

AI ITA Guidelines



MDIA Circular No.6

Introduction

In support of the Strategy and Vision for Artificial Intelligence in Malta 2030 and the achievement of the Malta Ethical AI Framework, the MDIA is in the process of expanding the ITA certification framework for AI-based solutions. It will be the world's first national AI certification programme aiming for AI solutions to be developed in an ethically aligned, transparent and socially responsible manner.

With this in mind, the MDIA will be issuing a set of guidance notes aimed at assisting Service Providers and AI-ITA Applicants when approaching the MDIA for registration and certification respectively. It is the MDIA's intention to seek feedback on each of the following documents through public consultation:

- AI ITA Guidelines
- AI ITA Blueprint Guidelines
- AI ITA Nomenclature
- AI Systems Auditor Control Objectives

MDIA Public Consultation Ref No. 02/19

The MDIA is publishing the AI guidelines for consultation to support the National AI Strategy and Vision. These guidelines are to set a regulatory framework around the expectations of what MDIA will consider to be an AI-ITA. The MDIA invites members of the public, industry and academia to provide feedback on these consultation documents.

Responding to these consultation documents

The purpose of this public consultation is to seek your feedback on these documents. Your feedback will inform the MDIA's recommendations on Malta's approach to establishing ethical and trustworthy AI.

Questions for consideration:

1. Are there any suggestions on improvements that the MDIA should consider with respect to the certification of AI-ITAs?
2. Are there any elements you feel the MDIA may have overlooked in the drafting of these guidelines?
3. Are there any additional qualifying features and attributes you would like to see added, clarified, or amended with respect to the AI-ITA qualification criteria?

Concluding Remarks

The consultation period is open to the public from 03 October 2019 until 01 November 2019. Interested parties are requested to submit their comments and feedback by email on info@mdia.gov.mt by not later than 01 November 2019.

Malta Digital Innovation Authority
03 October 2019

AI Innovative Technology Arrangement Guidelines

Digital Innovation is, by definition, a rapidly evolving sector. These guidelines are expected to be updated to keep abreast with technology, regulatory and operational developments.

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1. Definitions

“Applicant”, within the context of this document, refers to an individual and/or legal organisation applying for Certification of an Innovative Technology Arrangement (ITA) with the Authority.

“Auditee” refers to the individual and/or legal organisation that is subject to a Systems Audit as required by the Authority in the case of an owner or controller of an ITA (‘ITA Owner’), or as required by another recognised Lead Authority.

“Authority” refers to the Malta Digital Innovation Authority (‘MDIA’), as defined by the Malta Digital Innovation Authority Act, 2018 (‘MDIA Act’).

“Lead Authority” refers to the “national competent authority” as defined within the Innovative Technology Arrangements and Services Act, 2018, which has a leading role within that application of the ITA.

“Blueprint” refers to a document that includes a description of the qualities, attributes, features, behaviours or aspects of an ITA as defined in the ‘ITA Blueprint Guidelines’.

“Innovative Technology Arrangement”, also referred to as ‘ITA’ within this document, as defined within the First Schedule of the Innovative Technology Arrangements and Services Act, 2018.

“AI-ITA” refers to Innovative Technology Arrangements that exhibit features or qualities of Artificial Intelligence as recognised by the Authority and described in the ‘AI Innovative Technology Arrangements Guidelines’.

“ITAS Act” refers to the Innovative Technology Arrangements and Services Act, 2018.

“Register of Recognitions” is an electronic register, also referred to as "the Register", of all recognitions issued by the Authority, which recognitions shall include the certification of ITAs, and registration of Systems Auditors and Technical Administrators. The Register shall include all such details as the Authority shall consider necessary to identify the relevant Applicant and the activities being carried out. In addition, the Register shall be available to the public on the website of the Authority.

“Systems Auditor” (‘SA’) as defined in the Innovative Technology Arrangements and Services Act, 2018, and in line with further guidance issued by the Authority within the ‘Systems Auditor Guidelines’.

“Technical Administrator” (‘TA’) as defined in the *Innovative Technology Arrangements and Services Act, 2018*, and in line with further guidance issued by the Authority under Chapter 3 of the Guidance Notes.

“Forensic Node” as defined by the Authority within the ‘Forensic Node Guidelines’.

“Ethical and Trustworthy AI Framework” refers to the *Malta Towards Trustworthy AI: Malta Ethical AI Framework* guidelines, published by the *Malta.AI* Taskforce on <https://malta.ai/>

2. Applicability and Scope

These Guidelines shall apply to Innovative Technology Arrangements ('ITAs'), specifically Artificial Intelligence solutions ('AI-ITAs'), in terms of the Innovative Technology Arrangements and Services Act ('ITAS Act') seeking a voluntary certification by the MDIA.

The Minister for the Digital Economy, on the recommendation of the Authority, may designate any other innovative technology arrangement to fall in scope of these guidelines and relative guidance will be issued accordingly.

These guidelines outline the high-level standards that an AI-ITA seeking voluntary certification from the Authority needs to follow.

The voluntary certification granted by the Authority covers a set of core features that the Authority deems essential to ensure that reasonable standards are met with respect to purpose, qualities, features, attributes, failure modes or aspects of the AI-ITA.

3. Qualifying features and qualities of AI-ITAs

Artificial Intelligence may be recognised as an innovative technology arrangement by the Authority where it consists of software, the logic of which is based on underlying data sets and which exhibits one or more of the following functions:

1. The ability to use knowledge acquired in a flexible manner in order to perform specific tasks and/or reach specific goals;
2. Evolution, adaptation and/or production of results based on interpreting and processing data;
3. A systems logic based on the process of knowledge acquisition, learning, reasoning, problem solving, and/or planning; and
4. Prediction forecast and/or approximation of results for inputs that were not previously encountered.

In particular, Artificial Intelligence may be recognised as an innovative technology arrangement by the Authority where such software applies one or more of the below techniques and/or algorithms:

- (a) Machine learning and variations thereof (E.G. Deep learning);
- (b) Neural networks or variation thereof (E.G. Convolutional Neural Networks (CNN) or Recurrent Neural Networks);
- (c) Pattern recognition (E.G. Computer Vision);
- (d) Natural Language Processing (NLP);
- (e) Predictive Systems;
- (f) Fuzzy Systems;
- (g) Expert Systems;
- (h) Optimisation algorithms (E.G. Evolutionary and/or Hill climbing algorithms);
- (i) Probabilistic classifiers (E.G. Naïve Bayes); and
- (j) Cluster Analysis algorithms (E.G. k-means clustering).

The Authority may assess and determine Artificial Intelligence which in all cases shall not be considered as ITAs, and may issue a list of such software.

The Authority may refuse to certify Artificial Intelligence which does not satisfy the Malta Ethical AI Framework, or any other standard as the Authority may determine from time to time.

4. Eligibility

Prospective AI-ITAs may submit an 'Innovative Technology Arrangement Application Form' ('ITA Application Form') to the Authority for certification of the technology arrangement.

For an application to be considered by the MDIA, the Applicant will need to include a justification why the certification is being sought clearly indicating:

- a) the mandate that entitles the Applicant to submit such an application; and
- b) the governance structure of the ITA.

In line with Article 8 of the ITAS Act, the MDIA will only certify AI-ITAs once it is satisfied that the general and specific requirements of said article have been fulfilled, and the AI-ITA meets the qualifying criteria as further described in Section '3. Qualifying features and qualities of AI-ITAs'.

To determine this, the Authority will:

- Review and assess the information provided in the ITA Application Form;
- Review the documentation submitted as detailed in these guidelines, as well as, any additional documentation that the Authority may request;
- Carry out the necessary due diligence on the Applicant, including the Administrator and Qualifying Shareholders, as applicable;
- Assess whether the appointed Technical Administrator can fulfil such a role with respect to the AI-ITA seeking certification; and
- Rely on the Systems Auditor opinion to confirm that reasonable standards with reference to the specific purposes, qualities, features, attributes, failure modes and/or aspects of the AI-ITA are met. For details on the Systems Auditor and the Systems Auditor Report, refer to the 'AI-ITA Systems Auditor Guidelines'.

The Authority reserves the right to vary any of the requirements in particular cases upon reasonable justification. The Authority will ensure that this is done in a consistent and equitable manner.

5. Application Process

The application process for certification of an ITA is divided into two stages:



1: Stage 1 2: Stage 2

*Refer to Chapter 1 of the MDIA Guidance Notes

During Stage 1, the Authority will assess the ITA's capability to meet the generic and specific requirements as stated in Articles 8(3) and 8(4) of the ITAS Act respectively, including the fit and properness of the Applicant, Administrator and Qualifying Shareholders. A satisfactory conclusion of Stage 1 will enable the Authority to issue a Letter of Intent to the Applicant. The Authority may indicate issues in the Letter of Intent that will impinge on the Authority's decision to grant certification to the Applicant if these are not addressed during Stage 2 of the Certification application process.

Upon receipt of the Letter of Intent, the Applicant must engage a Systems Auditor to carry out the Systems Audit as indicated by the MDIA in the Letter of Intent. Upon conclusion of the Systems Audit, the Applicant shall remit the Systems Auditor Report to the MDIA. The Authority will review the opinion provided by the Systems Auditor, assess if issues raised in the Letter of Intent have been satisfactorily resolved and if it deems that the AI-ITA satisfactorily meets the criteria of the ITAS Act together with the features and qualities of Artificial Intelligence (as further described in Section '3. Qualifying features and qualities of AI-ITAs'), proceed to grant the Certification.

In order not to delay the application process unnecessarily, the Authority recommends that the Applicant identifies a potential Systems Auditor prior to submitting the ITA Application Form. To assist in this identification process, the Authority draws to the attention of the Applicant the Register of Recognitions, which is available to the public and maintained by the Authority. The Register of Recognitions, contains amongst other listings, a list of Systems Auditors that have been granted recognition by the Authority to carry out Systems Audits. It is pertinent to note that a registered Systems Auditor must have suitable experience related to the AI-ITA to be audited. Therefore, the Authority strongly recommends prospective Applicants to identify a suitable Systems Auditor prior to submitting the ITA Application Form.

In appointing a Systems Auditor, the Applicant, together with the Systems Auditor would also need to consider independence. Further guidance on this matter can be found in the 'AI-ITA Systems Auditor Guidelines'.

5.1. Stage 1

The Authority will need to ascertain that the ITA meets the generic and specific requirements contemplated within the ITAS Act. Apart from looking at the technological aspect, prior to issuing a Certificate, the Authority will also need to ascertain that the Applicant of the ITA, as well as, key functionaries are of good repute and standing. In this respect, the Applicant is required to complete and submit an ITA Application Form to the Authority.

The ITA Application Form must be accompanied by:

- all the supporting documentation (*refer to Section 5.4 for details*);
- completed and signed Fit and Proper Questionnaires for the individuals indicated (*refer to Section 5.4 for details*); and
- the first non-refundable instalment of the Processing Fee (*refer to Section 5.3 for details*).

These three elements determine the completeness of an application.

The Authority will only process fully completed applications. In case of incomplete application forms, the Authority will indicate pending requirements to the Applicant. Processing of application shall not commence prior to receipt of outstanding items. If pending items remain outstanding after one (1) month from communication issued by the Authority without an explanation from the Applicant, the Authority will terminate the application process and shall inform the Applicant accordingly.

Upon receipt of a completed application, the Authority will commence its review process to ensure that:

- in principle, the AI-ITA meets the generic and specific requirements; and
- the individuals / functionaries involved are fit and proper as further described in Section 7.1.

Once the Authority is satisfied that the above requirements are met, the Authority will provide the Applicant with a Letter of Intent and instruct the Applicant to formalise the appointment of the Systems Auditor and initiate the Systems Audit.

5.2. Stage 2

Following receipt of the Letter of Intent, the Applicant shall engage with the Systems Auditor to carry out the Systems Audit as indicated by the Authority. Upon conclusion of the Systems Audit and receipt of the Systems Auditor Report, the Applicant shall forward the Systems Audit Report to the Authority to initiate the second stage of the certification application process. This submission shall be accompanied by the second instalment of the Processing Fee.

Upon receipt, the Authority shall review the Systems Audit Report to establish whether following the opinion issued by the Systems Auditor, the AI-ITA is adequately meeting the generic and specific requirements contemplated in the ITAS Act, as well as, the standards the Authority deems necessary for the certification sought. The Authority will also look at any elements highlighted in the Letter of Intent, as well as, changes that occurred since the issuance of the Letter of Intent that could impact the AI-ITA.

Upon a positive conclusion of this stage, the Authority will issue the Certification of the AI-ITA and update the Register of Recognitions accordingly. In line with the Third Schedule of the ITAS Act, the ITA Certification shall be valid for a term of two (2) years.

5.3. ITA Processing Fees

Initial certification of an ITA carries a Processing Fee which is payable in two instalments as follows:

	1 st Instalment	2 nd Instalment
Phase:	Stage 1	Stage 2
When:	Concurrently with the submission of ITA Application Form	Concurrently with the submission of the Systems Audit Report
How:	Details provided on the ITA Application Form	Details provided on the Systems Audit Report Submission Form
Amount:	As determined in the Innovative Technology Arrangements and Services (Fees) Regulations	As determined in the Innovative Technology Arrangements and Services (Fees) Regulations

The Stage 1 fee instalment shall be remitted concurrently with the ITA Application Form, in line with the payment details provided on the form. It is important that Applicants follow the remittance instructions provided to avoid processing delays. Payment details are to be included on the ITA Application Form in the respective section.

The Stage 2 fee instalment shall become payable with the submission of the Systems Audit Report Submission Form following the remittance instructions on the form and including payment details in the relative section on the form.

5.4. Documentation Required

Applicants are required to supplement the ITA Application Form with a number of documents as indicated below. The documents required will vary according to the type of Applicant, type of ITA and organisational setup of the Applicant.

Document	Individual	Legal Organisation
1. Valid identification document	✓	
2. Verification of residential address (if not included on identification document)	✓	
3. Fit and Proper Questionnaire of personal Applicant	✓	
4. Explanation of the ownership and control structure		✓

Document	Individual	Legal Organisation
5. Corporate structure chart showing the ownership structure		✓
6. Memorandum and Articles of Association, or equivalent document		✓
7. If directors and shareholders details are not included in the Memorandum and Articles of Association: <ul style="list-style-type: none"> • Directors register, or equivalent document • Shareholders register, or equivalent document 		✓
8. Fit and Proper Questionnaire for every Qualifying Shareholder		✓
9. For every Qualifying Shareholder documents 1 and 2 above, as applicable		✓
10. Business model	✓	✓
11. Blueprint (<i>refer to Section 7. Specific Requirements below for details</i>)	✓	✓
12. If the Applicant falls under Article 8(5) of the ITAS Act, confirmation by a registered Systems Auditor of the requirements that the ITA is not in compliance with and the technical challenges encountered.	✓	✓
13. Where an Administrator (as defined in Article 2 of the ITAS Act) is appointed, the following must be provided: <ul style="list-style-type: none"> • Valid identification document • Verification of residential address (if not included on identification document) • Fit and Proper Questionnaire 		✓
14. Letter or appointment for every Technical Administrator engaged	✓	✓

Document	Individual	Legal Organisation
<p>15. Where a Resident Agent is appointed, the following must be provided:</p> <ul style="list-style-type: none"> • Valid identification document • Verification of residential address (if not included on identification document) • Fit and Proper Questionnaire 	✓	✓

6. General Requirements

In line with Article 8(3) of the ITAS Act, the AI-ITA must satisfy the general requirements intended to meet the standards of:

- **Legality** of the purpose and function of the AI-ITA;
- **Integrity** of the Applicant, including Administrator and Qualifying Shareholders, where applicable;
- **Transparency** of the functions and limitations of the AI-ITA to its users;
- **Compliance** with all applicable legal obligations; and
- **Accountability**, by clearly identifying who will be fulfilling the roles contemplated in the ITAS Act and defining the responsibilities of each individual, particularly in instances where there are multiple appointments.

Additionally, specifically for AI-ITAs, the AI-ITA must be in compliance with the 'Ethical & Trustworthy AI Framework', with any exceptions adequately justified as further expanded upon in the 'AI-ITA Blueprint Guidelines'.

The Authority will assess all the information provided in the ITA application and will review all documents provided supporting said application in order to reach a conclusion.

7. Specific Requirements

In line with Article 8(4) of the ITAS Act, the Authority shall issue an ITA Certification only when the following specific requirements have been met to the satisfaction of the Authority:

- a) fit and properness;
- b) positive assurance from Systems Auditor/s;
- c) appointment of Technical Administrator/s;
- d) compliance with applicable and mandatory laws, rules and guidelines; and
- e) adequate disclosures to users and affected third parties.

7.1. Fit and properness

In issuing a certification to an AI-ITA, the Authority will need to ascertain both the fitness and properness of the AI-ITA and the person/s exercising control.

Fitness and properness of the AI-ITA

In its review and assessment of an ITA application, the Authority will need to ascertain that the ITA:

- is fit and proper for the purpose/s declared; and
- has the qualities, attributes, features, behaviours or aspects declared.

In this respect, when submitting an application for an ITA certification, Applicants are required to submit a Blueprint to the Authority, which shall include, inter alia, the following information:

Specific Requirements	Typical questions to be answered
Purposes <i>The reasons for which the ITA is being, or was, created.</i>	<ul style="list-style-type: none"> • What social or business needs is the ITA trying to address (if any)? • What benefits are expected to be derived from the ITA?
Qualities <i>The specific characteristics that the ITA offers to its users.</i>	<ul style="list-style-type: none"> • What are the specific characteristics that will allow the ITA to achieve its Purposes? • How does it align with the 'Ethical and Trustworthy AI Framework'?
Aspects <i>The specific elements or boundaries of the ITA that are subject to the certification.</i>	<ul style="list-style-type: none"> • What are the defined boundaries of the ITA that are subject to the ITA certification? • How is the ITA designed from a technical perspective (making reference to the Technology Stack – refer to the 'ITA Blueprint Guidelines')? • What IT security considerations are being applied?

Specific Requirements	Typical questions to be answered
<p>Features <i>The distinctive functional capabilities of the ITA.</i></p>	<ul style="list-style-type: none"> • What are the expected data sources to be used as inputs? • How large is the training data set (if any)? • What algorithm/s will be used? • How will the ITA operate in achieving the specific purposes? • Is the ITA linked to other external systems? If so, how is the ITA interfacing with such systems? • How will the ITA provide functionality to allow the Technical Administrator to exercise the duty to intervene as required in Article 8 of the ITAS Act? • What specific functionality will allow the ITA to meet the obligations of applicable and mandatory law?
<p>Attributes <i>The inherent capabilities of the ITA.</i></p>	<ul style="list-style-type: none"> • What Codebase is being used (open-source, closed-source)? • What type of constraints can be defined in the ITA (if any)? And if so, what is the agreed process if the solution does not meet all constraints? • How can the network be accessed? • How is data shared within the ITA? • If a training data set is being used, what type of data is it? And how will it be collected? What data quality checks will be enforced?
<p>Failure Modes <i>The manner how the ITA responds to unexpected processes and inputs.</i></p>	<ul style="list-style-type: none"> • Does the ITA have monitoring and enforcement capabilities to detect inaccurate behaviour and stop from producing incorrect results? • How will the ITA react to unexpected circumstances? How will the ITA report critical issues to users? • Does the ITA have functionality to identify trends and predict issues beforehand?
<p>Verification <i>The substantiation of the results produced by the ITA.</i></p>	<ul style="list-style-type: none"> • If able to compute, what is the accuracy percentage of the results? • What process will be followed to verify the results produced by the ITA? • What testing strategies will be used?
<p>Limitations <i>The technical and/or operational restrictions of the ITA.</i></p>	<ul style="list-style-type: none"> • Does the ITA have any inherent limitations (such as scaling limitations, performance issues, etc.)? • What are the reasons, if any, that the ITA is not in position to provide functionality to the Technical

Specific Requirements	Typical questions to be answered
	Administrator to intervene as required in Article 8 of the ITAS Act?

The Authority has issued further guidance on the Blueprint within the 'AI-ITA Blueprint Guidelines'.

The Applicant must ensure that any information included in the Blueprint, the basis of which a user and other third parties will use, rely on or otherwise be directly or indirectly affected by in the ITA, shall be disclosed to the users and other third parties as outlined below in Section '6.5 Adequate disclosures to users'.

In addition, the Applicant must ensure that the AI-ITA is implemented in line with the submitted Blueprint, and that the Blueprint is maintained in a timely manner, as this document will serve as the basis for the Systems Audit as outlined below in Section '7.2 Positive assurance from Systems Auditor/s'.

Fitness and properness of the Applicant

The individual and/or legal organisation, in the name of which an application for an ITA certification is submitted to the Authority, shall be required to be fit and proper at all times. Specifically, as required in Article 8(4)(a) of the ITAS Act, in the case where the Applicant is a legal organisation, the Applicant shall ensure that:

- an appointed Administrator of the legal organisation, if any, is fit and proper to carry out the functions of an administrator (refer to Appendix I for more detail); and
- any Qualifying Shareholder (refer to Appendix II for more detail) of the legal organisation is a fit and proper person.

In order to enable the Authority to determine the fitness and properness of these individuals, each individual that meets the above criteria is required to submit a 'Fit and Proper Questionnaire' to the Authority as part of the ITA Application Form.

Moreover, the Applicant must also provide the MDIA with a business model and demonstrate how the service or technology shall be sustainably financed, and how it is aligned with the 'Ethical and Trustworthy AI Framework' by defining how, amongst others, it considers aspects such as: (i) fairness; (ii) bias; (iii) explainability; (iv) social inclusion; and (v) avoidance of human coercion.

7.2. Positive assurance from Systems Auditor/s

Upon successful completion of Stage 1 of the application process, the Authority will issue a Letter of Intent and inform the Applicant to proceed with the appointment of a Systems Auditor. In line with Article 8(4)(b) of the ITAS Act, the Systems Auditor is required to provide the Authority with an opinion on whether the AI-ITA meets reasonable standards as set out by the Authority, which, inter alia, shall include:

- the specific purposes, qualities, features, attributes, failure modes or aspects of the AI-ITA as declared in the Blueprint;
- where applicable, authorisations or powers granted to the Authority, Lead Authority, Technical Administrator or the AI-ITA itself; and
- compliance with any rules and regulations made within the ITAS Act and any guidelines issued by the Authority, as well as any conditions established by the Authority in the particular case.

The Authority will indicate the type of Systems Audit that is required as part of Stage 2 of the application process. Details on the different types of Systems Audits and standards to be met are included in the ‘Systems Auditor Guidelines’. However, it is important that Applicants are aware of the different types of Systems Audits and the frequency of Audit the Authority has set out.

In the case of non-operative AI-ITAs (i.e. AI-ITAs that, at the time of application for an ITA certification, are not yet live or have been operating for less than six (6) months), the Authority shall initially require a Type 1 Systems Audit to be conducted. If the Authority, following the Type 1 Systems Audit, issues an ITA certification, the Applicant will be then required to undergo a Systems Audit for compliance purposes. In this regard, a Type 2 Systems Audit will be required following 6 months from the ITA Go Live date. Thereafter, a Type 2 Systems Audit shall be required on an annual basis.

On the other hand, in case of operative AI-ITAs (i.e. AI-ITAs that, at the time of application for an ITA certification, are live and have been operating for at least six (6) months), the Authority shall request a Type 2 Systems Audit. Thereafter, the ITA shall undergo a Type 2 Systems Audit on an annual basis.

Upon receipt of the Systems Audit Report the Applicant shall complete and submit the Systems Audit Report Submission Form to the Authority.

Applicants need to take note of the following time frames for completion of Systems Audits:

	Systems Audit Type	Initiation of Systems Audit	Report submitted to MDIA
Non-operative ITA	Type 1 <i>(Stage 2 of Application Process)</i>	At any point in time following MDIA’s Letter of Intent.	Within 3 months from the Systems Auditor Green Light* issued by the Authority.
	Type 2 <i>(First Type 2 following Certification)</i>	Within six (6) months from Go Live date.	
	Type 2 <i>(Annual)</i>	After twelve (12) months from the period-end of the latest Type 2 Systems Audit.	

	Systems Audit Type	Initiation of Systems Audit	Report submitted to MDIA
Operative ITA	Type 2 <i>(Stage 2 of Application Process)</i>	At any point in time following MDIA’s Letter of Intent	Within 3 months from Systems Auditor Green Light* issued by the Authority.
	Type 2 <i>(Annual)</i>	After twelve (12) months from the period-end of the latest Type 2 Systems Audit.	

** The Systems Auditor must notify the MDIA upon engagement by the Applicant (refer to Chapter 1 Section 7 – Systems Auditor Guidelines). The MDIA will issue the Green Light to the Systems Auditor to commence the Systems Audit once it is satisfied that the Systems Auditor is competent to audit the respective AI-ITA.*

The AI-ITA is required to provide the Systems Auditor with all information, explanations, documentation and resources necessary to perform the audit.

7.3. Appointment of Technical Administrator/s

An AI-ITA shall have a Technical Administrator, registered with the Authority, in office at all times. An AI-ITA may have more than one Technical Administrator appointed either as an employee or as a subcontractor. Details of the Technical Administrator/s appointed shall be provided as part of the ITA Application Form.

In considering the application for an ITA certification, the Authority will need to ascertain that the appointed Technical Administrator/s is/are registered with the Authority and can fulfil their duties and responsibilities with respect to the AI-ITA being certified. Specifically, in line with Article 8(4)(c) of the ITAS Act, the Technical Administrator shall demonstrate to the Authority that the AI-ITA is able to:

- satisfy all pre-requisites for the certification which may be granted to it under this Act;
- meet standards on a continuing basis, address critical matters and how to address them, as are stated in Guidelines, if any, by the Authority in the event they occur;
- vary parameters or functionalities where the objective of the system is to address mandatory legal requirements which may reasonably be predicted to change over time; and
- with reference to matters, if any, upon which, the Technical Administrator; the Authority or Lead Authority; or any other designated person, may be given the discretion or may be required to intervene and which are addressed by the software, all authorisations or powers required to carry out such interventions exist and operate as intended

by completing the respective declaration in the ‘ITA Application Form’.

In addition, Article 8(4)(d)(iii) of the ITAS Act requires that AI-ITAs shall have in-built technology features, to enable the Technical Administrator, to intervene in a transparent and effective manner in the event of:

- a) a material cause of loss to any user; or
- b) a material breach of law,

so as to ensure that the cause of loss or breach of law is satisfactorily addressed to the best of his/her abilities and to ensure it does not occur or re-occur, and in case of unjustifiable failure by the Technical Administrator, on the intervention of the Authority.

However, the Authority acknowledges that, in specific AI-ITA implementations, the level of intervention of Technical Administrator as required in Article 8(4)(c)(iv) and Article 8(4)(d)(iii) of the ITAS Act, may vary depending on the technology. In this regard, when it is clearly justified, the Authority reserves the right to vary this requirement. In doing so, subject to all other requirements being successfully met by the Applicant, the Authority may issue an ITA certification that clearly states that the requirements of Article 8(4)(c)(iv) and Article 8(4)(d)(iii) of the ITAS Act are not being fully met. In addition, the Applicant shall be required to disclose such limitation to all users as part of the Terms of Service.

Further details on the eligibility criteria and duties of the Technical Administrator is included in the 'Technical Administrator Guidelines'.

7.4. Compliance with applicable and mandatory laws, rules and guidelines

As required by Articles 8(4)(d)(i) and 8(4)(d)(ii) of the ITAS Act, the Applicant needs to demonstrate to the Authority how the AI-ITA will meet obligations imposed upon it by applicable and mandatory law, including but not limited to, those relating to:

- a) the prevention of money laundering and the financing of terrorism;
- b) the protection of personal data,
- c) the respect of the rights of consumers; and
- d) other mandatory laws, depending on the purpose and functionalities of the AI-ITA; and
- e) adherence to the 'Ethical and Trustworthy AI Framework'.

In submitting an application for an ITA certification, the Applicant shall clearly indicate whether these obligations will be met by implementing physical/manual procedures outside the AI-ITA boundaries or through in-built functionalities within the AI-ITA, such as the ITA Harness process as described in the 'AI-ITA Nomenclature'. In the case of the latter, the Blueprint shall clearly indicate these functionalities. In addition, in the case where the Applicant states that any mandatory law, rule or guideline is not applicable, including any aspects mentioned within the 'Ethical and Trustworthy AI Framework', the Applicant is also required to provide justification as to why such requirements do not apply. This information will be reviewed by the Authority as part of Stage 1 of the application process, and the Applicant may be requested to provide additional information or clarifications.

The Applicant is responsible for ensuring that the procedures implemented to meet obligations with applicable and mandatory law, as indicated by the Applicant in the application for an ITA certification, shall be in line with any guidance issued by the Lead Authority on the respective subject, and which may be updated from time to time.

6.5 Adequate disclosures to users and affected third parties

The Applicant must ensure that the specific purposes, qualities, features, attributes, limitations, conditions, terms of service and behaviours or aspects of the AI-ITA, the basis of which a user is invited to participate in, rely on or use the AI-ITA, shall be adequately disclosed to all users or prospective users. Additionally, in line with the 'Ethical and Trustworthy AI Framework', these considerations must also be extended to third parties that may be directly or indirectly affected. Specifically, Article 8(4)(e) of the ITAS Act requires that such disclosures are made in the English language and are in an easily accessible and intelligible format.

Where the Applicant wishes to use multiple languages for this purpose, in case of conflict between languages, the English language version shall prevail. In addition, in the case of conflict between the English language and the underlying code of the innovative technology arrangement, the English language shall prevail.

8. Resident Agent

In line with Article 15 of the ITAS Act, an Applicant that is not habitually resident in Malta is required to appoint a Resident Agent. Details of the appointed Resident Agent shall be provided to the Authority as part of the application for ITA certification.

Refer to the 'Resident Agent Guidelines' issued by the Authority for further guidance.

9. Outsourcing

The Applicant may need to outsource some functions in view of resource constraints. In granting a certification, the Authority must be made aware of material functions that are being outsourced.

Material functions are those functions that are fundamental for the AI-ITA to meet the generic and specific requirements under Article 8 of the ITAS Act. In this respect the Applicant needs to demonstrate to the Authority how the process to operate the AI-ITA will be managed and by whom.

The Authority reserves the right to request copies of outsourcing agreements.

The Authority may also, from time to time issue standards in this respect, which shall be binding on the AI-ITAs seeking certification from the Authority and are eventually certified by the MDIA.

10. Certification

10.1. Full certification

Upon satisfactory conclusion of the application process, the MDIA will proceed to issue a certificate to the AI-ITA stating the qualities, features, attributes, failure modes and aspect of the arrangement.

In line with Article 8(8) of the ITAS Act, in cases where the AI-ITA is held within a legal organisation, whether with legal personality or not, the certification shall be made in name of the legal organisation. In case of applications in the name of individuals the certificate shall be issued in the name of the Applicant and if so requested, also in the name of the Technical Administrator.

In line with Article 8(6) of the ITAS Act, the Authority shall also enter the name of the certified AI-ITA on the Register of recognised innovative technology arrangements, under the applicable category.

10.2. Conditional certification

In the case of AI-ITAs which are in operation, or at a very advanced stage of development on the date the ITAS Act come into force, where compliance with one of the requirements for certification of an AI-ITA stated in Article 8 of the ITAS Act is not practicable within short time frames due to technical challenges, the Applicant may still submit an application for certification by the MDIA subject to a number of conditions:

- a) a Systems Auditor (recognised and confirmed by the Authority that he/she can audit such AI-ITA), must confirm what the shortcomings are, the technical challenges encountered and the reason why these cannot be implemented in a short time scale; and
- b) the Authority together with the Applicant shall identify:
 - i. the issues on which there is non-compliance with the legal requirements stated in Article 8 of the ITAS;
 - ii. the matters which need to be overcome for such issues to be addressed;
 - iii. the manner in which such issues may be addressed as would satisfy the Authority of compliance with said Article; and
 - iv. the time frame within which the issues are to be addressed.

Based on the above the Authority may proceed to issue a Conditional Certificate to an AI-ITA in these circumstances.

The AI-ITA will have to comply with all the requirements of Article 8 within the time frames agreed. In addition a Systems Auditor (recognised by the MDIA) will need to issue a positive assurance that the necessary actions and modifications have been made to the AI-ITA to achieve the agreed outcomes and compliance.

The condition shall be recorded in the certification and subsequently the register for recognised innovative technology arrangements held by the MDIA.

11. Ongoing obligations

11.1. Display of certificate

Once the certification process is completed successfully, an AI-ITA shall be granted a Certificate under the ITAS Act. The Certificate will state the details of how the AI-ITA shall be identified, including a brand name or any applicable cryptographic verification techniques. The Certificate will carry a unique number for purposes of identification.

The Certified AI-ITA shall post the Certificate on the arrangement, in a specific location which shall be notified to the Authority, in an easily accessible and legible format so it can be viewed and understood by all users of the AI-ITA.

11.2. Go Live Date

Once the Authority certifies a non-operative AI-ITA, it is expected that it goes live within the time frame indicated in the ITA Application Form.

If, for any reason the Certified AI-ITA is not in a position to comply with this condition, it shall notify the Authority in writing setting out the reason/s for such a delay together with a revised expected Go Live date.

Should the Certified AI-ITA not manage to achieve a Go Live date within 12 months from date of Certification, the Authority reserves the right to suspend the Certification pending further developments from the AI-ITA.

11.3. Material Changes

In the event of any material changes, the Certified AI-ITA is obliged to engage with the Authority to either obtain the Authority's prior approval to the change or notify the Authority of the change as further explained below.

Where the Certified AI-ITA needs to notify the Authority of a material change, such notification shall be made to the Authority formally, in a durable medium and the applicable fees paid. The request to notify the Authority of a change shall not be satisfied merely by the fact that the information which ought to be notified to the Authority is included in a standard annual return.

For the purpose of these ongoing obligations, "material changes" with reference to an AI-ITA arrangement shall include:

- a) any alterations of any of elements including, but not limited to the software, algorithms, data, and training sets on which an assurance has been provided by a Systems Auditor;
- b) any development altering the rights of users or that may affect third parties either directly or indirectly;
- c) any development altering the rights, authorisation and powers of the technical administrator or the Authority;

- d) any change in the Technical Administrator;
- e) any change in an administrator of a relevant legal organisation;
- f) any change in a Qualifying Shareholder; and
- g) any change in the person with reference to whom a certification has been issued.

Prior approval by the Authority

The following material changes require the Certified AI-ITA to provide the Authority all the relevant details, as well as, any applicable fees, prior to the changes taking place:

- a) any change in the Technical Administrator;
- b) any change in an Administrator of a relevant legal organisation;
- c) any change in a Qualifying Shareholder; and
- d) any change in the person with reference to whom a certification has been issued.

The Authority shall review the proposed changes and following its assessment the Authority will advise the Applicant whether such changes may be implemented.

Notification to the Authority

In the following instances, the Certified AI-ITA must provide the Authority with the particulars of the change, as well as, any applicable fees, within thirty (30) days of such changes:

- a) any alterations of any of the software on which an assurance has been provided by a Systems Auditor;
- b) any development altering the rights of users; and
- c) any development altering the rights, authorisation and powers of the technical administrator or the Authority.

Notification of these changes is permitted as long as the notification is accompanied by documentation showing that:

- (i) a Systems Auditor (recognised by the MDIA) confirms that such changes do not impact on the last Systems Audit Opinion issued on the AI-ITA; and
- (ii) the Technical Administrator confirms that they have reviewed the changes and confirm the continuing validity of the declaration issued at the time the ITA submitted the application for certification.

The AI-ITA should not undertake the change unless both the Systems Auditor and the Technical Administrator confirm the change.

12. Renewal process

A Certified AI-ITA seeking renewal of its certification must submit an ITA Certification Renewal Form to the Authority, three (3) months prior to the expiration of the current certification, together with the applicable fees.

Appendix I - Who is the Administrator?

In line with the Fourth Schedule of the ITAS Act, an Administrator means an officer or any person who is appointed to carry out representative and fiduciary functions in the control and administration of a legal organisation, and any person who carries out such functions even if under another name, but shall not include a Technical Administrator or a Resident Agent under the ITAS Act. The term "board of administrators" shall be construed accordingly.

The term Administrator shall not include any user who has the right or power to express their views or consent to a proposal in relation to the software consisting of an AI-ITA when such user is a member of the user community and their holding or functions do not permit them to influence decisions on their own. Having said this, a user shall be considered to be in a position to influence decisions as an Administrator if they hold a post within the organisation which enables them to vote with a weighting of more than 25% in favour of or against material decisions relating to the governance of the arrangement.

For avoidance of doubt, Administrator shall mean:

- a) a person who has powers of representation and may generally bind the legal organisation in contract;
- b) a person who has control of assets belonging to the legal organisation and who has any powers in relation to the assets of any user which may be using the arrangement;
- c) a person who has supervisory functions over the operation of the software and may intervene in the normal course of business to respond to queries by the users, in particular for access to the software, access to and powers to amend documentation evidencing the terms and conditions applicable to participation on the arrangement, taking decisions relating to on-boarding of persons onto the arrangement, decisions on the application of mandatory laws and generally on changes relating to the software itself when prompted by the market in which it operates, the Technical Administrator or the Authority, including taking final decisions on proposed changes that may affect the behaviour of the arrangement; and
- d) a person having general governance functions in relation to the arrangement, duties under any rules of an exchange, duties of compliance with any mandatory laws applicable to the context and other fiduciary obligations listed in article 1124A of the Civil Code¹.

¹ Chapter 16 of the Laws of Malta

Appendix II - Who are the Qualifying Shareholders?

In line with the Fourth Schedule of the ITAS Act, the term Qualifying Shareholder includes any shareholder who:

- owns or controls the AI-ITA;
- holds more than 25% of the shares or ownership interests in the legal organisation; or
- through provisions of the statute, has special voting or other rights permitting them to exercise effective control over the activities of the legal organisation.

Where in any particular case and on analysis of an arrangement it is not possible for any person to be identified as falling within the above categories, then the Authority shall proceed on the basis that there are none and may

- tailor the conditions of recognition to such context; or
- require that reference be made to any other person who may be providing material operational services to the AI-ITA or who may be receiving material economic benefit from the operations of the arrangement.

For the avoidance of doubt, the term 'shareholder':

- a) shall include any holder of shares in a company, any partner in a partnership, any beneficiary under a foundation or any other member in a co-operative or association of persons who has a share in the capital or a share in the profits of the legal organisation, and who may vote on general matters raised for the holders thereof to express their view;
- b) shall refer to persons who have the power to vote on a proposal to amend the software or architecture of an ITA which can modify the rights of the holders thereof other than on inconsequential administrative aspects;
- c) only includes a holder of tokens, which:
 - i. are issued by a legal organisation with reference to an AI-ITA, and which grants such rights to the holder thereof with the intention of reflecting the same status and powers in the legal organisation which owns the AI-ITA; or
 - ii. qualify as "equity" in the legal organisation or the arrangement, in that they give the holder thereof a share in the capital and profits of, or in relation to, the arrangement and voting powers in relation to an AI-ITA and which enable them to vote in favour of material decisions relating to defined matters established for the continuing operations of the arrangement and has:
 - A. a weighting of more than 25% of the total tokens in issue;
 - B. under reserved powers, a veto or similar power where they may determine the outcome of a vote or a proposal due to special rights vested in him notwithstanding that he may hold less than 25%, and shall not include any other user or owner of tokens or other digital

assets even if they have a voting right, a right to be granted additional tokens in specified circumstances or any other power or right to participate in specified circumstances.