Climate change REsilience framework for health SYStems and hospiTALs

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Preparation Slip			
	Name	**Partner**	**Date**
From	Ruben Valsecchi, Celina Solari,	RINA-C	30/11/2022
Reviewer	Kristen MacAskill, Felipe Rojas	UCAM	19/01/2023
Reviewer	Stelios Karozis	NCSRD	19/01/2023
Reviewer	Paolo Basso, Clemente Fuggini	RINA-C	20/11/2023; 19/01/2023
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EXECUTIVE SUMMARY

This deliverable was produced as part of action C4.1 of the LIFE RESYSTAL project, which aims to analyse and review the general set of procedures defined by ISO 55 000 in the context of AIM (Asset Integrity Management) to the health sector as currently mostly absent.

The deliverable comprises the following:

- An introduction, in which are briefly mentioned the motivation for the implementation and the scope of the report.
- The description of the current legislation on Asset Integrity Management, with its main concept and aspects.
- Definition of the similarities and the divergence between the Industrial and the Health sector, in terms of structure, plans, profitability, etc.
- The consideration and recommendation about the lack of the current standard, in terms of definition of the correct counter condition for also the health sector

This report is intended as a review and recommendation document that is developed starting from a preliminary review of the general set of standards defined by the ISO 55 000. Therefore the methodology adopted consists of an initial phase of research and review of the current Integrity Asset Management state of the art. This procedure is carried out through both literature review and RINA-C knowledge on regulatory procedures in this domain.
A second phase of evaluation, processing and elaboration is developed in order to analyse the efficiency and consistency of the ISO 55 000 framework in the Healthcare fields. So, due to this process, the identification of the possible gaps and shortcomings is carried out.

TABLE OF CONTENT

INTRODUCTION

Currently, the ISO 55 000 standards can be defined as a family, which includes the following aspect of Asset Management:

- ISO 55 000 Asset Management - Overview, principles, and terminology.
  Introduces the critical concepts and terminology needed to develop a long-term plan that incorporates an organisation's mission, values, objectives, business policies and stakeholder requirements.
- ISO 55 001 Asset Management – Requirements.
  Specifies the requirements for the establishment, implementation, maintenance, and improvement of an asset management system.
- ISO 55 002 Asset Management - Guidelines on the application of ISO 55001.
  Provides guidance for the application of an asset management system, in accordance with the requirements of ISO 55001.

Some additional considerations are made on the business continuity and crisis management concept, which are related to ISO 22 361 and ISO 22 301. These ISOs must be considered since a complex system such as health care must be resilient to crises that may affect it and ensure business continuity under emergency conditions. These conditions must be ensured to fully guarantee the structural and functional integrity of the service. In so doing these further observations are made to consider multiple sets of standards since the asset integrity management complexity.

In the following chapter the introduction to the scope of work of this deliverable is defined according to three main steps:

- The boundary conditions of the ISO and of the different economic sectors in which different assets can be classified.
- The motivation for the implementation since the existence of differences among the characteristics of different sectors.
- Report scopes, in terms of which themes must be dealt with.

BOUNDARY CONDITIONS OVERVIEW

The history of ISO 55 000 is deeply connected to the very first specification enhanced for the optimization of the management of physical assets, developed by the British Standards Institution (BSI) in the early 2000s.

Therefore, in 2004 this first Publicly Available Specification, PAS 55, was released and it quickly became adopted worldwide, for asset management, in the different industrial sectors, such as utilities, transport, mining, process, and manufacturing. Consequently, in 2008 an updated version was developed taking into consideration a stakeholder group composed of a wider worldwide representation of the industrial sector [12]. After that, the International Standards Organization defined this specification update (PAS 55:2008)

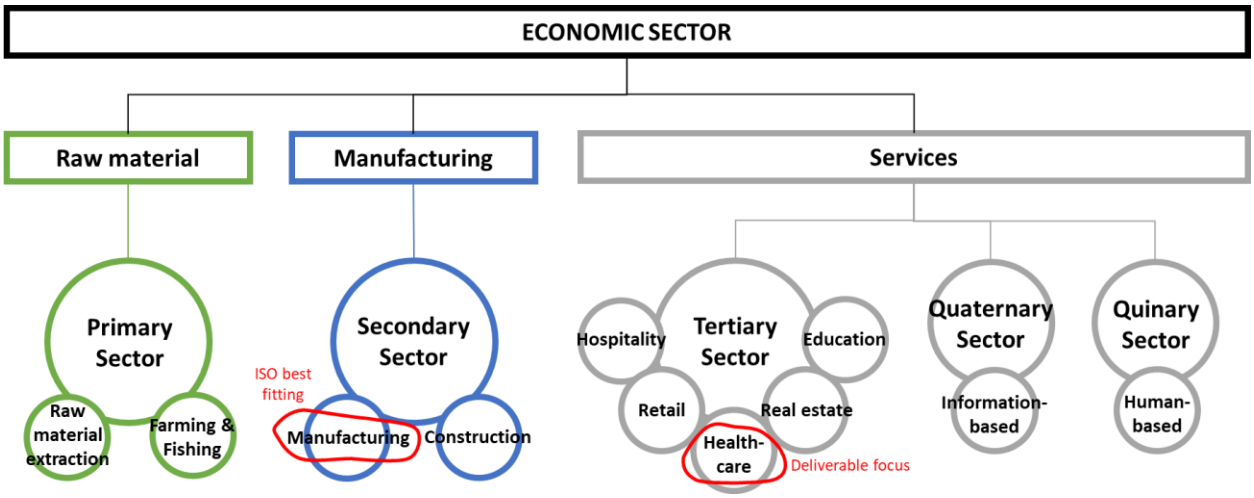
as the main basis for the development of the new ISO 55 000 series of international standards, on asset integrity management.

As mentioned in the previous paragraph this standard was created based on a restricted stakeholder group, with their expertise focused on a certain field. This field is strictly related to a singular, of the plenty varieties of economic activities. All the economic activities can be divided according to the so-called three-sector model **Error! Reference source not found.** [20], with the following distinction:

- Primary, related to the economic activities related to the direct use of natural resources, which commonly includes agriculture, forestry and fishing, mining, and extraction of oil and gas.
- Secondary, related to the activities that produce manufactures, other processed goods, and construction, starting from the transformation of the natural resources.
- The tertiary sector, is related to the activities producing services to the customers.

It must be said that the development raised in the post-industrial society, led to a further division of the service-related sector: quaternary sector concerned with information-based or knowledge-oriented products and services. And quinary sector related to the services more human-related.

The industrial sector, mentioned before, is completely related to the definition of the secondary manufacturing sector. In here it can be seen the first problem, that ISO was developed according to only a strict part the economic activities. In addition to that, this deliverable aim is to assess the goodness of the use of that ISO for the health-care sector, which is a part of the Tertiary sector.



Therefore, the characteristics of the different activities of the various economic sector are deeply different. So an analysis of how these differences affect the application of the ISO 55 000 must be performed.

MOTIVATION ON IMPLEMENTATION

The status of ISO 55 000 can be currently defined as a strong basis for the definition of an Asset Management System capable to support and/or ensure the integrity of a generic asset against risk, by adopting a certain management framework.

Thus, the usefulness of ISO 55 000 in the field of Asset Integrity Management can be defined as undeniable, nevertheless the way in which this ISO was developed is mainly related to the industry (secondary) sector. The basis for the development of this ISO started from the 2008 update of the British standard regarding Asset Management, since this update was performed by a group of stakeholders composed of 50 organizations working on 15 different industry sector organizations, providing also the experience coming from 10 different countries.

The healthcare (tertiary) context also, unlike industrial and manufacturing contexts, must ensure business continuity as it falls under the definition of critical infrastructure.

Therefore, the current ISO 55 000 is mainly industrial-focused, leading to a lack of consistency in the main concept of the standard regarding the Healthcare system, which is very different with respect to the Industrial one.

REPORT SCOPE

The current application of Asset Integrity Management is based on ISO 55 000. The concepts contained in it, as already mentioned, are mainly based on a framework defined for industrial assets. So, in the following chapters, it is carried out an analysis of the similarities and the divergence between the Industrial and Healthcare sector, in terms of structure, plans, profitability, etc. This comparison is implied to better understand in which way the current lack can be overcome, for the Healthcare sector.

Within the scope of this deliverable, the main outcomes should be the definition of some considerations and recommendations, on the update of the ISO 55 000 families. The Life Resystal project is based on the assessment of a particular kind of Critical Infrastructure, the hospitals. In this chapter is always remarked the needs of improving the standards for the general health sector, although the CIs under study are not representing the whole sector but a wider part of it. The terminology is related to the whole sector since further improvement in this field must be related to hospitals and all the related assets belonging to this sector. We will therefore try to make a parallelism between the GAP existing in the standard on asset management unless other standards are also adopted. This is only a description, not going to the particular and specific definition of each step of the analysis.

Unlike a standard describing the management of an asset in ordinary times, therefore, it is necessary to broaden the vision to the difficulties in presenting a methodology for dealing with crises, which lies in the impossibility of compiling a complete list of the possible variants that may be encountered. No crisis can be foreseen, but it is possible to be prepared for them, and the combination of various methodological standards is necessary for complex systems like hospitals.

CURRENT LEGISLATION ON ASSET INTEGRITY MANAGEMENT

ISO 55 000 – ASSET MANAGEMENT OVERVIEW

ISO 55 000 provides an overview of asset management, its principles and terminology, and the expected benefits of adopting asset management. This International Standard can be applied to all types of assets and by all types and sizes of organizations. It also provides the context for ISO 55001 and ISO 55002. International cooperation in the preparation of these standards has identified common practices that can be applied to the broadest range of assets, in the broadest range of organizations, across the broadest range of cultures.

The three standards, ISO 55 000, ISO 55001, and ISO 55002 can be used in combination with any relevant sector or asset type-specific asset management standards and technical specifications. ISO 55001 specifies requirements for an asset management system, while ISO 55002 details sector-specific, asset-specific, or activity-specific technical requirements or give guidance on how ISO 55001 should be interpreted and applied within a specific sector or to particular asset types.

This International Standard is primarily intended for use by:

- Those considering how to improve the realization of value for their organization from their asset Base.
- Those involved in the establishment, implementation, maintenance, and improvement of an asset management system.
- Those involved in the planning, design, implementation, and review of asset management activities, along with service providers.

The adoption of ISO 55 000, ISO 55001, and ISO 55002 enables an organization to achieve its objectives through the effective and efficient management of its assets. They can help organisations of all sizes and sectors to:

- Establish an asset management system to optimally manage assets
- Implement, maintain, and improve an asset management system
- Comply with asset management policy and strategy
- Demonstrate that they are applying best practice
- Seek external certification of their asset management system or make a self-declaration of compliance

MAIN CONCEPTS OF ASSET MANAGEMENT

The Standard defines physical assets management as a coordinated activity of an organisation to realise value from its assets [4]. It specifically defines the key concepts required for application in any organisation. As part of some qualitative and quantitative analyses of ISO 55 000, performed by us and also from literature. The concepts for the application of ISO 55 000 were described by industry experts

who sat on the committee for the development of ISO 55 000:2014 [10]. These concepts are described below:

1. The concept of value vs. performance.

   The ISO defines that: Assets exist to Provide value to the organization and its stakeholders [4]. Asset management should focus on the contribution of assets to the organisation's mission and not just on their performance, which has traditionally been the financial bottom line desired by the business, even if performance remains a component of value [10].

2. Strategic Alignment Concept.

   The ISO defines that: Asset management translates into the organizational objectives, technical and financial decisions, plans, and activities [4]. The asset management objectives contained in the strategic asset management plan (SAMP) must be aligned and consistent with the organisation's objectives [5]. In most organisations, the asset management strategy may differ from the organisation's strategy, but it must support the organisation in achieving its objectives [10].

3. Life cycle management of assets vs. management – triennial, quinquennial, or a program.

   It allows assets to be managed according to their life cycle and in accordance with policy, strategy and corporate objectives, with a long-term vision (strategic dimension) rather than according to a short-term (tactical) and medium-term vision (operational aspect) [11].

4. 'Line of Sight' Concept.

   The possibility of transmission from the lower level of ideas and asset management activities to the top management [10].

5. An acceptable level of risk vs. opportunities.

   Asset management must not only focus on opportunities but must integrate an acceptable level of risk into the asset management strategic plan [10].

6. Leadership Concept.

   The ISO defines that: Leadership and workplace culture, are determinants of the realization of value [4].

COMPARISON BETWEEN THE INDUSTRIAL AND HEALTH SECTOR NEEDS

The three essential goals in the management of healthcare physical assets are [7]:

- Ensure that the clinical services offered meet the appropriate needs.
- Efficiency and Safety must be fundamental keys.
- Represent a value investment.

The hospitals priority is to ensure the prevention of damage, to patients (users), this also imply the preservation of the environment, by ensuring the proper functioning of their medical physical assets 0. With increasing pressure on healthcare organisations, such as hospitals, to improve their operations and prove their quality and efficiency, management techniques originating from the industrial sector are spreading in hospitals [3].

ISO 55 000 is intended to be a standard for optimising the management of all physical assets of any size or type [4], as it is for the management techniques used in manufacturing. However, the hospital context is different from other industries and has specific characteristics for the adoption of management techniques developed from the industrial context [3][8][9][13].

In the health sector, organisations function better in a non-profit business environment that requires cooperation rather than competition between the different actors [15]. Indeed, the hospital context requires a particular approach to the implementation of ISO 55 000, since some of the key concepts are mainly related to the industrial-competitive word.

First, the concept of leadership (concept #6) must take a different form for the health sector, taking into consideration the multidisciplinary context characterizing the hospitals framework. Hospitals can be defined as a fragmented industry, composed by different professional organisational structures, characterised by different skills-based organisations. In so doing, the internal leadership inside the different skills-based organizations can be compared in terms of framework with respect to the industrial sector. While the highest level of leadership should be confronted with the widest variety of skills among the different organizations. Therefore, the concept of leadership can change ‘vertically’ among the different levels of the management framework. This should imply considering the concept of the delegation that can be lower to highest from the bottom to the top. Unlike the standardisation of products and services in the common industries, the healthcare services cannot be standardised from one patient to another one, as each patient’s treatment is focused to their needs and health condition [13][14][15].

Also in this context, the strategic alignment (concept #2) and the concept of 'line of sight' (concept #4), as described above, require a particular reformulation to take into account this reality of multidisciplinary collaboration that affects leadership, in the hospital case respect to the industrial sector.

The aspect of life cycle management (concept #3) should be related to the profitability layout of an asset. Since, in the case of impossibility in making profit, the management should be defined in long term to get more access to the widest finical ‘budget’. Before starting with the comparison, a distinction must be made in terms of profitability layout. The health sector is composed of two different types of assets with the opposite layout in terms of profitability. On one hand, there are the non-profit assets, which are usually composed of the national public healthcare system. The funding of the management of this kind

of health facility is purely non-profit. The main objective is to ensure safe and quality care for users. Their aim is not about making savings on the money invested, as is the case with for-profit organisations, i.e. industrial sector. These kinds of Hospitals are non-profit organisations that focus their functioning on the quality of patient care services, while for-profit organisations, such as manufacturing, the focus is related to the production of those products and marketing to maximise their profits [8][9][15]. Secondly, there is the private sector, that in the last decades had started to grow at the expense of the public one. For what concerns the private for-profit sector, the consideration already defined within the standard are fitting better, since its 'more industrial-oriented' profitability layout.

Regarding the relationship between risk and opportunity (concept #5): risks in the health sector are mainly related to the adverse event, such as the patient mortality and are controlled by strict rules of 'zero risk'; while opportunity, as for whichever organization, involves the lucrative aspect or the financial advantage. Therefore, the importance of risk must have a different weight in the health sector rather than the balance between risk and opportunity usually set in the industrial sector. In the same way, the concept of values vs. performance (concept #1) seems to fit very well, for health sector, with what has already been defined here. Since the performance can represent the reduction of the risk and values can be defined as the financial benefits.

BUSINESS CONTINUITY AND CRISIS MANAGEMENT CONCEPT

A healthcare system, must not only provide structural and functional service integrity but be resilient to the crisis that may affect it. A hospital has crisis plans that provide for a massive influx of patients by redeploying hospital wards and staff. However, this plan is designed for the short term, guaranteeing first aid, and basic health care from triage to clinicisation.

For business continuity, on the other hand, we mean actions and approaches aimed at maintaining basic functions even in the presence of factors that compromise their functions. these actions are defined in peacetime, approved and viewed by the actors involved, who must be aware of their existence. Already here we see the first difference with ISO 55000 which is only intended for the managerial part.

The adoption of business continuity (ISO 22301) provides a clear view of the functioning of an organisation or system in general. The standard provides a detailed overview useful for strategic planning of the service being provided (healthcare), risk management, procurement management, business (or service) adaptation and resource management. Other benefits are:

- Better understanding of the business through analysis of critical issues and areas of vulnerability. This does not replace the contingency plan, but tests it so that it can actually work, which is critical for a public service;
- Increased organisational resilience through collaboration between teams and functional resilience through departmental arrangement;
- Reduced costs and less impact on hospital performance in the event of various impediments;
- Demonstration of your commitment to stakeholders such as the public, suppliers and regulators by adopting sound processes for business continuity;
- Benefits of reduced insurance premiums with reduced annual costs

Another standard for a healthcare system is that of Crisis management (ISO 22361), the process of which consists of three phases:

- Research, monitoring and preparation, in this phase an analysis of the internal and external environment of the system is implemented, identifying limitations, shortcomings, or any type of vulnerability that may pose a risk to the integrity of the business/service. On the basis of the analysis carried out, a crisis management plan is drawn up and crisis drill and simulation practices are implemented.
- Response and Adaptation, this second phase concerns the company's reaction to an imminent or ongoing crisis, based on the guidelines established during the preparation phase and the possibility of remedying unexpected incidents and various crisis scenarios that may arise.
- Recovery, in this last phase, all actions aimed at restoring operations, minimising and repairing any damage incurred are analysed.

In addition but not the purpose of this document, critical infrastructures must meet certain standards defined by the European Commission and national entities, so it is clear that similar approaches cannot coexist between an industrial plant and a hospital. The GAP consists in not knowing how to define the interconnection between the critical entities therefore to generate plans relatively suited to their corporate assets. This limited vision is slowly disappearing with the European rules coming out, but adoption by the structures would seem to be the most difficult part.

FINAL CONSIDERATIONS & RECOMMENDATIONS

The contribution of the report helps to understand some common aspects and characteristics the hospital context that differ from those in the industrial context. This reflects the differences between the paradigms of the industrial world and the hospital world that influence and specify the transfer of knowledge in the management of physical assets from the former to the latter. The highlighting of these essential paradigms in the hospital context compared to the industrial context is useful in stimulating the interest of hospital managers in adopting ISO 55 000.

Rather than defining a general concept of leadership (concept #6) shaped by industry, it seems more appropriate to define here an organisational structure with a kind of mixed configuration in which the internal leadership inside the different skills-based organization can be taken as for the industrial sector. While the highest level of leadership should consider the intrinsic skills among the different organizations, changing the common 'vertically-shape' among the different levels of the management framework. This should imply the 'horizontal-directional' collaboration between actors and multidisciplinary bodies at a high level.

As far as leadership is concerned, the strategic direction (concept #2) and the concept of line of sight (concept #4) also need to be reorganised according to the mixed configuration mentioned above:

- The concept of line of sight must consider the possibility of transferring ideas not only in the Lower-Top direction but also horizontally among the different professional units.
- The strategic alignment must consider the possibility of a link between the different management objectives.

Within the concept of life cycle management (concept #3), covering the life cycle of the facility is preferable to a standard yearly or multiyear plan and a programme promoted by the standard requires a specific approach. It would be necessary to plan an investment for the entire life cycle of assets by incorporating the reality of the 'non-profit' while ensuring optimal operation to provide safe care to patients.

It is necessary for the application of the concept of risk vs. opportunity (concept #5) promoted by ISO 55 000 to use a particular approach, where the risks (patient mortality) are put above and clearly prioritized over any idea of opportunity (financial benefit). The high priority that must be given to patient mortality reduction with respect to the financial benefit describes very well the new approach that must be followed for the definition of the relation values vs. performance (concept #1).

For critical systems such as hospitals, it is therefore unlikely and deleterious to act with only one standard. The adoption of ISO 55000 in healthcare systems must be contextual to the adoption of ISO 22301 but also to others such as crisis management ISO 22361 in order to arrive at a general standard on system resilience in the future.

The implementation of business continuity in the health care system will serve to have a better understanding of the organisation of services but also to implement strategies to ensure business continuity using appropriate response actions. This is a process that involves an analysis of the impact on the business/service, and therefore requires a careful cross-sectoral assessment, thus also questioning the supply services external to the system.

REFERENCE

[1] Chien, C. H., Huang, Y. Y., & Chong, F. C. (2010, August). A framework of medical equipment management system for in-house clinical engineering department. In 2010 annual international conference of the IEEE engineering in medicine and biology (pp. 6054-6057). IEEE

[2] Crowe, K. M. (2014). Collaborative leadership: A model for reference services. In Managing the Twenty-First Century Reference Department (pp. 77-88). Routledge.

[3] Hellström, A., Lifvergren, S., & Quist, J. (2010). Process management in healthcare: investigating why it's easier said than done. Journal of Manufacturing Technology Management.

[4] International Organization for Standardization (2014). ISO 55 000: Asset Management-Overview, Principles and Terminology. International Organization for Standardization: Geneva, Switzerland.

[5] International Organization for Standardization (2014). ISO 55001: Asset Management - Management systems. International Organization for Standardization: Geneva, Switzerland.

[6] International Organization for Standardization (2014). ISO 55001: Asset Management - Guidelines for the application. International Organization for Standardization: Geneva, Switzerland.

[7] Keith, W., Keith, I., & Slavik, T. (2013). Medical Equipment Management. London, UK: CRC Press, 295 p. Consulté le mars 2014.

[8] McCarthy, J. P., Hegarty, F. J., Scott, R. S., Amoore, J. N., & Blackett, P. A. (2013). Innovations in managing healthcare technology equipment assets. In IET IAM Asset Management Conference 2013.

[9] Suebsin, C., & Gerdsri, N. (2010). Technology adoption: A case study of ERP implementation in one of healthcare organizations in Thailand. In PICMET 2010 Technology management for global economic growth (pp. 1-8). IEEE.

[10] O'Hanlon, T., Smith, T., Wireman, T., Morris, S., Fogel, G., Griffin, D., Vlok PJ, DiStefano, R., McWilliam, S., Fogel, G., Swanepoel, S., Lafraia, J., Hardwick, J., O'Hanlon, T., Smith, J., Armstrong, D., Barringer, P., Van Hardeveld, T., Barnard, I., DeStefano, B., Goetz, W., Storino, B., Gulati, R. (2014). The (New) Asset Management Handbook: The Guide to ISO55000 (2014). United States of America: Reliabilityweb.com, 320 p.

[11] Zhuang, Q., Van der Lei, T. E., Djairam, D., & Smit, J. J. (2011, April). Interdependencies at the strategic asset management level: A systems analysis of the utility sector. In 2011 International Conference on Networking, Sensing and Control (pp. 365-370). IEEE.

[12] https://www.assetmanagementstandards.com/iso-55000-standards-for-asset-management/ Last consulted 23/11/2022.

[13] Lee, C. W., & Kwak, N. K. (2011). Strategic enterprise resource planning in a health-care system using a multicriteria decision-making model. Journal of medical systems, 35(2), 265-275.

[14] Herzlinger, R. E. (2006). Innovating in health care-framework. Harvard Business Review, 9, 306-342.

[15] Mintzberg, H. (2012). Managing the myths of health care. World Hospitals and Health Services, 48(3), 4-7.

[16] Houessou, B., Gardoni, M., & Rioux, M. (2016). The analysis of application of ISO 55000 concepts in hospital context: the case of CT scanner life cycle management in a Quebec public hospital. MOSIM.

[17]International Organization for Standardization (2022). ISO 22361: Security and resilience — Crisis management — Guidelines: Geneva, Switzerland.

[18]International Organization for Standardization (2014). ISO 22301: Societal security — Business continuity management systems — Requirements: Geneva, Switzerland.

[19] Kenessey, Z. (1987). The primary, secondary, tertiary and quaternary sectors of the economy. Review of income and wealth, 33(4), 359-385.

[20]Thakur, S. K. (2011). Fundamental economic structure and structural change in regional economies: a methodological approach. Région et développement, 33, 9-38.