Enabling Multi-Functional Performance through Multi-Material Additive Manufacturing

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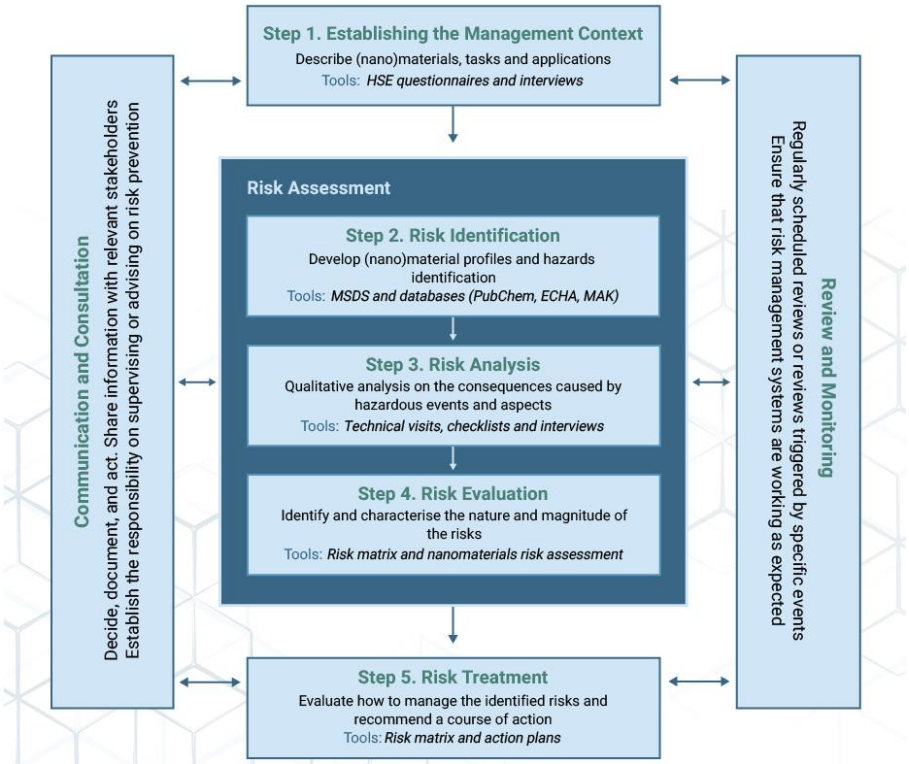
ISQ in charge of MULTI-FUN's Risk Assessment Framework

WP1, particularly risk assessment, will contribute to the safety of the MULTI-FUN materials, Additive Manufacturing (AM) processes and demonstrations, promoting safe practices during production. To identify and control any potential hazardous issue or events, a risk management framework has been established based on:

– ISO 31000:2018 "Risk management — Guidelines" &
– ISO/TR 13121:2011 "Nanotechnologies — Nanomaterial risk evaluation"

The framework consists of **three main phases** and **five steps**: establishing the context, risk assessment (subdivided into 3 steps) and risk treatment.

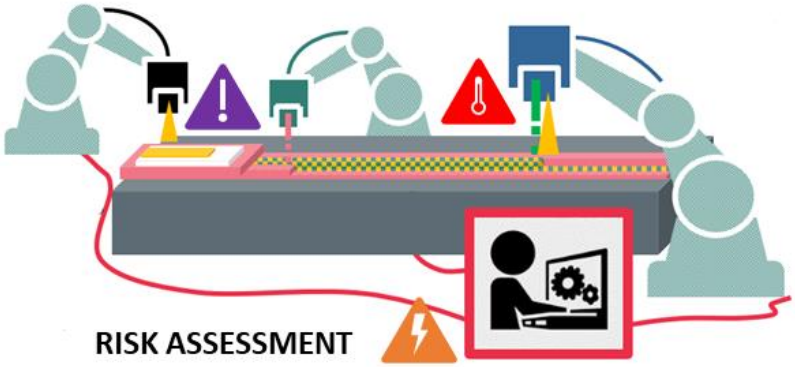


MULTI-FUN RISK MANAGEMENT FRAMEWORK BASED ON ISO 31000:2018 & ISO/TR 13121:2011

The purpose of **risk assessment** is to comprehend the nature of risk and its characteristics including, where appropriate, the level of risk. Firstly, **risk identification** will find, recognize and describe risks that might help or prevent the MULTI-FUN project in achieving its objectives. Relevant, appropriate and up-to-date information is important in identifying risks, which include: 1) Description of processes, materials (nanomaterials) and equipment being evaluated and their intended uses or functions (including potential benefits); 2) Orderly analysis according to the events involved in the processes, without excluding preliminary basic steps (e.g., use of tools); and 3) Where required, identification of analogous materials that might help address data gaps.

Risk analysis involves a detailed consideration of uncertainties, risk sources, consequences, likelihood, events, scenarios, controls and their effectiveness. An event can have multiple causes and consequences and can affect multiple objectives.

Risk analysis can be undertaken with varying degrees of detail and complexity, depending on the purpose of the analysis, the availability and reliability of information, and the resources available. Information to be considered in MULTI-FUN risk analysis includes: 1) nanomaterial's physicochemical properties; 2) inherent environmental, health and safety hazards of (nano)materials and AM technologies; 3) potential human and environmental exposures throughout the (nano)material's lifecycle; and 4) qualitative analysis of the consequences that such events/aspects could have on workers or the environment and their probabilities of occurrence.



The purpose of **risk evaluation** is to support decision making. Risk evaluation involves comparing the results of the risk analysis with the established risk criteria to determine where additional action is required. A risk level will be given according to the combination between probability and consequences. Once the risk evaluation is completed, the risk treatment is now the next step. Selecting the most appropriate control option(s) involves balancing the potential benefits derived in relation to the achievement of MULTI-FUN safety objectives against costs, effort or disadvantages of implementation. Options might include: 1) product or process modifications (including elimination and substitution); 2) engineering controls (such as isolations or enclosures); 3) personal protective equipment; 4) risk communication; or 5) administrative controls.

The **risk assessment** process will be documented and repeated whenever changes are made to the process or materials, or when new information becomes available. The know-how gained during the project will contribute in the future to the upscaling of MULTI-FUN technological developments. The information gathered, at the early phase of development (lab phase), in terms of new/modified AM risks and nanoparticles monitoring data (e.g., particles size and concentration) could be used to draw a risk profile of the MULTI-FUN innovations.

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