quality assurance (the system to ensure the quality of products) and ‘quality management’ (the system to manage quality). The management system is a set of interrelated or interacting elements that establishes policies and objectives and which enables those objectives to be achieved in a safe, efficient and effective manner.				Keine Anforderung
1.5.	The content of this publication is based on two key concepts: that work may be structured and interpreted as a set of interacting processes; and that all individuals involved contribute to achieving safety and quality objectives.				Keine Anforderung
1.6.	The requirements established in this publication may be used by organizations in the following ways:				Keine Anforderung

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	<ul style="list-style-type: none"> - As the basis for the management systems of organizations directly responsible for operating facilities and activities and providing services, as described in para. 1.8; - As the basis for the regulation of these facilities and activities by the regulatory body; - As the basis for the management systems of regulatory bodies [6]; - By the operator, to specify to a supplier, via contractual documentation, any specific requirements of this Safety Requirements publication that must be included in the supplier's management system for the supply and delivery of products⁴. <p>⁴ A product is an output from a process. Examples include a radionuclide, a waste package or electricity.</p>				
1.7.	A Safety Guide in support of this publication provides generic guidance on the application of the management system for all activities and facilities and for their regulation [7]. In addition to the generic guidance, there are several specific Safety Guides that provide additional guidance on implementing these requirements in specific areas.				Keine Anforderung
	OBJECTIVE				
1.8.	The objective of this publication is to define requirements for establishing, implementing, assessing and continually improving a management system that integrates safety, health, environmental, security, quality and economic related elements to ensure that safety is properly taken into account in all the activities of an organization.				Keine Anforderung
1.9.	The main objective of the requirements for the management system is to ensure, by considering the implications of all actions not in separate management systems but with regard to safety as a whole, that safety is not compromised. ⁵				Keine Anforderung
	⁵ There have been many instances in which decisions have been taken without considering the impact on safety (e.g. economic decisions such as reducing costs by cutting staff), which has led to safety related problems.				
	SCOPE				
1.10.	This publication is applicable for the establishment, implementation, assessment and continual improvement of management systems for: <ul style="list-style-type: none"> - Nuclear facilities; - Activities using sources of ionizing radiation; - Radioactive waste management; - The transport of radioactive material; - Radiation protection activities; - Any other practices or circumstances in which people may be exposed to radiation from naturally occurring or artificial sources; - The regulation of such facilities and activities. 				Keine Anforderung
1.11.	This Safety Requirements publication is applicable to all phases of the life cycle of facilities and for the entire duration of activities in normal, transient and emergency situations. This includes any subsequent period of institutional control that may be necessary. For a facility, these phases usually include siting, design, construction, commissioning, operation and decommissioning.				Keine Anforderung

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	sioning (or close-out or closure).				
1.12.	This publication does not attempt to define all those specific health, environmental, security, quality and economic related requirements to be addressed that have already been established elsewhere (in other IAEA publications and in international codes and standards). Furthermore, this publication does not set out to duplicate any of those specific requirements; rather, it defines the requirements for managing their fulfilment in an integrated manner.				Keine Anforderung
1.13.	The integrated management system requirements defined in this publication cover topics that either relate directly to safety or are part of the managerial framework without which safety cannot be ensured and maintained. Thus, topics such as management commitment, communications and other aspects are included from the perspective of seeking to enhance safety as well as performance.				Keine Anforderung
	STRUCTURE				
1.14.	This Safety Requirements publication consists of six sections. Section 2 establishes the general requirements for the management system, including those relating to safety culture, grading and documentation. Section 3 establishes the requirements for and responsibilities of senior management ⁶ for the development and implementation of a management system. Section 4 establishes the requirements for resource management. Section 5 establishes the requirements for the processes of the organization ↓ their specification, development and management ↓ and for the generic processes of the management system. Section 6 establishes the requirements for measuring, assessing and improving the management system. The Appendix shows the structure of the intended IAEA safety standards for management systems. ⁶ 'Senior management' means the person or persons who have ultimate responsibility to lead an organization at the highest level. Many different terms are used, including, for example: chief executive officer (CEO), director general, executive team, plant manager, top manager, chief regulator, site vice-president, managing director, laboratory director.				Keine Anforderung
2.	MANAGEMENT SYSTEM				
	GENERAL REQUIREMENTS				
2.1.	A management system shall be established, implemented, assessed and continually improved. It shall be aligned with the goals of the organization and shall contribute to their achievement. The main aim of the management system shall be to achieve and enhance safety by: – Bringing together in a coherent manner all the requirements for managing the organization; – Describing the planned and systematic actions necessary to provide adequate confidence that all these requirements are satisfied; – Ensuring that health, environmental, security, quality and economic related requirements are not considered separately from safety requirements, to help preclude their possible negative impact on safety.	8	a	M8) 2.3	.
2.2.	Safety shall be paramount within the management system, overriding all other demands.	1, 8	a	M1) Grundsätz e	

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				M8) 2.3 M8) 3.2(1)-	
2.3.	<p>The management system shall identify and integrate with the requirements contained within this publication:</p> <ul style="list-style-type: none"> – The statutory and regulatory requirements of the Member State; – Any requirements formally agreed with stakeholders⁷; – All other relevant IAEA Safety Requirements publications, such as those on emergency preparedness and response [8] and safety assessment [9]; and – Requirements from other relevant codes and standards adopted for use by the organization. <p>⁷ ‘Stakeholder’ means interested party; concerned party. To have a stake in something figuratively means to have something to gain or lose by, or to have an interest in, the turn of events. The term stakeholder is used in a broad sense to mean a person or group having an interest in the performance of an organization. Stakeholders have typically included the following: customers, owners, operators, employees, suppliers, partners, trade unions, the regulated industry or professionals; scientific bodies; governmental agencies or regulators (local, regional and national) whose responsibilities may cover nuclear energy; the media; the public (individuals, community groups and interest groups); and other States, especially neighbouring States that have entered into agreements providing for an exchange of information concerning possible transboundary impacts, or States involved in the export or import of certain technologies or materials.</p>	8	b	M8) 3.2(1)	Die in GS-R-3 genannten Bezüge sind in M8) nicht enthalten.
2.4.	<p>The organization shall be able to demonstrate the effective fulfilment of its management system requirements.</p>	8	b	M8) 3.2(1) M8) 3.3	In M8) ist diese Anforderung implizit in der Sicherheitspolitik enthalten.
	SAFETY CULTURE				
2.5.	<p>The management system shall be used to promote and support a strong safety culture by:</p> <ul style="list-style-type: none"> – Ensuring a common understanding of the key aspects of safety culture within the organization; – Providing the means by which the organization supports individuals and teams to carry out their tasks safely and successfully, taking into account the interaction between individuals, technology and the organization; – Reinforcing a learning and questioning attitude at all levels of the organization; and – Providing the means by which the organization continually seeks to develop and improve its safety culture. 	8	b	M1) Grundsätze M8) 2.2 M8) 2.3 M8) 3.1(1) M8) 3.2 (3)	Die Spiegelstrichliste ist an verschiedenen Stellen in M8) enthalten aber nicht wortgleich abgedeckt.
	GRADING THE APPLICATION OF MANAGEMENT SYSTEM REQUIREMENTS				
2.6.	<p>The application of management system requirements shall be graded so as to deploy appropriate resources, on the basis of the consideration of:</p> <ul style="list-style-type: none"> – The significance and complexity of each product or activity; – The hazards and the magnitude of the potential impact (risks) associated with the safety, health, environmental, security, quality and economic related elements of each product and activity; – The possible consequences if a product fails or an activity is carried out incorrectly. 	8	b	M8) 4.1 (1) M8) 4.3 (3)	Die Anforderung ist in Modul anders umgesetzt, da das Managementsystem durch gehend angewendet werden muss, lediglich die Maßnahmen zum Nachweis der Erfüllung sind gestuft anzuwenden.
2.7.	Grading the application of management system requirements shall be applied to the products	8	b	M8) 4.1 (1)	s.o.

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	and activities of each process.			M8) 4.3 (3)	
	DOCUMENTATION OF THE MANAGEMENT SYSTEM				
2.8.	The documentation of the management system shall include the following: – The policy statements of the organization; – A description of the management system; – A description of the structure of the organization; – A description of the functional responsibilities, accountabilities, levels of authority and interactions of those managing, performing and assessing work; – A description of the processes and supporting information that explain how work is to be prepared, reviewed, carried out, recorded, assessed and improved.	8	a	M8) 3.4(1)	
2.9.	The documentation of the management system shall be developed to be understandable to those who use it. Documents shall be legible, readily identifiable and available at the point of use.	8	a	M6) 7 (2) M8) 3.4 (2)	Diese allgemeinen Punkte der Dokumentation sind nach M6) verschoben worden. M8) hat lediglich den Verweis darauf.
2.10.	The documentation for the management system shall reflect: – the characteristics of the organization and its activities; and – the complexities of processes and their interactions.	8	a	M6) 7(1) M8) 3.4	Diese allgemeinen Punkte der Dokumentation sind nach M6) verschoben worden. M8) hat lediglich den Verweis darauf.
3.	MANAGEMENT RESPONSIBILITY				
	MANAGEMENT COMMITMENT				
3.1.	Management at all levels shall demonstrate its commitment to the establishment, implementation, assessment and continual improvement of the management system and shall allocate adequate resources to carry out these activities.	8	a	M8) 3.5 M8) 3.6 M8) 3.3(3)	
3.2.	Senior management shall develop individual values, institutional values and behavioural expectations for the organization to support the implementation of the management system and shall act as role models in the visible promulgation of these values and expectations.	8	b	M8) 3.5 M8) 3.6 M8) 3.2(3)	
3.3.	Management at all levels shall communicate to individuals the need to adopt to these individual values, institutional values and behavioural expectations as well as to comply with the requirements of the management system.	8	b	M8) 2.2 M8) 3.2(3) M8) 4.2 (2)	
3.4.	Management at all levels shall foster the involvement of all individuals in the implementation and continual improvement of the management system.	8	a	M8) 3.2 (3) M8) 3.5 M8) 3.6	
3.5.	Senior management shall ensure that it is clear when, how and by whom decisions are to be made within the management system.	8	a	M8) 3.5 M8) 3.8	
	STAKEHOLDER SATISFACTION				
3.6.	The expectations of stakeholders shall be considered by senior management in the activities and interactions in the processes of the management system, with the aim of enhancing stakeholder satisfaction while at the same time ensuring that safety is not compromised.	8	b	M8) 3.1 (6)	
	ORGANIZATIONAL POLICIES				

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3.7.	Senior management shall develop the policies of the organization. The policies shall be appropriate to the activities and facilities of the organization.	8	a	M8) 3.2 (1)	
	PLANNING				
3.8.	Senior management shall establish goals, strategies, plans and objectives ⁸ that are consistent with the policies of the organization. ⁸ These goals, strategies, plans and objectives are sometimes collectively referred to as a 'business plan'.	8	a	M8) 3.2(2)	
3.9.	Senior management shall develop the goals, strategies, plans and objectives of the organization in an integrated manner so that their collective impact on safety is understood and managed.	8	a	M8) 3.2 (1) M8) 2.3	
3.10.	Senior management shall ensure that measurable objectives for implementing the goals, strategies and plans are established through appropriate processes at various levels in the organization.	8	a	M8) 3.2(2)	
3.11.	Senior management shall ensure that the implementation of the plans is regularly reviewed against these objectives and actions taken to address deviations from the plans where necessary.	8	a	M8) 3.2(4) M8) 3.2(5)	
	RESPONSIBILITY AND AUTHORITY FOR THE MANAGEMENT SYSTEM				
3.12.	Senior management in the organization shall be ultimately responsible for the management system and shall ensure that it is established, implemented, assessed and continually improved.	8	a	M8) 3.5	
3.13.	An individual reporting directly to senior management shall have specific responsibility and authority for: – Coordinating the development and implementation of the management system, and for its assessment and continual improvement; – Reporting on the performance of the management system, including its influence on safety and safety culture, and any need for improvement; – Resolving any potential conflicts between requirements and within the processes of the management system.	8	a	M8) 3.5	
3.14.	The organization shall retain overall responsibility for the management system when an external organization is involved in the work of developing all or part of the management system.	8	a	M1) Grundsätze M8) 3.5, 3.1(3)	
4.	RESOURCE MANAGEMENT				
	PROVISION OF RESOURCES				
4.1.	Senior management shall determine the amount of resources necessary and provide the resources ⁹ to carry out the activities of the organization and to establish, implement, assess and continually improve the management system.	8	a	M8) 3.5 M8) 3.2(1) M8) 3.7	

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	⁹ 'Resources' includes people, infrastructure, the working environment, information and knowledge, as well as material and financial resources.				
4.2.	The information and knowledge of the organization shall be managed as a resource.	8	a	M8) 3.7(3)	
	HUMAN RESOURCES				
4.3.	Senior management shall determine the competence requirements for individuals at all levels and shall provide training or take other actions to achieve the required level of competence. An evaluation of the effectiveness of the actions taken shall be conducted. Suitable proficiency shall be achieved and maintained.	8	a	M8) 3.7(3)	
4.4.	Senior management shall ensure that individuals are competent to perform their assigned work and that they understand the consequences for safety of their activities. Individuals shall have received appropriate education and training, and shall have acquired suitable skills, knowledge and experience to ensure their competence. Training shall ensure that individuals are aware of the relevance and importance of their activities and of how their activities contribute to safety in the achievement of the organization's objectives.	8	a	M8) 3.7(3)2 M8) 3.7(3)3	
	INFRASTRUCTURE AND THE WORK ENVIRONMENT				
4.5.	Senior management shall determine, provide, maintain and re-evaluate the infrastructure and the working environment necessary for work to be carried out in a safe manner and for requirements to be met.	8	a	M8) 3.7(2) M8) 3.7(4)	
5.	PROCESS IMPLEMENTATION				
	DEVELOPING PROCESSES				
5.1.	The processes of the management system that are needed to achieve the goals, provide the means to meet all requirements and deliver the products of the organization shall be identified and their development shall be planned, implemented, assessed and continually improved.	8	a	M8) 3.1(3) M8) 3.1 (4)	
5.2.	The sequence and interactions of the processes shall be determined.	8	a	M8) 3.1 (4)	
5.3.	The methods necessary to ensure the effectiveness of both the implementation and the control of the processes shall be determined and implemented.	8	a	M8) 4.1(3) 4.1 (3) 1 3.3 (4) 1	
5.4.	The development of each process shall ensure that the following are achieved: – Process requirements, such as applicable regulatory, statutory, legal, safety, health, environmental, security, quality and economic related requirements, are specified and addressed; – Hazards and risks are identified, together with any necessary mitigatory actions; – Interactions with interfacing processes are identified; – Process inputs are identified; – The process flow is described; – Process outputs (products) are identified; – Process measurement criteria are established.	8	b	M8) 2.3 M8) 4.1	
5.5.	The activities of and interfaces between different individuals or groups involved in a single process shall be planned, controlled and managed in a manner that ensures effective communication and the clear assignment of responsibilities.	8	a	M8) 3.9	

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	PROCESS MANAGEMENT				
5.6.	For each process a designated individual shall be given the authority and responsibility for: – Developing and documenting the process and maintaining the necessary supporting documentation; – Ensuring that there is effective interaction between interfacing processes; – Ensuring that process documentation is consistent with any existing documents; – Ensuring that the records required to demonstrate that the process results have been achieved are specified in the process documentation; – Monitoring and reporting on the performance of the process; – Promoting improvement in the process; – Ensuring that the process, including any subsequent changes to it, is aligned with the goals, strategies, plans and objectives of the organization.	8	b	M8) 3.9 (1) M8) 4.1	Die Anforderungen sind bis auf die einleitende Zeile vollständig übernommen. Die in der ersten Zeile gestellten Anforderungen entsprechen nicht dem Detaillierungsniveau von Modul 8.
5.7.	For each process, any activities for inspection, testing, verification and validation, their acceptance criteria and the responsibilities for carrying out these activities shall be specified. For each process, it shall be specified if and when these activities are to be performed by designated individuals or groups other than those who originally performed the work.	8	a	M8) 4.1(3) 4.1 (3) 1 3.3 (4) 1 M8) 4.1 (3) 3.3	
5.8.	Each process shall be evaluated to ensure that it remains effective.	8	a	M8) 3.3	
5.9.	The work performed in each process shall be carried out under controlled conditions, by using approved current procedures, instructions, drawings or other appropriate means that are periodically reviewed to ensure their adequacy and effectiveness. Results shall be compared with expected values.	8	a	M8) 4.1	
5.10.	The control of processes contracted to external organizations shall be identified within the management system. The organization shall retain overall responsibility when contracting any processes.	8	a	M1) Grundsätze M8) 4.4 4.4 (4) 4.4 (5) 4.4 (6) 4.4 (8)	
	GENERIC MANAGEMENT SYSTEM PROCESSES				
5.11.	The following generic processes shall be developed in the management system. Control of documents				keine Anforderung
5.12.	Documents ¹⁰ shall be controlled. All individuals involved in preparing, revising, reviewing or approving documents shall be specifically assigned this work, shall be competent to carry it out and shall be given access to appropriate information on which to base their input or decisions. It shall be ensured that document users are aware of and use appropriate and correct documents.	8	a	M8) 3.7(3) M8) 3.4 M8) 3.10	

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	¹⁰ Documents may include: policies; procedures; instructions; specifications and drawings (or representations in other media); training materials; and any other documents describe processes, specify requirements or establish product specifications.				
5.13.	Changes to documents shall be reviewed and recorded and shall be subject to the same level of approval.	8	a	M8) 3.4 M8) 3.10	
	Control of products				In GS-R-3 werden unter „products“ stets Einrichtungen und Dienstleistungen verstanden. Im Modul sind stets die Tätigkeiten und Prozesse geregelt, die diese „products“ betreffen, nicht die „products“ selbst.
5.14.	Specifications and requirements for products, including any subsequent changes, shall be in accordance with established standards and shall incorporate applicable requirements. Products that interface or interact with each other shall be identified and controlled.	8	a	M8) 4.1 (1)	
5.15.	Activities for inspection, testing, verification and validation shall be completed before the acceptance, implementation or operational use of products. The tools and equipment used for these activities shall be of the proper range, type, accuracy and precision.	8	b	M8) 4.1 (1)	Es ist in M8) die (aus Sicht von Regeln) triviale Forderung nach dem Abschluss der Tätigkeiten vor Gebrauch nicht direkt gestellt sondern implizit enthalten.
5.16.	The organization shall confirm that products meet the specified requirements and shall ensure that products perform satisfactorily in service.	8	a	M8) 4.1 (1)	
5.17.	Products shall be provided in such a form that it can be verified that they satisfy the requirements.	8	a	M8) 4.1 (1)	
5.18.	Controls shall be used to ensure that products do not bypass the required verification activities.	8	a	M8) 4.1 (1)	
5.19.	Products shall be identified to ensure their proper use. Where traceability is a requirement, the organization shall control and record the unique identification of the product.	8	c		siehe allgemeine Bemerkung oben, diese Anforderung ist grundsätzlich in KTA 1401 enthalten
5.20.	Products shall be handled, transported, stored, maintained and operated as specified, to prevent their damage, loss, deterioration or inadvertent use.	8	c		Diese Anforderung ist nicht spezifisch für nukleare Anlagen und wurde daher nicht in Modul 8 aufgenommen. Sie findet sich z. B. in ISO 9001.2000.
	Control of records				
5.21.	Records shall be specified in the process documentation and shall be controlled. All records shall be readable, complete, identifiable and easily retrievable.	8	a	M8) 3.4(2) M8) 3.10	Ein Teil dieser Anforderungen finden sich in M6, Kap. 7.
5.22.	Retention times of records and associated test materials and specimens shall be established to be consistent with the statutory requirements and knowledge management obligations of the organization. The media used for records shall be such as to ensure that the records are readable for the duration of the retention times specified for each record.	8	c		In KTA 1201 werden Angaben zu Aufbewahrungspflichten gemacht. In M8 ist die Gültigkeit des Sicherheitsmanagementsystems auf die Betriebszeit der Anlage bezogen. Spezi-

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					fische Angaben zur Dokumentation wird nicht gemacht, aus etlichen Anforderungen (z.B. Ressourcen) kann aber abgeleitet werden, dass diese solange bestehen soll, wie das Sicherheitsmanagementsystem in Kraft ist. Der Bezug zum Knowledge Management wird ebenfalls nur indirekt über die Dokumentationspflicht, die Verbesserungsmaßnahmen und die Schulungspflicht des Personals gewährleistet.
	Purchasing				
5.23.	Suppliers of products shall be selected on the basis of specified criteria and their performance shall be evaluated.	8	a	M8) 4.4 4.4 (4) 4.4 (5) 4.4 (6) 4.4 (8)	
5.24.	Purchasing requirements shall be developed and specified in procurement documents. Evidence that products meet these requirements shall be available to the organization before the product is used.	8	c		Dies ist keine spezifische Anforderung an die Kerntechnik. Sie ist zum Beispiel durch ISO 9000.2001 abgedeckt. In allgemeiner Form ist die Anforderung in 3.5(3)2 implizit enthalten.
5.25.	Requirements for the reporting and resolution of non-conformances shall be specified in procurement documents.	8	b	M8) 4.1 (3)3 M8) 4.5.1	Diese Anforderung wird in M8) nur in allgemeiner Form (nicht nur bezogen auf "Purchasing") gestellt.
	Communication				
5.26.	Information relevant to safety, health, environmental, security, quality and economic related goals shall be communicated to individuals in the organization and, where necessary to other stakeholders.	8	a	M8) 2.3 M8) 3.2(1) M8) 4.2	
5.27.	Internal communication concerning the implementation and effectiveness of the management system shall take place between the various levels and functions of the organization.	8	a	M8) 3.1(1) M8) 3.2(1) M8) 4.2	
	Managing organizational change				
5.28.	Organizational changes shall be evaluated and classified according to their importance to safety and each change shall be justified.	8	a	M8) 3.8(4) M8) 4.3	
5.29.	The implementation of such changes shall be planned, controlled, communicated, monitored, tracked and recorded to ensure that safety is not compromised.	8	a	M8) 3.8(4) M8) 4.3	
6.	MEASUREMENT, ASSESSMENT AND IMPROVEMENT				

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Art.	Inhalt	Team	*Kennung	Kapitel im Modul	Begründung
	MONITORING AND MEASUREMENT				
6.1.	The effectiveness of the management system shall be monitored and measured to confirm the ability of the processes to achieve the intended results and to identify opportunities for improvement.	8	a	M8) 3.3 3.3 (1) 3.3 (4)1 M8) 3.5 (1) M8) 4.1(3) 4.1 (3) 1	
	SELF-ASSESSMENT				
6.2.	Senior management and management at all other levels in the organization shall carry out self-assessment to evaluate the performance of work and the improvement of the safety culture.	8	a	M8) 3.2(1) M8) 3.3 (1) 3.3 (4)	
	INDEPENDENT ASSESSMENT				
6.3.	Independent assessments shall be conducted regularly on behalf of senior management: – To evaluate the effectiveness of processes in meeting and fulfilling goals, strategies, plans and objectives; – To evaluate the organization's safety culture; – To determine the adequacy of work performance and leadership; – To monitor product quality; – To identify opportunities for improvement.	8	a	M8) 4.1(3) 4.1 (3) 1 M8) 3.3 M8) 3.3 (2) M8) 3.3(3) 3.3 (4)	
6.4.	An organizational unit shall be established with the responsibility for conducting independent assessments. ¹¹ This unit shall have sufficient authority to discharge its responsibilities. ¹¹ The size of the assessment unit differs from organization to organization. In some organizations, the assessment function may even be a responsibility assigned to a single individual or to an external organization.	8	a	M8) 3.8 M8) 3.3(2)	
6.5.	Individuals conducting independent assessments shall not assess their own work.	8	a	M8) 3.8 M8) 3.3(2)	Wird in M8) durch die Begriffe "unabhängig" und „keine Interessenskonflikte“ umschrieben.
6.6.	Senior management shall evaluate the results of the independent assessments, take any necessary actions, and shall record and communicate their decisions and reasons.	8	a	M8) 3.5 (1)	
	MANAGEMENT SYSTEM REVIEW				
6.7.	A management system review shall be conducted at planned intervals to ensure the continuing suitability and effectiveness of the management system and its ability to enable the accomplishment of the objectives set for the organization.	8	a	M8) 4.1(3) 4.1 (3) 1 M8) 3.3 (3) 3.3 (4)	
6.8.	The review shall cover but shall not be limited to: – Outputs from all forms of assessment;	8	a	M8) 4.1(3) 4.1 (3) 1	Die Beispielliste ist in M8 nicht explizit enthalten sondern in allgemeiner

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Art.	Inhalt	Team	*Kennung	Kapitel im Modul	Begründung
	<ul style="list-style-type: none"> - Results delivered and objectives achieved by the organization and its processes; - Non-conformances and corrective and preventive actions; - Lessons learned from other organizations; - Opportunities for improvement. 			M8) 3.3 (3) 3.3 (4)	Form umschrieben.
6.9.	Weaknesses and obstacles shall be identified, evaluated and remedied in a timely manner.	8	a	M8) 3.3(5)	
6.10.	The review shall identify whether there is a need to make changes to or improvements in policies, goals, strategies, plans, objectives and the processes.	8	a	M8) 3.3(5) M8) 3.2(5)	
	NON-CONFORMANCES AND CORRECTIVE AND PREVENTIVE ACTIONS				
6.11.	The causes of non-conformances shall be determined and remedial actions shall be taken to prevent their recurrence.	8	a	M8) 4.5.1 (5)	
6.12.	<p>Products and processes that do not conform to the specified requirements shall be identified, segregated, controlled, recorded and reported to an appropriate level of management within the organization. The impact of non-conformances shall be evaluated and non-conforming products or processes shall be either:</p> <ul style="list-style-type: none"> - Accepted; - Reworked or corrected within a specified time period; or - Rejected and discarded or destroyed to prevent their inadvertent use. 	8	b	M8) 4.1 (3) 4.1 (3) 1 3.3 (4)	Die Spiegelstrichliste ist nicht nuklearspezifisch und wurde daher nicht ins Modul übernommen.
6.13.	Concessions granted to accept a non-conforming product or process shall be subject to authorization. When non-conforming products or processes are reworked or corrected, they shall be subject to inspection to demonstrate their conformity with requirements or expected results.	8	c		Diese Anforderung ist nicht explizit enthalten. Allgemein ist die Anforderung aus 4.1(3)3 abzuleiten.
6.14.	Corrective actions for eliminating non-conformances shall be determined and implemented. Preventive actions to eliminate the causes of potential non-conformances shall be determined and taken.	8	a	M8) 4.1 (3)3	
6.15.	The status and effectiveness of all corrective and preventive actions shall be monitored and reported to management at an appropriate level of in the organization.	8	a	M8) 4.1 (3)3	
6.16.	Potential non-conformances that could detract from the organization's performance shall be identified. This shall be done: by using feedback from other organizations, both internal and external; through the use of technical advances and research; through the sharing of knowledge and experience; and through the use of techniques that identify best practices.	8	c		Es sind in M8) keine Anforderungen speziell an mögliche Abweichungen gestellt. Diese wären ggf. genauso zu behandeln wie tatsächliche Abweichungen.
	IMPROVEMENT				
6.17.	Opportunities for the improvement of the management system shall be identified and actions to improve the processes shall be selected, planned and recorded.	8	a	M8) 4.1(4) 3.3 (5)	
6.18.	Actions for improvement shall be monitored through to their completion and the effectiveness of the improvement shall be checked. Improvement plans shall include plans for the provision of adequate resources.	8	a	M8) 4.1(4) M8) 3.3	

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