



**GOVERNING BOARD OF THE GLOBAL HEALTH EDCTP3 JOINT UNDERTAKING
DECISION N° GB/11/2023**

on adopting the Internal Control Framework

THE GOVERNING BOARD OF THE OF THE GLOBAL HEALTH EDCTP3 JOINT UNDERTAKING, (hereafter referred as “GH EDCTP3 JU”)

Having regard to Council Regulation (EU) No 2021/2085 of 19 November 2021 establishing the Joint Undertakings under Horizon Europe and repealing Regulations (EC) No 219/2007, (EU) No 557/2014, (EU) No 558/2014, (EU) No 559/2014, (EU) No 560/2014, (EU) No 561/2014 and (EU) No 642/2014;

Having regard to the GH EDCTP3 JU Financial Rules adopted by the Governing Board on 3 May 2022 (hereafter the “Financial Rules”) and in particular Articles 20 (4) (“Powers and duties of the authorising officer”) and 14 (“Internal control of budget implementation”);

Having regard to the Regulation (EU, Euratom) 2018/1046 of the European Parliament and of the Council of 18 July 2018 on the financial rules applicable to the general budget of the Union (hereafter “EU Financial Regulation”) and in particular Article 36 thereof;

Whereas:

- (1) Internal Control is a process that helps an organisation to achieve its objectives and sustain operational and financial performance, complying with rules and regulations. It supports sound decision making, taking into account risks to the achievement of objectives and reducing them to acceptable levels through cost-effective controls,
- (2) The European Commission has adopted on 19 April 2017 (C(2017) 2373 Final) a revised Internal Control Framework (ICF) to better reflect today’s ever-changing environment and to allow the services the necessary flexibility to adapt to their specific characteristics and circumstances while ensuring a robust internal control with a consistent assessment,
- (3) The internal control framework is designed to provide reasonable assurance regarding the achievement of five objectives set in Article 36(2) of the EU Financial Regulation as well as Article 14(2) of the Global Health EDCTP 3 JU Financial Rules : 1) effectiveness, efficiency and economy of operations; (2) reliability of reporting; (3) safeguarding of assets and information; (4) prevention, detection, correction and follow-up of fraud and irregularities, and (5) adequate management of the risks relating to the legality and

regularity of the underlying transactions, taking into account the multiannual character of programmes as well as the nature of the payments concerned.

HAS ADOPTED THIS DECISION:

Article 1

The Internal Control Framework of the GH EDCTP3 JU, as laid down in the Annex, is hereby adopted.

Article 2

This decision shall enter into force on the day of its adoption.

Done at Brussels, on 10 August 2023

For the Global Health EDCTP3 Joint Undertaking Governing Board


Dr. Henning Gädeke

Chairperson of the Governing Board

Annex:

1. Internal Control Framework of the Global Health EDCTP3 JU

For adoption by the GH EDCTP3 JU Governing Board: Internal Control Framework
Explanatory document

According to Article 36.2 of the EU Financial Regulation¹, the Global Health EDCTP3 JU, an entrusted body implementing EU Budget, shall have a proper management and control mechanism in place. According to Article 36.2 of the EU Financial Regulation, and Article 14 of the Global Health EDCTP 3 JU Financial Rules, there is a need to implement and maintain an effective internal control system.

The JU Internal Control Framework aims to provide reasonable assurance so that resources assigned to the activities are used according to the principles of sound financial management. It also aims to ensure that the existing control procedures provide the necessary guarantees concerning the legality and regularity of transactions.

Based on the Commission's framework of Internal Control, following the COSO 2013 Internal Control-Integrated Framework, the GH EDCTP3 JU has developed a set of 17 Internal Control principles adapted to the environment of GH EDCTP3 JU.² They encompass baseline requirements for controls in different management areas as well as appropriate measures for a self-assessment of their effective implementation. The table below presents the GH EDCTP3 JU Internal Control Framework composed of five internal control components and 17 principles.

| Components | Principles |
|-----------------------------|---|
| Control Environment | <ol style="list-style-type: none"> 1. Demonstrates commitment to integrity and ethical values 2. Exercises oversight responsibility 3. Establishes structure, authority and responsibility 4. Demonstrates commitment to competence 5. Enforces accountability |
| Risk Assessment | <ol style="list-style-type: none"> 6. Specifies suitable objectives 7. Identifies and analyzes risk 8. Assesses fraud risk 9. Identifies and analyzes significant change |
| Control Activities | <ol style="list-style-type: none"> 10. Selects and develops control activities 11. Selects and develops general controls over technology 12. Deploys through policies and procedures |
| Information & Communication | <ol style="list-style-type: none"> 13. Uses relevant information 14. Communicates internally 15. Communicates externally |
| Monitoring Activities | <ol style="list-style-type: none"> 16. Conducts ongoing and/or separate evaluations /internal audits 17. Evaluates and communicates deficiencies |

Annually, internal controls are reported in the Annual Activity Report (AAR). The Executive Director signs a declaration assurance that includes the assessment of the Internal Control system in place. In their role of Authorising Officer, the Executive Director provides assurance regarding the legality and regularity and the sound financial management of all financial transactions under his/her responsibility and the non-omission of significant information. Assurance is key in the discharge procedure³ by which the budgetary authority decides to approve the implementation of the budget.

¹ OJ-L 193/30.07.2018

² COSO is an acronym for the Committee of Sponsoring Organizations of the Treadway Commission, which is made up of five global accountancy and auditing organizations: American Accounting Association (AAA); Association of International Certified Public Accountants (AICPA); Financial Executives International (FEI); Institute of Management Accountants; and The Institute of Internal Auditors. The COSO Framework is a system used to establish internal controls to be integrated into business processes. The COSO Internal Control-Integrated Framework was refreshed in 2013 to “focus on five integrated components of internal controls: control environment, risk assessment, control activities, information and communication, and monitoring activities”. The full text of the Internal Control-Integrated Framework is available at www.coso.org.

³ The Discharge procedure aims to verify whether implementation was in accordance with relevant rules (compliance), including the principles of sound financial management (performance).

Internal Control Framework of the Global Health EDCTP3 JU

INTERNAL CONTROL FRAMEWORK OF THE GH EDCTP3 JU

I — Context and definitions

Internal control applies to all activities, irrespective of whether they are financial or non-financial. It is a process that helps an organisation achieve its objectives and sustain operational and financial performance, respecting rules and regulations. It supports sound decision-making, taking into account risks to the achievement of objectives and reducing them to acceptable levels through cost-effective controls.

The European Commission adopted on 19/04/2017 (C (2017) 2373 Final) a revised Internal Control Framework (ICF) to better reflect today's ever-changing environment and to allow its services the necessary flexibility to adapt to their specific characteristics and circumstances while ensuring a robust internal control with a consistent assessment. The revised Internal Control Framework consists of five internal control components and 17 principles based on the COSO 2013 Internal Control-Integrated Framework.¹

According to Article 14 of the Global Health EDCTP 3 JU Financial Rules and Article 36.2 of the EU Financial Regulation, the internal control framework is designed to provide reasonable assurance regarding the achievement of the following five objectives: (1) effectiveness, efficiency and economy of operations; (2) reliability of reporting; (3) safeguarding of assets and information; (4) prevention, detection, correction and follow-up of fraud and irregularities, and (5) adequate management of the risks relating to the legality and regularity of the underlying transactions, taking into account the multiannual character of programmes as well as the nature of the payments concerned.

As an entrusted body implementing EU Budget, the Global Health EDCTP3 JU should ensure a proper management and control mechanism in accordance with Article 36.2 of the EU Financial Regulation² and provide a level of assurance from their systems at least equivalent to the one of the European Commission.

The Global Health EDCTP3 JU internal control components are:

- control environment,
- risk assessment,
- control activities,
- information and communication and
- monitoring activities.

They are the building blocks that underpin the framework's structure and support the Global Health

¹ COSO is an acronym for the Committee of Sponsoring Organizations of the Treadway Commission, which is made up of five global accountancy and auditing organizations: American Accounting Association (AAA); Association of International Certified Public Accountants (AICPA); Financial Executives International (FEI); Institute of Management Accountants; and The Institute of Internal Auditors. The COSO Framework is a system used to establish internal controls to be integrated into business processes. The COSO Internal Control-Integrated Framework was refreshed in 2013 to "focus on five integrated components of internal controls: control environment, risk assessment, control activities, information and communication, and monitoring activities". The full text of the Internal Control-Integrated Framework is available at www.coso.org.

² OJ-L 193/30.07.2018

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EDCTP3 JU in its efforts to achieve its objectives. The five components are interrelated and must be present and effective at all levels of the organisation for internal control over operations to be considered effective.

To facilitate the implementation of the internal control framework and management's assessment of whether each component is present and functioning and whether the components are functioning well together, each component consists of several principles. Working with these principles helps provide reasonable assurance that the organisation's objectives are met. The principles specify the actions required for internal control to be effective.

These characteristics of each principle are defined to assist management in implementing internal control procedures and in assessing whether the principles are present and functioning. Management is expected to have persuasive evidence to support their assessment.

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II — The components, principles and characteristics of the Global Health EDCTP3 JU Internal Control Framework

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| CONTROL ENVIRONMENT | <ol style="list-style-type: none"> 1. Demonstrates commitment to integrity and ethical values 2. Exercises oversight responsibility 3. Establishes structure, authority and responsibility 4. Demonstrates commitment to competence 5. Enforces accountability |
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The control environment is the set of standards of conduct, processes, and structures that provide the basis for carrying out internal control across an organisation. The Governing Board and management set the tone at the top for the importance of internal control, including expected standards of conduct.

1. The Global Health EDCTP3 JU demonstrates a commitment to integrity and ethical values.

Characteristics:

- **Tone at the top.** *The Governing Board, the Executive Director and all management levels respect integrity and ethical values in their instructions, actions and behaviour.*
- **Standards of conduct.** *The Global Health EDCTP3 JU's expectations on integrity and ethical values are set out in standards of conduct and understood at all levels of the organisation, as well as outsourced service providers and beneficiaries.*
- **Alignment with standards.** *Processes are in place to assess whether individuals and departments are aligned with the Global Health EDCTP3 JU's expected standards of conduct and to address deviations in a timely manner.*

2. The Governing Board demonstrates independence from management and exercises oversight of the development and performance of internal control.

Characteristics:

- **The Governing Board oversees the Global Health EDCTP3 JU's governance, risk management and internal control practices and takes overall responsibility for management carried out by the Executive Director.** *This happens through the use of appropriate working arrangements and communication channels between the Governing Board, advisory bodies, the Programme Office, the Accounting Officer and the Internal Audit Service.*

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- *The Executive Director oversees the internal control systems within the Programme Office as well as the development and performance of internal control. The Executive Director is supported in this task by the Internal Control Coordinator and the Internal Control and Audit Manager.*
- *In her/his capacity as **Authorising Officer**, the Executive Director provides a Declaration of Assurance on the appropriate allocation of resources and their use for their intended purpose and in accordance with the principle of sound financial management, as well as on the adequacy of the control procedures in place (see Appendix 2).*
- *The **Internal Control Coordinator** plays a key role by coordinating the preparation of the **Annual Activity Report**. Senior Management (i.e. Heads of Unit) sign a declaration taking responsibility for the completeness and reliability of management reporting (see Appendix 3). This declaration covers both the state of internal control in the Programme Office and the robustness of reporting on operational performance. However, responsibility for achieving operational objectives remains with the relevant unit.*

3. Management establishes structures, reporting lines, and appropriate authorities and responsibilities in the pursuit of objectives.

Characteristics:

- ***Management structures are comprehensive.** The design and implementation of management and supervision structures cover all programmes and activities. In particular for spending programmes, they cover all expenditure types, delivery mechanisms and budget implementation to support the achievement of policy, operational and control objectives.*
- ***Authorities and responsibilities.** The Governing Board and the Executive Director, as appropriate, delegate authority and use appropriate processes and technology to assign responsibility and segregate duties as necessary at the various levels of the JU.*
- ***Reporting lines.** The Executive Director designs and evaluates reporting lines within departments to enable the execution of authority, fulfilment of responsibilities, and flow of information.*

4. The Global Health EDCTP3 JU demonstrates a commitment to attract, develop and retain competent individuals in alignment with objectives.

Characteristics:

- ***Competence framework.** The Executive Director defines the competences necessary to support the achievement of objectives and regularly evaluates them across the Programme Office, taking action to address shortcomings where necessary.*
- ***Professional development.** The Programme Office provides the training and coaching needed to attract, develop and retain a sufficient number of competent staff.*
- ***Mobility.** The Programme Office promotes and plans staff mobility compatible with the size and mandate of the organisation so as to strike the right balance between continuity and renewal.*

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- *Succession planning and deputising arrangements for operational activities and financial transactions are in place to ensure continuity of operations.*

5. The Global Health EDCTP3 JU holds individuals accountable for their internal control responsibilities in the pursuit of objectives.

Characteristics:

- ***Enforcing accountability.** The Global Health EDCTP3 JU defines clear roles and responsibilities and holds individuals accountable for the performance of internal control responsibilities across the organisation and for the implementation of corrective action as necessary.*
- ***Staff appraisal.** Staff efficiency, abilities and conduct in the service are assessed annually against expected standards of conduct and set objectives. Cases of underperformance are appropriately addressed.*
- ***Staff reclassification.** Reclassification is decided after consideration of the comparative merits of eligible staff taking into account, in particular, their appraisal reports.*

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| RISK ASSESSMENT | <p>6. Specifies suitable objectives</p> <p>7. Identifies and analyses risk</p> <p>8. Assesses fraud risk</p> <p>9. Identifies and analyses significant change</p> |
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Risk assessment is a dynamic and iterative process for identifying and assessing risks which could affect the achievement of objectives, and for determining how such risks should be managed.

6. The Global Health EDCTP3 JU specifies objectives with sufficient clarity to enable the identification and assessment of risks relating to objectives.

Characteristics:

- ***Mission.** The Programme Office has up-to-date mission statements that are aligned across all hierarchical levels, down to the tasks and objectives assigned to individual staff members. Mission statements are aligned with the Global Health EDCTP3 JU's responsibilities and the policy objectives set in the legal base.*
- ***Objectives are set at every level.** The Programme Office's objectives are clearly set and updated when necessary (e.g. significant changes in priorities, activities and/or the organigram). They are consistently filtered down from the higher JU's level to the various levels of the organisation, and are communicated and understood by management and staff.*
- ***Objectives are set for the most significant activities.** Objectives³ and indicators⁴ cover the Programme Office's most significant activities contributing to the delivery of Global Health EDCTP3 JU priorities or other priorities relating to the core business, as well as operational management.*
- ***Objectives form the basis for committing resources.** Management uses the objectives set as a basis for allocating available resources as needed to achieve policy, operational and financial performance goals.*
- ***Financial reporting objectives.** Financial reporting objectives are consistent with the accounting principles applicable in the Global Health EDCTP3 JU.*
- ***Non-financial reporting objectives.** Non-financial reporting provides management with accurate and complete information needed to manage the organisation at Programme Office level.*
- ***Risk tolerance and materiality.** When setting objectives, management defines the acceptable levels of variation relative to their achievement (tolerance for risk) as well as the appropriate level of*

³ Objectives must be SMART (specific, measurable, achievable, relevant and time-framed).

⁴ Indicators must be RACER (relevant, accepted, credible, easy to monitor and robust).

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materiality for reporting purposes, taking into account cost-effectiveness.

- **Monitoring.** *Setting objectives and performance indicators makes it possible to monitor progress towards their achievement.*

7. The Global Health EDCTP3 JU identifies risks to the achievement of its objectives across the organisation and analyses risks as a basis for determining how the risks should be managed.

Characteristics:

- **Risk identification.** *The Programme Office identifies and assesses risks at the various organisational levels, analysing internal and external factors. Management and staff are involved in the process at the appropriate level.*
- **Risk assessment.** *The Programme Office estimates the significance of the risks identified and determines how to respond to significant risks considering how each one should be managed and whether to accept, avoid, reduce or share the risk. The intensity of mitigating controls is proportional to the significance of the risk.*
- **Risk identification and risk assessment are integrated** *into the annual activity planning and are regularly monitored.*

8. The Global Health EDCTP3 JU considers the potential for fraud in assessing risks to the achievement of objectives.

Characteristics:

- **Risk of fraud.** *The risk identification and assessment procedures (see principle 7) consider possible incentives, pressures, opportunities and attitudes which may lead to any type of fraud, notably fraudulent reporting, loss of assets, disclosure of sensitive information and corruption.*
- **Anti-fraud strategy.** *The Global Health EDCTP3 JU sets up and implements measures to counter fraud and any illegal activities affecting the financial interests of the EU. The JU does this by putting in place a sound anti-fraud strategy to improve the prevention, detection and conditions for investigating fraud, and to set out reparation and deterrence measures, with proportionate and dissuasive sanctions.*

9. The Global Health EDCTP3 JU identifies and assesses changes that could significantly impact the internal control system.

Characteristics:

- **Assess changes.** *The risk identification process considers changes in the internal and external environment, in policies and operational priorities, as well as in management's attitude towards the internal control system.*

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| CONTROL ACTIVITIES | <p>10. Selects and develops control activities</p> <p>11. Selects and develops general control over technology</p> <p>12. Deploys control through policies and procedures</p> |
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Control activities ensure the mitigation of risks related to the achievement of policy, operational and internal control objectives. They are performed at all levels of the organisation, at various stages of business processes, and across the technology environment. They may be preventive or detective and encompass a range of manual and automated activities as well as segregation of duties.

10. The Global Health EDCTP3 JU selects and develops control activities that contribute to the mitigation of risks to the achievement of objectives to acceptable levels.

Characteristics:

- **Control activities are performed to mitigate the identified risks and are cost-effective.** They are tailored to the specific activities and risks of the Programme Office and their intensity is proportional to the underlying risks.
- **Control activities are integrated in a control strategy.** The control strategy includes a variety of checks, including supervision arrangements, and where appropriate, should include a balance of approaches to mitigate risks, considering manual and automated controls, and preventive and detective controls.
- **Segregation of duties.** *When putting in place control measures, management considers whether duties are correctly divided between staff members to reduce risks of error and inappropriate or fraudulent actions.*
- **Business continuity plans** based on a business impact analysis following corporate guidance are in place, up-to-date and used by trained staff to ensure that the Programme Office is able to continue working to the extent possible in case of a major disruption. *Where necessary, business continuity plans must include coordinated and agreed disaster recovery plans for time-sensitive supporting infrastructure (e.g. IT systems).*

11. The Global Health EDCTP3 JU selects and develops general control activities over technology to support the achievement of objectives.

Characteristics:

- **Control over technology.** *To ensure that technology used in business processes, including automated controls, is reliable, and taking into account the overall corporate processes, the Programme Office selects and develops control activities over the acquisition, development and maintenance of technology and related infrastructure.*

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- **Security of IT systems.** *The Global Health EDCTP3 JU applies appropriate controls to ensure the security of the IT systems of which they are the system owners. They do so in accordance with the IT security governance principles, in particular as regards data protection, professional secrecy, availability, confidentiality and integrity.*

12. The Global Health EDCTP3 JU deploys control activities through corporate policies that establish what is expected and in procedures that put policies into action.

Characteristics:

- **Appropriate control procedures ensure that objectives are achieved.** *The control procedures assign responsibility for control activities to the department or individual responsible for the risk in question. The staff member(s) put in charge perform the control activities in a timely manner and with due diligence, taking corrective action where needed. Management periodically reassesses the control procedures to ensure that they remain relevant.*
- **Exception reporting** *is one of the management tools used to draw conclusions about the effectiveness of internal controls and/or the changes needed in the internal control system. A system is in place to ensure that all instances of overriding controls or deviations from established processes and procedures are documented in exception reports. All instances must be justified and approved before action is taken, and logged centrally.*
- **There are evaluations** *of the Global Health EDCTP3 JU initiative performed by the European Commission (and possibly the JU itself) and recommendations resulting from the exercise(s) are implemented by the JU to the extent they are addressed to its bodies and to the Programme Office.*

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| INFORMATION AND COMMUNICATION | <p>13. Uses relevant information</p> <p>14. Communicates internally</p> <p>15. Communicates externally</p> |
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Information is necessary for the organisation to carry out internal control and to support the achievement of objectives. There is external and internal communication. External communication provides the public and stakeholders with information on the Global Health EDCTP3 JU's objectives and actions. Internal communication provides staff with the information it needs to achieve its objectives and to carry out day-to-day controls.

13. The Global Health EDCTP3 JU obtains or generates and uses relevant quality information to support the functioning of internal control.

Characteristics:

- *Information and document management.* The Programme Office identifies the information required to support the functioning of the internal control system and the achievement of Global Health EDCTP3 JU's objectives. Information systems process relevant data, captured from both internal and external sources, to obtain the required and expected quality information, in compliance with applicable security, document management and data protection rules. This information is produced in a timely manner, and is reliable, current, accurate, complete, accessible, protected, verifiable, filed and preserved. It is shared within the organisation in line with prevailing guidelines.

14. The Global Health EDCTP3 JU internally communicates information, including objectives and responsibilities for internal control, necessary to support the functioning of internal control.

Characteristics:

- *Internal communication.* The Global Health EDCTP3 JU communicates internally about its objectives, challenges, actions taken and results achieved, including but not limited to the objectives and responsibilities of internal control.
- *Separate communication lines* are in place at Programme Office level to ensure information flow when normal channels are ineffective.

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15. The Global Health EDCTP3 JU communicates with external parties about matters affecting the functioning of internal control.

Characteristics:

- **External communication:** *The Global Health EDCTP3 JU ensures that its external communication is consistent, relevant to the audience being targeted, and cost-effective. The Global Health EDCTP3 JU establishes clear responsibilities to align the Programme Office communication activities with the Global Health EDCTP3 JU's priorities and narrative of the organisation.*

- **Communication on internal control.** *The Global Health EDCTP3 JU communicates with external parties⁵ on the functioning of the components of internal control. Relevant and timely information is communicated externally, taking into account the timing, audience and nature of the communication, as well as legal, regulatory and fiduciary requirements.*

⁵ Not only to the other EU institutions, but also stakeholders and the general public.

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| MONITORING ACTIVITIES | <p>16. Conducts ongoing and/or separate assessments</p> <p>17. Assesses and communicates deficiencies</p> |
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Continuous and specific assessments are used to ascertain whether each of the five components of internal control is present and functioning. Continuous assessments, built into business processes at different levels of the organisation, provide timely information on any deficiencies. Findings are assessed and deficiencies are communicated and corrected in a timely manner, with serious matters reported as appropriate.

16. The Global Health EDCTP3 JU selects, develops, and performs ongoing and/or separate assessments to ascertain whether the components of internal control are present and functioning.

Characteristics:

- ***Continuous and specific assessments.** The Programme Office continuously monitors the performance of the internal control system with tools that make it possible to identify internal control deficiencies, register and assess the results of controls, and control deviations and exceptions. In addition, when necessary, the Programme Office carries out specific assessments, taking into account changes in the control environment. Ongoing assessments are built into business processes and adjusted to changing conditions. Both kinds of assessment must be based on the general principles set out in Appendix 1.*
- ***Sufficient knowledge and information.** Staff performing ongoing or separate assessments has sufficient knowledge and information to do this, specifically on the scope and completeness of the results of controls, control deviations and exceptions.*
- ***Risk-based and periodical assessments.** The Programme Office varies the scope and frequency of specific assessments depending on the identified risks. Specific assessments are performed periodically to provide objective feedback.*

17. The Global Health EDCTP3 JU assesses and communicates internal control deficiencies in a timely manner to those parties responsible for taking corrective action, including management and the Governing Board of Global Health EDCTP3 JU, as appropriate.

Characteristics:

- ***Deficiencies.** With the support of the Manager in charge of risk management and internal control, the Executive Director considers the results of the assessments of how the internal control system is functioning within the JU. Deficiencies are communicated to management and to the departments responsible for taking corrective action. They are reported in the Annual Activity Reports and to the Governing Board of Global Health EDCTP3 JU, as appropriate.*
The term 'internal control deficiency' means a shortcoming in a component or components and relevant principle(s) that reduces the likelihood of the Global Health EDCTP3 JU achieving its

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objectives. There is a major deficiency in the internal control system if management determines that a component and one or more relevant principles are not present or functioning or that components are not working together. When a major deficiency exists, the Executive Director cannot conclude that it has met the requirements of an effective system of internal control. To classify the severity of internal control deficiencies, management has to use judgment based on relevant criteria contained in regulations, rules or external standards.

- **Remedial action.** *Corrective action is taken in a timely manner by the staff member(s) in charge of the processes concerned, under the supervision of their management. With the support of the Manager in charge of risk management and internal control, the Executive Director monitors and takes responsibility for the timely implementation of corrective action.*

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Appendix 1 — General principles for the assessment of internal control

A system of internal control allows management to stay focused on the pursuit of the operational and financial objectives of the JU. In addition, the Global Health EDCTP3 JU Financial Rules require that the budget must be implemented in compliance with effective and efficient internal control.

The Executive Director must be able to demonstrate not only that he/she has put controls in place but also that these controls take account of the risks involved and that they work as intended.

Internal control principle 16 states that the Programme Office must carry out continuous and specific assessments to ascertain whether the internal control systems and their components are present and functioning. It must carry out an overall assessment of the presence and functioning of all internal control components at least once per year.

Even though the principles and their characteristics are straightforward, their implementation in practice, and therefore the assessment of their implementation, can vary from one organisation to another.

Therefore, before assessing its internal control system, the Global Health EDCTP3 JU must set its own baseline for each principle, as best adapted to its specificities and risks. These baselines are a starting point for effective internal control, from which regular monitoring and specific assessments can be implemented.

The baselines should be expressed in terms of relevant and pertinent indicators. Where possible, these indicators should be quantitative.

Since the principles are interdependent, sometimes it is impossible to fully quantify the effective implementation of each individual principle other than through generic qualitative indicators. Nonetheless, effective implementation can be assessed based on a variety of sources of evidence (e.g. process reviews, register of exceptions, reporting of internal control weaknesses, management supervision and ad-hoc verification, surveys and interviews, management self-assessments, audit reports, stakeholder feedback). The baselines may be adapted in subsequent years in order to make sure monitoring activities remain appropriate and up-to-date.

The assessment of whether the internal control system reduces the risk of not achieving an objective to an acceptable level should follow these logical steps, leading to the identification of internal control deficiencies:

- establishment of a baseline for each principle;
- assessment at principle and at component level;
- overall assessment.

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Appendix 2 — Declaration of Assurance of the Authorising Officer

*I, the undersigned,
Executive Director of the Global Health EDCTP3 JU*

In my capacity as the authorising officer

Declare that to the best of my knowledge the information contained in this report gives a true and fair view.⁶

State that I have reasonable assurance that the resources assigned to the activities described in this report have been used for their intended purpose and in accordance with the principles of sound financial management, and that the control procedures put in place give the necessary guarantees concerning the legality and regularity of the underlying transactions.

This reasonable assurance is based on my own judgement and on the information at my disposal, such as the results of the self-assessment, ex-post controls, the work of the Internal Audit Service and the lessons learnt from the reports of the Court of Auditors for years prior to the year of this declaration.

Confirm that I am not aware of anything not reported here which could harm the interests of the institution Global Health EDCTP3 JU.

[However, the following reservations should be noted:] (delete this sentence if not applicable)

Place....., date.....

.....

(signature)

[Name of the AO]

⁶ True and fair in this context means a reliable, complete and correct view on the state of affairs in the Global Health EDCTP3 JU.

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Appendix 3 —Statement of the Manager in charge of risk and internal control

- a) **If the Manager in charge of risk management and internal control takes responsibility for the completeness and reliability of all management reporting, the declaration should read:**

'I declare that in accordance with the Commission's communication on the internal control framework,⁷ I have reported my advice and recommendations on the overall state of internal control in the Joint Undertaking to the Executive Director.

I hereby certify that the information provided in the present Annual Activity Report and in its annexes is, to the best of my knowledge, accurate and complete.'

Place , date

.....

(Signature) [Name and function]

- b) **If responsibility for the completeness and reliability of management reporting is split between two people, the text of the declarations should be amended as follows:**

For the Manager in charge of risk management and internal control:

'I declare that in accordance with the Commission's communication on the internal control framework, I have reported my advice and recommendations on the overall state of internal control in the Joint Undertaking to the Executive Director.

I hereby certify that the information provided in Section X of the present Annual Activity Report and in its annexes is, to the best of my knowledge, accurate and complete.'

For the Manager taking responsibility for the completeness and reliability of management reporting on results and on the achievement of objectives:

'I hereby certify that the information provided in Section X of the present Annual Activity Report and in its annexes is, to the best of my knowledge, accurate and complete.'

Place , date

(Signature) [Name and function]

⁷ C(2017) 2373 of 19/04/2019.