











	NVSB/PRO/01 NANO <i>Verify</i> Programme Standard Operating Procedure (SOP)	Issue 2.0
	Controlled/For information	Revision 3.0

NANO *VERIFY* PROGRAMME STANDARD OPERATING PROCEDURE (SOP) (NVSB/PRO/01)

	NVSB/PRO/01 NANO Verify Programme Standard Operating Procedure (SOP)	Issue 2.0
	Controlled/For information	Revision 3.0

Template Version Control Revision History

Rev.	Issue	Prepared by	Date	Sign	Reviewed by	Date	Sign	Approved by	Date	Sign
0	1	Syahireen	13/1/2021		Dr. Nur Aimi	26/1/2021		En. Johan	28/1/2021	
1	2	Munirah	6/5/2023		Dr Nur Aimi	16/6/2023		En Johan	20/6/2023	
2	2	Munirah	11/12/2023		Dr Nur Aimi	12/12/2023		En. Johan	13/12/2023	
3	2	Syahireen	2/5/2024		Dr Nur Aimi	7/5/2024		En. Johan	9/5/2024	

	NVSB/PRO/01 NANO <i>Verify</i> Programme Standard Operating Procedure (SOP)	Issue 2.0
	Controlled/For information	Revision 3.0

This document is cited as follows:

NANO *Verify* Product Certification Scheme Standard Operating Procedure, Revision 2024.

This document replaces the NANO *Verify* Programme Standard Operating Procedure Issue 2, Revision 2 (2023).


Publisher
 NanoVerify Sdn Bhd (NVSB)
 E-5-6 (Suite 5.8 and Suite 5.9),
 Megan Avenue 1,
 189, Jalan Tun Razak,
 50400 Kuala Lumpur

Copyright © 2023

No part of this document may be produced in any form or means electronic or mechanical by photocopying, recording or otherwise without written permission of the publisher.

This document will be subjected to review to reflect current needs and conditions. Users and other interested parties may submit comments on the contents of this document for consideration into future versions.

Compliance with this document does not by itself grant immunity from legal obligations.

	NVSB/PRO/01 NANO Verify Programme Standard Operating Procedure (SOP)	Issue 2.0
	Controlled/For information	Revision 3.0

NANO Verify Programme Technical Committee

Johan Iskandar Hasan	Chairman
Dr Nur Aimi Mohd Nasir	NanoVerify Sdn Bhd (NVSB)
Siti Munirah Salimah Abd Rashid	NanoVerify Sdn Bhd (NVSB)
Muhammad Syahireen Jamain	NanoVerify Sdn Bhd (NVSB)
Dr Daniel Bien Chia Sheng	NanoMalaysia Berhad (NMB)
Mr Devandran Krishnan	NanoMalaysia Berhad (NMB)
Dr Azira Abd Aziz	Malaysian Rubber Board (MRB)
Dr Nik Intan Nik Ismail	Malaysian Rubber Board (MRB)
Mr Mohamad Fauzi Ahmad	National Metrology Institute of Malaysia (NMIM)
Dr Lee Hing Wah	MIMOS Berhad
Dr Asrulnizam Abd Manaf	Universiti Sains Malaysia (USM)
Dr Hayyiratul Fatimah Mohd Zaid	Universiti Teknologi PETRONAS (UTP)
Dr Nurul Azhani Yunus	Universiti Teknologi PETRONAS (UTP)
Assoc Prof Dr Yap Boon Kar	Universiti Tenaga Nasional (UNITEN)
Prof. Dr. Mat Uzir Wahit	Universiti Teknologi Malaysia (UNITEN)
Ts Dr Norhasnidawani Johari	Malaysia-Japan International Institute of Technology (MJIT), Universiti Teknologi Malaysia (UTM)



	NVSB/PRO/01 NANO <i>Verify</i> Programme Standard Operating Procedure (SOP)	Issue 2.0
	Controlled/For information	Revision 3.0

TABLE OF CONTENT

Section	Title	Page
1.0	Introduction	7
2.0	Objective and Scope of the Document	7
3.0	Normative References	8
4.0	Terms and Definitions	8
5.0	Baseline Requirement	10
Annex A	Normative Reference	16
Annex B	Procedure of Product Certification - NANO <i>Verify</i> Programme	19
Annex C	Test Report	30

	NVSB/PRO/01 NANO <i>Verify</i> Programme Standard Operating Procedure (SOP)	Issue 2.0
	Controlled/For information	Revision 3.0

PREFACE

The NANO *Verify* Programme was first launched in 2015 and was the first nanotechnology-based product certification programme recognized by the Ministry of Science, Technology and Innovation (MOSTI), Malaysia owned by NanoMalaysia Berhad (NMB) and operated by NanoVerify Sdn Bhd (NVSB).

NANO *Verify* Programme is a voluntary certification programme for processes and/or products that have incorporated nanomaterials and/or utilize nanotechnology with claims of size in the range from 1 to 100 nm (“nm” referring to nanometre). There are three schemes under the programme which are NANO *Verify*, NANO *Trust* and GRAPHENE *Verify*. However, the scheme that involved Type 5 (as ISO/IEC 17067)- a comprehensive evaluation and review following the requirement of ISO/IEC 17065 is known as the NANO *Verify* Product Certification Scheme. “NANO *Verified*” certification will be awarded to the processes and products upon successful completion of the scheme which subject to the approval committee for this programme.

As the nanotechnology market trends evolve, the standard operating procedure for this programme is also evolving towards the requirement of the ISO/IEC 17065 requirement, introduction of new standards and other regulatory requirements so that the NANO *Verify* Programme remains relevant. Among the improvements incorporated in this edition are the revision of the document based on ISO/IEC 17065 requirements and comments including comprehensive test requirements for the programme.


NVSB reflects a comprehensive product certification framework together with the yearly surveillance evaluation and internal periodic monitoring to ensure compliance with all rules and regulations stipulated according to the NANO *Verify* Programme. Continuous support from relevant stakeholders will allow further recognition of the NANO *Verify* Programme towards attaining universal acceptance.

NVSB is committed to ensuring that all stakeholders perform their functions in a manner that is professional and founded on high ethical standards which reflects all stakeholders’ integrity as well as safeguarding impartiality.

This document provides SOP in support of best practices for the successful implementation of the verification and certification process. To achieve this as it relates to this SOPs:

- a) stakeholders/ parties to which this SOP relates must have, and be seen to have, the highest standard of honesty, propriety and integrity in the exercise of their duties;
- b) NVSB shall need to ensure that this SOP safeguard impartiality.

Chairman of NANO *Verify* Programme
29 May 2023


	NVSB/PRO/01 NANO <i>Verify</i> Programme Standard Operating Procedure (SOP)	Issue 2.0
	Controlled/For information	Revision 3.0

1.0 Introduction

- 1.1 NANO *Verify* Programme is a voluntary certification programme for processes and/or products that have incorporated nanomaterials and/or utilize nanotechnology with claims of size in the range from 1 to 100 nm (“nm” referring to nanometre). NANO *Verify* Programme is open to all manufacturers/ businesses located locally (in Malaysia) and internationally. This certification programme is owned by NanoMalaysia Berhad (NMB) and fully operated by NanoVerify Sdn Bhd (NVSB).
- 1.2 There are three schemes under NANO *Verify* Programme which are NANO *Verify*, NANO *Trust* and GRAPHENE *Verify*. NANO *Verify* and NANO *Trust* Product Certification Scheme mainly encompass two categories: size characterization and functionality (surface, mechanical, and/or electrical) enhancement related to the nanotechnology-based claim products/processes. However, NANO *Trust* has an additional element characterization category. Likewise, GRAPHENE *Verify* focuses mainly on the characterization of graphene-based products.
- 1.3 Nevertheless, only the NANO *Verify* Product Certification Scheme which is a Type 5 scheme (as ISO/IEC 17067) a comprehensive evaluation and reviews following the requirement of ISO/IEC 17065 and size characterization shall be the primary scope of accreditation. This scheme focuses on processes and/or products that have incorporated nanomaterials and/or utilize nanotechnology with claims of size in the range from 1 to 100 nm (“nm” referring to nanometre). “NANO *Verified*” certification will be awarded to the processes and products upon successful completion of the scheme which subject to the approval committee for this programme. This document is mainly covering the Standard Operating Procedure (SOP) for the NANO *Verify* Product Certification Scheme.

2.0 Objective and Scope of the Document

- 2.1 This document was developed with the following objectives:
- a) to provide basic requirements on the size characterization for nanotechnology-based claimed products/processes;
 - b) to assure the characterization (size) of the products containing nanomaterials/utilizing nanotechnology to safeguard against fake nanotechnology-based products;
 - c) to support the implementation of the certification programme for nanomaterials;
 - d) to standardize the workflow and ensure mutual understanding between parties involved in the certification process.
- 2.2 This document prescribes the main category in the scheme, which is size characterization, which focuses on processes and/or products that have incorporated nanomaterials and/or utilize nanotechnology with claims of size in the range from 1 to 100 nm (“nm” referring to nanometre) in any dimensions,

	NVSB/PRO/01 NANO Verify Programme Standard Operating Procedure (SOP)	Issue 2.0
	Controlled/For information	Revision 3.0

shapes and forms using various measurement methods. The presence of nanomaterials, information on sample preparation before the size characterization testing and method of creating the image analysis shall not be defined further in this document.


3.0 Normative References

Refer to **Annex A**.

4.0 Terms and definitions

For this document, the terms and definitions apply:

Atomic force microscopy (AFM)	Type of scanning probe microscopy (SPM), with demonstrated resolution on the order of fractions of a nanometre, more than 1000 times better than the optical diffraction limit.
Brunauer-Emmett-Teller (BET)	Analytical technique utilized for determining specific surface areas and pore size distributions of solid materials. The technique is based on the physical adsorption of inert gas, such as nitrogen, on the solid surface of the sample.
Central Limit Theorem	Distribution of a sample variable approximates a normal distribution.
Certification Panel Meeting	The meeting that held to approve, reject, suspend, terminate and/ or withdraw applications in accordance with the stipulations of ISO/IEC 17065 for the specific products to be certified.
Certification Unit	Unit that consists of Certification Manager, Auditors and/or Admin Personnel.
Client	Organisation or person responsible to NVSB or ensuring that certification requirements including product requirements are fulfilled as specified in standards or in other normative documents identified by the certification scheme. This term applies to both the “Applicant” and the “Client”.
Dynamic Light Scattering (DLS)	Technique in physics that can be used to determine the size distribution profile of small particles in suspension or polymers in solution.

	NVSB/PRO/01 NANO <i>Verify</i> Programme Standard Operating Procedure (SOP)	Issue 2.0
	Controlled/For information	Revision 3.0

Electron Microscopy (EM) Technique for obtaining high resolution images of biological and non-biological specimens.

Evaluation Combination of the selection and determination functions of conformity assessment activities. The evaluation process for the scheme is categorized into line audit and remote audit.

Line audit is a physical evaluation activity that is conducted at the manufacturer's place.

Remote audit is virtual evaluation activity conducted by video conferencing, email, and telephone to obtain audit evidence, if there are difficulties such as movement control order (MCO) to replace line audit.

Laser Diffraction Analysis Technology that utilizes diffraction patterns of a laser beam passed through any object ranging from nanometre to millimetre in size to quickly measure geometrical dimensions of a particle.

Mean The average of a data set, found by adding all numbers together and then dividing the sum of the numbers by the number of numbers.


Nanomaterial Material with any external dimension in the nanoscale or having an internal structure or surface structure in the nanoscale of 1 nm to 100 nm in accordance with ISO standards.

However, if the nanomaterials/ nanotechnology-based products are the statutory control products, they are requested to meet the requirements of relevant laws and regulations, therefore the definition may be defined further supporting by legit standard and test guideline. For example, using OECD as guideline for cosmetic.

NANO *Verify* Product Certification Scheme A product/process certification scheme Type 5 (ISO/IEC 17067) for nanotechnology-based products/processes with claims of size from 1 to 100 nm as the main criteria.

NANO *Verified* The certification mark after the product/process is granted to be certified.

Particle Size Analysis A technique which determines the size range, and/or the average, or mean size of the particles in a powder or liquid sample.

	NVSB/PRO/01 NANO <i>Verify</i> Programme Standard Operating Procedure (SOP)	Issue 2.0
	Controlled/For information	Revision 3.0

Process Capability (Cpk) Measures how close a process is performing compared to its specification limits and accounting for the natural variability of the process.

Small Angle X-ray Scattering (SAXS) A technique by which nanoscale density differences in a sample can be quantified. This means that it can determine nanoparticle size distributions, resolve the size and shape of (monodisperse) macromolecules, determine pore sizes, characteristic distances of partially ordered materials, and much more. This is achieved by analysing the elastic scattering behaviour of X-rays when travelling through the material, recording their scattering at small angles (typically 0.1 – 10°, hence the "Small-angle" in its name).

5.0 Baseline Requirement

5.1 The products that claim to be genuine nanotechnology-based are required to have a size range from 1 to 100 nm regardless of any dimensions, shapes, forms and features. It shall need to be tested according to the measurement method (Table 1) stipulated in this document to conform with the NANO *Verify* Programme. However, if the nanomaterials/nanotechnology-based products are the statutory control products, they are requested to meet the requirements of relevant laws and regulations. Further standard operating procedures on the NANO *Verify* Product Certification Scheme shall be explained in **Annex B**.




	NVSB/PRO/01 NANO <i>Verify</i> Programme Standard Operating Procedure (SOP)	Issue 2.0
	Controlled/For information	Revision 3.0

Table 1: General methods for size characterization and its brief detail under NANO *Verify* Programme

Method	Atomic Force Microscopy (AFM)	Brunauer-Emmett-Teller (BET)	Electron Microscopy (EM)	Particle Size Analyzer			
				Dynamic Light Scattering (DLS)	Laser Diffraction Analysis	Particle Tracking Analysis (PTA)	Small Angle X-ray Scattering (SAXS)
Type of Diameter (d in nm)	Height-based equivalent circular diameter	Determining specific surface areas and pore size distributions of solid materials	Equivalent circular diameter. Can be obtained either minimum or maximum ferret.	Hydrodynamic equivalent spherical diameter.	Hydrodynamic equivalent spherical diameter.	Hydrodynamic equivalent spherical diameter.	Volume square equivalent diameter.
Measurement Principle	Height	Gas-adsorption method	Projection (TEM) and imaging of signal electrons (SEM). In relation to particle size image analysis either static or dynamic.	Time resolved light scattering.	Intensity of light scattered as a laser beam passes through a dispersed particulate sample.	Diffusion.	Intensity of scattered light.
Applicability	Can be applied for particles in the size range 1 nm to 1000 nm and even larger particles. Can distinguish between individual particles and agglomerates/ aggregates only under specific conditions. Measure the size regardless of the	This method is applicable only to adsorption isotherms of type II (disperse, nonporous or macroporous solids) and type IV (mesoporous solids, pore diameter between 2 nm and 50 nm). Inaccessible pores are not detected.	This method can be applied for particles in the size range from 1 nm to 1000 nm. The actual accessible size range depends on the instrument settings, technical specifications of the equipment used and on the test material properties.	The measured size is based on the scattering properties which is measured based on the physical structure and the chemistry of the particles.	Can be applied to a wide variety of particulate systems- particle sizes ranging from approximately 0.1 μm to 3 mm. For spherical and non-spherical particles, a size distribution is reported, where the predicted scattering pattern for the volumetric sum of spherical particles matches the measured scattering pattern.	Can be applied for particles with diameters in the size range from 10 nm to 1000 nm and even larger. Measured size is based on the physical structure and the chemistry of the particles.	Can be applied for particles in the size range from 1 nm to 200 nm. Can distinguish between individual particles and agglomerate/aggregates under specific conditions.

	NVSB/PRO/01 NANO <i>Verify</i> Programme Standard Operating Procedure (SOP)	Issue 2.0
	Controlled/For information	Revision 3.0

	particles chemical or structural identity.	The BET method cannot reliably be applied to solids which absorb the measuring gas.			This is because the technique assumes a spherical particle shape in its optical model. For non-spherical particles the resulting particle size distribution is different from that obtained by methods based on other physical principles (e.g. sedimentation, sieving).		
Important influencing Factors	<p>Tip quality.</p> <p>Roughness of the substrate surface.</p> <p>Intermittent contact mode (also called tapping mode or amplitude-controlled mode).</p> <p>Vibration, acoustic and electronic noise.</p>	<p>Homogeneous surface.</p> <p>No lateral interactions between molecules.</p>	<p>Electron dose applied, imaging mode.</p> <p>Acceleration voltage.</p> <p>Beam-induced solution chemistry changes.</p> <p>Specifics of solution reactivity.</p>	<p>Polydispersity Index.</p> <p>Temperature.</p> <p>Viscosity.</p> <p>Sample concentration.</p>	<p>Sampling and method of procedure are crucial in the final data interpretation.</p> <p>The prevalence of laser techniques.</p> <p>Visually outcome confirmation using an orthogonal tool (i.e. microscopy).</p> <p>Wet dispersion is the most used method due to its suitability for a wider range of samples.</p>	<p>Dispersion medium (concentration range from 10⁶ to 10⁹ particles per ml).</p> <p>Thickness of the double layer which can change the dispersing conditions.</p>	<p>Scattering contrast.</p> <p>Concentration of the sample.</p> <p>Electron density.</p>


	NVSB/PRO/01 NANO Verify Programme Standard Operating Procedure (SOP)	Issue 2.0
	Controlled/For information	Revision 3.0

- 5.2 Table 1 illustrates that there are four (4) main methods used for size characterization testing under the NANO Verify Programme. Different measurement method delivers different kinds of diameters which depend on the material and properties of the measured particles. On a side note, a different method has different prerequisites as it mainly depends on the proper sample preparation technique as well as software that is available in the chosen equipment.
- 5.3 Nonetheless, the baseline requirement for nanotechnology-based products to be certified shall be from 1 to 100 nm for AFM, BET and EM methods that give the results in the measurement size range form, while for the particle size analysis method that gives the results in percentage form (if there have done via DLS, PTA, laser diffraction and SAXS method), the percentage of size from 1 to 100 nm shall need to be above 10%.
- 5.4 Concerning the NANO Verify Standard Operating Procedure (**Annex B**), the product for size characterization testing will be taken at random during the evaluation activities. The product may also be taken during the surveillance audit activity. The selection of the product to be tested and its amount shall depend on its form (Table 2).

Table 2. Selection of the product to be tested and its amount

Type of Sample	Amount of Sample
Solid	Minimum of 3 pieces
	Minimum of 2cm (wide) and minimum of 2cm (length)
Powder	Minimum of 20g (10g duplicate)
Liquid/emulsion	Minimum of 20ml (10ml duplicate)
Gel/cream-based	Minimum of 20g (10g duplicate)

- 5.5 However, the amount of tested sample taken is not limited to the amount tabulated in Table 2 as it is subject to the production volume of the product and its availability for testing and backup. NVSB procedure in selecting the laboratory service provider (NVSB/QPRO/10) shall be the supplement in this document as there is a form to fill for selection of sample as well as laboratory to be chosen by NVSB before further certification process.
- 5.6 The size characterization testing shall be realised on the central limit theorem as a minimum of 30 measurements is taken during the analysis. The results shall need to be statistically reported encompassing the result of medium, standard deviation as well as process capability (Cpk) values.
- 5.7 The process capability (Cpk) value shall need to be stated in the testing report as it will be an indicator for whether to retest or not during the surveillance audit.

	NVSB/PRO/01 NANO Verify Programme Standard Operating Procedure (SOP)	Issue 2.0
	Controlled/For information	Revision 3.0

Retest of the certified products shall be done if it is having process capability (Cpk) value less than 1 (need to refer to the initial testing report).

- 5.8 As for the image analysis, it will be concentrates upon the analysis of digital images created from either light or electron detection systems to get better quality and particle size accuracy measurement within the measurement frame if it used electron microscopy. This does not apply on the method of creating the image although the detection settings chosen together with its calibration are important for sizing accuracy.
- 5.9 Test methods other than those specified in this document may be used, provided that the test methods can be verified against accepted standard test methods (Table 3). This shall be accompanied by supporting documents provided by the independent testing laboratory together with all testing results previously conducted by the applicant.
- 5.10 Table 3 illustrates the standards that shall be referred to in this certification programme. At the time of publication of this document, the editions are valid. All standards are subject to revision and parties to agreements based on this document are encouraged to investigate the possibility of applying the most recent standards indicated below:

Table 3: Test Method for size characterization

Method	Standard
Atomic Force Microscopy (AFM)	ISO 13095:2014
	ISO 23729:2022
	ISO/TS 23151:2021
	ISO/TR 11811:2012
Brunauer, Emmett and Teller (BET)	ISO 9277:2010
Electron Microscope (EM)	ISO 21363:2020
	ISO 29301:2017
	ISO 25498:2018
	ISO 20263:2017
	ISO 22493:2014
	ISO/TS 24597:2011
Particle Size Analysis	
Dynamic Light Scattering (DLS)	ISO 22412:2017
	ISO/TR 22814:2020



	NVSB/PRO/01 NANO Verify Programme Standard Operating Procedure (SOP)	Issue 2.0
	Controlled/For information	Revision 3.0

Image Analysis	ISO 13322-1:2014
	ISO 13322:2021
Laser Diffraction Analysis	ISO 13320:2020
Particle Tracking Analysis (PTA)	ISO 19430:2016
	ISO/DIS 19430
Small Angle X-ray Scattering (SAXS)	ISO 17867:2020


5.11 The test report format shall be further explained in **Annex C**.

	NVSB/PRO/01 NANO Verify Programme Standard Operating Procedure (SOP)	Issue 2.0
	Controlled/For information	Revision 3.0


Annex A

Normative Reference

ASTM-E2859-11	Standard Guide for Size Measurement of Nanoparticles Using Atomic Force Microscopy
ISO 13095:2014	Surface Chemical Analysis — Atomic force microscopy — Procedure for in situ characterization of AFM probe shank profile used for nanostructure measurement
ISO 13320:2020	Particle size analysis – Laser diffraction methods
ISO 13322-1:2014	Particle size analysis – Image analysis methods – Part 1: Static image analysis method
ISO 13322-2:2021	Particle size analysis – Image analysis methods – Part 2: Dynamic image analysis methods
ISO 16700:2004	Microbeam analysis - Scanning electron microscopy - Guidelines for calibrating image magnification
ISO 17867:2020	Particle size analysis – Small angle X-ray scattering (SAXS)
ISO 19430:2016	Particle size analysis – Particle tracking analysis (PTA) method
ISO 20263:2017	Microbeam analysis — Analytical electron microscopy — Method for the determination of interface position in the cross-sectional image of the layered materials
ISO 21363:2020	Nanotechnologies — Measurements of particle size and shape distributions by transmission electron microscopy
ISO 22412:2017	Particle size analysis Dynamic Light Scattering (DLS)
ISO 22493:2014	Microbeam analysis — Scanning electron microscopy — Vocabulary
ISO 23729:2022	Surface chemical analysis — Atomic force microscopy — Guideline for restoration procedure for atomic force microscopy images dilated by finite probe size
ISO 25498:2018	Microbeam analysis — Analytical electron microscopy — Selected area electron diffraction analysis using a transmission electron microscope

	NVSB/PRO/01 NANO Verify Programme Standard Operating Procedure (SOP)	Issue 2.0
	Controlled/For information	Revision 3.0

ISO 29301:2017	Microbeam analysis — Analytical electron microscopy — Methods for calibrating image magnification by using reference materials with periodic structures
ISO 9277:2010	Determination of the specific surface area of solids by gas adsorption — BET method
ISO/DIS 19430	Determination of particle size distribution and number concentration by particle tracking analysis (PTA)
ISO/IEC 17065:2012	Conformity assessment — Requirements for bodies certifying products, processes and services
ISO/IEC 17025	Testing and calibration laboratories
ISO/TR 11360:2010	Nanotechnologies- Methodology for classification and categorization of nanomaterials
ISO/TR 22814:2020	Good practice for Dynamic Light Scattering (DLS) measurements
ISO/TS 12805:2011	Nanotechnologies - Materials specifications - Guidance on specifying nano-objects
ISO/TS 23151:2021	Nanotechnologies — Particle size distribution for cellulose nanocrystals
ISO/TS 24597:2011	Microbeam analysis - Scanning electron microscopy - Methods of evaluating image sharpness
ISO 80004-1:2023	Nanotechnologies – Vocabulary — Part 1: Core vocabulary
ISO/TS 80004-3:2020	Nanotechnologies — Vocabulary — Part 3: Carbon nano-objects
ISO/TS 80004-5:2011	Nanotechnologies — Vocabulary — Part 5: Nano/bio interface
ISO/TS 80004-6:2021	Nanotechnologies — Vocabulary — Part 6: Nano-object characterization
ISO/TS 80004-7:2011	Nanotechnologies — Vocabulary — Part 7: Diagnostics and therapeutics for healthcare
ISO/TS 80004-8:2020	Nanotechnologies — Vocabulary — Part 8: Nanomanufacturing processes

	NVSB/PRO/01 NANO Verify Programme Standard Operating Procedure (SOP)	Issue 2.0
	Controlled/For information	Revision 3.0

IEC/TS 80004-9:2017 Nanotechnologies — Vocabulary — Part 9: Nano-enabled electrotechnical products and systems

ISO/TS 80004-12:2016 Nanotechnologies — Vocabulary — Part 12: Quantum phenomena in nanotechnology


NVSB/PRO/03 NANO Verify Trademark and Logo Procedure

NVSB/QPRO/003 Management of Certification Panel

NVSB/QPRO/005 General Evaluation Procedure

NVSB/QPRO/010 Procedure of Outsourcing Laboratory

OECD Test Guideline No 125 Nanomaterial Particle Size and Size Distribution of Nanomaterials

	NVSB/PRO/01 NANO <i>Verify</i> Programme Standard Operating Procedure (SOP)	Issue 2.0
	Controlled/For information	Revision 3.0

Annex B

Procedure of Product Certification - NANO *Verify* Programme

1. This NVSB product certification is granted only if the applicant complies with NANO *Verify* Programme Standard Operating Procedures. The applicant shall maintain an established quality management system to ensure continuous compliance with the standard operating procedures. Since this is a voluntary type of certification, thus there is a need for the applicant to comply with the legal and regulatory requirements if the products are under statutory control before applying for this certification.
2. The objective of the certification is to:
 - a) ensure the genuineness of nanotechnology-based products against fake products;
 - b) facilitate the sales of genuine nanotechnology products;
 - c) create greater market acceptance locally and overseas;
 - d) boost consumer confidence and trust.
3. The general guideline in conducting the NANO *Verify* Product Certification Scheme is proposed to ensure proper action, evaluation, supplementation and/or documentation for every application by the clients.
4. The NANO *Verify* Product Certification Scheme is open to all includes and is not limited to:
 - a) nanomaterial manufacturer;
 - b) nanomaterial user (producer of nano-intermediates and nano-application products);
 - c) nanomaterial trader;
 - d) nanotechnology products seller;
 - e) user of nanotechnology in the operations/ processes;
 - f) others (for the company/applicant to specify).
5. Figure 1 shows the workflow for the SOP while the description of each step explained in Table 4.

	NVSB/PRO/01 NANO Verify Programme Standard Operating Procedure (SOP)	Issue 2.0
	Controlled/For information	Revision 3.0

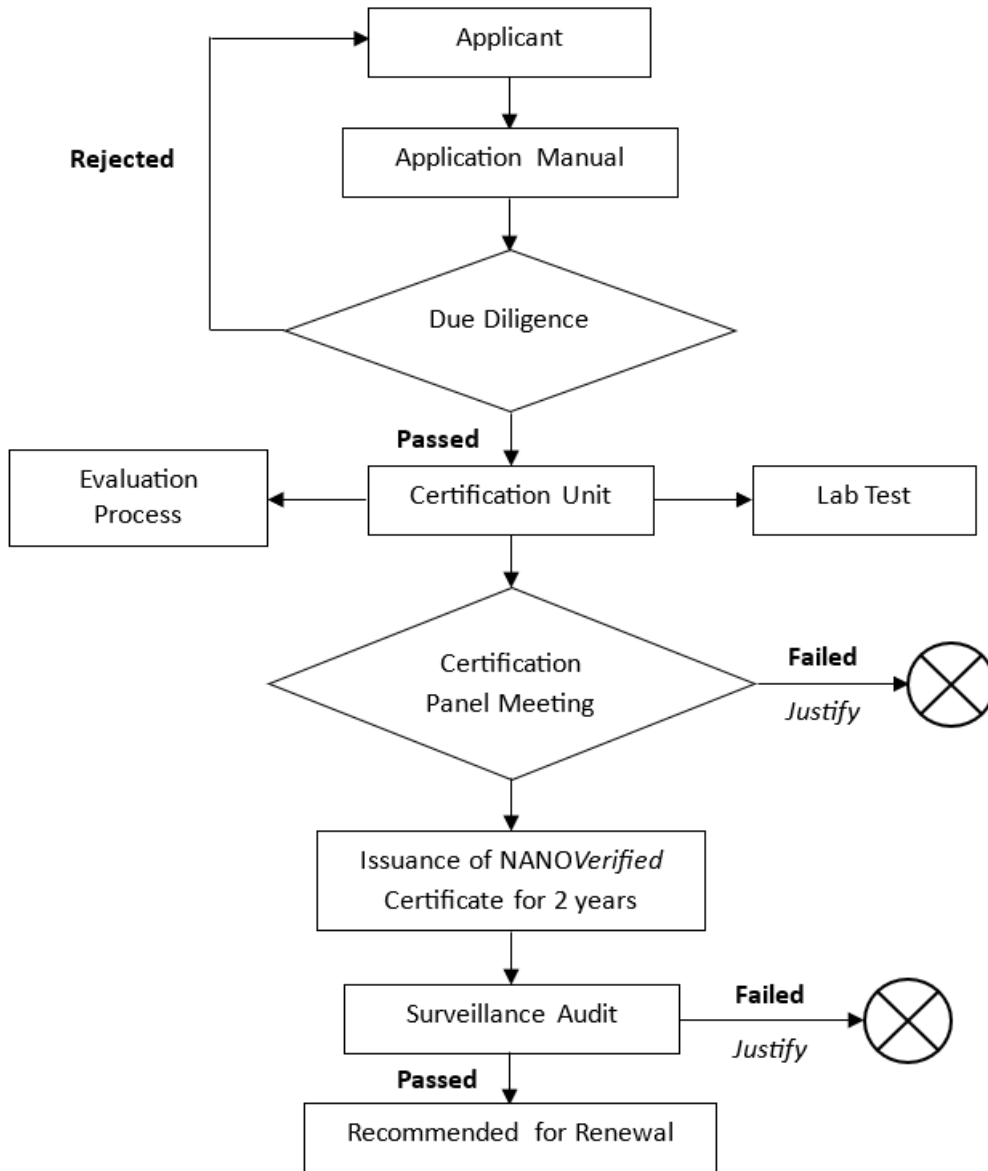


Figure 1: Standard operating procedures (SOP) for NANO Verify Product Certification Scheme




	NVSB/PRO/01 NANO Verify Programme Standard Operating Procedure (SOP)	Issue 2.0
	Controlled/For information	Revision 3.0

Table 4: Detailed description of each step in the SOP's workflow


No.	Step	Description	Responsibility
1	Application (Manual)	<p>i. Application form (NVP-05-FOR-01) can be found manually through the NVSB website or direct request to NVSB via meeting, email or fax.</p> <p>ii. NVSB provides a quotation for the certification fee based on the scope of certification (size characterization or functionality) chosen by the client.</p> <p>iii. Certification fee structure (valid for 2 years of certification)</p> <p>a) characterization (size): *MYR10,000/year/product</p> <p>b) functionality (surface/mechanical/ electrical): *MYR 12,500/ year/product</p> <p>*The fee above is exclusive of current sales and service tax rate (SST). Note that, the SST value may vary based on the government instruction.</p> <p>iv. The client shall remit payment (fee inclusive of SST) upon the confirmation of the scope of certification by submitting a purchase order (PO) to NVSB.</p> <p>v. The certification fee shall be paid upon the receipt of the NVSB invoice either annually or lumpsum (depending on the client's option). The payment is not refundable once it has been made. No monthly instalment payment method.</p> <p>vi. The client shall fill in the application form and prepare documents as per review checklist (NVP-05-FOR-02) and sign the non-disclosure agreement (NVP-05-FOR-03) upon payment.</p>	NVSB and Client

	NVSB/PRO/01 NANO Verify Programme Standard Operating Procedure (SOP)	Issue 2.0
	Controlled/For information	Revision 3.0


2	Due Diligence	i. Upon remittance of payment by the client and signing of the non-disclosure agreement, NVSB will start to conduct a due diligence exercise on the product/process to be certified. The due diligence will be conducted based on the review checklist (NVP-05-FOR-02).	NVSB and Client
		ii. The client will need to: <ul style="list-style-type: none"> a) Provide sufficient information about their company and the product to be certified. b) Understand the certification programme including any agreement regarding standards or other normative documents: c) Acknowledge the scope of certification that has been chosen. d) Ensure that there will be evaluation needs to be done for the certification and acknowledge the access of NVSB personnel to their manufacturer site for such activity. e) Acknowledge that NVSB has the competence and capability to perform the certification activity for the product to be certified. f) Provide sufficient additional information about the productions (if any). g) Provide sufficient related documentary evidence whichever is relevant to the Quality Management System (QMS) (if any). h) Ensure that the payment is made before the certification is done. i) Ensure that they are available to be contacted throughout the certification period. j) Permit NVSB to use and release whatever information obtained during the application to the public or government authorities as deemed proper and necessary by NVSB, or as required by existing law or regulation. 	Client
		iii. If the information/documentation is not within the NVSB procedure at this stage, NVSB will provide a written justification to the client upon any rejection/declination. In contrast, If the	NVSB

	NVSB/PRO/01 NANO Verify Programme Standard Operating Procedure (SOP)	Issue 2.0
	Controlled/For information	Revision 3.0

		information is sufficient and all the matters on due diligence are clearly defined/resolved, NVSB will notify the client via email for the next step of certification.	
3	Evaluation Process	<p>i. Evaluation process shall be conducted by the NVSB Certification Unit upon the completeness of due diligence stage. The detailed process for the evaluation process is elaborated in NVSB/QPRO/005 (General Evaluation Procedure). This includes the following items:</p> <ul style="list-style-type: none"> a) NVP-05-FOR-04 (Notification Letter to Auditor) b) NVP-05-FOR-05 (Audit Notice) c) NVP-05-FOR-06 (Audit Plan) d) NVP-05-FOR-07 (Audit Checklist) e) NVP-05-FOR-08 (Audit Attendance) f) NVP-05-FOR-09 (Audit Notes) g) NVP-05-FOR-10 (Audit Report) h) NVP-05-FOR-11 (Audit Non-Conformance Form) i) NVP-05-FOR-12 (Sample Selection Form) j) NVP-05-FOR-13 (Remote Audit Form) <p>ii. A notification through the audit notice on the evaluation date and method shall be sent to the client upon agreement by both parties.</p>	<p>NVSB</p> <p>NVSB and Client</p>
4	Lab Test	<p>i. Laboratory service providers for the scheme will be identified by NVSB.</p> <p>ii. Approved laboratory service provider under NVSB will meet the following criteria:</p> <ul style="list-style-type: none"> a) tested at the accredited laboratory under ISO/IEC 17025, or b) tested at any laboratory that follows the requirement of ISO/IEC 17025 (non- 	NVSB and laboratory service provider

	NVSB/PRO/01 NANO Verify Programme Standard Operating Procedure (SOP)	Issue 2.0
	Controlled/For information	Revision 3.0


		<p>accredited) - based on NVSB assessment as per the procedure of outsourcing laboratory (NVSB/QPRO/010).</p> <p>iii. The method(s) and instrument(s) to be used for the testing will be determined by NVSB depending on the product to be certified and availability and/or capability of the chosen laboratory.</p> <p>iv. The results of testing will be submitted to NVSB a minimum of one (1) month from the receipt of the samples but subject to the availability of the equipment, difficulty level of the samples as well as other external or internal factors such as testing payment, breakdown of equipment etc.</p>	
5	Certification Panel Meeting	<p>i. The meeting that is held to approve, reject, suspend, terminate and/ or withdraw applications following ISO/IEC 17065, for the specific products to be certified. This meeting will be done at least once per quarter or when necessary.</p> <p>ii. During this meeting, all decisions are based on all information related to the evaluation, its review, testing report and any other relevant information.</p> <p>iii. Successful applications will be issued an approval letter (NVP-05-FOR-14) and awarded with the NANO <i>Verified</i> certificate (NVP-05-FOR-15) as well as the NANO <i>Verify</i> Programme Agreement (NVP-05-FOR-16).</p> <p>iv. Failed applications will be provided with justification for the decision made by the NVSB.</p>	NVSB
6	Issuance of NANO <i>Verified</i> certificate	<p>i. The final certificate (NVP-05-FOR-15) shall be sent to the client along with conditions for the use of the logo and the certification mark upon the decision during the certification panel meeting and written approval by NVSB.</p>	NVSB

	NVSB/PRO/01 NANO Verify Programme Standard Operating Procedure (SOP)	Issue 2.0
	Controlled/For information	Revision 3.0


		<p>ii. Besides NANO <i>Verified</i> certificate issuance, the client will obtain below documents:</p> <ul style="list-style-type: none"> a) NVP-05-FOR-14 (Approval Letter) b) NVP-05-FOR-15 (Certificate) c) NVP-05-FOR-16 (NANO <i>Verify</i> Programme Agreement) d) NVP-05-FOR-18 (Certification Report) <p>iii. The validity of the certificate is two (2) years.</p> <p>iv. The entire process of issuance of the NANO <i>Verified</i> certificate maximum three (3) months. However, NVSB shall need to inform the client if there is/are issue occur during the certification process.</p> <p>v. The client shall inform NVSB if there is a need to change the details in the certificate within 2 years of certification. They need to fill in the form (NVP-05-FOR-17) for such a case.</p> <p>vi. The charge for changing the details on the certificate and changing the formulation of the certified product will be borne by the client as per below:</p> <ul style="list-style-type: none"> a) *cost of change of details in the certificate: MYR 300 (exclusive SST). *The fee above is exclusive of current sales and service tax rate (SST). Note that, the SST value may vary based on the government instruction b) cost of testing if the certified product changes its formulation/ingredients- depending on the complexity and difficulty level of the product. The client shall need to give further information on sample preparation to ease the analysis. 	<p>NVSB</p> <p>Client</p>
7	Issuance of NANO <i>Verified</i> Certification Mark	i. Upon successful completion of the NANO <i>Verify</i> Product Certification Scheme, the Certification Holder shall be approved in writing by NVSB considering the product has	NVSB and Client

	NVSB/PRO/01 NANO Verify Programme Standard Operating Procedure (SOP)	Issue 2.0
	Controlled/For information	Revision 3.0


		<p>been genuinely nanotechnology-based certified with given an exclusive certification number and entitled to publish and display the certificate and the certification mark on promotional materials, correspondence and advertising with strict adherence format, terms and conditions concerning the scope of certification.</p> <p>ii. The client shall need to adhere to the procedure of using the Certification Mark. Further information on the procedure of the Certification Mark shall need to be referred to NVSB/PRO/03.</p>	Client
8	Surveillance audit, renewal/ withdrawal/ suspension/ termination of certification,	<p>i. Successfully certified product(s) shall be subjected to the NVSB surveillance audit which will be done once per year to comply with ISO/IEC 17067 Type 5 requirements.</p> <p>ii. Retest during the surveillance audit shall be conducted if the certified products having process capability (Cpk) value less than 1 (referred to initial testing report).</p> <p>iii. However, the retest/re-evaluation shall be done every 5 years, if the certified product has the process capability (Cpk) value of more than 1 and there is no change in the product's formulation/ingredients within 2 years of the certification period.</p> <p>iv. The Client shall bear the cost of retest if there is any change of formulation/ingredient within 2 years of the certification period (invoice will be given by NVSB).</p> <p>v. NVSB shall issue the surveillance audit report (NVP-05-FOR-10) to the client with a renewal recommendation upon the success of the surveillance audit. Meanwhile, the NVSB shall need to give justification for the failure of a surveillance audit to the client. The client shall need to cease all the use of the logo and the exclusivity-certified number.</p>	<p>NVSB and Client</p> <p>Client</p> <p>NVSB and Client</p>

	NVSB/PRO/01 NANO Verify Programme Standard Operating Procedure (SOP)	Issue 2.0
	Controlled/For information	Revision 3.0


	<p>vi. NVSB shall make decisions on renewal certification based on the evaluation of the surveillance audit subjected to a satisfactory audit report and/or closure of non-conformance (if applicable). Additionally, further decision on the renewal is solely dependent on the client even if it has already been recommended as the client needs to pay first before the issuance of the renewed certificate.</p> <p>vii. Clients that are interested to renew their certificate after 2 years can express their interest by approaching NVSB and starting the renewal process with the following charges:</p> <p style="padding-left: 40px;">a) Characterization (size): *MYR6,500/year b) Functionality (surface/mechanical/electrical): *MYR 8,500/year</p> <p>*The fee above is exclusive of current sales and service tax rate (SST). Note that, the SST value may vary based on the government instruction</p> <p>viii. If there is no response to renew the certificate by the client, the certification shall be recommended for withdrawal 2 months after the expiry date. The withdrawal of certification may also be initiated through a written request from the client. Notification letter on the withdrawal (NVP-05-FOR-24) shall be issued to the client and to make aware that the client is to stop using the certification mark.</p> <p>ix. The certification may be suspended for a minimum of 3 months. The need for suspension shall be determined based on the notification and recommendation form (NVP-05-FOR-21 and NVP-05-FOR-22) by NVSB. NVSB shall recommend suspension by filling out the recommendation of suspension form (NVP-05-FOR-22) if any non-compliance was detected during the certification period.</p> <p>x. The termination of certification shall be recommended with notification (NVP-05-FOR-</p>	<p>Client</p> <p>NVSB and Client</p> <p>NVSB</p>
--	--	--

	NVSB/PRO/01 NANO Verify Programme Standard Operating Procedure (SOP)	Issue 2.0
	Controlled/For information	Revision 3.0

		<p>25) if the response/ corrective action to suspension is not satisfactory. The termination also will be made if certification holder does not follow NANOVerify requirement.</p> <p>xi. Should the client be the subject of suspension or termination and disagree with the certification decision, the client may appeal to the Certification Unit.</p>	Client
9	Complaint and Appeal	<p>i. If the client is not satisfied with any matters related to certification activities, they may make a complaint to NVSB by filling in the Client Complaint Form (NVP-08-FOR-01) which can be obtained through the website. NVSB shall record all client complaints by completing the Client Complaint Form including any necessary corrective action to be taken. If the decision is not acceptable to the complainant, the client is advised to resort to a formal appeal. Any verbal complaint shall not be entertained.</p> <p>ii. In addition, clients can file an appeal using the Client Appeal Form (NVP-08-FOR-02) if they are not satisfied/agree with any decision in certification activities. All appeals must be accompanied by an appeals deposit of MYR 5000 to cover any cost which might be incurred for the appeal. Any balance arising from the deposit shall be returned to the appellant (subject to the appeal decision).</p> <p>ii. The appellant shall be informed of the panel's decision 2 weeks of working days after the judgement is made on the appeal. NVSB shall give formal notice of the outcome at the end of the appeal process to the appellant. The decision of the appeals panel is final and binding.</p>	NVSB and Client
10	Change Affecting Certification	<p>i. When NVSB introduces new or revised requirements scheme that affect the client, NVSB shall ensure these changes are communicated to all clients. NVSB shall verify the implementation of the changes by its</p>	NVSB and Client

	NVSB/PRO/01 NANO Verify Programme Standard Operating Procedure (SOP)	Issue 2.0
	Controlled/For information	Revision 3.0


		<p>client and shall take actions required by the scheme.</p> <p>ii. NVSB shall consider other changes affecting certification, including changes initiated by the client, and shall decide upon the appropriate action.</p>	
--	--	---	--

	NVSB/PRO/01 NANO Verify Programme Standard Operating Procedure (SOP)	Issue 2.0
	Controlled/For information	Revision 3.0

Annex C

Test Report

1. The results of each test or series of tests carried out by the laboratory shall be reported accurately, clearly, unambiguously and objectively, and in accordance with any specific instructions in the test methods.
2. Each test report shall include at least the following information but not limited to:
 - a) a title (e.g. "Test Report");
 - b) the name and address of the laboratory, and the location where the tests were carried out, if different from the address of the laboratory;
 - c) unique identification of the test report (such as serial number), and on each page an identification in order to ensure that the page is recognised as a part of the test report, and a clear identification of the end of the test report;
 - d) the name and address of the customer;
 - e) identification of the analysis and test method used;
 - f) tested sample information;
 - g) the date of receipt and the analysis of the test sample where this is critical to the validity and application of the results
 - h) testing procedures used by the laboratory or other bodies where these are relevant to the validity or application of the results;
 - i) the test results with, where appropriate, the units of measurement;
 - j) the name(s), function(s) and signature(s) or equivalent identification of person(s) authorising the test report;
 - k) where relevant, a statement to the effect that the results relate only to the sample tested;
 - l) where applicable, deviations from, additions to, or exclusions from the test method, and information on specific test conditions, such as environmental conditions;
 - m) where relevant, a statement of compliance or non-compliance with requirements and/or specifications;

	NVSB/PRO/01 NANO Verify Programme Standard Operating Procedure (SOP)	Issue 2.0
	Controlled/For information	Revision 3.0

- n) where applicable, a statement on the estimated uncertainty of measurement; information on uncertainty is needed in test reports when it is relevant to the validity or application of the test results, when a customer's instruction so requires, or when the uncertainty affects compliance to a specification limit;
- o) where appropriate and needed, opinions and interpretations;
- p) where necessary, the location of sampling which may include any diagrams, sketches or photographs;
- q) details of any environmental conditions during sampling that may affect the interpretation of the test results;
- r) any standard or other specification for the sampling method or procedure, and deviations, additions to or exclusions from the specification concerned;
- s) additional information which may be required by specific methods, customers or groups of customers. (For example, statement of traceability/reference).