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Approach for Acquiring Multiple Regulatory Requirements for New Information Technology Products in Technical Domains

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ABSTRACT

This article discusses the development of a new approach to simplify the collection and balancing of regulatory requirements for new IT products in technical domains. The relevance of this topic stems from the complex challenges associated with gathering and managing the requirements from a large number of regulatory documents, particularly in the development of IT products within interdisciplinary fields. This methodology was developed based on existing principles and practices included in the approaches to System engineering and Requirements management approaches. It was tested through a case study in the field of construction survey. And, as a result, the developed algorithm helped to simplify the collection and balancing of regulatory requirements for solving problems in technical subject areas, taking into account the potential of AI technologies application.

Keywords: *Legal Requirements; Legal Frames for Technology; Regulatory Document Requirements Management; System Engineering.*

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INTRODUCTION

While developing or introducing a new IT product, especially one utilizing artificial intelligence (AI) technologies, it is crucial to be fully aware of and compliant with the applicable laws and regulations in the target market. In the context of globalization and increasingly stringent regulatory frameworks, businesses, particularly SMEs and startups, often face substantial challenges when launching products in new jurisdictions, such as the EU, the US, or other international markets.

Some researchers' criticisms persist about its potential to stifle innovation, especially for smaller enterprises. For example, high compliance costs and resource-intensive conformity assessments can disproportionately impact startups compared to larger corporations[1]. "*The Draft AI Act imposes compliance burdens that may stifle innovation, particularly for small businesses and startups, without a detailed assessment of associated costs*[2]."

This complexity arises not only from AI-specific regulations and data protection regulations but also from additional field-specific laws, compounding the compliance burden. The lack of clear definitions and harmonized guidelines further complicates compliance, necessitating systematic approaches to integrate legal and technical requirements effectively.

Such regulatory fragmentation is particularly problematic in technical domains, such as automated building inspection, where legal requirements stem from international standards (e.g., EN 1990:2002 Eurocode - Basis of structural design, ISO 12006-2:2015), national safety codes (e.g., Germany's Betriebssicherheitsverordnung), and personal data regulations (e.g.,

[1] Philipp Hacker, "AI Regulation in Europe: From the AI Act to Future Regulatory Challenges," *Oxford Handbook of Algorithmic Governance and the Law* (forthcoming, 2024), October 6, 2023, arXiv preprint.

[2] Michael Veale and Frederik Zuiderveen Borgesius, "Demystifying the Draft EU Artificial Intelligence Act...", *Computer Law Review International*, Vol. 4, 2021, pp. 98.

GDPR), and additionally, AI regulations (AI Act). In these cases, organizations face the dual challenge of understanding the regulatory landscape and aligning it with the technical structure of the product being developed.

In this regulatory landscape, developers are not only confronted with a high volume of overlapping obligations but also with unresolved legal questions. For instance, the AI Act lacks clear criteria for borderline cases when defining "high-risk" AI systems under Article 6[3] and Annex III[4], while the GDPR's Article 22(1) leaves ambiguity around what constitutes a "decision based solely on automated processing[5]." Similarly, the threshold for requiring a Data Protection Impact Assessment (DPIA) under Article 35 GDPR[6] is open to interpretation, making risk assessments legally uncertain.

For instance, a tool that performs automated structural assessments may be subject to risk classification under the AI Act while also triggering DPIA obligations under the GDPR, even though the thresholds for each remain independently vague and jurisdictionally interpreted

While the methodology proposed in this article does not aim to resolve such doctrinal ambiguities, it is designed to support developers in systematically identifying, organizing, and reconciling regulatory requirements across legal sources and jurisdictions. In this

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[3] European Commission, Article 6: Classification Rules for High-Risk AI Systems, in Chapter III, Section 1 of the Proposal for a Regulation of the European Parliament and of the Council laying down harmonised rules on artificial intelligence (Artificial Intelligence Act), COM(2021) 206 final, 21 April 2021.

[4] European Commission, Annex III: High-Risk AI Systems Referred to in Article 6(2), in Proposal for a Regulation of the European Parliament and of the Council laying down harmonised rules on artificial intelligence (Artificial Intelligence Act), COM(2021) 206 final, 21 April 2021

[5] European Union, Article 22: Automated Individual Decision-Making, Including Profiling, in Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data (General Data Protection Regulation), OJ L 119, 4.5.2016, pp. 1–88.

[6] European Commission, Annex III: High-Risk AI Systems, in Proposal for a Regulation of the European Parliament and of the Council laying down harmonised rules on artificial intelligence (Artificial Intelligence Act), COM(2021) 206 final, 21 April 2021

way, it mitigates the operational consequences of legal uncertainty by structuring compliance workflows around available legal texts, even when they remain indeterminate.

Given the complexities outlined in navigating multifaceted regulatory frameworks, the need for effective and systematic management of regulatory requirements becomes a strategic imperative. Specifically, ensuring clarity and consistency in understanding, interpreting, and applying these diverse legal standards necessitates advanced requirements management.

Thus, to practically address these regulatory challenges, this paper proposes a structured, systematic methodology leveraging principles of requirements management and systems engineering, detailed in the following sections.

REQUIREMENT MANAGEMENT AND PROPOSED METHODOLOGY

Requirements management is a key aspect in the development of IT products, playing a crucial role in project success. Effective requirements management enables project teams to clearly understand what needs to be developed and which standards and norms must be adhered to. In modern conditions, where IT projects are becoming increasingly complex and multidisciplinary, the task of collecting, analyzing, and balancing requirements becomes particularly relevant[7]. Scientific research and practical experience confirm that deficiencies in requirements management often lead to

[7] Daojin, F., "Analysis of Critical Success Factors in IT Project Management," in *Proceedings of the 2nd International Conference on Industrial and Information Systems (IIS 2010)*, Vol. 2, 2010.

delays[8], increased project costs, and even project termination[9]. Consequently, the development and application of effective methods for collecting and analyzing regulatory requirements becomes a strategic necessity.

Requirements management is a comprehensive process that includes planning, collection, analysis, verification, and management of changes to requirements[10]. Systems engineering plays a crucial role in requirements management. It provides a structured approach to the collection, analysis, and verification of requirements throughout the entire project lifecycle[11]. This approach ensures that the product meets the functional and operational requirements of the customer[12].

In the modern world of globalization, where IT products are developed for many countries and jurisdictions, the model-based systems engineering approach (MBSE)[13] may serve as a foundation for managing and balancing requirements, including regulatory ones. It involves a structured identification of requirements, functions, components, and processes in the product, and aligning them with all stakeholders[14].

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[12] Hu, Z.; Lu, J.; Chen, J.; Zheng, X.; Kyritsis, D.; Zhang, H. A Complexity Analysis Approach for Model-based System Engineering. In Proceedings of the SOSE 2020 - *IEEE 15th International Conference of System of Systems Engineering, Proceedings*; 2020. 10.1109/SoSE50414.2020.9130478.

[13] Yadykin, V.; Barykin, S.; Badenko, V.; Bolshakov, N.; de la Poza, E.; Fedotov, A. Global challenges of digital transformation of markets: Collaboration and digital assets. Sustain. 2021, 13. 10.3390/su131910619.

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When developing such products for multiple countries simultaneously, there is also the challenge of collecting these requirements within the relevant subject areas[15]. Requirement identification is also considered in socio-technical systems engineering. For instance, study[16] explores methods for collecting and balancing regulatory requirements in socio-technical systems engineering. The main theses emphasize the necessity for stages of collecting initial data, analyzing and structuring, forming the system, and its subsequent use and change management.

Additionally, ontological models are one of the methods for collecting and managing requirements, thanks to the unification and structuring of information[17]. Ontological models represent formal and structured ways of representing data and knowledge in a specific area[18]. Ontologies provide mechanisms for identifying implicit dependencies and contradictions between requirements. They can be used to create extensive knowledge bases that support various aspects of requirements management, including requirement verification and change management[19]. Ontologies[20] offer a deep understanding of the

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[15] Bolshakov, N.; Rakova, X.; Celani, A.; Badenko, V. Operation Principles of the Industrial Facility Infrastructures Using Building Information Modeling (BIM) Technology in Conjunction with Model-Based System Engineering (MBSE). Appl. Sci. 2023, 13. 10.3390/app132111804.

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structure and semantics of requirements, which facilitates their more accurate specification and analysis[21].

With the advancement of artificial intelligence, new methods for collecting requirements have emerged[22]. Primarily, this involves using the capability of language models for semantic analysis[23]. AI can help accelerate the collection, analysis, and classification of requirements. AI can automate the creation of ontological models for various subject areas and systems by utilizing the capabilities of language models to create semantic models in a hierarchical structure, similar to XML or JSON formats[24]. Due to the multilingual capabilities of large language models, this process can be implemented for laws and regulatory documents from many countries simultaneously, which can significantly speed up the deployment of new IT solutions and enhance their return on investment.

Currently, a pressing issue in the development of multinational IT solutions remains the collection of a comprehensive list of requirements, the normalization of their semantic meaning to a unified list of terms and definitions within the scope of the project, and their balancing.

The aim of this article is to develop a new methodology that will allow for the collection of all requirements from necessary regulatory documentation and perform their balancing when developing IT products. This study is limited to technical subject areas, as other fields may have their own specific characteristics that require separate

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[21] Wibowo, A.; Davis, J. Requirements Traceability Ontology to Support Requirements Management. In Proceedings of the *ACM International Conference Proceeding Series*; 2020. 10.1145/3373017.3373038.

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[24] AL-Aswadi, F.N.; Chan, H.Y.; Gan, K.H. From Ontology to Knowledge Graph Trend: Ontology as Foundation Layer for Knowledge Graph. In *Communications in Computer and Information Science*; 2022; Vol. 1686 CCIS, pp. 330–340. 10.1007/978-3-031-21422-6_25.

research and development of appropriate methodologies. To illustrate its practical applicability, the proposed approach was tested at a basic level of an AI-based application designed to automate building and technical inspections in the construction sector. The sources of regulatory requirements for this example were the European Union legal acts and international standards. However, the methodology itself is universal and can be adapted to work with the regulatory framework of various jurisdictions in technical domains.
To achieve this goal, the following tasks were addressed:

1. Existing methods for collecting and balancing regulatory requirements used in systems engineering and other methodologies were analyzed;
2. The final outcome of applying the methodology was determined;
3. Based on the above, an action algorithm for collecting requirements was developed.

To develop a method that meets our basic hypothesis, it is first necessary to define the boundaries of our research. We address the task of collecting regulatory requirements from various disciplines and jurisdictions within a specific project. Within this methodology, we specifically tackle the task of collecting and balancing a comprehensive list of requirements. This involves using approaches and principles of systems engineering, but parallel processes not related to regulatory requirements are not considered in this article. Additionally, the process and techniques for searching information and documents by keywords are not covered.

To develop this methodology, the following criteria were established:

1. The methodology should be designed to be applicable using automation tools, including AI. This is verified by ensuring that each step of the algorithm can be partially or fully implemented

using automation tools or machine learning techniques, such as large language models;

2. The requirements directory generated by the methodology must be comprehensive, meaning that no regulatory requirements relevant to the project should be omitted. This requirement is verified through semantic search. After this search, the directory can be extended.

3. The methodology must take into account the goals and objectives of the project. This requirement is verified by ensuring that the methodology considers the project's goal and will approach the collection and balancing of regulatory requirements from this perspective. During the verification stage, each requirement and the results of the balancing process should be checked for alignment with this goal;
4. The methodology should be applicable to any IT product within technical domains (it should be universal). Verifying this requirement within the scope of the research is challenging, as it would require extensive testing across various technical domains. However, the primary criterion is the formulation of algorithm elements in a general manner, without referencing the specific characteristics of a particular domain. It is assumed that such specifics can be addressed within the comprehensive system design of the product, and addressing these specifics is beyond the scope of this article.

The algorithm development method involves adapting classical methods and principles of systems architecture to the task of collecting and balancing regulatory requirements. The main principles are mentioned in INCOSE publications[25], and a similar

[25] Walden, D.; Shortell, T.; Rodler, G.; Delicado, B.; Mornas, O.; Yew-Seng, Y.; Endler, D. INCOSE Systems Engineering Handbook, 5th Edition. INCOSE SeBok. Guid. to Syst. Eng. Body Knowl. 2016.

approach is used in the TOGAF methodology[26]. Adaptation is carried out considering the necessary final outcome and the requirements for the methodology. To achieve this, we address the task of implementing the set final outcome by applying various principles and methods of systems engineering and requirements management, from which we develop a unified algorithm.

INTEGRATIVE FRAMEWORK FOR REQUIREMENT ANALYSIS AND BALANCING

According to the principles of INCOSE[27], system architecture must consider all stakeholders, system elements, and their interrelationships. It also emphasizes the need for normalization (a middle-range set of theories) and the translation of concepts, connections, and logic into a mathematical format to standardize operations. In the legal field, a comparable approach could involve creating a unified list of terms and definitions and ensuring that requirements and descriptions of elements are standardized by describing them using terms from this list.

Valuable concepts are also outlined in the TOGAF methodology[28]. TOGAF defines architecture as: "The structure of components, their interrelationships, and the principles and guidelines governing their design and evolution over time." This implies the necessity of incorporating principles and roadmaps for the collection and management of requirements and their balancing into the algorithm. In the context of the task at hand, where we focus not on the entire system architecture but only on the aspect related to the

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[26] Kotusev, S. TOGAF-based enterprise architecture practice: An exploratory case study. *Commun. Assoc. Inf. Syst.* 2018, 43. 10.17705/1CAIS.04320.

[27] Watson -Chair, M.; Mesmer, B.; Roedler, G.; Rousseau, D.; Calvo-Amodio, J.; Keating, C.; Miller, W.D.; Lucero, S.; Gold, R.; Jones, C.; et al. Systems Egngineering Principles; 2022; ISBN 9781937076085.

[28] The Open Group The Open Group Standard. The TOGAF® Standard, Version 9.2; 2018;

collection and balancing of requirements, such principles and roadmaps can be applied based on those developed for the entire project and may not require separate development.

The task of the methodology concerning requirements balancing can be addressed using well-known approaches like the Design Structure Matrix (DSM). This method was developed for organizing and balancing numerous system entities[29]. Additionally, there are studies that use DSM for knowledge management[30], which is closely related to the task of requirements management and collection. In the proposed method, this approach will be used to identify interconnections and balance requirements.

The final outcome of applying the methodology is a requirements directory relevant to the project under development, along with a tool for balancing and managing changes. The directory should be organized hierarchically and take into account its connections with regulatory sources. It should be standardized to a unified semantic framework of terms and definitions. This means all requirements and their meanings are retained, but the wording of each is described using standardized terms to resolve conflicts. If it is not possible to resolve a requirement conflict terminologically, adjustments to the IT project may be indicated.

Considering the above, the following algorithm was developed:

1. Identify stakeholders, components, and processes affected by the IT solution. This step is conducted in the primary jurisdiction of the product, usually in the country where the product is being developed and where the legislation is most familiar to the developer. Initially, this step involves collecting all information about the stakeholders, components, and processes. Then, the collected raw data is structured, from

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[29] Steward, D. V. DESIGN STRUCTURE SYSTEM: A METHOD FOR MANAGING THE DESIGN OF COMPLEX SYSTEMS. IEEE Trans. Eng. Manag. 1981, EM-28, 71–74. 10.1109/TEM.1981.6448589.

[30] Tang, D.; Zhu, R.; Tang, J.; Xu, R.; He, R. Product design knowledge management based on design structure matrix. Adv. Eng. Informatics 2010, 24, 159–166. 10.1016/J.AEI.2009.08.005.

which comprehensive lists of these three components are formed, and duplicates, erroneous, and redundant information are removed.

2. The second step involves a semantic analysis of each component. For each identified stakeholder, component, and process, a detailed definition and explanation are provided, which are then entered into a corresponding table. Legal definitions from applicable regulations should also be included to align the semantic understanding with jurisdiction-specific terminology (e.g., "data controller" under GDPR, or "high-risk system" under the EU AI Act). This table can be referred to as the project elements directory.
3. In the third step, a search and selection of laws and regulations are performed, specifically those containing provisions on regulatory requirements that are semantically related to one of the elements listed in the directory. The selection process should include international, regional, and national regulatory instruments relevant to the product's operation, especially when cross-border data flows or AI functionalities are involved.
4. These requirements are then listed in a separate table, indicating the project entities to which each of them relates. Each regulatory requirement should be referenced with the specific article and clause from its legal source to support traceability and legal auditability. This table can be called the regulatory requirements directory.
5. An analysis of these requirements is then performed. A matrix of connections between regulatory requirements (column headers) and project elements (row headers) is formed, and the intersections are marked to indicate connections. This step also clarifies which technical components of the project fall under legal obligations and highlights areas where legal interpretation may affect engineering decisions.

6. Using the obtained matrix, requirements that relate to the same project elements are identified, after which another matrix is formed exclusively from the regulatory requirements in the row and column headers. The intersection cells of this matrix address the question, "How does requirement Y affect requirement X?" The following scenarios are possible:
   a) Requirements do not contradict each other and can be implemented simultaneously;
   b) Requirements do not contradict each other, but cannot be implemented simultaneously;
   c) Requirements contradict each other;
   d) Requirements partially contradict each other;
   e) Requirements complement each other and can be combined into a single requirement.
7. The two tables of project elements and regulatory requirements, as well as the matrices of connections between the regulatory requirements and the project elements, and among themselves, form the basis for further analysis and balancing. Balancing is carried out iteratively by returning to a certain stage of the algorithm and repeating subsequent steps to refine data or resolve requirement conflicts.
8. In cases where a contradiction in requirements is identified or their simultaneous fulfillment is unachievable, normalization is performed, meaning their formulations are described using definitions and concepts from the project's terminology directory, after which their conflict is re-evaluated. Persisting conflicts indicate the need to make changes to the project elements, account for this in the project elements directory, and undergo another iteration of the algorithm.
9. In subsequent iterations, the connections between requirements and project elements may be enhanced by analyzing the interrelationships among project elements themselves, as well as by incorporating into the analysis regulatory documentation

from foreign countries where the project is planned to be implemented.

10. Requirement balancing is considered complete when all identified conflicts in the matrix of connections have been resolved.

As an illustration, let us present an example of implementing the algorithm for collecting requirements for an IT product aimed at automating building inspections. For illustrative purposes, the algorithm is implemented in a simplified manner, with a limited number of entities, meaning that not all components, processes, stakeholders, and requirements are utilized.

1. In the first step, we identify:
   a) Stakeholders – building inspection engineers, building inspection clients;
   b) Components – building structures;
   c) Processes – the process of visual building inspection, the process of instrumental building inspection, and the process of data software processing.
2. Subsequently, a directory of the semantics of the identified entities is compiled (Table 1).

Table 1. Project Entity's Directory

No	Entity Name	Definition
E1	Building Inspection Engineers	Specialists who perform visual and instrumental inspections of structures, as well as process the data collected from building inspections.
E2	Building Inspection Clients	Organizations that order building inspections (owners or management companies), issue technical specifications, and conduct acceptance of work from contractors.
E3	Building Structures	Parts of a building that serve structural or enclosing functions, or act as decorative elements.
E4	Visual Building Inspection Process	Building inspection is a specialized type of engineering survey that includes a comprehensive set of activities aimed at determining and assessing the actual values of controlled parameters, which characterize the operational capability of the inspected object and determine the possibility of its further

		operation, reconstruction, or the need for restoration, reinforcement, repair, or demolition. This includes inspecting the foundation soils and structural constructions to identify changes in soil properties, deformation damages, defects in load-bearing and enclosing structures, and determining their actual load-bearing capacity. Visual inspections are conducted to preliminarily assess the technical condition of construction structures based on external signs, to determine the necessity for instrumental inspections, and to refine the work program.
E5	Instrumental Building Inspection Process	The instrumental inspection of a building's technical condition includes: 1) Measuring the geometric parameters of buildings, structures, their elements, and assemblies; 2) Determining the parameters of defects and damages instrumentally; 3) Assessing the dynamic parameters of buildings and individual structures; 4) Conducting openings of building structures and exploratory trenching to determine the structural design, measurements, load collection, and detection of hidden defects; 5) Instrumentally determining the physical and mechanical characteristics of the materials of the main load-bearing structures and their components; 6) Measuring parameters of the operational environment; 7) Determining operational loads and impacts perceived by the inspected structures, considering the effects of deformations of load-bearing structures and foundation soils; 8) Defining the calculation scheme of the building or structure and its individual components; 9) Performing verification calculations of structures based on inspection results to determine the design forces in load-bearing structures; 10) Analyzing the causes of defects in structures; 11) Compiling a final document with conclusions based on the inspection results.
E6	Automatic data analysis process	Automated analysis of building data (photos, documents, and textual data) and personal data.

3. In the third step, a selection of regulatory documents and laws relevant to these entities is carried out. In this case, they include:
   a) EN 1990:2002 Basis of structural design;
   b) ISO 12006-2:2015 Building Construction – Organization of information about construction works;

c) Regulation (EU) 2016/679 (General Data Protection Regulation).

4. In the fourth step, we compile a directory of requirements from the regulatory standards and laws (Table 2). Based on the definitions in Table 1, a search is conducted for information about requirements related to any aspect of these definitions.

Table 2. Directory of Regulatory Requirements

No	Requirement	Corresponding Project Entities
R.1	Qualified specialists from certified organizations with higher education in construction should conduct building structure inspections and formulate inspection tasks.	Building Inspection Engineers; Building Inspection Clients.
R.2	Building structure inspections must be conducted at least once every 10 years.	Building Structures; Visual Building Inspection Process; Instrumental Building Inspection Process; Automatic Data Analysis Process
R.3	Processed data must be protected, and its non-disclosure to third parties must be guaranteed.	Automatic Data Analysis Process Building Inspection Engineers; Building Inspection Clients.

5. The next step is a matrix outlining the relationships between requirements and project entities is created (Figure 1).

	R.1	**R.2**	**R.3**
E.1	X		
E.2	X		X
E.3		X	X
E.4		X	
E.5		X	
E.6		X	X

Figure 1. Matrix of relationships between requirements and project entities

6. Based on the identified relationships, the requirements cross-reference matrix was created (Figure 2).

	R.1	R.2	R.3
R.1			No conflict
R.2			No conflict
R.3	No conflict	No conflict	

Figure 2. Matrix of requirements balancing

7. For further balancing, let's assume that this IT product is planned to be implemented in a country with a local regulation requiring that "building structure inspections must be conducted at least once every 20 years." We will designate this requirement as R.4 .It copies the interrelationships of requirement R.2 and contradicts it from the functional point of view. (see Figure 3).

	R.1	R.2	R.3	R.4
E.1	X			
E.2	X		X	
E.3		X	X	X
E.4		X		X
E.5		X		X
E.6		X	X	X

	R.1	R.2	R.3
R.1			No conflict
R.2			No conflict
R.3	No conflict	No conflict	
R.4		**Conflict**	No conflict

Figure 3. Addition of the new requirement

8. To resolve the conflict, modifications are made to the inspection definitions to specify the frequency according to local legislation, and the definitions in the requirements directory are updated to include jurisdictional references. Based on this updated information, corresponding changes are made to the product. As a result, the requirements will have an additional country-specific attribute, ensuring they do not conflict with each other.
9. The directories and matrices obtained through subsequent iterations are provided in this example.

10. Since the conflict between requirements from different jurisdictions has been resolved, the balancing process is considered complete and can be handed over to the product developers.

As can be seen, the algorithm successfully addresses the task of gathering requirements and creating a unified requirements directory. This study did not consider the case of more complex systems where it is necessary to establish a hierarchy and classification of requirements, which could be the subject of further research and refinement. It is crucial first to determine the perspective from which the requirements system will be viewed (for instance, laws may be grouped by "subject area" or by geographical location or jurisdiction, such as the construction sector in a specific country is regulated by particular laws, acts, etc.). This perspective is determined based on the project's objectives.

Additionally, the proposed methodology allows for the balancing of requirements, as well as their supplementation and modification, for example, in response to changes in legislation. However, this study did not explore the more complex task of balancing the entire IT project system, including its architecture, management, and economic domains.

Thanks to artificial intelligence technologies, this methodology could potentially enable the collection and systematization of data for larger-scale projects in the future. For example, future research could focus on establishing and mapping connections between various laws, acts, and legal documents across different countries, regions, and jurisdictions, ultimately aiding in the development of a global international legal database.

CONCLUSION

A methodology for managing regulatory requirements for IT products in technical domains has been developed, specifically designed for use in multidisciplinary and multinational projects. This methodology enables the efficient collection, analysis, and balancing of requirements from various jurisdictions, ensuring compliance with legislative and regulatory acts across different countries.

Artificial intelligence can be leveraged to automate the process of gathering and processing requirements, as well as for creating ontological models. This has the potential to significantly accelerate the implementation of this methodology when integrated with comprehensive systems engineering.

Future research could focus on adapting the methodology for more complex systems and developing global regulatory requirements management systems. Such advancements would enable more effective IT product development across different regions and jurisdictions, taking into account their multidisciplinary and multinational aspects.

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