



INTERREG ATLANTIC AREA 2021-2027

Methodology for risk-based management verifications in 2021-2027

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1 Introduction

The regulatory framework on management verifications in the 2021-2027 programming period aims to guarantee a proper balance between the efficient implementation of the programmes and the associated administrative costs and burdens.

Following article 74 of the Regulation (EU) 2021/1060 (CPR), *“management verifications shall be risk-based and proportionate to the risks identified ex ante and in writing.”*

A risk-based management verification methodology is needed to support this approach. It must encompass a systematic process to identify and evaluate potential risks to the Interreg Atlantic Area Programme (Interreg AA), supporting the mitigation of risks and ensuring the success of our projects. The managing authority (MA) will consider the annual revisions of the methodology based on the results of the management verifications and audit findings, if relevant.

Adequate management verifications procedures are a key requirement (KR) of a programme's management and control system. In addition, as described in article 69, Annex XI of the CPR, they are a section of the audit authority's (AA) system audit (KR 4, management verifications).

Management verifications include administrative verifications on payment claims made by beneficiaries and on-the-spot verifications of operations. Verifications must be carried out before submission of the accounts in line with article 98 of the CPR.

For Interreg programmes, special conditions regarding management and control and financial management are in place, and management verifications can be carried out by controllers appointed by each Member State (MS). Therefore, to organise risk-based management verifications in the Interreg AA, the MA delegates the responsibility for developing the methodology to the MS, following article 46(3) of the Regulation (EU) 2021/1059 (Interreg Regulation). The MA must ensure the equal treatment of beneficiaries by requiring that variations in the methodologies to management verifications between the MS must be duly justified. The MA develops minimum requirements guidelines for risk-based management verifications that the controllers shall consider in each MS.

Management verifications, aiming to verify the compliance with legality and regularity, the principle of sound financial management, and the correct implementation of the operations, shall consider separate and independent functions for the selection of operations on the one hand and management verifications on the other hand, as much as possible. This procedure contributes significantly to objective and adequate verifications.

A well-defined risk analysis methodology is vital for guaranteeing the efficient implementation of the Interreg AA. The methodology proposed by the MA is presented below and aims to identify potential risks, assess their impact, prioritize them, and develop efficient strategies to mitigate them.

The methodology and the procedures for the risk-based management verifications are part of the Interreg AA management and control system description. With this approach, we expect the Programme will be more efficiently implemented, targeting result-orientation.

2 The risk-based methodology

Controlling expenditures based on risk analysis requires identifying and prioritizing risks, estimating the cost of potential risk events, and then developing strategies to mitigate those risks.

Risk-based implies that controllers must focus their verifications on areas where the risk of material error is high based on the risk assessment. The control should be reduced in areas with a minimal risk of material misstatement. Since administrative and on-the-spot management verifications focus on risky features, not all projects, beneficiaries, payment claims, and items within the payment claims must be checked 100%.

As recommended in the Reflection Paper provided by the European Commission (EC) “*Risk based management verifications. Article 74 (2) CPR 2021-2027*” (hereafter “Reflection Paper”), the methodology of risk assessment encompasses the analysis of risk factors, identifying the conditions and determinants for regular revision. This periodic review must consider results from previous management verifications, outcomes associated with the work of control bodies such as the AA, the EC auditors, and the European Court of Auditors, and external determinants that may impact the implementation of operations, such as conflict of interests.

The National Authority (NA) may also decide to extend the verifications of the declarations of its beneficiaries taking into account the risks detected in the beneficiaries.

2.1 The risk assessment based on the historical data of the Interreg AA

As mentioned above, the risk-based management verification methodology starts with risk assessment, which encompasses identifying, assessing, and evaluating potential risks. The following steps are considered:

1. Identify the management procedures that need to be verified clearly: control verifications related to expenditures and the implementation of funded operations.
2. Identify the potential risks that may influence the Interreg AA implementation: to be done by revising historical data, performing risk assessments, and consulting with national and audit authorities.
3. Assess the risk level: evaluate the risk associated with each potential risk identified in step 2. A risk matrix, mapping the likelihood and impact of each risk, is produced.
4. Prioritize the risks: order potential risks based on their potential impact on the Interreg AA management. Risks with higher scores will be selected for further verification.
5. Develop and implement verification plans to validate the management verifications by reviewing documentation, creating checklists, and involving the national authorities (NA) since the selection of operations.
6. Monitor and review: observe and review the results of management verifications, including tracking progress, identifying trends, and revising the methodology as needed.

A well-designed risk-based management verification methodology will allow for mitigating risks in funding expenditures by identifying potential risks, assessing their impact on funding, and developing strategies to minimize or manage them. The method to reduce high-priority risks involves implementing further control, monitoring the effectiveness of the implemented management verifications, and adjusting them as needed. This approach will help ensure that the control of funding expenditures remains effective over time. Communication is also crucial in this

strategy by ensuring partners are kept informed of legal requirements. This interaction will help build trust and support during the implementation of projects. A proactive approach must be adopted to identify and manage risks.

Having identified management verifications done by controllers as the focus of the risk analysis, we move to step 2 to identify the potential risks, starting by revising the historical data of the Interreg AA. This analysis allows the detection of risk factors that have caused past irregularities and errors in the programme.

The MA considered the historical data of the Interreg AA 2014-2020, decomposed at several layers:¹

- beneficiary (e.g., entity type, number of partners in the project, previous experience);
- payment claim (e.g. timing of the request);
- budgetary categories within payment claims (e.g., specific cost category, public procurement expenditure);
- on-the-spot management verifications.

The historical data comprises data from the project monitoring (e.g., expenditures corrected at the level of the controllers and NA), findings from the audits on the operations, and data on financial corrections and irregularities. In the programming period 2014-2020, the Interreg AA supported thematic projects following the ‘traditional’ approach, involving, on average, nine partners. Therefore, there was no need to decompose the risk analysis by type of project.

The analysis of the programme data will allow to identify the most frequent irregularities, providing proxies to spot the risky areas.

The historical data was analysed considering two datasets: (i) cuts made by controllers (first and second levels) and (ii) irregularities identified by the Audit Authority. In addition, anomalies detected by the MA were also considered.

The **analysis of the first data set, cuts made by controllers**, conducted to the following conclusions:

- The budget lines with more errors detected correspond to, by decreasing order, **“staff costs” (43,7%)**, with an impact on administrative and office expenditures due to the existence of a simplified cost that corresponds to 15% of staff expenditures), **“external expertise and services” (26,2%)**, and **“equipment” (11,3%)**.
- Considering the relative importance of each entity type shows that the relative incidence of errors is **higher for “Organisations under international or transnational law”** (with a very small relative weight in the Programme). In **second** place appears **“Public Bodies”**. The incidence is **smaller for “Not-for-profit private organization”**, whereas **“Profit-making private organizations” are in an intermediate position**. The ranking cannot consider the relative importance in total errors since the comparison can only be made considering the total budget *per* entity type.
- Regarding the evolution of corrections, the incidence of errors was **higher in project payment claims related to the second year of the reporting period (4th payment claim**

¹ Also based on the document provided by Interact, “Guidance on the risk-based management verifications for 2021-2027 and HIT methodology”, November 2022, Version 2.

with **30,5%** of total corrections). The first payment claims usually present a low amount of expenditure which may explain this result.

- The analysis of the corrections done during on-the-spot verifications confirms that the riskiest budget line is “**staff costs**” (**37,7%**), with “**small infrastructure and works**” in the second place (**28,8%**) and “**external expertise and services**” in third (**13,3%**).

The **assessment of the second data set, irregularities identified by the Audit Authority**, conducted to the following conclusions:

- The budget lines with more errors detected correspond to, by decreasing order, “staff costs” (43,7%), with an impact on administrative and office expenditures due to the existence of a simplified cost that corresponds to 15% of staff expenditures), “external expertise and services” (26,2%), and “equipment” (11,3%).

Based on the above, the MA considers that, due to the associated risk, the **budget categories** listed below must be **100% controlled by first level controllers during the complete lifecycle of the project**:

- real staff costs;
- small infrastructure and works;
- equipment when the corresponding expenditure is equal to or higher than 2500 euros;
- all the expenditures associated with public procurement processes.

Concerning the last item, it is important to recall that, as highlighted in the Programme Manual, beneficiaries must respect the basic principles of public procurement (transparency, non-discrimination, and equal treatment, even if they are private entities since they are supported by EU funds, as stated in the Programme Manual.

The **relevance of control for staff costs** is enhanced because it is the **baseline budget category** used to **compute SCO for office and travel costs**.

In addition, the **experience of the controller must guide further verifications**, which shall be duly justified. **Results from previous audits and controls will also be considered** and may justify more verifications.

A final note for controllers is related to the need to check if controlled expenditures are within the budget categories as planned in the Project Approved Form of the project.

Assessment and selection of operations

According to article 22(4)(d) of Regulation 1059/2021, within the scope of selecting operations, the Monitoring Committee is responsible for “*verify[ing] that the beneficiary has the necessary financial resources and mechanisms to cover operation and maintenance costs for operations comprising investment in infrastructure or productive investment, so as to ensure their financial sustainability*”. This assurance must be before an approval decision. As the “Reflection Paper” emphasises, applicants must have the operational, technical, and administrative capacity to proceed with their proposals; otherwise, the risk may increase for later management verifications.

A risk-based approach must encompass a formal and systematic risk assessment at the level of the analysis and selection of operations. For this purpose, the analysis of applications must consider this capacity, explicitly highlighting the presence of considerable risks in the online assessment template available in the management and information IT system (*Sistema de Informação e Gestão Integrada, SIGI*).

At this stage, it is relevant to recall that subjectivity in risk assessment can occur, for example, when evaluators have distinct perceptions or interpretations of the risks involved due to differences in experience, expertise, intrinsic biases, *etc.*

To mitigate subjectivity at this level, evaluators shall consider the assessment criteria and this internal note as a baseline. The work as a team is essential to identify differences in perception or interpretation of risks and enhance a more comprehensive and accurate risk assessment.

The risk-based methodology and associated procedures will help ensure transparency and accountability and provide a basis for future risk assessment reviews.

National correspondents (NC) have full access to the data on applications in SIGI and, during the stage of analysis of the applications, shall inform the MA through the JS if partners located in their territories do not comply with the regulatory requirements. The NC must identify any potentially risky situations related to the received applications they know.

Potential risk factors must be considered during the stage of appraisal and selection of operations, both at the level of operations and beneficiaries. Other elements must be considered by project and financial managers during the follow-up of the implementation of the approved operations. The factors **only available during the implementation stage** are marked in **bold** (Table 1).

Table 1 – Potential risk elements at the stage of appraisal and selection of operations and implementation stage

Operations level	Beneficiary level
Substantial budget,	Type and legal status.
<p>The complexity of the budget,</p> <p><i>To check</i></p> <ul style="list-style-type: none"> • <i>The clarity of the project cost structure</i> • <i>Different cost categories, namely items that are supposed to be procured in line with applicable EU or national regulations (e.g., acquisition of machinery and equipment or significant services such as consulting, technical assistance, marketing, publicity, infrastructures)</i> • <i>Use of SCOs (the use of all options may increase risk due to the impact of an irregularity in the baseline real costs category)</i> • <i>Subcontracting and outsourcing costs</i> 	The risk level of potential conflicts of interest related to a certain type of beneficiary and the type of operation the beneficiary is implementing.

<ul style="list-style-type: none"> • <i>Salaries and labour costs since often represent a significant part of project costs.</i> • <i>Risk of state aids</i> 	
<p>Nature of the project.</p> <p>Only some tangible outputs, with a scarce connection between the resources allocated to the operation and outputs.</p> <p><i>To highlight if there is a potential risk that output cannot be adequately measured. Examples of intangible outputs are training, workshops, conferences, and publicity campaigns. Check outputs and related descriptions.</i></p> <p><i>Projects must provide evidence, for example, training records, attendance lists, reports, meetings, etc. Projects involving intellectual property, such as patents, trademarks, and copyrights.</i></p>	Number of projects implemented by the same Lead partner/partners.
On-the-spot visits not possible or delayed (e.g., COVID pandemic, other reasons)	Number of partners above the average in the project.
Started near the end of the programming period.	The capacity of the Lead partner to implement the operation, considering the experience in Interreg programmes.
Started before selection or are close to the conclusion.	Change of partners during the project implementation, in particular, the Lead partner.
ISO1 projects due to their strategic nature.	The beneficiary is experienced or newcomer.
Output indicators not reported until the operation has been completed.	Experience in project management and European projects of the Partner representatives
Duration higher than the average.	
Delays in the implementation.	
Instability at the level of the project manager in charge of the setting up and monitoring of the operation (changes due to labour links or other reasons).	
Number of project modifications above average.	
Conflict of interests.	

Source: based on the "Reflection Paper".

To identify risks at the beneficiary level, the MA may also refer to IT tools such as data mining tools (e.g., Arachne, if possible), and open data platforms under article 49(a) CPR (e.g., Kohesio).

2.2 Main measures to mitigate risks

The simplification at the level of the expenditures' reimbursement may reduce risks. First, the decrease of the number of options offered by the programme at this level, for example regarding staff costs, may contribute to reduce errors simply due to a better understanding of the associated procedures.

In line with the simplification and harmonisation efforts across the European Structural Funds, the programme should consider different mitigation measures to make programme procedures simpler and reduce the risk of errors as much as possible. A few examples of such mitigation measures are listed below:

- The MA and NA shall guide beneficiaries and controllers concerning calls and during the implementation of projects.
- Targeted training and informative sessions shall be offered to beneficiaries.
- Controllers combine administrative verification with on-the-spot checks.
- Development of templates that would facilitate the organization and validation of information (reports, staff Allocation, public Procurement, etc.)
- An annual event for controllers and financial managers to pass on information on the main difficulties and risks identified.

2.3 Management verifications of payment claims

Management verifications of payment claims include both administrative verifications and on-the-spot verifications. As mentioned, management verifications in the Interreg AA will be carried out by controllers appointed by each Member State (MS). Controllers must be aware of and apply the relevant legislation and the rules of the Programme. In line with these, verifications must check if the operation is in line with the Union's policies and horizontal principles: accessibility for people with disabilities, state aid, public procurement, sustainable development, non-discrimination, partnership and multi-level governance (transparency and equal treatment), promotion of equality between men and women, and environmental rules – the “Do No Significant Harm Principle” (DNHSP).

2.3.1 Administrative verifications

These verifications must consider the financial implementation of operations, being conducted within an adequate timeframe after the beneficiary submits a payment claim. According to article 74(1) (b) of the CPR, the beneficiary must receive the amount due in full and no later than 80 days from the date of submission of the payment claim by the beneficiary, subject to the availability of funds.

The detection of irregularities shall occur earlier, so it is possible to correct them before the AA draws the sample of operations to be audited. In this case, those flaws will not increase the total error rate to be computed by the AA and the EC. Therefore, the MA recommends that NA define early management verifications. The errors identified must be corrected, and the MA must evaluate if there are systematic impacts on operations, beneficiaries, measures, or the programme level.

As mentioned above, to mitigate risks and prevent errors, guidance to beneficiaries and controllers will be provided by the MA and NA, namely concerning calls and during the implementation of operations. This support will reinforce the third KR, “adequate information to beneficiaries”. The MA also provides targeted training and informative sessions to beneficiaries.

NA, responsible for management verifications, must ensure that verifications are carried out before the submission of the accounts. An indicative plan for each accounting year is highly recommended based on the following elements (based on the “Reflection Paper”):

- the findings of the risk assessment at the stage of selection of projects;
- The planning of the submission of the payment claims based on the (indicative) schedules for the project implementation and the related financial forecasts in the approved projects; and
- The number of days by which administrative verifications must be made to comply with the requirement on payment delays.

As pointed out, following the Interreg Regulation, the MA delegates the responsibility for developing the methodology to the MS and defines minimum requirements orientations for risk-based management verifications. MS must duly justify deviations in their procedures that the MA will analyse before accepting them to ensure similar treatment for all beneficiaries.

Selection of payment claims for administrative verifications

The MA developed a risk-based analysis to support selecting payment claims for administrative verifications, as explained in Section 2.1. The exercise was based on the historical data of the Interreg AA and allowed the identification of risky areas targeted in management verifications in the 2021-2027 programming period.

The first step for the selection of payment claims is considering the risks identified at the stage of selecting operations, as described in Section 2.2. The second step corresponds to the application of the requirements for control that resulted from the risk assessment exercise.

The **first task of the controller** should be to **revise the expenditure lists submitted by the beneficiary, which must detail all expenditure items claimed**. This **review is essential to understand the type and category of claimed expenditures**.

Controllers must consider in their administrative verifications the payment claims listed below:

- **First payment claim of each beneficiary** so that it is possible to assess potential risks associated with the specific project and/or the beneficiary;
- **All expenditures on real staff costs;**
- Equipment expenditures when the corresponding value is equal to or higher than 2500 euros;
- **All expenditures subject to public procurement** according to EU and national laws in all payment claims;
- Expenditures on **small infrastructure and works** (also to be controlled with on-the-spot verifications physically implemented and not in virtual mode);
- Payment claims for projects for which potential risks were identified during the selection stage;

- Any payment claim that corresponds to **50% or more of the approved budget** for the beneficiary;
- **Final payment claim of each beneficiary**, since in case of errors, it will be easy to recover any undue payment.

In case irregularities are identified in one verified item, the controller must extend the control to all the expenditure covered by the payment claim.

After accommodating the requirements listed above, where controllers choose to select a sample for additional checks (*e.g.*, in case of risk mitigation), they should consider the following:

- a) the sample verification option can only be taken if the payment claim contains more than 30 expenditure documents for the categories not subject to 100% verification.;
- b) the sample should be random and have a minimum of 30 documents and a minimum volume of declared expenses whose percentage should be representative;
- c) where systemic errors are identified, the sample size shall be increased to identify the error and quantify its overall impact.

The **controller, based on the experience and lessons learned**, may consider that **certain expenditures items have a higher intrinsic risk, are unusual or give rise to suspicion of fraud**. In these cases, **even if expenditures are not in the list above, they must 100% verified**.

Where materially relevant random errors ($\geq 2\%$) are identified, MA may choose to check all the expenditures included in the payment claim, extend the sample following EC guidance on sampling.

Suppose the random sample does not mitigate all risk factors identified in the risk assessment carried out by the MA. In that case, it should be complemented by a sample of transactions selected, considering risk factors (*e.g.*, value, type of beneficiary, nature of expenditure, random errors, experience).

2.3.2 On-the-spot verifications

On-the-spot verifications aim to cover risks associated with the lifecycle of operations and expenditure, the delivery of the product or service in compliance with the conditions of the subsidy contract, physical development, and respect for the EU rules on publicity. In addition, a visit *in situ* confirms whether the beneficiary is providing precise information on the physical and financial implementation of the operation. Therefore, on-the-spot verifications should be carried out when the operation is well on track, both in terms of physical and financial undertaking. Indeed, these verifications of operations are intended to certify their effective execution and compliance with the terms under which they were approved.

These verifications should, as a minimum, cover (where applicable) the following elements:

- existence and organization of the operation dossier;
- the originals of expenditure and discharge documents that have been entered in the list of supporting documents for expenditure already presented in payment requests. For work contracts, the expenditures documents (invoices) must be accompanied by the measurement reports of the work invoiced;

- the existence of a statement of receipt and final accounts for completed works at the date of verification;
- the existence of a separate accounting system or adequate accounting coding for all transactions relating to the operation;
- evidence of adequate accounting records of the ERDF and national co-financing received about the operation;
- provision of goods and services following the terms and conditions of the subsidy contract;
- the generation of revenues that, if existent, must be deducted to the subvention received by the beneficiary;
- compliance with European and national rules on publicity;
- progress of the operation assessed through programme specific output targets and, where applicable, result indicators and disaggregated data;
- no duplication of aid.

The NA responsible by the management verifications must ensure that verifications are carried out before the submission of the accounts. An indicative plan for each accounting year is highly recommended, also including orientations for the controllers concerning on-the-spot verifications. Small infrastructure and works must always be controlled with on-the-spot verifications on their final stage.

The on-the-spot verifications are carried out on operations with expenditures included in a particular accounting year. **One verification by a beneficiary is required during the project's life cycle before submitting its final report but this check may be done online, except when partners claim the reimbursement of equipment and/ or infrastructure & works costs related to a pilot action.**

Combining an administrative verification with an *in situ* one may be efficient. A combination must guarantee adequate mitigation of risks, as above mentioned.

Additional on-the-spot verifications may be required due to eventual risks identified at the selection of operations stage and during administrative verifications. The MA may also refer to Arachne (if possible) or other data mining tools.

In addition, controllers may consider the subsequent operations for on-the-spot management verifications:

- Expected to be completed within the accounting year and not previously subject to on-the-spot verification;
- With high levels of implementation;
- With issues previously identified by controllers, the MA, the JS, or under audits through monitoring, for example, at the level of progress reports (*e.g.*, related to financial corrections, delays in the implementation, irregularities, fraud, suspicious of corruption, complaints, *etc.*).

Concerning the expenditures to be checked under the on-the-spot management verification, if operations are completed or almost implemented, the verification must cover the entire set

implemented at a certain point in time independently of the accounting year in which the payment claim is submitted to the MA.

Controllers may also decide to check only a part of an operation, which can occur at distinct levels, for example:

- If just part of the beneficiaries implements the associated actions at a certain point in time, only that part may be selected for verification;
- When the claim selected for verification encompasses several expenditures items and invoices, benefiting from the scope of the associated administrative verifications, the on-the-spot check may cover part of these expenditures, always focusing on physical existence if applicable and verifying public procurement procedures, in line with what was defined for administrative verifications;
- When several payment claims were already subject to administrative verifications, the controller may select only some to further check during on-the-spot verifications; the experience of the controller is essential at this stage, and an option for choosing all the claims to check further on-the-spot and namely to address issues and doubts raised during previous administrative checks may be done;
- Suppose the risks are similar for specific categories of expenditure. In that case, the selection of items may be made randomly (e.g., if a project has identical equipment, the controller may choose a sample of equipment to verify on the spot).

3 Audit trail and single audit arrangements

It is important to mention that the use of e-Cohesion (article 69(8), CPR) allows suitable electronic audit trails, complying with relevant requirements on the availability of documents (articles 69(6), 82 and Annex XIII of CPR). E-Cohesion and the electronic data exchange systems used in the context of management verifications contribute significantly to reducing the audit and control burden.

To guarantee the audit trail, documents must be kept following article 82 of the CPR. All supporting documents relating to expenditure claimed for an operation in electronic and/or paper form shall be held at the appropriate level for five years from 31 December of the year in which the last payment by the MA to the beneficiary was made.

Beneficiaries shall methodically upload their payment claims with all related supporting documents (in electronic form) to SIGI (article 69(8), CPR). The systematic uploading of supporting documents is required even if the related payment claim is not going to be made subject to an administrative verification, for example, when a simplified cost option covers it. This practice enables access to any future verification or audit. Moreover, this procedure can substantially reduce the administrative burden for beneficiaries.

The principle of single audit arrangements (article 80, CPR) is vital for preventing the multiplication of controls at the beneficiary level. In the programming period 2021-2027, this principle was expanded to audits (EC, AA) and management verifications. Applying the single audit principle is facilitated if supporting documents are available in SIGI.

As established in article 74(2) of the CPR, *“If an operation has already been audited (on the spot) by the audit authority, the EC or ECA auditors and the same operation is included in the MA’s risk-based plan for on-the-spot verifications after the audit, the MA takes account of the results of these audits and may exclude this operation from its risk-based plan for management verifications”*.

4 Conclusion

With the risk-based methodology proposed in this document, the MA can draw a conclusion from the implemented management verifications, even if these do not encompass 100% of all payment claims to be submitted to the EC. This method allows reasonable assurance so that the MA certifies all expenditures included in payment claims.

Acknowledging the difference between management verifications and the audits implemented by the AA, the EC the ECA is essential. The first is part of the internal control function of the MA, and the main goal is to identify errors in beneficiaries’ payment claims and correct them in a preventive role. The audits are made by professionals independent from the MA and NA and may test if management verifications, as defined in article 74 (CPR), work in proper terms. Audits aim to offer an independent guarantee on the appropriate functioning of the Management Control System (MCS) and the legality and regularity of the expenditure declared to the EC.

Suppose the AA identifies irregularities on a payment claim that were not detected by controllers, depending on the extent and incidence of those irregularities (one-time or systemic). In that case, the AA may advise the MA to review and amend the risk-based methodology for management verifications, possibly by enlarging the coverage of the payment claims to be subject to verifications in subsequent accounting years.

The MA and the AA must systematically review and discuss issues detected by audits. This collaborative approach is a valuable contribution to administrative capacity building by promoting a mutual understanding of remaining risks and reassessing future management verifications.

The risk assessment methodology includes the conditions and factors for regularly revising the proposed method and the risk assessment. As mentioned, any changes in identified risks may cause a revision. Those modifications may be external to the programme (*i.e.*, a pandemic) or internal (*i.e.*, based on the experience and results of the verifications already implemented).