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Sustainable Nanomanufacturing Framework

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Sustainable Nanomanufacturing Framework

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CWA 17935:2022(E)**Foreword**

This CEN Workshop Agreement (CWA 17935:2022) has been developed in accordance with the CEN-CENELEC Guide 29 “CEN/CENELEC Workshop Agreements – A rapid prototyping to standardization” and with the relevant provisions of CEN/CENELEC Internal Regulations - Part 2. It was approved by a Workshop of representatives of interested parties on 2022-09-20, the constitution of which was supported by CEN following the public call for participation made on 2021-11-24. However, this CEN Workshop Agreement does not necessarily include all relevant stakeholders.

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Introduction

European manufacturing is determined to provide by 2030 a robust foundation for the economic, social and ecologically sustainable development of the European Union, which will contribute to increasing sustainability in a global context. It is also expected that both nanotechnology and sustainability, will be two important sources of differentiation and competitiveness for the European manufacturing industry in the global market.

Although different definitions are used for the concept of sustainable manufacturing, there is no official standardized one. The U.S. Department of Commerce [50] proposed in 2008 one of the first and most widely used definitions of sustainable manufacturing: “*the creation of manufactured products that use processes that are non-polluting, conserve energy and natural resources, and are economically sound and safe for employees, communities, and consumers*”. This definition has supported other definitions such as those produced by the US EPA [51] or ASTM [43].

Despite the fact that the concept of sustainability has been traditionally associated with an environmental dimension, all these definitions highlight the three-dimensionality of sustainable manufacturing, that encapsulates three basic dimensions: social, environment and economy.

In the literature review, different relevant initiatives on sustainable manufacturing can be found: the European Commission (EC) [45] [46] [47] through the S3-Smart Specialization Platform [48], the US Department of Commerce [49] [50], the US Environmental Protection Agency [51], the OECD through the sustainable manufacturing toolkit [44], among others. Various methods, tools and metrics have been applied for sustainability performance assessment in manufacturing. In the field of standardization, several ISO standards, some of them adopted by CEN as European standards, address issues related to sustainability such as quality [1] [2] [7], environment [3] [4], safety [35], responsibility, social, governance, etc. Those can be applied to manufacturing processes to cover such sustainability items. In this regard, standards developed by ASTM - Subcommittee E60.13 on Sustainable Manufacturing [43] are of particular interest.

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The sustainable manufacturing of nanotechnology supports the needs of the industry, contributes to the industrial policies of the EU and promotes the technological leadership of Europe. At the same time, it minimizes negative environmental impacts, conserves energy and natural resources, is safe for employees, communities, and consumers, and is economically sound.

Pilot Lines (PLs) are strategic instruments of the European Commission to bridge the "valley of death", and successfully introduce innovations based on Key Enabling Technologies (KETs) into the market. In particular, in the field of nanotechnology, they are the embryo of tomorrow's nano-manufacturing industry in Europe. Nanomanufacturing Pilot Lines (NPLs) are responsible for the potential impacts on sustainability (social, environmental, economic) that their nanomanufacturing activities can produce.

The incorporation of sustainability requirements in these NPLs, from the first stages of design and operation of the new processes, constitutes a proactive strategy to ensure equally sustainable future commercial nanomanufacturing processes. Consequently, there is a need to define requirements to guarantee the environmental, social and economic sustainability of these NPLs, considering at the same time their embryonic and pre-commercial nature. This requires simple sustainability management schemes easy to use and apply.

In this context, this document inserts the concept of sustainable manufacturing into the field of nanotechnology, by proposing a new simplified conceptual framework to implement sustainability in NPLs and evaluate their sustainable manufacturing performance. Our ambition is to contribute to the deployment of more efficient and sustainable nano-manufacturing processes that enable the manufacture of safer and more sustainable nanomaterials and nanoproducts, as the European Commission recently pointed out.

The Sustainable Nanomanufacturing Framework (SNF) described in this document is based on the one developed by the H2020 OASIS project OASIS “Open Access Single entry point for scale-up of Innovative

Smart lightweight composite materials and components”. The OASIS model is a simple and user-friendly screening tool designed to carry out the initial diagnosis, define the improvement plans and evaluate the sustainability and evolution of NPLs. This framework has been tested in 12 NPLs of the OASIS project (GA 814581) and 7 NPLs of the INNOMEM project (GA 862630).

Annex A shows, using an example based on the OASIS NPL4, the practical application of the 10-step SNF evaluation procedure described in this document. Annex B of this document shows the results corresponding to the diagnosis and planning stages of the Plan-Do-Check-Act (PDCA) cycle in four of the 12 NPLs of OASIS. Subsequently, the H2020 INNOMEM project “Open Innovation Test Bed for nano-enabled Membranes”, also used the model to assess the sustainability of the NPLs incorporated in its manufacturing ecosystem. Annex C of this document shows the results corresponding to the initial diagnosis and planning stages in two NPLs of this last project.

The OASIS project has developed a simple software based on MS Excel (OASIS-SNF Tool) to automate the practical application of the 10-step SNF evaluation procedure. This tool has been used by the project to diagnose, implement, monitor and re-evaluate management practices and sustainability results in NPLs, in conformity with the requirements of the SNF model. It is envisaged that a new version of the OASIS-SNF Tool will be publicly available at the website of OASIS (<https://project-oasis.eu/>) at the end of the project (November 2022).

The SNF was initially conceived and designed as a resilient model to be used in the broad scope of sustainable manufacturing (SM), for any manufacturing process. However, given the scope of the OASIS project, the primary model was later customized to be used in the field of sustainable nanomanufacturing (SN).

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CWA 17935:2022(E)**1 Scope**

This document describes and specifies the requirements of a simplified Sustainability Nanomanufacturing Framework (SNF) for sustainability management in Nanomanufacturing Pilot Lines (NPLs), appropriate to their size, management capabilities and sustainability priorities.

The SNF sets up the basic requirements for a screening methodology to quickly assess the sustainability of a NPL. It provides guidance for diagnosis, implementation, and monitoring, to proactively improve nano-sustainability performances in NPLs, considering its sustainability management and results.

The model can be used by NPLs to achieve its intended outcomes in the field of nano-sustainability.

The SNF is intended to be applied to any NPL regardless of its size, type and activities. Similarly, the model could be scaled to manage the sustainability of a manufacturing area/plant that integrates multiple NPLs.

This document can be used in whole or in part to systematically improve the sustainability in NPLs.

2 Normative references

There are no normative references in this document.

3 Terms, definitions and abbreviated terms**3.1 General**

For the purposes of this document, the following terms and definitions apply.

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

— ISO Online browsing platform: available at <https://www.iso.org/obp/>

— IEC Electropedia: available at <https://www.electropedia.org/>

3.2 Terms related to nanotechnology**3.2.1****nano-enabled product**

product exhibiting function or performance only possible with nanotechnology.

Note 1 to entry: finished goods incorporating nanotechnology.

Note 2 to entry: term customized from ISO/TS 80004-1:2015 [36].

3.2.2**nano-intermediate**

intermediate product with nanoscale features.

3.2.3**nanomanufacturing pilot line**

pilot line conceived for the manufacture of nanomaterials, nano-intermediates or nano-enabled products.

3.2.4**nanomanufacturing process**

ensemble of activities to intentionally synthesize, generate or control nanomaterials, or fabrication steps in the nanoscale, for commercial purposes.

[SOURCE: ISO/TS 80004-1:2015, definition 2.12] [36]

3.2.5

nanomaterial

material with any external dimension in the nanoscale or having internal structure or surface structure in the nanoscale.

Note 1 to entry: This generic term is inclusive of nano-object and nanostructured material.

Note 2 to entry has been deleted.

[SOURCE: ISO/TS 80004-1:2015, definition 2.11] [36]

3.2.6

NOAA

nano-objects, and their agglomerates and aggregates.

Note 1 to entry: NOAAs include structures with one, two or three external dimensions in the nanoscale, which might be spheres, fibres, tubes and others as primary structures. NOAAs can consist of individual primary structures in the nanoscale and aggregated or agglomerated structures, including those with sizes larger than 100 nm.

[SOURCE: ISO/DIS 80004-1, definition 2.11] [37]

3.3 Terms related to production and manufacturing

3.3.1

process

set of interrelated or interacting activities that use inputs to deliver an intended result.

[SOURCE: ISO 9000:2015, definition 3.4.1 (without notes)] [1]

3.3.2

manufacturing process

structured set of activities involving a flow and/or transformation of material, information, energy, or any other element in a manufacturing area.

[SOURCE: ISO 20140-1:2019, 3.14] [17]

3.3.3

pilot line

the physical infrastructure and equipment needed to produce small series of pre-commercial products.

[SOURCE: Pilot Production in Key Enabling Technologies, EC 2017] [47]

3.4 Terms related to sustainability

3.4.1

economic aspect

element of an organization's activities or products or services that interacts or can interact with the economy.

[SOURCE: ISO 23434-1:2021] [32]

3.4.2

economic sustainability

ability to provide sustainable, successful places in an economic context.

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Note 1 to entry: Economic considerations include employment, competitiveness, wealth and distribution, welfare, accounting and regulation.

[SOURCE: ISO 17889-1:2021] [15]

3.4.3**environmental aspect**

element of an organization's activities or products or services that interacts or can interact with the environment.

[SOURCE: EN ISO 14001:2015] [3]

3.4.4**environmental sustainability**

state in which the ecosystem and its functions are maintained for the present and future generation.

[SOURCE: ISO 17889-1:2021] [15]

3.4.5**social aspect**

element of an organization's activities or products or services that interacts or can interact with society or quality of life.

[SOURCE: ISO 23434-1:2021] [32]

3.4.6**social sustainability**

ability to provide sustainable, successful places in a social context.

Note 1 to entry: Social sustainability combines design of the physical realm with design of the world, infrastructure to support social and cultural life, provides social amenities, systems for citizen engagement and spaces for people and places to evolve.

[SOURCE: ISO 17889-1:2021] [15]

3.4.7**sustainability**

state of the global system, including environmental, social and economic aspects, in which the needs of the present are met without compromising the ability of future generations to meet their own needs.

Note 1 to entry: The environmental, social and economic aspects interact, are interdependent and are often referred to as the three dimensions of sustainability.

Note 2 to entry: Sustainability is the goal of sustainable development (3.2).

[SOURCE: ISO Guide 82:2019, definition 3.1] [40]

3.4.8**sustainable development**

development that meets the environmental, social and economic needs of the present without compromising the ability of future generations to meet their own needs.

Note 1 to entry: Derived from the Brundtland Report [18].

[SOURCE: ISO Guide 82:2019, definition 3.2] [38]

3.4.9**sustainability aspect**

aspect of an activity or goods or services that, during the life cycle of the activity, or goods or services, is related to sustainability, positively or negatively.

[SOURCE: ISO 20400:2017] [18]

3.4.10**sustainability dimension**

Each of the three pillars on which the concept of sustainability is based: environmental, economic and social.

3.4.11**sustainability indicator**

indicator related to economic, environmental or social impacts.

[SOURCE: ISO 21929-1:2011, 3.33] [22]

3.4.12**sustainability item**

Each of the sustainability aspects that build the three sustainability dimensions.

3.4.13**sustainability KPI**

key performance indicator that represents sustainability performance.

3.4.14**sustainability objective**

intent to achieve global sustainability, resulting from the sustainability policy that an enterprise or destination sets itself to achieve, being quantified whenever possible.

[SOURCE: ISO 23405:2022, 3.1.5] [31]

3.4.15**sustainability performance**

combination of environmental performance, social performance and economic performance of an organization.

Note 1 to entry: measurable results related to sustainability aspects.

[SOURCE: ISO 21931-2:2019(en), 3.30 modified – Note 1 adapted.] [25]

3.4.16**sustainability management**

set of coordinated activities within an organization related to its sustainability aspects.

3.4.17**sustainability requirement**

requirement related to sustainability.

CWA 17935:2022(E)**3.5 Terms related to management****3.5.1****baseline**

reference basis for comparison against which performance is monitored and controlled.

[SOURCE: ISO/TR 21506:2018, 3.5] [19]

3.5.2**continual improvement**

recurring activity to enhance performance.

[SOURCE: EN ISO 9000:2015, without notes] [1]

3.5.3**indicator**

quantitative, qualitative or binary variable that can be measured, calculated or described, representing the status of operations, management, conditions or impacts.

[SOURCE: 14050:2020] [5]

3.5.4**key performance indicator**

indicator of performance deemed by an organization to be significant and giving prominence and attention to certain aspects of operations, management, conditions or impacts.

Note 1 to entry: The KPIs are derived directly from, or through an aggregation function of, physical measurements, data and/or other KPIs.

[SOURCE: ISO 14050:2020; Note 1 to entry from ISO 22400-1:2014, 2.1.5] [5] [6] [27]

3.5.5**lagging indicator**

metric that gives an indication of past performance.

[SOURCE: ISO 10014:2021] [7]

3.5.6**leading indicator**

metric that gives an indication of expected performance.

[SOURCE: ISO 10014:2021] [7]

3.5.7**legal requirements and other requirements**

legal requirements that an organization has to comply with and other requirements that an organization has to or chooses to comply with.

[SOURCE: ISO 45001:2018, without notes] [35]

3.5.8**management**

coordinated activities to direct and control an organization.

[SOURCE: EN ISO 9000:2015, without notes] [1]

3.5.9

management system

set of interrelated or interacting elements of an organization to establish policies and objectives, and processes to achieve those objectives.

[SOURCE: EN ISO 9000:2015, without notes] [1]

3.5.10

nonconformity

non-fulfilment of a requirement.

[SOURCE: EN ISO 9000:2015, without notes] [1]

3.5.11

regulatory requirement

obligatory requirement specified by an authority mandated by a legislative body.

[SOURCE: EN ISO 9000:2015] [1]

3.5.12

requirement

need or expectation that is stated, generally implied or obligatory.

[SOURCE: EN ISO 9000:2015, without notes] [1]

3.5.13

strategy

plan to achieve a long-term or overall objective.

[SOURCE: EN ISO 9000:2015] [1]

3.6 Abbreviated terms

EHS	Environment, Health and Safety
IP	Improvement Plan
KPI	Key Performance Indicator
NEP	Nano-Enabled Product
NM	Nanomaterial
NPL	Nanomanufacturing Pilot Line
NQA	Number of Question
OHS	Occupational Health and Safety
PDCA	Plan-Do-Check-Act (continuous improvement cycle)
PL	Pilot Line
QES	Quality, Environment and Safety
SBQ	Score By question
SD	Sustainability Dimension