SHAPING THE FUTURE

AGIOMETRIX

IATF 16949 section 7.1.5.3.1 Internal Laboratories

Agiometrix srl Declaration of conformity

Introduction

In accordance with the most recent update of the IATF16949:2016 regulation (Ref: "SI 23-25 issued in May 2022, effective from June 2022"), organizations are allowed to make use of external laboratories where there is evidence that this laboratory has been evaluated and meets the requirements of Section: “7.1.5.3.1 Internal Laboratories”

This document aims to provide the appropriate evidence and/or references so that an organization can consider Agiometrix equivalent to an internal but physically separate laboratory within the requirements of the IATF standard.

Then integrate this document into the supplier evaluation and be able to demonstrate to your Customers and Certification Bodies compliance with standard point “7.1.5.3.2. External Laboratories” even if Agiometrix is not ISO/IEC 17025 accredited.

Demonstration of compliance

Below are the points of section 7.1.5.3.1 of IATF 16949 to be satisfied and the evidence of Agiometrix srl's compliance with these points.

NR	CHECKLIST	EVALUATION
1.	A laboratory within the organization must have a **defined scope of activity** that includes the ability to perform the required inspection, testing or calibration services. This field of activity of the laboratory must be included in the quality management system documentation	**Description:** *Agiometrix's field of activity consists of 3D scans aimed at obtaining the precise and accurate digitization of reality. The digital files obtained are processed to carry out metrological verification, defect analyses and reverse engineering in accordance with customer specifications. The field of application, as per EN9100 and ISO 9001 certification, is:* PROVISION OF HIGH TECHNOLOGICAL ENGINEERING SERVICES AIMED AT REVERSE ENGINEERING ACTIVITIES, QUALITY CONTROL AND NDT DEFECTOLOGY OF INDUSTRIAL PRODUCTS **Procedure:** MQ_Ed.1_Rev.02 Manuale_della_Qualità
2.	The laboratory must specify and implement at least the requirements for: **a) the adequacy of the laboratory's technical procedures;**	**Description:** *Each technical activity, both scanning and post-processing of the acquired data, is performed and validated in accordance with both general procedures (in relation to the instrumentation and technology used) and specific operational procedures (related to the various specific projects).* **Procedures:** PQ.04 (PROD. E EROG. DEI SERVIZI) Rev03 PQ.08 (GESTIONE DEI SISTEMI DI MISURA E CONTROLLO) REV02 GOP_AGT_01-Processo di scansione ottica digitale GOP_AGT_02-Processo di scansione con Laser e fotogrammetria GOP_MTX_01-CT Tomography NDT Serial Component Testing_Rev04 GOP_MTX_02-Processo di scansione tomografica 3D a raggi X_Rev07

NR	CHECKLIST	EVALUATION
3.	The laboratory must specify and implement at least the requirements for: **b) the competence of the laboratory staff;**	**Description:** *Agiometrix staff is constantly trained both on technical aspects and on management and code of ethics aspects.* *This continuous training is periodically verified and recorded through professional refresher meetings and operational verification sessions (Proficiency review).* **Procedures:** PQ.03(GESTIONE DELLE RISORSE) Rev03 MANSIONARIO_GMTX REGOLAMENTO_GMTX Modulo_Valutazione_GMTX_Rev03 Mod.07_PQ03_Checklist Proficiency Review Annuale_Rev00
4.	The laboratory must specify and implement at least the requirements for: **c) product testing**	**Description:** *Agiometrix process flow is carried out in distinct phases, each of which is validated before moving on to the next. Each validation check is recorded and remains available within each operational order. The active registration procedures and forms are:* **Procedures:** PQ.04 (PROD. E EROG. DEI SERVIZI) Rev03 PQ.06 (GESTIONE QUALITA,NC,RECAMI-AZ_CORR)_Rev03 PQ.08 (GESTIONE DEI SISTEMI DI MISURA E CONTROLLO) REV02 Mod.02A_PQ08_Verifica Taratura Strumento Ottico Mod.05A_PQ04_Controllo Scansione Ottica_Rev_01 Mod.05M_PQ04_ControlloCTScan
5.	The laboratory must specify and implement at least the requirements for: **d) the ability to perform these engineering services correctly, with reference to the relevant process standards (such as ASTM, EN, etc.); when no national or international standard is available, the organization must define and implement a methodology to verify the capability of the measurement system;**	**Description:** *The first step of each activity is the technical analysis of the specific customer requests both for the feasibility assessment and for the regulations referred to and requested. If these standards are not available, it is the responsibility of the technical body to request them from the customer or request the supply management before carrying out the feasibility check and sizing of execution times. Everything is specified in the procedure:* PQ.04 (PROD. E EROG. DEI SERVIZI) Rev03 *The company has a history of over twenty years and therefore has an adequate standards archive which is kept updated as prescribed in the procedure:* PQ.07 (GESTIONE DELLA DOCUMENTAZIONE)_Rev01 *The technologies available to Agiometrix and the activities that can be performed are of various types and are specified below together with the international reference regulations for the correct management of these technologies* ***X Ray Digital radiography (DR):** is performed according to international standards (ASTM E1025 – ASTM E0747 – ASTM E1025 – ASTM E1165 – ASTM E1742 – ASTM E2002 – ASTM E2597 – ASTM E2698 – ASTM E2736 – ASTM E 2737) with certified image quality verification tools (IQI) and by qualified operators: n.2 Liv.3 e n.2 Liv.2 according to ISO9712* ***X Ray 3D Computed Tomography (CT):** the acquisitions are carried out in compliance with the regulations in force on CT systems (ASTM E1441 – ASTM E1570 – ASTM E1672 – ASTM E2903).* *All CT systems are calibrated and maintained according to internal procedures compliant with ASTM E 1695.* *The measurement accuracy of each CT system is verified by the manufacturer in compliance with VDI2630 during the initial approval phase and periodically verified both by the manufacturer's technicians during periodic maintenance and by Agiometrix personnel trained for the purpose according to the internal calibration plan defined in the instrument management database* *Mod.01_PQ08_Lista Generale Strumenti.* *For this purpose, Agiometrix has various primary samples properly managed with a periodic check plan defined in the instrument management database* *Mod.01_PQ08_ Lista Generale Strumenti.*

NR	CHECKLIST	VALUTAZIONE
5.	following	*Further active internal procedures are:* GOP_MTX_03-New procedure for Voxel Size Correction GOP_MTX_06-Procedura di calibrazione X-Alignment Yxlon CT Modular GOP_MTX_07-Procedura di calibrazione Z-Alignment Yxlon CT Modular GOP_MTX_08-Procedura Wobble Check-ONLINE GOP_MTX_09-Procedura Generale Calibrazione Yxlon CT Modular ***Optical 3D scans:*** *are performed with structured light optical instrumentation, multiple laser blades and rotary laser that are calibrated instruments whose accuracy is verified by the manufacturer in compliance with VDI2634 (structured light and maxshot photogrammetry) or ISO17025 (multiple blade laser and laser scanner) in the approval phase initial and periodically verified both by the manufacturer's technicians during periodic maintenance and by Agiometrix personnel trained for the purpose (normally in the start acquisition phase) according to the internal calibration plan defined in the instrument management database Mod.01_PQ08_Lista Generale Strumenti.* *For this purpose, Agiometrix has various primary samples appropriately managed with a periodic check plan defined in the instrument management database Mod.01_PQ08_Lista Generale Strumenti.* *Further active internal procedures are:* GOP_AGT_03-Procedura di verifica della calibrazione Metrscan 750 Elite GOP_AM_01-Taratura del Calibro a Corsoio GOP_AM_02-Taratura del Micrometro
6.	The laboratory must specify and implement at least the requirements for: **e) customer requests, when available**	**Description:** *All the activities carried out by Agiometrix are in accordance with customer specifications, therefore the first step of each activity is the technical analysis of these specifications both for the feasibility assessment and for the regulations referred to and requested. If these standards are not available, it is the responsibility of the technical body to request them from the customer or request the supply management before carrying out the feasibility check and the sizing of the execution times and consequently the costs.* *The company has a history of over twenty years and therefore has an adequate standards archive which is kept updated as prescribed in the dedicated procedure.* **Procedures:** PQ.02 (PROCESSO COMMERCIALE) Rev04 PQ.04 (PROD. E EROG. DEI SERVIZI) Rev03 PQ.07 (GESTIONE DELLA DOCUMENTAZIONE)_Rev01 PQ.01 (Gestione e Sicurezza dei Dati) Rev05
7.	The laboratory must specify and implement at least the requirements for: **f) The review of the relevant records.**	**Description:** *Each technical activity carried out in Agiometrix is subjected to a verification and validation process carried out by both the operator who performed it and technical responsible of the department. If the requirements are not respected and the checks and validations are not passed, it will not be possible to proceed to the next step of the activity. Everything is recorded on the final reports and on appropriate registration forms with the unique identification of both the operator and the technical responsible.* **Procedure:** PQ.04 (PROD. E EROG. DEI SERVIZI) Rev03 **Records:** Mod.04_PQ/02 Gest. Check List Richiesta Cliente. Mod.01A_PQ/04 (Report CQA AGT) Mod.01M_PQ/04 (Report CQA MTX) Mod.02_PQ/04 (Calendario Attività) Mod.03_PQ04 (Scheda identificativa Proprietà del Cliente) Mod.04A_PQ04 (Foglio Assistenza Cliente) Mod.08_PQ/02 (An. Fattibilità-Commessa) – Copia per Produzione

Conclusions

The acquisition data and test reports are the property of the customer and are properly managed both in terms of data confidentiality and archiving and conservation in compliance with the customer's requirements agreed upon in the supply contract.

Everything is specified and described in the procedure:

PQ.01 (Gestione e Sicurezza dei Dati) Rev05

The vastness of the technology portfolio available in AgioMetrix is unique on the Italian market: the company is able to scan and verify any type of object, from the very small (e.g. jewellery, micro-gears for watches) to the very large (e.g. ships, buildings) always with the highest level of accuracy and precision available on the market. The experience and know-how acquired in over 20 years of work exclusively in the field of engineering services (as stated in the field of application of the quality certifications) make Agiometrix a center of excellence in the activities offered to the market.

Agiometrix is available for any necessary further information and for this purpose, a visit to the headquarters is always very welcome to see and experience first-hand the technologies, working methods and skills.