

A Simplified Explanation of the Use of Standards in an Emerging Field Such as Regenerative Medicine

- **What are some of the kinds of standards?**
 - Documentary standards: Written documents that describe expectations, minimum requirements, terminology, guidelines or recommendations. A documentary standard can be of a general nature and applicable to a range of technologies and methods, or it can be specific to a particular method or analyte.
 - Reference standards: Also known as reference materials. Highly qualified reference materials from NIST are Standard Reference Materials (SRMs™). Reference materials can be stratified with respect to how thoroughly their properties are specified. Reference materials may be used, for example, to provide confidence in a measurement process, provide evidence of limit of detection, provide a means of normalizing data from different sources, or serve as calibrants for producing a standard curve.
 - Consensus: Agreement of many experts. A standard should attempt to consider the input from a broad community.

- **Standards are appropriate when they:**
 - Facilitate innovation by allowing data and conclusions to be understood and built on by others.
 - Identify principles, conditions, procedures or outcomes that all (or almost all) experts agree on.
 - Provide assurance about processes, equipment, reagents, etc., that a practitioner will use during the development of a complex product or process, and thereby speed the development of the product or process.

- **Examples of standards:**
 - Guidelines that promote consistency in the reporting of parameters that are thought to be of most importance to a process or an assay. Such standards can enable the meaningful comparison of results.
 - Documentary standards that delineate accepted or required characteristics of products, ancillary materials, instruments and equipment, disposables, conditions, etc., for a specific purpose. These standards are based on highly qualified data.
 - Reference or test materials shared between labs that enable comparison of analytical precision and accuracy of methods. Such materials that are homogenous and stable can help to uncover sources of uncertainty associated with differences in location, personnel, instrumentation, etc.
 - Reference materials that provide known values and uncertainties against which one's results can be compared. These 'ground truth' materials can improve confidence in the accuracy of a method or result.

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- Standard protocols that have been optimized and demonstrated to be robust. Such protocols can improve analytical precision when they are followed carefully.
 - Benchmark data that are highly qualified. Favorable comparison with user's data provides the user with a high level of confidence about the system under observation, and therefore enables confident decision making. Such data that have been collected over time can indicate that the current process is under control and within specifications.
 - **When is it inappropriate to develop a standard?**
 - When the scientific or technological understanding is evolving and the standard is too prescriptive and could lock in old technology or imperfect understanding.
 - When the method, protocol or understanding has not been sufficiently tested and the sources of variability, measurement bias, and underlying assumptions have not been thoroughly considered. Qualified methods, protocols and data are often achieved through iterative interlaboratory comparison studies that may be supported by formal experimental design.
 - Standards are more likely to be accepted when they are the product of a deliberate and thoughtful process that involves a diverse expert community.
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