DITTA GLOBAL DIAGNOSTIC IMAGING, HEALTHCARE IT & RADIATION THERAPY TRADE ASSOCIATION

WHY STANDARDS THAT FOLLOW THE GUIDANCE ARE GOOD FOR BUSINESS?

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DITTA Standardization WG

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PRESENTATION OUTLINE

1. Our vision
2. Challenge for Consensus Standards in regulatory use.
3. Good For Business
4. Challenge in the next step

1. OUR VISION

"Approved once, accepted everywhere"

→ Future Dream

- Standards are good tools to demonstrate to comply with essential principle for the medical devices in conformity assessment process in pre-market review.
- Their process is key elements for regulatory convergence.

In Real World ; Reduce duplication!
→ MDSAP, Single Review Program in IMDRF

2.CHALLENGES

Role of Standards in Conformity Assessment System

- streamline the device review process
- improve the efficiency of regulations
- establish productive dialogue among RAs, manufacturers, conformity assessment organizations (including accreditation and testing professionals), clinicians and the public.

2.CHALLENGES

Contents of Standards

- Uncertain Rational for the requirements
- Uncertain Scope and residual risk
- Uncertain how to address the resulting risk as appropriate.
- Uncertain acceptance criteria and testing methods
- Competition of national and international standards

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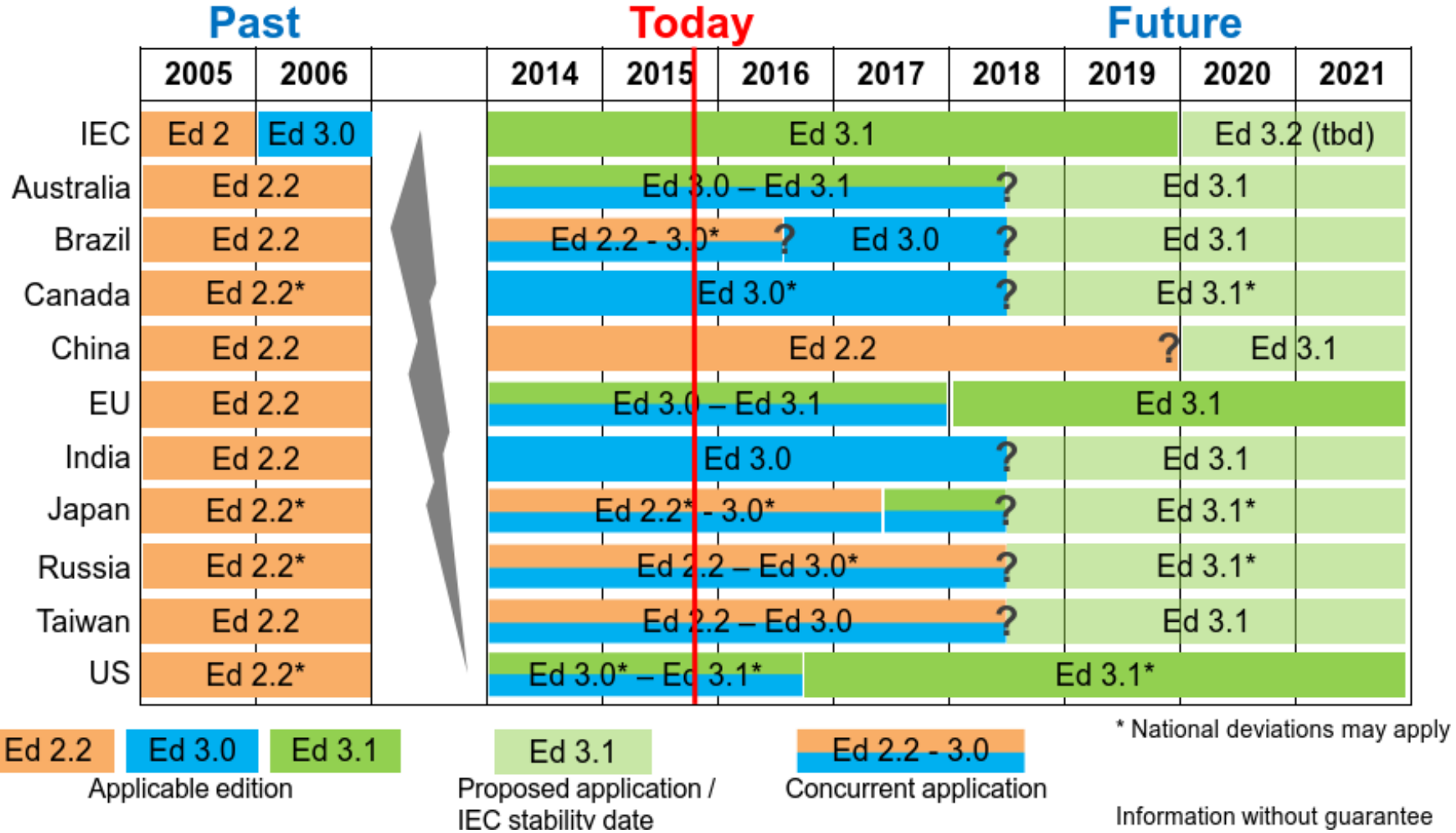
TYPICAL EXAMPLE IMPLEMENTATION OF IEC60601-1 ED3 (STATUS IN 2015)



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3.GOOD FOR BUSINESS

Expected affect after introducing this guidance document.

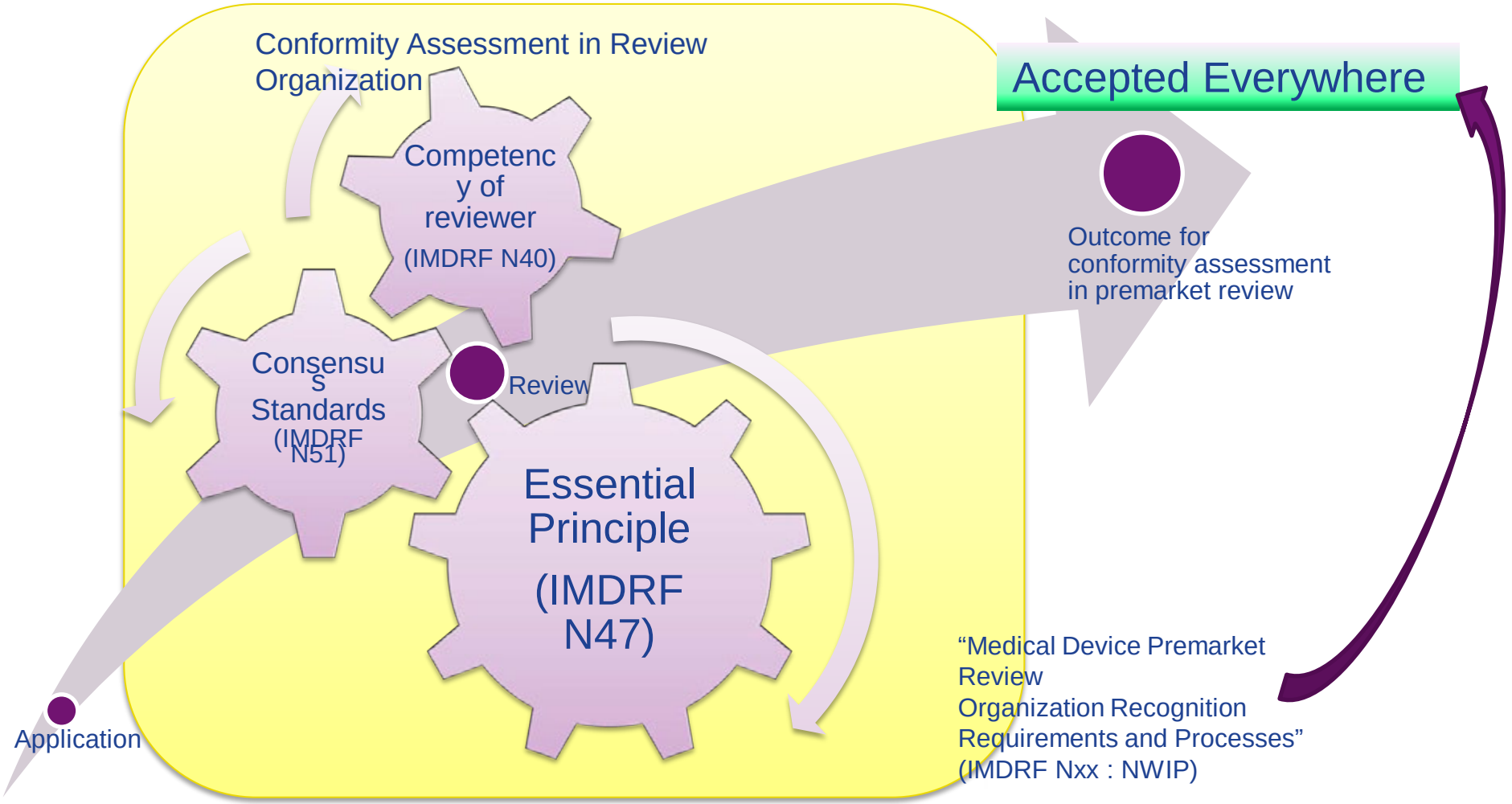
- Conformity Assessment system based on the essential principle with the consensus standards.
- Smooth introduction of international standards developed for regulatory use in each jurisdictions, and minimize the national deviations.
- Acceptance of outcome based on conformity assessment for the essential principle with the consensus standards.
- Avoid duplicative activities by agreeing which standards to use for regulatory framework.

3.GOOD FOR BUSINESS

Expected affect after introducing this guidance document.

- State of the art: standards represent the state of art in a technological field.
- Efficiency: they should also promote economic benefits, e.g., reducing redundant reporting requirements, etc.
- Verifiability: requirements include verifiable, objective measurements.
- Reproducibility: testing methods in standards yield consistent results across different test facilities.
- Risk Managements/Specific Requirement: When a standard identifies a hazard or a hazardous situation without giving a specific requirement.

3.GOOD FOR BUSINESS



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CHALLENGE IN THE NEXT STEP

- Establish IMDRF Liaison Program to support the developing process for regulatory use.

- Improvements the contents and the developing process for IEC60601-1 Ed4 !

◆ But still uncertain transition rule in the revision of standards.

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THANK YOU!

СПАСИБО!

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