Conceptual design

Conceptually, a Nano Risk (Innovation) Governance Project is occurs in two main layers:

1) The governance (management) layer where an accountable board is established to run the governance project and make “go”, “return” or “stop” decisions of the project based on answer to questions and results of specific governance projects or requests.

2) The operational project layer where specific projects are run to generate all the knowledge, data and documentation to develop and launch the product and answer to questions raised by the nano-risk governance project board.

This structure is made to reflect the structure of the ISO 21505:2017 *standard on Project, programme and portfolio management – Guidance on governance*. The actual structure and extent of the governance interface is established to be sufficiently flexible to accommodate that the governance may be required at different organizational levels and with scales ranging from projects to programs (Figure 1).

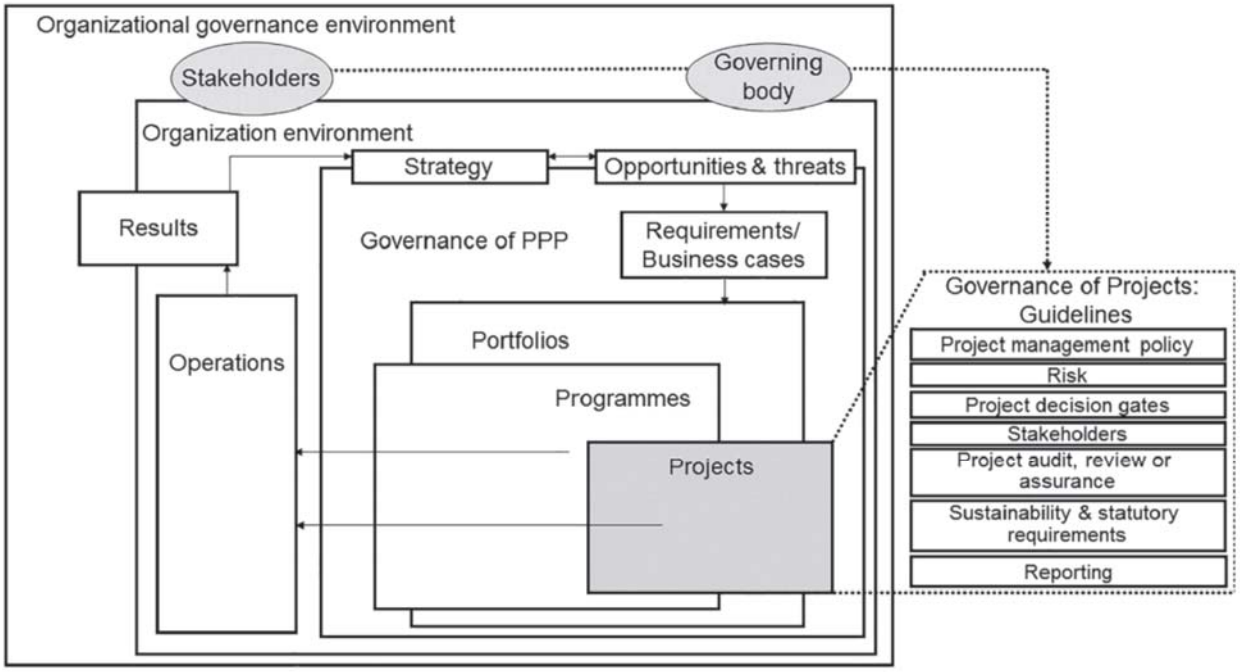

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Figure 1. Schematic structure of the portfolio, program, and project governance relationships in an overall organizational governance environment (Figure 3 in ISO 21505:2017)

Both the governance and program/project processes are organized to follow a modified Cooper Stage-Gate® idea-to-launch model (Figure 2). The framework tool is constructed so the user can decide which steps they wish to include in their project and at which project or stage-gate they enter. I.e. the innovation team and governance board should decide at the first concept review meeting which project phases and gates are required for their project. Examples could be a Low demand Stage-Gate project (e.g., Phase 3, 6-7), a Moderate demand Stage-Gate project (e.g., Phase 1, 3, 5-7), or a High demand Stage Gate Project (Phase 1-7), where the demand refers to the amount of knowledge development and investment required to complete the project.

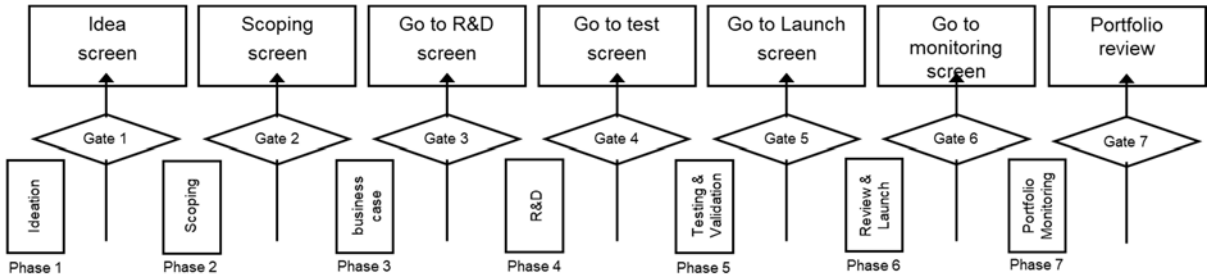

Figure 2. The adjusted Cooper-like Phase-Gate or Stage-Gate idea to launch model added a monitoring phase-gate. Modified images from http://apppm.man.dtu.dk/index.php/The_Stage-Gate_Model/phase-gate_process

Normally, several different sub-projects are undertaken to answer specific governance questions in each of the outlined project phases (Table 1).

Nano-risk assessment and management issues are included in each of the project phases and nano-risk assessment and mitigation solutions are specific “go”, “return” and “stop” topic at each of the advanced stage-gate decision meetings. At the last monitoring phase, the innovation is launched and the nanomaterial and/or nanoproduct is moved to the organizations portfolio management level.

In the last post-launch stage is recommended to establish monitoring of the relevant nanomaterial and / or nanoproduct, manufacturing processes, regulations and risk aspects according to a PDCA (Plan-Do-Check-Act) concept. This is to allow continual improvement of the product, production environment etc. The PDCA approach is for example outlined for occupational health and safety management in

ISO 45001:2018 *Occupational health and safety management systems – Requirements with guidance for use*.

Below, short guides are produced as general introduction for establishment of a nano-risk innovation governance board (**Error! Reference source not found.**), as well as for each of the framework stages (**Error! Reference source not found.**) in the nano-risk innovation governance project as a general guidance for preparation of stage-gate meeting (**Error! Reference source not found.**).

Table 1. Inspiration to nano-risk innovation governance subprojects or topics that may be performed in the different project stages from idea to portfolio monitoring.

Stage 1 Ideation	Stage 2 Scoping	Stage 3 Business case	Stage 4 R&D	Stage 5 Testing and validation	Stage 6 Launch	Stage 7 Portfolio monitoring
Idea description	Technical nanomaterial / nanoproduct description	Nanomaterial / nanoproduct specification and development plan	Technical nanomaterial / nanoproduct development and testing	Technical nanomaterial / nanoproduct testing and validation	Nanomaterial / nanoproduct production	
Brainstorming events	Brainstorming events					
	Internal stakeholder consultation and dialogue	Internal stakeholder consultation and dialogue	Internal stakeholder consultation and dialogue	Internal stakeholder consultation and dialogue		
External stakeholder consultation and dialogue	External stakeholder consultation and dialogue	External stakeholder consultation and dialogue	External stakeholder consultation and dialogue	External stakeholder consultation and dialogue		
Existing nanomaterial / nanoproduct characteristics	Existing nanomaterial / nanoproduct characteristics	Technical data sheet development	Technical data sheet development	Technical data sheet	Technical data sheet	
Existing nanomaterial health and safety data	Existing nanomaterial health and safety data	Safety data sheet development	Safety data sheet development	Safety data sheet	Safety data sheet	
Occupational pre-risk assessment	Occupational pre-risk assessment	Occupational pre-risk assessment and management	Occupational pre-risk assessment and management	Occupational risk assessment and management	Occupational risk assessment and management	Occupational risk assessment and management
Consumer pre-risk assessment	Consumer pre-risk assessment	Consumer pre-risk assessment and management	Consumer pre-risk assessment and management	Consumer risk assessment and management	Consumer risk assessment and management	Consumer risk assessment and management
Environmental pre-risk assessment	Environmental pre-risk assessment	Environmental pre-risk assessment and management	Environmental pre-risk assessment and management	Environmental risk assessment and management	Environmental risk assessment and management	Environmental risk assessment and management
	SbD analysis	SbDSTOP analysis and screening	SbDSTOP analysis and testing	STOP analysis	STOP analysis	STOP analysis
Societal and ethical impact pre-assessment	Societal and ethical impact pre-assessment	Societal and ethical impact assessment		Societal and ethical impact assessment		
Financial cost-benefit pre-assessment	Financial risk-benefit pre-assessment	Financial risk-benefit assessment		Financial risk-benefit assessment		
		Internal safety communication, training and instructions	Internal safety communication, training and instructions	Internal safety communication, training and instructions	Internal safety communication, training and instructions	
		External safety communication, training and instructions	External safety communication, training and instructions	External safety communication, training and instructions	External safety communication, training and instructions	
		Monitoring	Monitoring	Monitoring	Monitoring	Monitoring
		Regulatory compliance assessment		Regulatory and agency pre-registrations	Regulatory and agency registrations	
		Insurance aspects		Insurance aspects	Obtain Insurance	
			Marketing and production plan	Industrial production plan	Establish production facility	
Other case-specific relevant aspects	Other case-specific relevant aspects	Other case-specific relevant aspects	Other case-specific relevant aspects	Other case-specific relevant aspects	Other case-specific relevant aspects	Other case-specific relevant aspects
Documentation and reporting	Documentation and reporting	Documentation	Documentation and reporting	Documentation and reporting	Documentation and reporting	Documentation and reporting

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