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IAEA SAFETY STANDARDS

for protecting people and the environment

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Leadership and Management for Safety

DRAFT GENERAL SAFETY REQUIREMENTS

GSR Part 2

DS456



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1. INTRODUCTION

BACKGROUND

1.1. This Safety Requirements publication establishes the requirements for establishing, and sustaining effective leadership and management for safety¹ in facilities and activities² that give rise to radiation risks and organizations concerned with radiation risks.

1.2. This Safety Requirements publication supersedes the IAEA Safety Standards Series GS-R-3 on the management system for facilities and activities³. It continues to build on the concepts of GS-R-3 and emphasizes the principles that leadership and management for safety and an integrated management system are essential to the development of a strong safety culture and ultimately improve safety performance. The experience of Member States in developing, implementing and improving management systems was taken into account.

1.3. This publication applies the Fundamental Safety Objective and Safety Principles of the Fundamental in particular Principle 3, which states that “Effective leadership and management for safety must be established and sustained in organizations concerned with, and facilities and activities that give rise to, radiation risks.” It includes overarching requirements and associated requirements, both expressed as ‘shall’ statements. In addition, the publication includes explanatory text in support of the requirements.

¹ For the purpose of this publication, safety means the protection of people and the environment against radiation risks and the safety of facilities and activities that give rise to the radiation risks. Safety as used here includes the safety of nuclear installations, radiation safety, the safety of radioactive waste management and the safety in the transport of radioactive material.

² By facilities and activities that give rise to radiation risks it refers to regulated and/or licensed facilities and activities, typically:

- Nuclear facilities (power reactors, research reactors, fuel cycle facilities, isotope production facilities, facilities for mining and processing of radioactive ores, milling ...)
- Activities using sources of ionizing radiation (medical activities, non-destructive examination, measurement or detection purposes)
- Radioactive waste management facilities;
- The transport of radioactive material;
- Radiation protection activities.

³ INTERNATIONAL ATOMIC ENERGY AGENCY, The Management System for Facilities and Activities, IAEA Safety Standards Series No. GS-R-3, IAEA, Vienna (2006).

1.4. Safety has to be achieved by means of effective leadership ensuring a strong safety culture, and an effective management for safety based on integrated management system that controls all activities of the organization and gives safety an overriding priority. This system integrates all elements of management including safety, health, environmental, security, quality and economic elements so that safety is not compromised. An integrated management system is a single coherent system in which all constituents of an organization are integrated to enable the organization's objectives to be achieved. Such constituents include the organizational structure, resources and organizational processes.

1.5. It is fundamental that leadership for safety and management for safety are developed together and integrated so as to involve all individuals dealing with safety related activities in the organization and to ensure a high level of safety performance.

1.6. The difference between management and leadership can be stated simply whereby 'management' is a function and 'leadership' is a relationship. Management is about ensuring that an organization operates efficiently and that work is completed in accordance with requirements, plans and resources. Leadership aims at achieving commitment to goals, shared values and behaviours that influence and motivate individuals and organizations to continually improve performance.

OBJECTIVE

1.7 The objective of this publication is to establish requirements in respect of Principle 3 of the Fundamental Safety Principles [1] on leadership and management for safety, to develop, maintain and continually improve:

- Leadership for safety,
- Management for safety based on an integrated management system,
- Safety culture.

These requirements are based on the clear definition and allocation of responsibilities established in Principle 1 of the Fundamental Safety Principles [1] which states that "The prime responsibility for safety must rest with the person or organization responsible for facilities and activities that give rise to radiation risks."

The main aims of the requirements are to ensure:

- a. That every individual in an organization understands why and how their actions have to be performed to guarantee safety;
- b. The development of a strong safety culture supported by effective leadership and communication;
- c. A systemic approach to the whole range of interactions of individuals with the technology and the organization in order to prevent human and organizational failures.

SCOPE

1.8. The requirements established in this publication can be used in the following ways:

- By the licensee as a basis for leadership and management arrangements of organizations directly responsible for facilities and activities that give rise to radiation risk;
- By the licensee 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 safety related equipment, products and services;
- By the regulatory body as the basis for the regulation of above mentioned facilities and activities;
- By the regulatory body as the basis in conjunction with Ref. [2] for leadership and management arrangements to fulfil its responsibilities.

1.9. This Safety Requirements publication is applicable throughout the lifetime of facilities and for the entire duration of activities in normal, transient, as well as in accident conditions. This includes any subsequent period of institutional control that may be necessary. The lifetime for a facility includes its siting, design, construction, commissioning, operation and decommissioning (or closure).

1.10. This publication does not provide guidance on how to implement the requirements. Guidance on meeting the requirements is provided in related Safety Guides. International or national standards⁴ can be used to support the design of a management system but they are not sufficient to satisfy the requirements for safety.

1.11. This publication does not attempt to define all those specific health, environmental, quality and economic requirements to be addressed that have already been established elsewhere in other IAEA publications [2, 3, 4, 6, 7] and in international codes and standards [9, 10, 11, 12, 13]. 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 with focus on leadership and management for safety.

STRUCTURE

1.12. This Safety Requirements publication consists of five sections. Section 2 defines the responsibilities for safety. Section 3 establishes the requirements for effective and sustainable leadership for safety. Section 4 establishes the requirements for management for safety and improving the management system. Section 5 establishes the requirements to address safety culture.

⁴ International standards are for example from International Standards Organization (ISO 9000, ISO 14000, ISO 18000), European Foundation for Quality Management – National standards are for example Nuclear Quality Assurance standard (NQA-1) of the United States of America.

2. RESPONSIBILITY FOR SAFETY

Requirement 1: Responsibility for safety

The licensee⁵ shall retain the prime responsibility for safety throughout the lifetime of the facility or activity, and this responsibility shall not be delegated.

2.1. The highest priority shall be given to the fundamental safety objective to protect people and the environment from harmful effects of ionizing radiation.

2.2. The licensee shall provide effective leadership for safety that continually improves safety culture.

2.3. The licensee shall establish and implement an effective integrated management system for the purpose of ensuring safety.

2.4. The licensee shall promote safety culture in a systemic manner.

2.5. The licensee shall be responsible for:

- a. Establishing policies, procedures and arrangements to maintain safety under all conditions;
- b. Establishing and maintaining competences and resources necessary for safety;
- c. Providing adequate training and information necessary for safety;
- d. Verifying the appropriate design and the adequate quality of facilities and activities and of their associated equipment to ensure safety;
- e. Ensuring that suppliers understand and comply with safety requirements;
- f. Ensuring that suppliers understand and promote safety culture in a systemic manner;

⁵ For the purposes of this publication, the term 'licensee' is used; other forms of authorization such as registration might apply. In addition to Ref. [2] some of the requirements in this section may also apply to the regulatory body.

- g. Ensuring the safe control of all radioactive material that is used, produced, stored or transported;
- h. Ensuring the safe control of all generated radioactive waste.
- i. Ensuring provision, including resources and funding, for the long term management of radioactive waste, considering present and future generations.
- j. Ensuring communication inside the organization and with interested parties.

2.6. These responsibilities shall be fulfilled in accordance with applicable safety objectives and requirements as established or approved by the regulatory body, and their fulfilment shall be ensured through leadership and management for safety, including the development, maintenance and improvement of the management system.

2.7. The licensee shall clearly define the management structures, responsibilities and accountabilities for safety throughout the organization. Line managers shall be responsible for the safety of all activities under their control, and shall be held to account for the performance of such activities. Organizations shall be structured in a manner that promotes clear accountability for safety, for example:

- through establishment of spans of control for individual managers,
- specification of the number of layers of hierarchy ,
- taking of decisions on which resources and capabilities to retain or develop within the licensee's organization and which to outsource.

2.8. Senior management⁶ shall put in place effective arrangements for governance of safety, e.g. setting visions, strategy and policy, and overseeing implementation and performance. The most senior manager shall be the primary source of direction regarding safety.

⁶ 'Senior management' means the person who, or group of people which, directs, controls and assesses 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 and laboratory director.

2.9. The licensee shall consider the expectations of interested parties in such a way that safety is not compromised.

2.10. The licensee shall communicate safety aspects and requirements to suppliers and shall verify that they are implemented in safety related equipment, products and services that are supplied.

3. LEADERSHIP FOR SAFETY

Requirement 2: Leadership

Effective leadership for safety shall be demonstrated at the highest level in the organization.

3.1. Senior management shall develop shared values for safety, behavioural expectations, as well as promote ownership.

3.2. Senior management shall develop and communicate a clear safety policy, strategy, plans and objectives for safety.

3.3. Senior management shall ensure that responsibilities and accountabilities at all levels are in line with policies, strategy and objectives to ensure safety performance goals are met and to guide decision making or daily work.

3.4. Senior management shall develop and maintain leadership capabilities within the organization. Such capabilities shall include leadership in severe or unexpected situations.

3.5. Managers at all levels shall demonstrate leadership and shall be role models. They shall ensure the promulgation of shared values and expectations through the organization including when decisions are made, when problems arise and whenever communicating with others.

3.6. Leaders⁷ at all levels in the organization shall consistently demonstrate and support attitudes and behaviours that result in an enduring and strong safety culture. A prerequisite to this is a shared understanding throughout the organization of potential risks and consequences, and how to manage them.

3.7. Leaders at all levels shall actively seek information on safety performance within their span of control, share this information within the organization in an open and transparent manner and show commitment to continual improvement. Leaders shall ensure that their actions encourage an open reporting culture and a readiness to challenge acts or conditions adverse to safety.

3.8. Leaders at all levels shall use their influence to support and encourage employees to achieve safety in their work and seek their active involvement in improving safety performance including the consideration of staff's input in safety related decisions

3.9. Senior management shall encourage open communication and shall seek continual feedback on how effective the leadership is in ensuring safety, and shall take action as necessary.

4.MANAGEMENT FOR SAFETY

Requirement 3: Integrated management system

Senior management shall establish and implement an effective integrated management system to ensure safety.

4.1. The management system shall integrate all elements of management including safety, health, environmental, security, quality and economic elements so that safety is not compromised.

⁷ The term leader is used in this publication to refer to managers as leaders as well as other individuals demonstrating leadership.

4.2. The positions that constitute the senior management of the organization shall be defined in the management system.

4.3. The management structures, responsibilities and accountabilities shall be clearly defined in the management system. The relationship of the organization to other organizations, including its 'parent organization, shall also be clearly defined in the management system.

4.4. Senior management shall establish, implement, assess and continually improve the management system in order to achieve the safety goals, objectives and fulfil regulatory and other requirements.

4.5. The arrangements made by the senior management for the management for safety in order to achieve high-level safety performance shall be described in the management system.

4.6. The requirements for safety shall be established in the management system and shall be applied coherently with other requirements, so that safety is not compromised by other requirements or demands.

4.7. The main aim of the management system shall be to achieve and enhance safety by:

- a. Bringing together in a coherent manner all the requirements for managing the organization;
- b. Describing the planned and systematic actions necessary to provide adequate confidence that all requirements are satisfied;
- c. Ensuring that safety has the highest priority in all decision making.

4.8. Senior management shall retain overall responsibility for the management system, including when an external organization is involved in the work of developing all or part of the management system.

4.9. Senior management shall appoint an individual who has specific responsibility for coordinating the development and implementation of the management system. This individual shall have sufficient authority to discharge his responsibilities and shall have direct access to the senior management.

4.10. Management at all levels shall demonstrate commitment to the establishment, implementation, assessment and continual improvement of the management system.

4.11. Management at all levels shall foster and encourage the involvement of all individuals in the organization in the implementation and continual improvement of the management system.

4.12. Provision shall be made in the management system to ensure that the organizational structure, responsibilities, levels of authority, processes and interfaces for all organizations, units and individuals are clearly defined and documented.

4.13. Provision shall be made in the management system to ensure that any change to processes or the organization is evaluated and graded with regard to its importance to safety, justified and well communicated.

4.14. Where appropriate, arrangements shall be established as part of the management system for independent review before decisions important to safety are made.

4.15. Opportunities for the improvement of safety and the management system shall be identified and actions to improve the processes shall be selected, planned and recorded. Actions for improvement shall be monitored through to their completion and the effectiveness of such actions shall be checked.

4.16. Generic processes such as control of documents, control of records, communication, procurement, control of items and services, change control, management of non-conformances and corrective actions, knowledge management and management of human resources shall be identified and included in the management system.

Requirement 4: Graded approach

The application of the management system requirements shall be graded so as to deploy appropriate resources for any activity and process related to safety.

4.18. The grading principles shall be documented in the management system.

4.19. Grading principles shall take into account:

- a. The safety implication as well as the safety significance and complexity of each process, activity, structure, system, item of equipment, products and services;
- b. The hazards and the magnitude of the potential impact (risks) on safety associated with the safety, health, environmental, security, quality and economic elements of each activity;

- c. The possible consequences if a failure occurs or an activity is inadequately conceived or improperly carried out.

Requirement 5: Goals, strategies, plans and objectives

Senior management shall establish goals, strategies, plans and objectives for the organization that are consistent with the safety policy.

4.20. Senior management shall develop the policies of the organization; they shall be documented in the management system. The policies shall be appropriate to the activities and facilities of the organization and shall support the safety policy.

4.21. Senior management shall establish arrangements for the development of goals, strategies, plans and objectives taking into account feedback and involving all levels in the organization.

4.22. The goals, strategies, plans and objectives of the organization shall be developed in such a manner that safety is not compromised by other factors.

4.23. The goals, strategies, plans and objectives shall be communicated and managed at all levels in the organization. All individuals doing work under the organization's control shall be aware of and understand the policies and objectives, their contribution to the effectiveness of the management system and the safety implications of not conforming to its requirements.

4.24. Senior management shall ensure that measurable objectives for implementing the goals, strategies and plans are established at various levels in the organization. The objectives shall include the improved management of radiation risks.

4.25. Senior management shall ensure that the implementation of the plans is regularly reviewed against the objectives and that actions are taken to address deviations from the plans where necessary.

Requirement 6: Resources⁸

Senior management shall determine and provide the resources necessary to carry out the activities of the organization so that safety is not compromised.

4.26. Senior management shall determine the necessary resources and capabilities and shall provide these in a timely manner to carry out the activities of the organization.

4.27. Senior management shall put in place arrangements to ensure that the organization has and maintains, at each stage of the lifetime of the facilities and activities that give rise to radiation risks, the full range of resources and capabilities necessary to carry out all its activities and responsibilities to ensure safety.

4.28. Senior management shall ensure that the competence requirements for individuals at all levels are defined and shall ensure that training is performed or other actions are taken to achieve and sustain the required level of competence. An evaluation of the effectiveness of the actions taken shall be conducted. Suitable proficiency shall be achieved and maintained.

4.29. Capabilities maintained by the organization shall include effective leadership for safety at all levels, expertise to understand, maintain and improve processes and the safety basis of facilities and activities. The organization shall maintain access to relevant expertise including social and behavioural science.

4.30. Senior management shall ensure that all individuals, including management, are competent to perform their assigned work and that they understand the consequences for safety of their activities.

4.31. All individuals involved in the organization shall be trained in requirements of the management system. 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.

4.32. The information and knowledge of the organization shall be managed as a resource.

⁸ 'Resources' includes individuals (number and competence), infrastructure, the working environment, information and knowledge and suppliers, as well as material and financial resources.

Requirement 7: Management of process⁹ and activities

Processes and activities shall be developed and effectively managed to ensure safety

4.33. Each process shall be developed and managed in such a way that safety is not compromised and requirements are fulfilled. The processes shall be implemented, assessed and continually improved.

4.34. All process sequences and interfaces shall be defined so that safety is not compromised. Special attention shall be given to interfaces with the line management, who have the overall responsibility for safety.

4.35. New processes or changes to existing ones shall be designed, verified and implemented in such a way that safety is not compromised.

4.36. For each process, any activities for inspection, testing, verification and validation, their acceptance criteria and the responsibilities for carrying out such activities shall be specified in application of the graded approach, including if and when independent inspection, testing, verification and validation are required.

4.37. Each process that may affect safety shall be carried out under controlled conditions, by using easily understood, approved current procedures, instructions, drawings or other appropriate means. These shall be appropriately validated before first use and periodically reviewed to ensure their adequacy and effectiveness.

⁹ A process is an organized system of activities or tasks that uses resources (personnel, equipment, materials and machines, raw material and information) to transform entering elements (the inputs) in elements of exit (the outputs). It does not necessitate the use of a specific standard e.g. a standard issued by the International Organization for Standardization. Tasks or stand-alone activities can be organized without considering them as processes.

Requirement 8: Documentation

The management system shall be documented.

4.38. The documentation of the management system shall be developed to be understandable, clear, unambiguous and user friendly to those who will use it. Documents shall be controlled, readable, readily identifiable and easily available at the point of use.

4.39. The responsibilities for safety and the arrangements necessary to ensure safety shall be documented in the management system. The documentation of the management system shall, as a minimum, include the following:

- a. Policy statements of the organization: the policy on safety shall state that safety has an overriding priority;
- b. The values and expectations of senior management;
- c. A description of the structure of the organization;
- d. A description of the responsibilities, accountabilities, levels of authority and interactions of those managing, performing and assessing work;
- e. A clear description of 'when, how and by whom' decisions are to be made;
- f. A description of the processes as well as supporting information that explain how work is to be prepared, reviewed, carried out, recorded, assessed and improved. The description shall be based on and reflect the policies;
- g. A description of the interaction with external interested parties and organizations including a parent organization and the regulatory body as applicable.

Requirement 9: Measurement, assessment, evaluation and improvement.

Measurement, assessment and evaluation of the management system shall be performed in order to continually improve safety performance.

4.40. The effectiveness of the management system shall be monitored and measured to confirm the ability of the system to achieve the intended results and to identify opportunities for improvement.

4.41. All processes shall be periodically evaluated for their effectiveness. Suitable and sufficient assessments of the risk to safety arising from particular processes and activities shall be performed.

4.42. The causes of non-conformances and other safety issues that arise shall be determined and their potential consequences evaluated. Corrective actions for eliminating them shall be determined and implemented in a timely manner. Preventive actions to eliminate the causes of potential non-conformances shall be determined and taken.

4.43. The status and effectiveness of all corrective and preventive actions shall be monitored and reported to management at an appropriate level in the organization.

4.44. Self-assessment shall be used to prevent, identify and correct weaknesses that hinder the achievement of the organization's objectives, as well as to improve the management system and enhance the safety culture and the effectiveness of processes and activities. Self-assessment shall be performed by senior management and by individuals at all levels in the organization.

4.45. Self-assessments or other tools shall also be used to identify strengths and learn from them to improve.

4.46. Independent assessments shall be conducted regularly on behalf of senior management in order to evaluate the effectiveness of the management system and all processes and activities specified in the management system and identify opportunities for improvement. Such independent assessment shall critically evaluate:

- a. The fulfilment of requirements, goals, strategies, plans and objectives;
- b. The adequacy of work performance in achieving safety;
- c. Leadership and safety culture.

4.47. Assessment plans shall be reviewed and adjusted to reflect new or emergent management concerns and performance problems.

4.48. An organizational entity shall be established with the responsibility for conducting independent assessments. This entity shall have sufficient authority to discharge its responsibilities and shall have direct access to the senior management. Individuals conducting independent assessments shall not assess their own work.

4.49. A management system review shall be conducted by senior management at planned intervals to ensure the continuing suitability and effectiveness of the management system and its ability to enable the objectives of the organization to be accomplished.

4.50. The review shall at least cover:

- a. Outputs from different forms of assessments;
- b. Results delivered and objectives achieved by the organization and its processes and activities;
- c. Non-conformances and corrective and preventive actions;
- d. Lessons learned from other organizations including good practices;
- e. Opportunities for improvement.

4.51. Weaknesses and obstacles shall be identified, evaluated and remedied in a timely manner. The review shall identify whether there is a need to make changes or improvements in policies, goals, strategies, plans and objectives as well as in the processes or activities.

4.52. Performance indicators shall be used in order to monitor the effectiveness of the management system and to confirm the ability of the processes or activities to achieve the intended results. Performance indicators shall be trended and evaluated at regular intervals.

4.53. The management system shall include a systematic process for obtaining feedback from operating experience as well as provision for the evaluation of lessons learned. 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 good practices.

Requirement 10: Interested Parties

Interactions with interested parties¹⁰ shall be identified, continuously reviewed in an open and transparent manner and integrated in the management system when relevant.

4.54. Senior management shall acknowledge and make arrangements for identifying, understanding and implementing legal and regulatory requirements imposed on the organization. Such requirements shall be integrated in the management system in a systematic way in order to facilitate implementation, review and change management.

4.55. Senior management shall make arrangements to ensure that agreements with interested parties are defined and implemented. Such arrangements shall be integrated in the management system.

4.56. Senior management shall establish appropriate means for informing and consulting the public and other interested parties about the possible radiation risks associated with the operation of a facility or the conduct of an activity.

4.57. Senior management shall make arrangements to listen to interested parties, collect their comments and concerns relevant to safety and take appropriate actions.

Requirement 11: Management of suppliers¹¹

The licensee shall put in place effective arrangements with suppliers to monitor and control the supply of items, products and services that may affect safety.

¹⁰ Interested parties (stakeholders): 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 trans boundary impacts, or States involved in the export or import of certain technologies or materials.

¹¹Suppliers are typically designers, manufacturers and constructors, employers, contractors and consigners and carriers who are supplying safety related items.

4.58. The licensee shall retain responsibility for safety when contracting any processes and when receiving any item, product or service.

4.59. The following requirements shall, as a minimum, be controlled through the management system:

- a. Selection and qualification of suppliers of items, products and services on the basis of effectiveness of their own management system and performance;
- b. Specification of contractual requirements;
- c. Provision where appropriate of adequate advice, information and training to suppliers and their staff;
- d. Appropriate arrangements for communication and supervision;
- e. Periodic assessment of suppliers' management system and performance;
- f. Verification and validation that items, products and services meet the requirements.

5.SAFETY CULTURE

Requirement 12: Continual improvement of safety culture

All individuals in the organization, from the senior management down, shall promote safety and contribute to the continual improvement of safety culture, supported by the management system.

5.1. Desired and expected attitudes and behaviours that result in a strong safety culture shall be developed and integrated in the management system.

5.2. All individuals in the organization, from the senior management down, shall contribute to promoting and fostering a strong safety culture, by implementing and reinforcing:

- a. Individual and collective commitment to safety;
- b. Ownership of safety;

- c. An open culture that encourages trust, collaboration, free communication, ensures good working conditions and that values the reporting of human and organizational problems;
- d. The reporting of deficiencies of structures, systems and components to avoid degradation of safety;
- e. Prompt acknowledgement and feedback for identified problems and suggestions for improvement;
- f. Means by which the organization continually seeks to develop and improve safety and the safety culture;
- g. Responsibility and accountability of organizations and of individuals at all levels for safety;
- h. Measures to encourage a questioning and learning attitude and to discourage complacency at all levels in the organization with regard to safety;
- i. A common understanding of the key aspects of safety and safety culture within the organization;
- j. Awareness of the risks and hazards related to their work and work environment, and an understanding of potential consequences;
- k. Conservative decision making in all activities.

5.3. The management system shall make provision to ensure the involvement and visibility of all management, from senior managers down to supervisors, in field activities.

5.4. The management system shall make provision to support individuals and teams in carrying out their tasks successfully with regard to safety, taking into account the interactions between individuals, technology and organizations.

5.5. The management system shall require that knowledge of social and behavioural science be utilized to help achieve a high-level of performance and encourage good practices.

Requirement 13: Assessment of safety culture and leadership for safety.

Senior management shall periodically perform independent assessments and self-assessments of safety culture and leadership for safety.

5.6. The assessment of leadership and safety culture shall make use of several diverse methods.

5.7. The results of such assessments shall be communicated to all levels in the organization

5.8. The results of leadership and safety culture assessments shall be acted upon to ensure improvements and to promote a learning organization.

DRAFT

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