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CURRENT ADVANCES IN THE STANDARDIZATION OF MANAGEMENT SYSTEMS

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ABSTRACT

The article 'Current Advances in the Standardization of Management Systems' presents an overview and proposals for implementation of the new series of standards for management systems- for quality (ISO 9001), environment (ISO 14001), and energy (ISO 50001). Discussed is their integration with the Annex SL (previously ISO Guide 83) and the implications for organizations which already have implemented such management systems- both in the view of potential risks and new possibilities.

INTRODUCTION

Management system standards (MSS) have been in existence since the 1980s. After the first edition of the renowned ISO 9001 standard in 1987, it has caught the attention of businesses, consultants, educators, and society as a whole. The desire and will to improve and update the standard in order to stay relevant to the current developments in science and technology have led to the revisions of ISO 9001 in 1994, 2000, and 2008. In September 2015, the long awaited fifth edition of this standard has been published.

The International Organization for Standardization (ISO) and other organizations worldwide have also invested considerable efforts and funds to adapt ISO 9001 to specific industries, and to complement its requirements with other supporting documents. For example, in the automotive industry, the requirements of ISO 9001 are made more specific in ISO/TS 16949:2009 'Quality management systems - Particular requirements for the application of ISO 9001:2008 for automotive production and relevant service part organizations'.

For organizations in the healthcare industry there is ISO 13485:2003 'Medical devices - Quality management systems - Requirements for regulatory purposes', and for the management systems of municipalities- ISO 18091:2014 'Quality management systems - Guidelines for the application of ISO 9001:2008 in local government'.

Originally published in 1996, the third edition of ISO 14001- the environmental management system standard, came out in September 2015. This standard is one of the most widely used MSS and is a popular choice when organizations seek to win public tenders and prove their sustainability policies.

The management of energy efficiency, use and consumption is becoming a key issue. In 2011, a new MSS has joined the already popular ISO 9001 and ISO 14001. ISO 50001 contains requirements for energy management systems with guidance for use. From 2013 to 2014 it demonstrates a 40% growth, owed mainly to Germany, which has 3402 of the 6778 certificates reported [1].

The steady upward trend in the number of certified MSS since the first edition of ISO 9001, followed by ISO 14001 and ISO 50001, is shown on Fig. 1 [1, 2, 3]. It must be noted that the number of certificates reflects the active certification status of the organizations. If we consider the number of companies whose certifications have been suspended for some reason, then the number of certificates will be even greater.

Gone are the days when organizations needed 'wizards' like MSS consultants to help them integrate different ISO standards (usually for quality, environment, and occupational health and safety) in their management systems.

These smart people used to bring their complex tables of correspondence and ‘translate in plain words’ which part of one standard matches a specific clause from another standard. The need for alignment of MSS has been recognized by the ISO Joint Technical Coordination Group (JTCG). As Nigel Croft, Chair of ISO/TC176/SC2 ‘Quality Systems’ said, ‘The aim (of Annex SL) is to make life easier for those who wish to have a single management system’ [4].

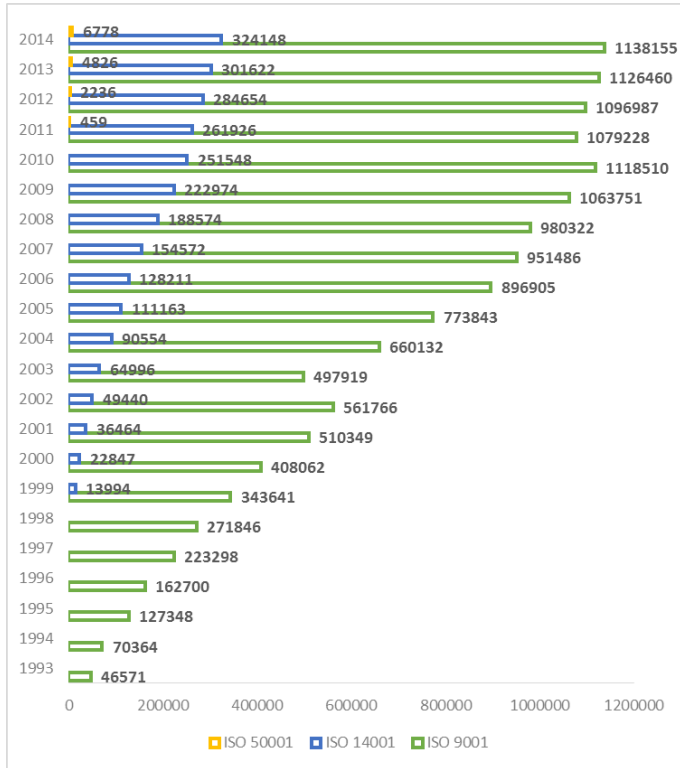


Figure 1. Number of ISO certificates between 1999 and 2014

Undoubtedly, the publication in 2012 of Annex SL as part of the ISO/IEC Directives, Part 1 (Consolidated ISO Supplement – Procedures specific to ISO) has opened the way for an avalanche of changes in the ISO management system standards. In its clause SL9 this document outlines the ‘high level structure (HLS), identical core text and common terms and core definitions for use in Management Systems Standards’ [5, 6]. The actual revolution in MSS is documented in the normative Appendix 2. It is based on a 10-clause structure:

1. Scope,
2. Normative references,
3. Terms and definitions,
4. Context of the organization,
5. Leadership,
6. Planning,
7. Support,
8. Operation,
9. Performance evaluation, and

10. Improvement.

The new HLS follows the well-known but underutilized PDCA cycle. This cycle, also known as the Deming or the Shewhart cycle, enables an organization provide the necessary resources to manage its processes, to discover opportunities for improvement, and to act upon them.

The PDCA cycle can be briefly described as follows:

- Plan: establish objectives, define and provide the resources needed to deliver the desired and required results. The chapters in Annex SL which deal with planning at system level are: Context of the organization (4), Leadership (5), Planning (6), and Support (7). In contrast with current MSS, within the planning stage the organizations are expected to identify and address risks and opportunities.

- Do: implement what was planned. Clause 8 ‘Operation’ is the system-level group of processes which are the main value adding processes for most companies.

- Check: monitor and measure processes and the resulting products and services against policies, objectives, requirements and planned activities, and report the results. The performance evaluation (Clause 9) is based on measuring the Key Performance Indicators (KPIs) defined for each process, discovering trends in the process characteristics, and defining possibilities for improvement.

- Act: take actions to improve performance, or MSS clause 10 ‘Improvement’. This is the factor which makes the difference between the organization and its competitors.

Annex SL already has established itself as a stable base for MSS starting with ISO 22301:2012 ‘Societal security – Business continuity management systems – Requirements’ (published on 2012-05-15), and continuing with ISO/IEC 27001:2013 ‘Information technology – Security techniques – Information security management systems – Requirements’ (published on 2013-10-01). The recently published ISO 9001:2015 and ISO 14001:2015 are soon to be followed by ISO 45001 ‘Occupational health and safety management systems – Requirements with guidance for use’, and very likely- by the standard for auditing MSs ISO 19011, industry specific standards (ISO/TS 16949), and other MSS. ISO 50001 is also expected to be revised based on a status of the standard, indicated by ISO on 2015-07-09.

Quality Management Principles

ISO has adopted a strictly pedagogical approach to management systems by defining the fundamental principles and terminology first, then specifying the requirements, and ultimately providing guidance documents such as: ISO Publicly Available Specifications (ISO/PAS), Technical Reports (ISO/TR), and Technical Specifications (ISO/TS).

Until September 2015, ISO 9000:2005 specified 8 quality management principles. The principles were ‘derived from the collective experience and knowledge of the international experts who participate in ISO Technical

Committee ISO/TC 176, Quality management and quality assurance', which is responsible for developing and maintaining the ISO 9000 standards. It can be said that the principles are also based on the human intelligence gained since historical times and converted into popular proverbs and sayings [7].

The eight quality management principles, formally defined in ISO 9000:2005, in ISO 9004:2009, and in ISO 10014:2006 were:

- Principle 1 – Customer focus,
- Principle 2 – Leadership,
- Principle 3 – Involvement of people,
- Principle 4 – Process approach,
- Principle 5 – System approach to management,
- Principle 6 – Continual improvement,
- Principle 7 – Factual approach to decision making, and
- Principle 8 – Mutually beneficial supplier relationships.

The new edition of ISO 9000:2015 [8] has reduced these 8 principles down to 7 (one for each day of the 'quality' week) and lists them in clause 2.3:

- Principle 1 - Customer focus,
- Principle 2 - Leadership,
- Principle 3 - Engagement of people,
- Principle 4 - Process approach,
- Principle 5 - Improvement,
- Principle 6 - Evidence-based decision making, and
- Principle 7 - Relationship management.

The explanations of each principle in ISO 9000 include:

- A *statement*, i.e. description of the principle,
- A *rationale* of why the principle is important for the organization,
- Examples of *potential benefits* associated with the principle, and
- Examples of typical *actions* to improve the organization's performance when applying the principle.

This specific organization of the description of each principle closely resembles the concept of "the golden circle" popularized by Simon Sinek in his best-selling book "Start with Why" [9]. The 'Rationale' answers the question '*Why the organization would address the principle?*', the 'Key benefits'- the question '*How can the organization benefit from applying the principle?*', and lastly, 'Possible actions'- the question whose answer most organizations intuitively guess - '*What can the organization do to apply the principle in reality?*'. This fresh breeze of leadership thoughts influences the new quality management principles in a positive way and promises a more profound understanding of the MSS by CEOs and top management.

There is a greater focus on the customer even though the title of the first quality management principle remains unchanged. At first glance, 'Principle 5 – System approach to management' is missing. In fact, this 'most obvious' change is

not a change in itself. The 'system approach to management' is now included in the 'Process approach' principle. This is its natural place, because the idea behind a Quality MS (QMS) has always implied that the processes within the organization should interact and be interrelated. The definition of a process is: '*a set of interrelated or interacting activities that use inputs to deliver an intended result*'. Thus, if the processes function as a coherent system, then the company will be able to achieve consistent and predictable results more effectively and efficiently.

The former 'Continual improvement' principle has been changed to just 'Improvement'. The justification for this change and the explanation, given by ISO, is that the 'continual improvement' traditionally is associated with the Japanese term 'kaizen', interpreted as 'gradual change in small steps'. The need to adapt to the rapidly changing world in which companies operate necessitates the implementation of breakthrough improvements as well. This is why the word 'continual' has been deleted, and probably some quality professionals were dismayed by the change.

The new principle 'Relationship management' goes beyond the outdated 'supplier relationships' by adding interested parties (or stakeholders) and partner networks to the 'providers' of products and services.

ISO 9000 Family of Standards

The ISO 9000 series of standards addresses various aspects of quality management and contains some of ISO's best known standards:

- ISO 9000:2015 - covers the basic concepts and language. Some of the terms contained in it constitute some of the common terms and core definitions for ISO management system standards given in Annex SL of the Consolidated ISO Supplement to the ISO/IEC Directives, Part 1. In addition, Annex A of ISO 9000 presents concept relationships and their graphical representation. As mentioned earlier, it also defines the seven new quality management principles.

- ISO 9001:2015 - sets out the requirements for a quality management system. This is the standard which is used for certification (registration) of QMS and as can be seen on Fig. 1 is the most popular MSS on a global scale. ISO experts claim that the new edition of the standard it is more general and specifies less strict requirements than its predecessor of 2008.

- ISO 9004:2009 - focuses on how to make a QMS more efficient and effective. This standard extends beyond the strict requirements of ISO 9001 and provides ideas and guidance for the sustained success of the organization. In Clause 8.3.2 it prescribes the identification of Key Performance Indicators and provides a framework for self-assessment of the organization. The maturity of the organization is described verbally and is defined in 5 levels, as 1 being the lowest, and 5 being the highest level which is supposed to reflect world-class performance.

- ISO 19011:2011 - sets out guidance on internal (first party) audits, which are required by ISO 9001, and external

audits (second and third party audits) of MSs. The second edition of the ISO 19011 standard defines auditing principles, explains how to manage the audit programme, and gives specific guidance on auditor competence and evaluation. This standard has also undergone changes to maintain its connection with changes in the MSs. In its Annex B, ISO 19011 provides examples of audit methods which can be used during the auditing process. What differs it from its previous version is the possibility to perform a remote audit in addition or even as an alternative to traditional on-site audits.

The development and introduction of new technologies is affecting the practical implementation of MSS in organizations. In the past it was ‘normal’ that the system was just in paper form, later it was partly digital, and partly on paper. Nowadays, smartphones and cloud technologies allow having a MS which is accessible and manageable anytime, from any place where there is internet access. Some informative and practical Android apps are HSEQ (Health and Safety, Environment, and Quality), ISO Mobile 2015, ISO 9001 Support, ISO Tools (ISO 9001:2015), KPI Monitor, etc.

ISO 9001:2015

ISO 9001:2015 is the only standard in the ISO 9000 family that an organization can be certified to. It sets out the criteria for a quality management system and can be used by any organization regardless of its size or field of activity.

The new edition of ISO 9001 uses the new HLS of all MSS and as a result- the identical text, common terms and core definitions. Nevertheless, ISO 9001:2015 has introduced the quality community to some new ideas which require a paradigm shift and not just a renumbering of the current systems [10, 11, 12].

Risk-Based Thinking (RBT)

This concept is given a ‘window seat’ in the new ISO 9001. As if for a purpose, it is mentioned 52 times in the standard- enough to keep quality managers busy for a year if they devote a week to each case in which RBT is mentioned. There are three clauses, specifically linked with RBT- Chapter 0.3.3, Appendix A.4, and most importantly- the requirements of Clause 6.1 ‘Actions to address risks and opportunities’.

ISO/TC 176 has prepared and published guidance documents which give simple examples of RBT in real life situations and point out that ‘the concept of risk has always been implicit in ISO 9001 – this edition makes it more explicit and builds it into the whole management system’. This is a ‘possibility for improvement’ of the structure of a documented procedure in the current edition of ISO/TR 10013:2001 ‘Guidelines for quality management system documentation’.

Context of the Organization

This new concept in ISO 9001:2015 is presented as a system level fishbone diagram on Fig. 2. The new edition of the standard really hit the bull’s-eye by expanding the former Clause 4 with ‘4.1 Understanding the organization and its

context’ and ‘4.2 Understanding the needs and expectations of interested parties’.

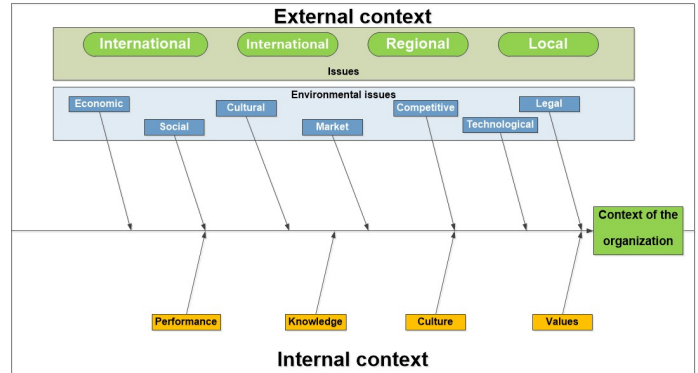


Figure 2 Context of the organization

Organizations are not static and do not operate in ‘sterile’ environments. There is a new requirement for *Change management* which is discussed in the following clauses of ISO 9001:2015: 6.3 Planning of changes, 8.1 Operational planning and control, 8.3.6 Design and development changes, and 8.5.6 Control of changes. Thus, it is crucial for the success of any company to identify and understand the influencing factors (termed ‘issues’ in ISO 9001) of the internal and external business context. Then the top management of the organization should define which of the interested parties have legitimate requirements for the products and services. Next, it shall determine if and how such demands are to be met.

The needs and expectations of the interested parties are supposed to influence the way the organization aligns its QMS policy and objectives with its mission, vision and strategic direction. Taking into consideration the requirements of the relevant interested parties, the company can enhance its ability to satisfy its customers.

Documented Information

It is a newly coined term which is a relief for the people who were confused with the two terms ‘document’ and ‘record’ used until the new editions of ISO 9000 and ISO 9001. The current standards allow greater flexibility with documentation, but this provokes questions about the need of the quality manual, the six ‘mandatory’ documented procedures, and other types of documents which shaped most of the QMSs implemented to the present moment. Here, once again, ISO/TC 176 provides clarifications in its ‘Guidance on the requirements for Documented Information of ISO 9001:2015’. ‘Documented information needed to be retained by the organization for the purpose of providing evidence of result achieved’ replaces the term ‘record’. The term ‘document’ is substituted by ‘Documented information needed to be maintained by the organization for the purposes of establishing a QMS’ (high level, transversal documents) and ‘Documented information maintained by the organization for the purpose of

communicating the information necessary for the organization to operate' (low level, specific documents).

ISO 14001:2015

This international MSS helps organizations 'improve their environmental performance through more efficient use of resources and reduction of waste, gaining a competitive advantage and the trust of stakeholders'. It requires that an organization considers all environmental issues relevant to its operations, such as

- air pollution,
- water and sewage issues,
- waste management,
- soil contamination,
- climate change mitigation and adaptation, and
- resource use and efficiency.

About the same time as ISO 9001, this standard has been revised to make sure it remains relevant to the marketplace. The new edition of ISO 14001 requires that environmental management has a more pivotal role within the organization. There is an increased focus on leadership commitment and life-cycle thinking, and a stakeholder-focused communication strategy is included in order to raise the awareness of interested parties [13, 14, 15].

Both ISO 9001 and ISO 14001 are aligned as much as possible. The HLS, the terminology, some official interpretations of the new principles and requirements, as well as a number of supporting documents for ISO 9000, ISO 9001 and ISO 14011 are given at [16]. Even though Annex SL has created considerable uniformity, some clauses still differ between ISO 9001 and ISO 14001.

Firstly, there are differences in the structure and text of the introduction (Chapter 0). ISO 14001 lacks clause 6.3 Planning of changes, which is an integral part of ISO 9001:2015.

Even greater are the 'gaps' in Clause 8 'Operation'. ISO 14001 requires the organization to establish and maintain emergency preparedness and response processes (Clause 8.2). On the other hand, ISO 9001 has a whole array of business processes which in part have been carried over from clause 7 of ISO 9001:2008:

- 8.2 Requirements for products and services,
- 8.3 Design and development of products and services,
- 8.4 Control of externally provided processes, products and services (formerly 'Purchasing' and outsourcing),
- 8.5 Production and service provision,
- 8.6 Release of products and services, and
- 8.7 Control of nonconforming outputs.

In Clause 9.1.2 of ISO 14001, there are requirements for evaluation of the organization's environmental compliance, whereas, in ISO 9001, clause 9.1.2 is 'Customer satisfaction', followed by 9.1.3 'Analysis and evaluation'.

The Annexes to ISO 14001 are much more detailed than the ones in ISO 9001, hence the standard provides better guidance on its application and implementation within companies.

ISO 14001:2015 is meant to respond to the latest trends, including the increasing recognition by companies of the need to factor in both external and internal elements that influence their environmental impact, such as climate volatility and the competitive context in which they work. The changes in the standard also ensure that it is compatible with other MSS, including other standards from the ISO 14000 series:

ISO 14004, *EMS — General guidelines on principles, systems and support techniques*,

ISO 14006 *EMS — Guidelines for incorporating eco-design*,

ISO 14031, *Environmental management (EM) — Environmental performance evaluation — Guidelines*,

ISO 14044 *EM — Life cycle assessment — Requirements and guidelines*, and

ISO 14063 *EM — Environmental communication — Guidelines and examples*.

Interestingly, at the end of ISO 14001:2015 and in the bibliography section, alongside the abovementioned EMS standards, the passionate eye would discover ISO 50001- the international standard for *Energy management systems — Requirements with guidance for use*.

ISO 50001

Energy management is the most significant factor influencing energy efficiency in industry. The ISO 50001 energy management standard provides a method for integrating energy efficiency into existing industrial or commercial management systems.

In 2009, the Committee Draft (CD) of ISO 50001 was prepared by Project Committee ISO/PC 242 'Energy management'. In just 2 years this CD turned 'from a cocoon to a butterfly', namely passing the next stages- Draft International Standard (DIS) and Final Draft International Standard (FDIS). The 13 pages of main text of the standard, including the specified in Clause 4 'Energy management system (EnMS) requirements', allow the enhancement of the more basic and general standards ISO 9001 and ISO 14011.

The implementation of an ISO 50001 energy management system is intended to result in improved energy performance. In its Annex A1 the standard stipulates that 'The concept of energy performance includes energy use, energy efficiency and energy consumption. Thus the organization can choose from a wide range of energy performance activities. For example, the organization could reduce peak demand, utilize surplus or waste energy or improve the operations of its systems, processes or equipment.' [17].

Similarly to ISO 9001 and ISO 14001, the EnMS standard is organized according to the stages of the Plan-Do-Check-Act cycle. The EnMS process model of ISO 50001 is shown on Figure 3.

In the planning phase, each organization which holds an ISO 50001 certificate is required to define its energy policy. This policy shall be appropriate to the nature and scale of the organization's energy use and consumption and shall serve as a proof of its commitment to continual improvement in energy performance.

The energy policy is supposed to trigger a process of documenting the energy planning process which shall include:

- Legal and other requirements,
- Energy review,
- Establishing an energy baseline using the information in the initial energy review,
- Energy performance indicators (EPIs) which are similar to the KPIs in QMSs,
- Energy objectives, targets and energy management action plans.

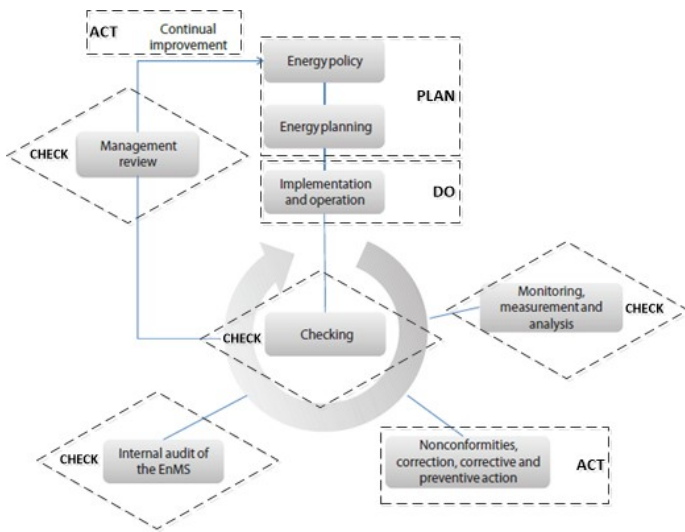


Figure 3 Energy management system model (based on fig. 1 of ISO 50001, p. iv)

The standard ISO 50001 requires that the organization uses the energy management action plans and other results from the planning process for implementation and operation of its EnMS.

Some of the benefits from implementing energy management action plans are:

- Developing a baseline of energy use,
- Actively managing energy use and costs,
- Reducing emissions without negative effect on operations,
- Improving the 'energy use/product output' ratio over time, and
- Documenting energy savings which may be used for internal and external purposes.

CONCLUSION

The ISO management systems standards have been implemented in various industries for nearly 30 years. The development of the global economy has stimulated the process of standardization. At the same time a growing number of requirements it being imposed on producers of material products and providers of services.

ISO 9001 is the undisputed leader in number of certificates worldwide. It has been used as a foundation for the elaboration and implementation of other industry-specific standards. The expansion of the applications has led to problems in developing and managing integrated management systems (quality, environment, occupational health and safety, information security, energy, etc.).

Annex SL has been published by ISO in order to facilitate the unification of different MSS in a single 'holistic' management system of any organization. It may be appropriate to call Annex SL the 'Esperanto' of MSS- or the 'language of hope' which all CEOs, managers, quality, environment and energy experts will use to better understand each other.

The authors of this article have more than 20 years of experience with the ISO 9000 series of standards [18, 19]. In the past 6 years they have published scientific research papers, partnered with Bulgarian companies and mentored bachelor and master degree students while using modern methods for documenting management system processes. Flowcharts and SIPOC diagrams are used for process description. Turtle diagrams are the visual 'business cards' of the process, and process interaction networks demonstrate the interfaces of the processes. Currently a new template for documented procedures is being assessed for suitability by companies and MSS consultants.

'Keep calm ... and prepare for ISO 9001:2015'. This slogan was on the front cover of the Quality Progress Magazine published in September 2015 by the American Society for Quality (ASQ). There is still enough time to update and migrate the existing management systems to the new edition of ISO 9001 and ISO 14001 until end of the 3-year transition period. Change is the only constant in the world of standards, and it is inevitable. Seeing so many positive changes provokes the optimism that management systems will indeed bring real value to the organizations.

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