

УПРАВЛІННЯ ЯКІСТЮ ТА БЕЗПЕЧНІСТЮ

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INTERNATIONAL STANDARD ISO 19011:2018: PERSPECTIVES OF IMPLEMENTATION

The content of the international standard ISO 19011:2018 was researched, its main innovations were determined in comparison with the previous version. The changes are due to the extension of the document scope, the unification of the ISO standards structure, ensuring the uniformity of terminology, the use of risk-oriented approach, increasing of the requirements for the audit team competence. The perspectives, that can be revealed while implementing an updated version of a regulation act, should increase the effectiveness of organizations' first- and second-party auditing practical application for the assurance of due performance, a higher level of ability to respond to risks and to achieve planned goals.

Keywords: audit, standard ISO 19011:2018, prospects of practical usage, conducting program, auditors' competence, criteria, control flowchart, risk-oriented approach.

Притульская Н., Антюшко Д., Гусаревич Н. Международный стандарт ISO 19011:2018: перспективы имплементации. Исследовано содержание международного стандарта ISO 19011:2018, определены его основные новации по сравнению с предыдущей версией. Внесенные изменения обусловлены расширением сферы применения документа, унификацией структуры стандартов ISO, обеспечением единства терминологической базы, использованием риск-ориентированного подхода, повышением требований к компетентности представителей группы аудита. Перспективами, которые могут открываться при имплементации обновленной версии нормативного акта, должны стать повышение эффективности практического

применения процедуры проведения организациями аудитов первой и второй сторон для обеспечения уверенности в должных результатах деятельности, более высокого уровня способности реагировать на риски и достигать запланированных целей.

Ключевые слова: аудит, стандарт ISO 19011:2018, перспективы практического применения, программа проведения, компетентность аудиторов, критерии, блок-схема управления, риск-ориентированный подход.

Background. Providing the right conditions for responsible business activities, that will maximally meet clients expectations and demonstrate long-term plans for working in the market, doing business, necessitates the introduction and usage of various organization's management systems (MS). A wide range of recommendations have been prepared under the auspices of the International Organization of the ISO, including quality, environment, food safety, social responsibility, information security, hygiene and health of personnel, energy resources and more. Under the auspices of the International Standard Organization (ISO) a wide range of recommendations, which can be applied to MS including quality, environment, food safety, social responsibility, information security, hygiene and health of personnel, energy and other kinds of have been prepared. The application of these standards implies ensuring the proper functioning of the implemented systems, confidence and trust of stakeholders (customers, suppliers, partners, society, government bodies, etc.), appropriate conditions for sustainable development and timely response to market environment and audits holding [1; 2].

In July 2018, the International Standard Organization's Project Committee ISO/PC 302 "Guidelines for auditing management systems", led by the representative of ISO/TC 176 "Quality Management and Quality Assurance" Denise Robitaille, published and put into effect a new version of the international standard ISO 19011:2018 "Guidelines for auditing management systems" [3; 4]. This version of the standard was prepared by representatives from 42 participating states, 12 observer countries and has been ongoing since August 2016 [5]. In the near future, this regulatory document [3] should be translated into Ukrainian and formally adopted at the national level.

So, a detailed analysis of the international standard ISO 19011 adopted version's content and specifics of the provisions is relevant to ensure practically improvement of the organizations MS's functioning, the credibility of works to assess their compliance with the requirements of various regulatory documents, the competence of specialists involved in the audit process, to achieve the unity and comparability of obtained results, Especially its important in the content of taking into account and implementing standard's requirements in practice while conducting audits by organizations' first and second sides. This, in turn, will ensure the effectiveness of the preparation for the audits, their implementation and further usage of obtained results. The practical application of the updated standard version's [3] requirements will be a reliable tool for the effectiveness of organizational MS's determination, basic processes optimization, and, overall, improvement of total productivity.

The analysis of recent research and publications. The scientific works of many foreign and domestic researchers and scientists were devoted to the study of determining the MS effectiveness, the development of criteria, methods and programs for conducting its audits, providing the necessary for the auditors' competencies. An important contribution in this sphere has been done by foreign and domestic scientists: D. Robitaille [6; 7], F. Dobb [8], J. Brennan [9], A. Kuceja [10], O. Kartashova [11], П. Kalyta [12], Ю. Veryha [13], A. Momot [14] and others.

The aim of work is detailed analysis of the innovations, the provisions' specifics and the implementation features of the international standard ISO 19011 "Guidelines for auditing management systems" new version, in particular in order to outline the prospects for its further application.

Materials and methods. As a methodological basis, the provisions of the international standard's ISO 19011 "Guidelines for auditing management systems" editions of 2011 [15] and 2018 [3], methods of comparison and generalization, scientific study, analysis and synthesis, research systematization of MS audits planning and implementation methodical aspects were used.

Results. In order to establish the prospects of using the new version of the international standard ISO 19011, it is of paramount importance to analyze its changes comparing with the previous one. It should be noted that the version adopted in July 2018 is the third version of this regulatory document. It repeals and replaces the previous one (adopted in 2011) without a transition period. The main reason for the revision of this regulation's content and requirements is the approval and release of a wide range of new standards for MSs, that currently have a single structure (in accordance with the provisions, stated in Annex SL to the Directive ISO/IEC, Part 1. ISO Consolidated Supplement – Special ISO Procedures" [16] in matter of High Level Structure), unified basic requirements and terminology. Namely taking into consideration these factors of carrying out MSs audits the approaches were expanded and recommendations were made regarding their planning, conducting and assuring the competence of persons, involved in these processes.

While characterizing the international standard ISO 19011: 2018 in general, it should be noted that it provides guidance for MSs audits in organizations of various sizes and areas of activity by both audit groups and individual auditors, users, including. for the purpose of developing own requirements for conducting audits, including for self-declaration. Regulatory document [3] consists of a forward, introduction, 7 sections (Scope, Normative references, Terms and definitions, Principles of auditing, Managing an auditing programme, Conducting an audit, Competence and evaluation of auditors), Annex (Annex A (informative). Additional guidance for auditors planning and conducting audits) and bibliographies (4 sources).

Basing on the results of the conducted study of the standard [3] provisions, it should be noted that the Forward of the document describes the current general principles of the international ISO standard development,

patent rights to it and the main differences from the previous (second) edition, which are following:

- updating the terminology base, changing the primary orientation from the audit object to its process;
- incorporating a risk-oriented approach to audit principles and management of the audit program;
- extension of the audit program management, including its section about planning and Annex A on recommending new concepts (organization context, leadership, top management responsibilities, virtual audits, compliance of the requirements, supply chain), general auditors competency requirements.

The results of conducted analysis of the introductory part of the standard ISO 19011:2018 shows that the revision of its content is primarily due to the necessity of updating the terminological base, structure and principles of the MS audit, to which a number of new standards have been published since 2011. It is worth noting that most of them have common structure, basic requirements, terminology and basic definitions. The new version of the document specifies that an audit may be conducted to determine whether a number of criteria, individually or in combination. It may include:

- the requirements, that are set in one or more standards on MS;
- the policies and requirements, established by the legislation base and relevant stakeholders;
- one or more organization's or other parties processes of MS;
- the plans of MS, related to achieving concrete results.

The study of the provisions shows that the normative act [3] also sets out its primary focus on audits of the first (internal) and second (external suppliers and stakeholders) parties. At the same time, regulation [3] may, in addition to ISO / IEC 17021-1 [17], provide guidance for certification, accreditation and / or verification of regulatory and normative requirements by a third party. The standard [3] is intended to provide guidance on the MS audit's management programme, its planning, conducting, as well as on the competence and assessment of auditors and audit teams.

It should be summarised that ISO 19011:2018 [3], as previously revised version [15], defines which guidance it contains, by whom, for what purposes and under what conditions audits can be done. Especially important is the fact, that analysed normative act [3] contains no references. The application of this part is made purely to preserve the overall structure of the ISO sections.

As a result of the conducted analysis of the terminology part, it was found that the used terminological base was refined and re-numbered in comparison with the previous version [15]. The numbering of terms and definitions was brought in accordance with the international standard ISO 9000: 2015 [18] (*Table*).

Numbering ratio of used terminological base

Terms and definitions	Number of point in the standard		
	ISO 19011:2011	ISO 19011:2018	ISO 9000:2015
Audit	3.1	3.1	3.13.1
Combined audit	–	3.2	3.13.2
Joint audit	–	3.3	3.13.3
Audit programme	3.13	3.4	3.13.4
Audit scope	3.14	3.5	3.13.5
Audit plan	3.15	3.6	3.13.6
Audit criteria	3.2	3.7	3.13.7
Objective evidence	–	3.8	3.8.3
Audit evidence	3.3	3.9	3.13.8
Audit findings	3.4	3.10	3.13.9
Audit conclusion	3.5	3.11	3.13.10
Audit client	3.6	3.12	3.13.11
Auditee	3.7	3.13	3.13.12
Audit team	3.9	3.14	3.13.14
Auditor	3.8	3.15	3.13.15
Technical expert	3.10	3.16	3.13.16
Observer	3.11	3.17	3.13.17
Management system	3.20	3.18	3.5.3
Risk	3.16	3.19	3.7.9
Conformity	3.18	3.20	3.6.11
Nonconformity	3.19	3.21	3.6.9
Competence	3.17	3.22	3.10.4
Requirement	–	3.23	3.6.4
Process	–	3.24	3.4.1
Performance	–	3.25	3.7.8
Effectiveness	–	3.26	3.7.11

In such a way, in the new version of the regulation act [3] the terms "audit", "audit program", "audit scope", "audit plan", "audit criteria", "audit team", "management system", "risk" have been changed and revised. These definitions now comply with ISO 9000:2015 [18]:

- combined audit – an audit, that is carried out together at a single auditee on two or more MS;
- joint audit – an audit, that is carried out at a single auditee by two or more auditing organizations;
- objective evidence – some data supporting the existence or verity of something;
- claim – a need or expectation which is stated, generally implied or obligatory;
- process – a set of interrelated or interacting activities, which use inputs to deliver an intended result;
- performance – a measurable result;
- effectiveness – an extent, to which planned activities are realized and planned results are achieved.

The introduction of the first 2 definitions is due to the inclusion of the conducting multiple audits possibility at the same time, the others – due to the need of provision a single terminological base for all ISO standards, which concern MS.

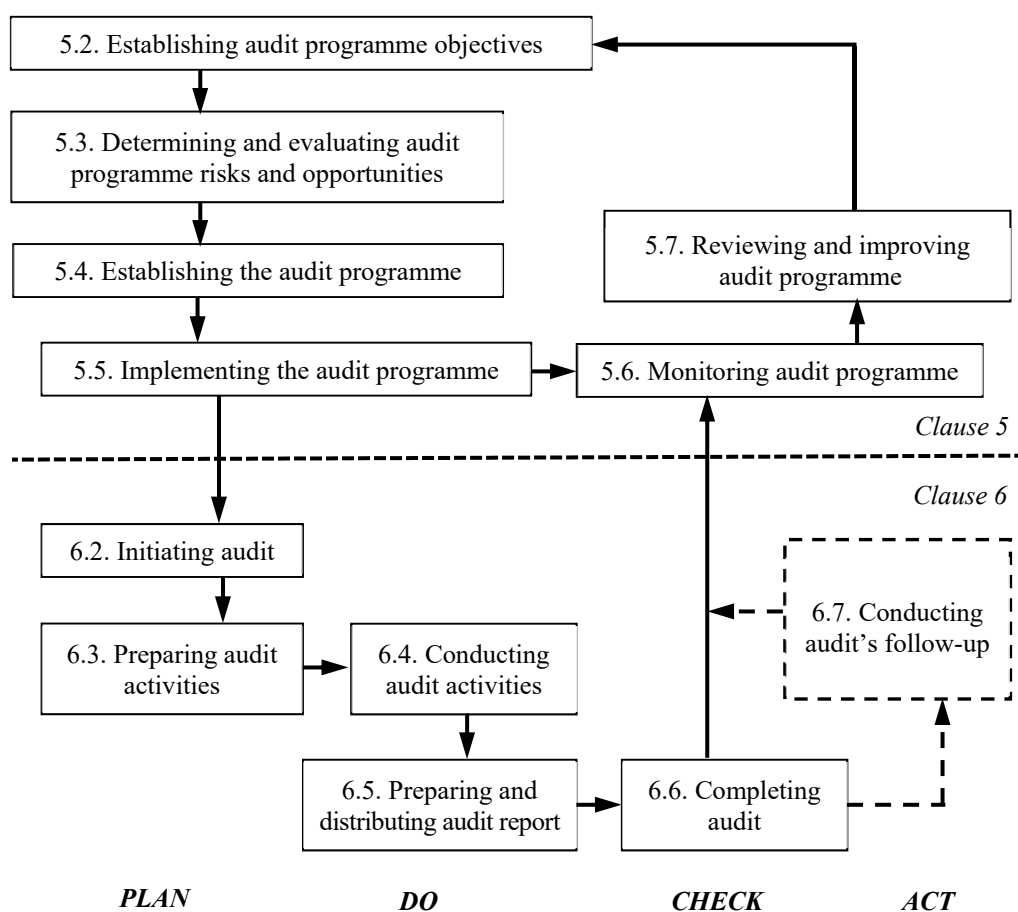
It should be noted that ISO 19011: 2018 [3] sets out 7 principles that aimed to achieve the effectiveness and reliability of this activity. In particular, the *risk-oriented approach* has been added to the ethics principles, which were set out in the previous version [15]. These ethics principles are honesty in the presentation of results, due professional care, confidentiality, independence and facts-based decision making. The implementation of risk-orientated approach should have a significant impact on the planning, conduct and reporting of these activities in order to ensure focus on issues relevant to the audit client and effectively achieve the objectives of the program developed. The application of this principle is closely linked to the further content of the new standard's version [3], and in particular the fifth section "Managing an audit program" and is aimed at identifying risks and opportunities and responding to them.

It should be noted that the updated version of the regulation act [3] defines the provisions for managing the audit program. In particular, the general rules for the implementation of this activity, the requirements for setting the goals of the audit program, its associated risks and opportunities, its development, implementation, monitoring, analysis and improvement are regulated.

While analyzing the innovations of the standard's latest version [3], it should also be noted that clause 5.1 "General" identified the need to predict the dependence of the audit program's scope on the scale and features of the audited organization, functional purpose, complexity, type of risks and opportunities, maturity level of certain MS(s). Particular attention is paid to the proposition that the MS's operation may be more difficult if most important functions are outsourced or managed by other organizations. In this case, the design, planning and validation of the audit program should take into account the aforementioned features. It is stated that in order to understand the context of the organization, the audit program should consider:

- activity goals;
- relevant internal and external factors;
- stakeholder needs and expectations;
- requirements for information security and privacy assurance.

Except this, the audit group should ensure the integrity of the profile activity and prevent the usage of undue influence. It has been stated that audit priority should be given to the allocation of resources and the choice of methods for MS's methods with higher-risk and low-activity elements. Also in this paragraph it is presented a modified block diagram of the audit program's management (*Figure*).



Process flow for the management of an audit programme
(based on PDCA cycle) [3]

Another innovation of ISO 19011:2018 [3], which must be discussed, is the introduction of the new paragraph 5.3 "Determining and evaluating audit programme risks and opportunities". It identifies that there are a variety of risks and opportunities inherent in the audited entity. It may affect the audit management program and the achievement of its objectives. These factors should be identified and communicated by the audit group members to the organization's representatives to take appropriate action. The mentioned risks may be related with:

- planning goals and determining the scope, number, duration, locations and timetable of the audit;
- resources for the development of the audit program and its implementation;
- communication (information exchange processes);
- the implementation of the program;
- managing documented information;
- monitoring, analyzing and improvement at the audit program;
- availability and willingness to cooperate with the verified organization, which is checked, the certificates to be collected.

The analysis of the document's [3] provisions allows to summarize the existence of a norm about the possibility of carrying out several audits at one time, minimizing the time and distance while moving, compliance with the level of the audit group competence, which is necessary to achieve the set goals, agreeing the dates of carrying out checks with the contact key employees of the organization.

The study of a new standard's version [3] indicates that changes have also been made in part regarding the definition of auditor's competence and the assessment. To ensure, identify, evaluate, maintain and enhance the overall competence of audit group members, including. during each individual checking, considerable attention should be paid to personal qualities (clause 7.2.2), general and profile knowledge and skills (clause 7.2.3), in particular in the part of the MS (clause 7.2.3.2) and their specific types in different spheres and industries (clauses 7.2.3 – 7.2.3.5).

It is also foreseen that in order to facilitate a successful and effective audit holding, the specialist should have competencies, including: to discuss strategic issues with top management of the audited entity to determine whether it has considered risk and opportunity assessment issues

The research of presented in normative act [3] Annex A "Additional guidance for auditors planning and conducting audits" allows to confirm an extension of the provisions set out in the audit recommendations for new MS aspects (organization context (internal and external factors), leadership, engaging top management and staff, etc.). Also it should be noted that Annex B "Additional guidance for auditors for planning and conducting audits" was taken away from the standard [3] because of extending these norms and moving them to the relevant section.

Taking into account the widespread implementation of MS by organizations in current practice, it is particularly important to establish the effectiveness of their operating process, which is carried out in the form of audits. In such a way, the speediest understanding and ability to put into practice the updated requirements of the international standard ISO 19011:2018 [3] will allow organizations of both state and private ownership at a higher level to provide adjust and improve the productivity of the implemented MS. For their work efficiency optimization the institutions will be able to respond on risks and opportunities more fully. Also they will be able to integrate simultaneous audits of different MS performance, expanding the range of clients and partners, taking more account of their interests and enhancing their business reputation. One of the important areas, where the analyzed standard [3] can be implemented, is the assuring the quality of education, including higher tuition.

Conclusion. The international standard ISO 19011:2018, that provides guidance and guidelines for auditing different MS of organizations in various fields of activity, is characterized by high availability and suppleness of usage for audit teams, their representatives and other stakeholders. First of all, the document is designed for audits that are held by representatives of first

(internal) and second (suppliers, customers and other interested parties) sides, but also may be useful for third parties (during certification). The main innovations of this normative act's edition are updating and alignment with other ISO standards terminology, usage of risk-oriented approach and improvement of the block diagram of audit program management, extension of requirements, regarding auditors' competencies, changes in annexes. These changes are intended to ensure higher efficiency of this activity type, simplification of carrying out procedure, expenses reduction, increasing of compatibility with other standards on MS by integrating the content into the High-level structure. The researched innovations of the normative act should have a positive impact on the market advantages from the audits of the first and second parties.

The prospect for further researches is the analysis of the international standard ISO 19011:2018 implementation status for audits of the first and second parties, including educational establishments, in Ukraine and the world, the state of bringing the national regulatory framework in compliance with the recently adopted international document.

REFERENCES

1. Antjushko, D. (2016). Implementacija polozhen' standartu ISO 9001:2015 dlja vdoskonalennja system upravlinnja jakistju [Implementation of the provisions of the standard ISO 9001: 2015 to improve quality management systems]. *Mizhnarodnyj naukovo-praktychnyj zhurnal "Tovary i rynky" – International scientific and practical journal "Commodities and Markets"*, 1 (21), 71-79 [in Ukrainian].
2. Antjushko, D., & Pavljuchenko, Ju. (2018). Audyt pest-menedzhmentu v systemi upravlinnja bezpechnistju [Pest management audit in security management system]. *Mizhnarodnyj naukovo-praktychnyj zhurnal "Tovary i rynky" – International scientific and practical journal "Commodities and Markets"*, 4 (28), 57-64. DOI: [https://doi.org/10.31617/tr.knute.2018\(28\)05](https://doi.org/10.31617/tr.knute.2018(28)05) [in Ukrainian].
3. Guidelines for auditing management systems. *ISO 19011:2018*. Retrieved from <https://www.iso.org/obp/ui/#iso:std:iso:19011:ed-3:v1:en> [in English].
4. Naden, C. Auditing standard for management system standards now updated. Retrieved from <https://www.iso.org/news/ref2304.html> [in English].
5. Coleman, Lance B. Quality progress. Game, set, march. *ISO 19011:2018*. Retrieved from <http://asq.org/quality-progress/2018/07/standard-issues/game-set-match.html> [in English].
6. Robitaille, D. E. (2004). *Root Cause Analysis: Basic Tools and Techniques*. NY: Paton Press [in English].
7. Robitaille, D. (2015). *Document Control: A Simple Guide to Managing Documentation: 3rd edition*. NY: Paton Press [in English].
8. Dobb, F. (2018). *The ISO 9001, 14001 or 18001(45001) certification audit: Make it painless Eliminate auditors' invalid nonconformities: 2nd edition*. London: Brodsworth & Woods [in English].
9. Brennan, J. Talking about quality: the changing uses and impact of quality assurance. Retrieved from <http://www.qaa.ac.uk/en/Publications/Documents/impact-of-quality-assurance.pdf> [in English].
10. Kuceja, A. Quality management system audit: a critical exploration of practice. Retrieved from <http://eprints.glos.ac.uk/4949/1/Thesis%20-%20Kuceja.pdf> [in English].

11. Kartashova, O. Vnutrennyj audyt system upravleniya [Internal audit of management systems]. Retrieved from <https://elib.gstu.by/bitstream/handle/220612/11142/%20%20.pdf> [in Russian].
12. Kalita, P. Ja. (2006). Sistemy kachestva i mezhdunarodnye standarty ISO serii 9000 [Quality systems and international standards ISO 9000 series]. Kiev: Ukrainskaja asociacija kachestva [in Russian].
13. Momot, A. I. (2010). Audit menedzhment kachestva i jelementy sistemy kachestva [Audit quality management and quality system elements]. Doneck: Nord-Press [in Russian].
14. Veryga, Ju. A. Provedennja vnutrishn'ogo audytu na pidpryjemstvi: procesnyj aspekt [Conducting internal audit at the enterprise: process aspect]. Retrieved from <http://dspace.kntu.kr.ua/jspui/bitstream/123456789/513/1/30.pdf> [in Ukrainian].
15. Guidelines for auditing management systems. *ISO 19011:2011*. Retrieved from <http://qic-eg.com/wp-content/uploads/2015/08/BS-EN-ISO-19011-2011.pdf> [in English].
16. Consolidated ISO Supplement – Procedures Specific to ISO. *ISO/IEC Directives. Part 1*. Retrieved from <https://www.iso.org/sites/directives/current/consolidated/index.xhtml> [in English].
17. Conformity assessment – Requirements for bodies providing audit and certification of management systems. *ISO/IEC 17021-1. Part 1. Requirements*. Retrieved from <https://www.iso.org/standard/61651.html> [in English].
18. Online Browsing Platform. *ISO 9000:2015*. Retrieved from <https://www.iso.org/obp/ui/#iso:std:iso:9000:ed-4:v1:en> [in English].

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Притульська Н., Антюшко Д., Гусаревич Н. Міжнародний стандарт ISO 19011:2018: перспективи імплементації.

Постановка проблеми. Забезпечення належних умов для ведення добросовісної ділової активності, що буде максимально відповідати очікуванням клієнтів і демонструвати довгострокові плани щодо роботи на ринку, ведення бізнесу, обумовлює необхідність впровадження та використання організаціями різноманітних систем управління. Їх застосування передбачає забезпечення належного рівня функціонування, впевненості та довіри зацікавлених сторін за допомогою проведення аудитів. Основним загально визнаним на світовому рівні документом у цій сфері є міжнародний стандарт *ISO 19011*, нова редакція якого набула чинності в липні 2018 р. Для забезпечення належного рівня функціонування систем управління організацій актуальним є детальний аналіз змісту та специфіки положень і застосування нової версії нормативного документа.

Мета роботи – детальний аналіз новацій, специфіки положень й особливостей імплементації нової редакції стандарту *ISO 19011* "Настанови щодо здійснення аудитів систем управління", зокрема, з метою окреслення перспектив подальшого застосування.

Матеріали та методи. Як методологічну базу застосовано положення міжнародного стандарту *ISO 19011* "Настанови щодо здійснення аудитів систем управління" редакцій 2011 та 2018 рр., методи порівняння й узагальнення, наукового вивчення, аналізу та синтезу, індукції та дедукції, дослідницької систематизації методичних аспектів планування і реалізації аудитів систем управління.

Результати дослідження. Для встановлення перспектив використання нової редакції міжнародного стандарту *ISO 19011* першочерговою є необхідність аналізу його змін проти попередньої. Міжнародний стандарт *ISO 19011:2018* містить настанови для реалізації аудитів систем управління організацій різних масштабів і сфер діяльності. Він складається з передмови, вступу, 7 розділів, додатку і бібліографії

з 4 джерел. Особливостями нової версії нормативного акта є доповнення змісту принципом ризик-орієнтованого підходу та пов'язаними з ним особливостями проведення аудитів, застосування видозміненої блок-схеми управління програмою аудиту. Також розширено вимоги до компетентності аудиторів.

Встановлено, що розуміння та здатність до практичної імплементації оновлених вимог міжнародного стандарту *ISO 19011:2018* дасть змогу організаціям як державної, так і приватної форм власності на більш високому рівні забезпечувати, коригувати та підвищувати продуктивність роботи впроваджених систем управління. Установи зможуть більш повно реагувати на ризики та можливості з метою оптимізації роботи, поєднувати одночасні перевірки результативності функціонування різних систем управління, розширювати коло клієнтів і партнерів, дієвіше враховувати їхні інтереси та підвищувати ділову репутацію.

Висновки. Міжнародний стандарт *ISO 19011:2018* характеризується високою доступністю та зручністю використання для аудиторських груп, їхніх представників та інших зацікавлених сторін.

Основними новаціями цієї редакції нормативного акта є актуалізація та приведення у відповідність до інших стандартів *ISO* термінології, використання ризик-орієнтованого підходу, удосконалення блок-схеми управління програмою аудиту, розширення вимог, що стосуються компетентності аудиторів, змін у додатках. Ці зміни покликані забезпечити вищу ефективність цього виду діяльності, спрощення процедури проведення та скорочення витрат, підвищення сумісності з іншими стандартами на СУ.

Перспективою подальших досліджень є аналіз стану застосування міжнародного стандарту *ISO 19011:2018* при аудитах першою і другою сторонами в Україні та світі, а також стану приведення вітчизняної нормативної бази у відповідність до нього.

Ключові слова: аудит, стандарт *ISO 19011:2018*, перспективи практичного використання, програма проведення, компетентність аудиторів, критерії, блок-схема управління, ризик-орієнтований підхід.