SILESIAN UNIVERSITY OF TECHNOLOGY PUBLISHING HOUSE

SCIENTIFIC PAPERS OF SILESIAN UNIVERSITY OF TECHNOLOGY 2025
ORGANIZATION AND MANAGEMENT SERIES NO. 241

PRINCE2 RISK MANAGEMENT IN FDM PROTOTYPING MANUFACTURING: CASE STUDY

Dagmara MICHTA

Department of Quality Management and Intellectual Property, Kielce University of Technology;
dmichta@tu.kielce.pl, ORCID: 0000-0002-5734-0394

Purpose: The aim of this study is to identify, assess, and classify key risks that arise at various stages of prototype development—planning, implementation, and testing—when using additive manufacturing techniques. It was determined, how structured project management practices, implemented in accordance with the PRINCE2 methodology, can enhance the predictability, quality, and efficiency of rapid prototyping processes. By analysing the technological, organizational, and operational risks, the study also explores how risk mitigation strategies can support decision-making and improve overall project outcomes.

Design/methodology/approach: The study employs a case-study approach supported by qualitative analysis of risk management procedures within the PRINCE2 framework. Particular emphasis is placed on identifying uncertainties specific to 3D printing with FDM technology, such as material performance, parameter selection, equipment limitations, and iteration-related delays. A full risk register was developed, alongside risk response plans and periodic reviews, demonstrating how PRINCE2 tools can be directly applied to a rapid prototyping environment.

Findings: The findings show that the structured PRINCE2 approach enhances control over both technological and organizational uncertainty. The method enables more effective planning of printing processes, improves communication between project stakeholders, and supports early identification of critical risks. As a result, organizations can achieve shorter project cycles, reduced costs, and higher-quality prototype outputs. The analysis of the printed stabilizer also revealed five significant opportunities—both realized and potential—related for example to print-time optimization, pre-print quality improvement or the prospective commercialization of medical-grade prints.

Research implications: During the risk analysis of the printed prototype, five opportunities were identified that have already occurred and those that are likely to occur if the concept of further research is accepted, and which will have a significant impact on obtaining/increasing profits: optimization of parameters to reduce printing time, the possibility of improving the quality of the prototype before printing, reduction of filament costs, acquisition of additional research data, the possibility of automating the preparation of the prototype model, commercialization of medical prints.

Practical implications: The presented case confirms that PRINCE2 risk management mechanisms—when embedded into rapid prototyping processes—can be effectively used by organisations of varying scale to improve predictability, efficiency, and product value.

http://dx.doi.org/10.29119/1641-3466.2025.241.17

Originality/value: The article emphasizes the importance of systematic risk management in innovative additive manufacturing environments and offers practical recommendations for enhancing project management practices in FDM-based prototyping.

Keywords: risk management, 3D printing, PRINCE2, medical prototype.

Category of the paper: Research paper / Case study.

1. Introduction

In 1901, A.H. Willet stated that risk is an objective phenomenon indirectly related to uncertainty. This definition is somewhat tautological and proves to be imprecise today, because uncertainty is not only ambiguous, but also difficult to define. F.H. Knight published his concept of uncertainty in 1921, dividing it into measurable and immeasurable. He called the former risk and the latter uncertainty in the strict sense. This division is still considered appropriate today.

In 1966, two further definitions of insurance risk were published in the United States. These were (Chong, Brown, 2001):

- risk defined as uncertainty about the occurrence of a specific event in conditions where there are two or more possibilities,
- in the second definition, insurance risk was understood as an insured person or object.

The above definitions became the subject of discussion, on the basis of which four fundamental conclusions were identified regarding the nature of risk:

1. risk is not a homogeneous phenomenon, which makes it impossible to provide a single universal and unambiguous definition of risk,
2. risk occurs in at least two forms – objective and subjective,
3. risk can be studied from different perspectives, as danger, gambling, uncertainty, or the probability of a specific phenomenon or set of phenomena occurring,
4. finally, risk is something variable and periodic, i.e. it is a variable process rather than a stable state of the environment.

The motivation for conducting a risk analysis is primarily the consequences that may occur when implementing a risky project or undertaking. An undertaking is any activity or task that can be undertaken. In a developed society, business activity in the general sense deserves special mention, because functioning in this space involves the continuous implementation of successive projects, which make up the process of project implementation. The responsibility of those who implement them, in turn, forces them to seek ever better methods that ensure not so much better results in the implementation of these projects, but above all the best possible predictability of the effects. Therefore, after defining the project, it is crucial to analyze the possible consequences of its implementation as deviations of the results from a certain assumed model.

Contemporary companies implementing small-batch, single-unit, or individual projects operate in conditions of increased uncertainty resulting from both the uniqueness of orders and the high variability of customer requirements. Such projects are characterized by limited process repeatability, which naturally hinders the use of standard planning and control methods. As a result, the importance of effective risk management as a tool to support decision-making, improve the predictability of results, and minimize the likelihood of costly deviations is growing (Dudziak, 2014).

One of the main applications of 3D printing in medicine, which is personalized orthopedic devices, belongs to this type of project. 3D modeling allows for understanding the individual conditions of the patient and adapting the treatment strategy to the specific case. The ability to quickly create prototypes leads to immediate testing and refinement of new medical solutions, which accelerates the research and development process. In addition, printed models can also be used for educational purposes, enabling students and young doctors to learn through practical exercises.

The literature on the subject emphasizes that individual projects generate specific categories of risk, including technological, design, scheduling, and communication risks, resulting from the need for close cooperation between many specialists and the adaptation of solutions to the individual expectations of recipients. Thus, classic approaches to risk management need to be adapted to the context of low-volume projects, where flexibility, iterative planning, and rapid identification of deviations play a key role (Jajuga, 2005; Jedynak et al., 1977; Kaczmarek, 2010).

The article presents the practical application of the PRINCE2 (Projects IN Controlled Environments) methodology in the field of risk management in a project to develop an individual prototype of a thumb stabilizer printed on a 3D printer. The structure of risk management and the main strategies for responding to risk are discussed, and a sample risk register is created. The aim of this article is to present the specifics of risk management according to the PRINCE2 method, taking into account small-batch projects based on 3D printing. The presented considerations provide valuable guidance for companies, enabling them to effectively reduce uncertainty in such projects, as well as a basis for further research on improving risk management processes in highly customized project environments.

2. Risk management methodology according to PRINCE2

Risk management, as defined in ISO 31000 "Risk management – Principles and guidelines", can be defined as coordinated activities aimed at directing and controlling a project in terms of risk. Project risk management is not optional: it is essential for effective project management. It should be applied to all projects and included in project plans and operational documents, becoming an integral part of every aspect of project management (ISO 31000, 2018; Pacana, 2017).

The risk management process according to PRINCE2

The project risk management addresses the uncertainty associated with project estimates and assumptions. In the early stages of a project, the level of risk exposure is highest, but information about project risk is minimal. PRINCE2 is based on seven principles, compliance with which ensures that the project is conducted in an orderly and controlled manner from the very beginning. One of the fundamental topics according to this methodology is risk management.

Risk management in PRINCE2 consists of the following stages (Ligarski, 2014; Wolniak, 2010):

- Risk identification – recognizing potential threats and opportunities that may affect the project's objectives. Identified risks are recorded in *the Risk Register*, forming the basis for further analysis. Various techniques are used in the process, such as brainstorming, document analysis, review of historical project data, and expert consultation.
- Risk assessment – determining the likelihood of occurrence and the potential impact of risks on the project. The purpose of this stage is to understand which risks require active measures and which can remain within the project tolerance.
- Risk response planning – selecting appropriate actions to minimize negative effects or take advantage of emerging opportunities.
- Implementing the risk management plan – carrying out the planned actions and monitoring their effectiveness.
- Risk monitoring and control – continuously updating the risk register and reporting on the status of risks at each stage of the project. PRINCE2 emphasizes clear and regular exchange of information on risks through periodic reports, stage reviews, and consultations with stakeholders.

Adapting PRINCE2 to small projects

Single-series projects with a short life cycle, such as the development of a prototype of an individual thumb stabilizer made using 3D printing technology, require the adaptation of the PRINCE2 methodology to the specific nature of small project teams and a limited scope of activities. PRINCE2 emphasizes the principle of tailoring to the project situation, which assumes the possibility of consciously simplifying processes, documentation, and tools without sacrificing their key functions. In practice, this means reducing formal procedures in favor of lightweight, iterative mechanisms that allow for quick responses to changes and emerging risks (Wróblewski, 2015).

Table 1.

Comparison of Full PRINCE2 Methodology and Tailored PRINCE2 for prototype development projects (e.g., a 3D-Printed Thumb Stabilizer)

PRINCE2 Area / Element	Full PRINCE2 Methodology	Tailored PRINCE2 for prototype development projects
Project scope	Clearly defined and formally documented; stable requirements approved at initiation	Broad, flexible scope allowing iterative adjustments as the prototype evolves
Roles and responsibilities	Multi-layer structure (Project Board, Project Manager, Team Manager, Delivery Team)	Combined roles; often one person performs management and technical tasks; simplified decision paths
Project documentation	Extensive documentation including PID, Quality Management Strategy, Risk Management Strategy, Communication Plan	Minimal documentation: short project brief, basic product specification, simplified risk register
Risk management	Formal risk register, structured analysis, periodic risk reviews at stage boundaries	Light, operational risk register; frequent short reviews; immediate response to emerging risks
Project stages (Stage management)	Project divided into multiple controlled stages supervised by the Project Board	Typically one or two stages: design/modeling and 3D printing + functional testing
Change control	Formal change management with impact assessment and authorization by the Project Board	Dynamic, on-the-spot changes; documented through brief notes or updated CAD versions
Product quality	Quality requirements defined in a formal Quality Plan; acceptance testing following standards	Quality assessed through rapid functional and visual checks; iterative refinements during prototyping
Schedule and progress control	Detailed schedules (e.g., Gantt charts), formal progress reporting, structured checkpoints	Short, flexible timelines reflecting the experimental and iterative nature of prototyping; daily or continuous monitoring
Communication management	Formal communication channels, regular reports, structured meetings	Direct, fast, informal communication; reporting limited to essential milestones
Project objectives	Delivery of a final product meeting predefined technical and functional criteria	Production of a functional prototype meeting minimum requirements for testing or validation
Stakeholder engagement	Regular interactions with multiple stakeholders; formal review sessions	Collaboration focused on one or two key stakeholders (e.g., user, designer, technician)
Benefits management	Formal Benefits Management Plan and post-project benefit review	No formal plan; benefits assessed through the prototype’s practical usefulness and test outcomes

Source: own work based on: Kaczmarek, 2010; Wróblewski, 2015.

In the case of prototype projects, it is important to reduce formal artifacts—such as extensive quality plans, detailed role descriptions, or multi-stage approvals—in favor of agile, operational documentation, e.g., in the form of a shortened risk register or a checklist covering key technological, organizational, and quality risks (Table 1). Regular, brief risk reviews conducted during the preparation of the CAD model, configuration of print parameters, or physical tests enable ongoing monitoring of significant factors affecting the project outcome, while minimizing the time required (Budzik, et al., 2022).

This approach is fully consistent with the logic of PRINCE2, which emphasizes the need to deliver a product in a controlled but not overly formalized manner. Simplified tools allow for transparency in the decision-making process, ensure communication between stakeholders, and maintain basic mechanisms for assessing and responding to risks without burdening the project with unnecessary administration. As a result, even small individual projects – such as the production of an orthopedic stabilizer prototype using the FDM method – can benefit from the advantages of the PRINCE2 structural approach, while maintaining the efficiency typical of experimental and iterative projects (Brahma et al., 2025)

3. 3D printed prototype project

The study involved designing and printing a functional prototype of a personalized thumb stabilizer for the right hand using an FDM 3D printer. The team consisted of two people: the author of the article, acting as a CAD designer, printer operator, and project manager, and an assistant, who was a potential customer. The project was scheduled to take four weeks, and the budget was limited to the funds allocated by the Kielce University of Technology for research activities at the Faculty of Management and Computer Modeling in the Department of Quality Management and Intellectual Property, of which the author is a member.

During the project, the following stages were planned:

- development of a 3D model,
- preparation of files for printing,
- performing material tests and calibrating the printer,
- production of a prototype,
- quality assessment and possible corrections.

A Shining3D EinScan-SP V2 rotary scanner was used to develop the 3D model, which was used to take a three-dimensional image of the customer's hand. Next, using SolidWorks software, a customized stabilizer model was designed (Fig. 1). After converting the stl file to g-code format in PrusaSlicer, the printing and 3D printer parameters were determined, in this case Prusa i3 MK3. The most important settings are (Kristiawan, 2021; Ngo, 2018):

- infill: 100%,
- head temperature: 200°C,
- table temperature: 60°C,

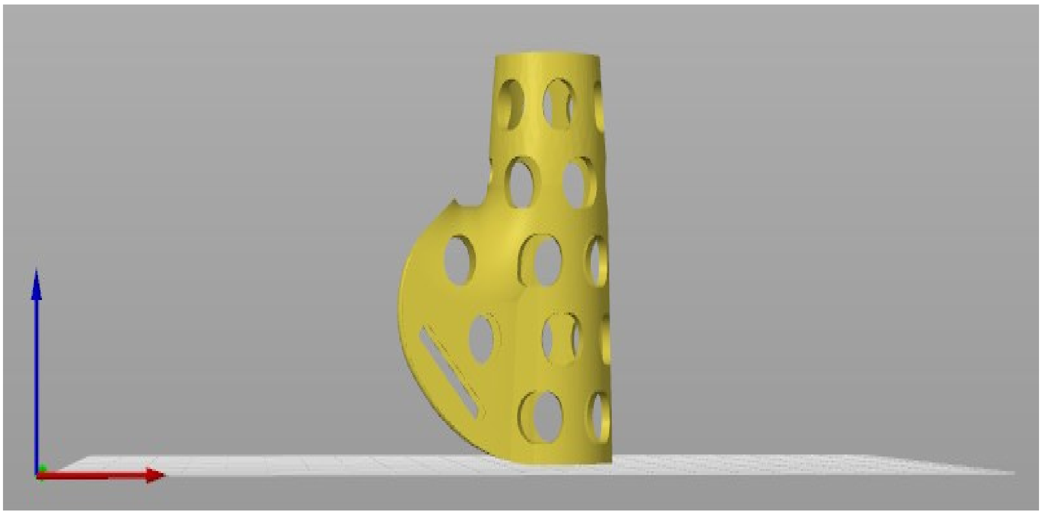

Figure 1. Thumb stabilizer model placed on the virtual printer table.

Source: own work.

Due to the fact that the stabilizer will be in direct contact with the skin, it was decided to use PLActiv filament to print the actual model, which is a combination of high-quality PLA with a patented and scientifically proven non-copper additive with antibacterial properties. The prototype used to validate the geometric parameters was made of standard PLA filament, which is significantly cheaper than PLActiv filament.

Figure 2. Printed stabilizer on the client's thumb.

Source: own work.

The prototype printing process took 1 hour and 16 minutes and ran smoothly. 4.14 meters of material from a 330-meter spool were used. Since the stabilizer test showed that no modifications were necessary, printing of the actual model began immediately after changing the filament. No difference was noticed between the printing processes. The printed stabilizer fit well and completely prevented thumb movement (Fig. 2), and thanks to the additional security provided by a non-elastic fabric strap, it will provide solid support.

4. Implementation of risk management in the project

Table 2.
Register and analysis of risks that may occur during the project

ID	Risk	Causes /sources	Possible consequences	Probability	Impact	Response strategy	Actions	Responsibility
R 01	3D printer failure	Mechanical damage, motor jam	production interruption, delay	3	3	Reduction	Arranging for a backup device or access to another printer	PM
R 02	Power outages	Network failure	Design interruption, production interruption, delay	1	3	Avoidance	Establishment of a backup power source	PM
R 03	Errors in the STL file or CAD model	Insufficient verification, incorrect scaling	print deformations, incorrect dimensions	2	3	Reduction	test print, model validation, slicer simulations	D
R 04	Lack of material or unsuitable filament	poor inventory planning, delivery problems	printing interruption	2	2	Avoidance	advance orders with buffer, alternative suppliers	PM
R 05	Problems with layer adhesion — peeling from the table	uneven heating table, contamination, lack of primer	deformation, print loss	3	2	Reduction	testing adhesives, adjusting temperatures, using raft/brim	PO
R 06	Delays in delivery of parts for assembly	incorrect orders, supplier fails to meet deadlines	delays in assembly and project completion	2	2	Transfer /Reduction	contract with deadline guarantee, selection of local suppliers	PM
R 07	Inappropriate design ergonomics	lack of end-user consultation	user dissatisfaction, need for modification	2	3	Reduction	early user consultation, partial prototypes	D
R 08	Overheating or print deformation	improper cooling, excessive speed	Surface defects, layers separating	2	2	Reduction	use of fans, cooling tests, speed reduction	PO
R 09	Damage to prototype during testing	operator errors, vibrations	need to repair or replace the printer	1	3	Acceptance / Reduction	compliance with procedures, offline testing, insurance	PO
R 10	Absence of a key team member	illness, other commitments	Delays in tasks	1	3	Reduction	documentation, substitution plan, cross-training	PM

Note: PM – project manager, D – designer, PO – printer operator.

Source: own work.

Ten key risks were identified at the planning stage (Table 2), including technical (e.g., printer failure), design (errors in the CAD model), logistical (lack of materials), and organizational risks. Each risk was assigned a probability and impact assessment, and a response strategy (e.g., reduction, avoidance) was developed.

For each defined risk, the response priority was calculated using the formula (Eq. 1):

$$\text{Priority} = P \times W \tag{1}$$

where:
probability (P): scale 1-3,
impact (I): scale 1-3.

The highest probability of occurrence combined with a high impact on the project's success was recorded for risk no. 01. A 3D printer failure—given that its correct operation is fundamental to the execution of the printing process—was identified as the most critical risk, as its occurrence would prevent the project from being carried out altogether. To mitigate this threat, appropriate actions were implemented, including obtaining permission to access an FDM 3D printer located at the Faculty of Mechatronics and Machine Design at the Kielce University of Technology, ensuring process continuity in the event of equipment malfunction.

A slightly lower response priority was assigned to risks no. 03, 05, and 07. Notably, risks 03 and 07 are associated with the same stage of project execution, as both directly relate to the design of the product. This stage is therefore crucial for the subsequent success of the project, as any design inaccuracies may propagate into later phases and significantly affect final quality. To address these risks, the stabilizer was printed early in the process in the form of a prototype using basic PLA filament. This preliminary print allowed for verification of the model's geometry, early detection of design flaws, and informed adjustments before committing to production using the final material.

5. Summary

Thanks to the development of a detailed register of risks that may occur throughout the project and the effective risk management approach—including risk analysis and, consequently, the preventive printing of a stabilizer prototype using a cheaper equivalent of the final material (PLActiv)—the risk of dimensional incompatibility between the printout and the customer's hand structure was significantly minimized. This preventive strategy allowed to eliminate one of the most critical technical risks at an early project stage, ensuring higher confidence in the final prototype's performance.

In addition, preparing the project according to the PRINCE2 methodology encouraged the author to undertake proactive actions aimed at identifying market and technological opportunities. As a result, several opportunities were recognized that are highly likely to occur and can substantially increase profitability if a strategy is implemented to further capitalize on the knowledge gained during the research. These opportunities include optimization of printing parameters to reduce production time, the possibility of improving prototype quality before final manufacturing, the use of lower-cost filament alternatives, acquisition of additional research data, automation of prototype model preparation, and commercialization of the final products derived from the developed methodology.

Collectively, these opportunities highlight the broader potential of integrating structured project management with additive manufacturing technologies. They demonstrate not only the advantages of systematic risk management but also the capacity of PRINCE2 to support entrepreneurial thinking and continuous improvement in rapid prototyping processes. Ultimately, the findings suggest that the combined use of disciplined project governance and iterative 3D printing workflows can significantly enhance both the technical outcomes and the business viability of future development projects.

6. Conclusions

3D printing (additive manufacturing) has revolutionized the prototyping process, enabling the rapid production of complex geometries without the need for molds or complex tools. Its use is growing in the industrial, medical, aerospace, education, and research sectors. Despite its popularity, this technology still faces numerous challenges: material limitations, printing precision, mechanical properties of layers, adhesion to the working platform, thermal stability, and many others.

Projects involving new technologies and prototyping carry a high degree of uncertainty. Although widely available, 3D printing requires experience in technical parameters, materials, and spatial design. Therefore, it is crucial to implement an effective risk management system that allows you to identify and mitigate the impact of undesirable events, as well as take advantage of emerging opportunities.

Technology projects, even smaller ones, are characterized by significant uncertainty. Technical problems, design errors, delivery delays, or limited budgets can significantly affect the success of a project. In such an environment, a formal approach to risk is crucial—identifying, controlling, and monitoring potential threats and opportunities. The PRINCE2 methodology, although often used in large organizations, can be effectively adapted to smaller-scale projects, providing a framework for logical, predictable risk management. Its versatility allows the approach to be adapted to the characteristics of both large corporate ventures and smaller technical projects. The application of the PRINCE2 methodology has made it possible to systematize the approach to risks in the project. Formalization of the risk management process:

- increased the predictability of project implementation,
- enabled faster response to technical problems,
- improved the quality of communication between the designer and the potential customer.

The risk analysis conducted in this single-series project provides a valuable knowledge base for future initiatives of a similar nature and opens the door to further research in several important directions. One promising area is the comparison of the PRINCE2 methodology with agile approaches, such as Agile or Scrum, specifically in the context of risk management for technical and prototyping projects. Such a comparison can help determine which methodology is more effective in mitigating uncertainties, ensuring that project objectives are met, and adapting to rapidly changing technological or organizational conditions. Another critical direction is assessing the impact of different risk strategies on both the cost and timeline of prototyping projects. Understanding how various approaches influence resource allocation, project duration, and potential bottlenecks allows organizations to optimize processes, reduce delays, and better anticipate challenges, ultimately improving overall project efficiency. Additionally, empirical studies comparing the effectiveness of PRINCE2 and PRINCE2 Lite in projects with similar characteristics could provide practical insights into whether a simplified version of the methodology can deliver comparable benefits in smaller-scale or less complex initiatives.

By pursuing these research directions, future studies can build on the lessons learned from this project, improving project management practices and supporting the more effective implementation of innovative additive manufacturing solutions. Ultimately, these investigations have the potential to contribute not only to the theoretical understanding of risk management methodologies but also to provide actionable guidance for practitioners seeking to integrate structured and iterative approaches into prototyping processes, enhancing both quality and efficiency in real-world applications.

References

1. Brahma, A., Hajali, T., Mallalieu, A., Ola, I., (2025). A risk analysis method for implementation of additive manufacturing. *Journal of Engineering Design*, pp. 1-28.
2. Budzik, G., Woźniak, J., Przeszłowski, Ł. (2022). *Druk 3D jako element przemysłu przyszłości. Analiza rynku i tendencje rozwoju.* Rzeszów: Oficyna Wydawnicza Politechniki Rzeszowskiej.
3. Chong, Y., Brown, E. (2001). *Zarządzanie Ryzykiem Projektu*. Kraków: Oficyna ekonomiczna.
4. Dudziak, A., Piekarski, W., Stoma, M. (2014). *Zarzadzanie produktywnością a ryzyko operacyjne w działalności polskich przedsiębiorstw.* Polskie Towarzystwo Zarządzania produkcją. Konferencje i Innowacje w Zarządzaniu i Inżynierii Produkcji, pp. 237-246.
5. Ficenes, M., Szymko, A. (2018). Wpływ gospodarki 4.0 na finanse przedsiębiorstwa. *Europa Regionum*, *34*, pp. 27-39.

6. ISO 31000:2018 – *Risk Management – Guidelines*. Geneva: International Organization for Standardization.
7. Jajuga, K. (2005). *Teoretyczne podstawy zarządzania ryzykiem.* Warszawa, PWN.
8. Jedynak, P., Szydło, S. (1977). *Zarządzanie ryzykiem.* Wrocław: Ossolineum.
9. Kaczmarek, T. (2010). *Zarządzanie ryzykiem. Ujęcie interdyscyplinarne.* Warszawa: Difin.
10. Kristiawan, R., Imaduddin, F., Ariawan, D., Sabino, U., Arifin, Z. (2021). A review on fused deposition modeling (FDM) 3D printing: Filament processing, materials, and printing parameters. *Open Engineering, 11.* Gliwice, pp. 639-649.
11. Ligarski, M. (2014). Diagnoza systemu zarządzania jakością w polskich organizacjach. *Problemy Jakości, 5.* Warszawa, pp. 14-22.
12. *Managing Successful Projects with PRINCE2. TSO* (2017). London: AXELOS.
13. Ministerstwo Finansów (2011). *Zarządzanie ryzykiem. Informacje ogólne.* Retrieved from: www.mf.gov.pl
14. Ngo, T.D., Kashani, A., Imbalzano, G., Nguyen, K.T.Q., Hui, D. (2018). Additive manufacturing (3D printing): a review of materials, methods, applications and challenges. *Compos. Part B Eng. Elsevier, 143.* Amsterdam, pp. 172-196.
15. Pacana, A. (2014). *Synteza i doskonalenie wdrażania systemów zarządzania jakością zgodnych z ISO 9001 w małych i średnich organizacjach.* Rzeszów: Oficyna Wydawnicza Politechniki Rzeszowskiej.
16. Pacana, A., Stadnicka, D. (2017). *Nowoczesne systemy zarządzania jakością zgodne z ISO 9001:2015*. Rzeszów: Wydawnictwo Politechniki Rzeszowskiej.
17. Prywata, M. *Zarządzanie ryzykiem w małych projektach*, www.web.gov.pl
18. Skrodzka, M., Cieślak, A., Łabowska, M.B., Detyna, J., Michalak, I. (2024). *Additive bioproduction: an overview*. Additive Manufacturing Materials and Technology. Amsterdam: Elsevier, pp. 291-316.
19. Wolniak, R., Skotnicka, B. (2010). *Metody i narzędzia zarządzania jakością: teoria i praktyka*. Gliwice: Wydawnictwo Politechniki Śląskiej.
20. Wróblewski, D. (ed.) (2015). *Zarządzanie ryzykiem. Przegląd wybranych metodyk.* Józefów: CNBOP-PIB.
21. Wysocki, R., McGary, R. (2005). *Efektywne zarządzanie projektami.* Gliwice: Helion One Press.