# Standards Transitions Position Paper:

# Considerations for Manufacturers and Regulators

## Introduction

MITA Members develop and use Standards to help ensure patients can access high-quality and safe medical imaging products. This whitepaper will provide considerations for regulators and manufacturers when developing medical imaging Standards and implementing transition periods between versions of such Standards.

## Definitions

*Standard:* Document approved by a recognized body, that provides, for common and repeated use, rules, guidelines or characteristics for products or related processes and production methods, with which compliance is not mandatory.[1]

*State of the art:* Developed stage of technical capability at a given time as regards products, processes and services, based on the relevant consolidated findings of science, technology and experience.[2]

*Transition time:* The length of time that the current version of a Standard is accepted by regulators for device applications concurrently with an updated version of the Standard until the updated Standard is expected to be used exclusively.

## Considerations

Optimally, Standards developers should include recommendations for transition times clearly within the Standard. Manufacturers should participate in the Standards development process of those Standards that may be adopted as international Standards by regulators. Regulators should also participate in these processes as they are able and consider the type of product and its complexity when setting transition times.

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[1] https://www.wto.org/english/docs_e/legal_e/17-tbt_e.htm.

[2]https://www.iec.ch/Standardsdev/resources/draftingpublications/directives/introductory/terms_and_definitions.htm.

## Background

### Around the world

Manufacturers and regulators both face the challenge of Standards transition times with the common goal to ensure patient safety and access. In some jurisdictions, the use of Standards for medical device declarations of conformity is voluntary, while in others these Standards are mandated by law. There is also variation among and within jurisdictions in transition times for Standards. The use of Standards in these situations may be mandated by law or voluntary. Standards transition time regulations vary among jurisdictions from having prescribed transition times to seemingly arbitrary transition periods.

### Average design process

Manufacturers require predictable Standards transition periods unless it is necessary to transition more quickly due to a newly discovered risk to public health. Brief transition times without pressing reason(s) unnecessarily raise cost. The typical transition period has been three years[3]. Historically, the perception was that the design cycle for many medical devices was 18 months, and a three-year Standard transition period corresponded to two design cycles.

However, timing of design cycles and corresponding transition time depends on the type of change made to the device. Manufacturers need more time for large software changes, such as new platforms or major updates. In this situation, regulators should strongly consider aligning Standards transitions to development realities of today vice one tied to design cycles of the past.

### Considerations for Standards development process

Optimally, Standards developers should include recommendations for transition times clearly within the Standard. There are differences in requirements among Standards organizations, however. For example, International Electrotechnical Commission (IEC) Standards generally suggest a three-year transition period for new medical device designs and five years for those already in production.

Whether done in the U.S. or elsewhere, manufacturers should participate and/or comment on all Standards. This would serve to ensure clear communication between those developing new products and those drafting Standards, whether voluntary industry Standards or governmental ones.

In the latter case, device manufacturers should participate in Standards drafting processes where government regulators may also be participating, e.g. in International Electrotechnical Commission Standards, to directly voice needed transition times as part of the drafting process.

Standards developers should be cautious when stating that a technology in a standard reflects the state of the art, as use of this term implies a technology is fully developed and adopted. Regulators reviewing this may assume a shorter transition time would be appropriate.

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[3] http://www.imdrf.org/docs/ghtf/final/sg1/procedural-docs/ghtf-sg1-n044-2008-Standards-in-assessment-of-medical-devices-080305.pdf.

**Considerations for manufacturer device application**

If medical device manufacturers need additional time to transition to a newer version of a government Standard, or to incorporate a Standard in a different manner, this may be discussed in a pre-submission meeting with the regulator prior to submitting an application for a product, if such meetings are available in the jurisdiction. Manufacturers should make use of this process.

**Considerations for regulators**

The complexity of the product and the type of upgrade are important considerations in determining transition times. If a product is already in the market and no significant changes are made, it should not be necessary to upgrade to the newer version of the Standard. If there is an imminent risk to public health, however, a shorter transition time may be appropriate. While all transitions raise costs, unnecessarily brief transition times profoundly raise them – if they can be met at all within a foreshortened time – and further burden manufacturers. This ultimately detracts from the goal of providing patients with safe, medically essential devices.

**Summary**

Standards developers should always include recommendations for transition times clearly within the Standard. This will provide needed clarity to manufacturers providing equipment to the marketplace and regulators ensuring public safety.