



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

# HOW NEW WORK ITEMS COME TO BE

“GOOD STANDARDS DEVELOPMENT PRACTICE”

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# PRESENTATION OUTLINE

1. Introduction
2. Mechanics of standards development
3. Structured approach
4. Tools
5. What's critical?
6. Take aways





Development of (IEC, ISO) standards is simple ...  
... if you know what to do

Oh well, there are a few boundary conditions:

- Adhere to WTO principles
- Adhere to prescribed format
- Follow prescribed processes
- Subject to national members approval

See ISO/IEC  
Directives 1&2



## WTO principles (Directives pt 1, Annex SM.1):

- Effectively respond to regulatory and market needs (in the global marketplace)
- Respond to scientific and technical developments in various countries
- Not distort the market
- Have no adverse effects on fair competition
- Not stifle innovation and technological development
- Not give preference to characteristics or requirements of specific countries or regions when different needs or interests exist in other countries or regions
- Be performance based as opposed to design prescriptive



## More principles (Directives pt 1, Annex SO.2):

- a) ISO and IEC are committed to creating **market-driven** International Standards, based on objective information and knowledge on which there is global consensus, and not on subjective judgments, in order to provide credible technical tools that can support the implementation of regulation and public policy initiatives.
- b) ISO and IEC are committed to developing International Standards that are market relevant, **meeting the needs and concerns of all relevant stakeholders** including public authorities where appropriate, without seeking to establish, drive or motivate public policy, regulations, or social and political agendas.



## Still more principles (Directives pt 1, Annex SO.3):

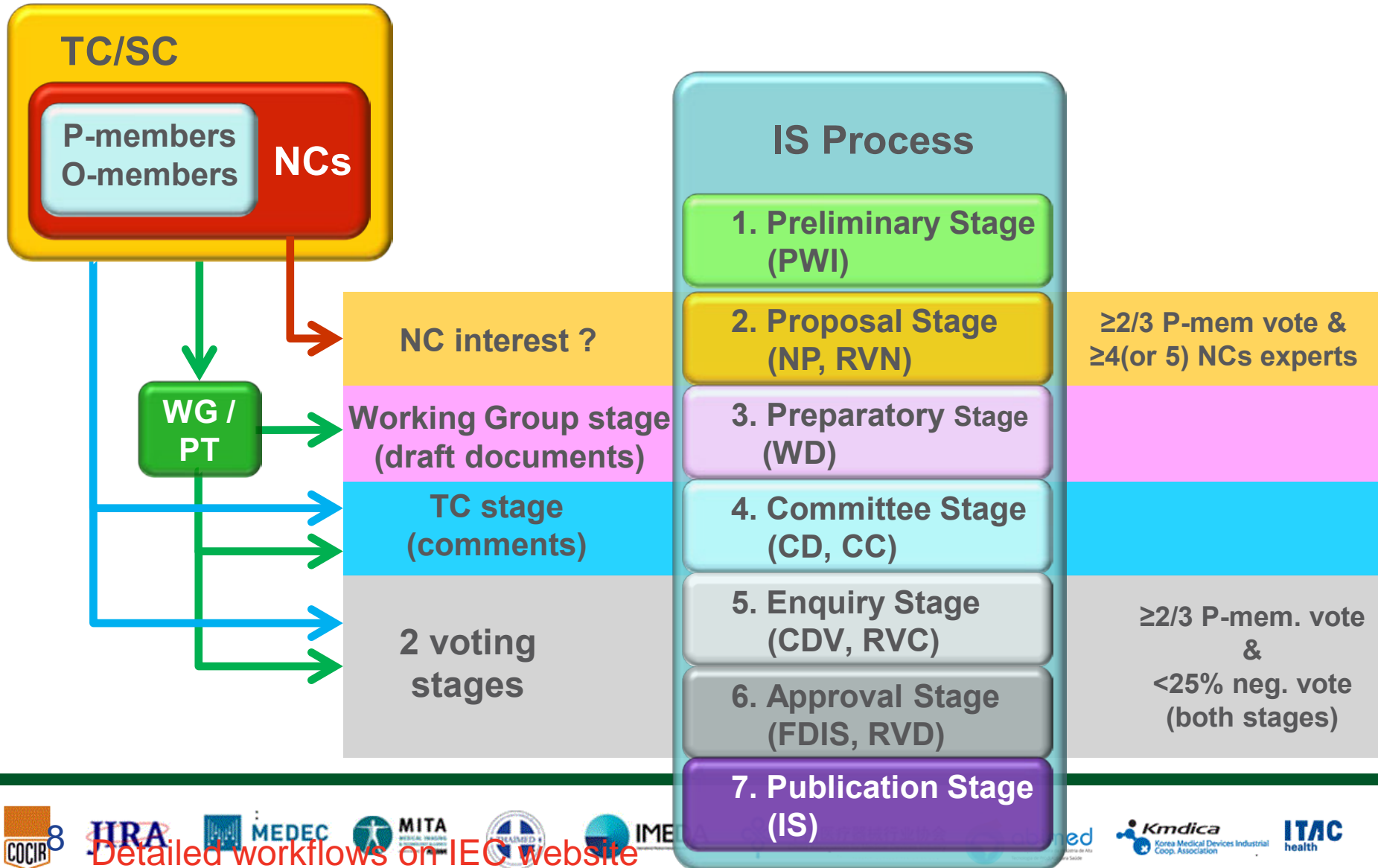
- transparency
- openness
- impartiality and consensus
- relevance and effectiveness
- coherence
- development dimension

For details of these principles, see [Annex 4](#) to the Second Triennial Review of the TBT Agreement.





# STRUCTURED APPROACH







## Obviously, IEC and ISO demand a “standard approach” ...

- Part 2 of ISO/IEC Directives describes just that ...
- Lots of support tools are there to help drafting of standards
- Among them: ISO/IEC Guides, e.g. Guide 51, Guide 63

NB – Part 1 of Directives is about structuring the work

SUBDIVISIONS OF THE DOCUMENT		24
<b>11</b>	<b>Title</b>	<b>25</b>
11.1	Purpose or rationale	25
11.2	Normative or informative?	25
11.3	Mandatory, conditional or optional?	25
11.4	Numbering and subdivision	25
11.5	Specific principles and rules	26
11.5.1	Avoidance of unintentional limitation of the scope	26
11.5.2	Wording	26
<b>12</b>	<b>Foreword</b>	<b>27</b>
12.1	Purpose or rationale	27
12.2	Normative or informative?	27
12.3	Mandatory, conditional or optional?	27
12.4	Numbering and subdivision	27
12.5	Specific principles and rules	27
12.5.1	Fixed text	27
12.5.2	Specific text	27
<b>13</b>	<b>Introduction</b>	<b>28</b>
13.1	Purpose or rationale	28
13.2	Normative or informative?	28
13.3	Mandatory, conditional or optional?	28
13.4	Numbering and subdivision	29
13.5	Specific principles and rules	29
<b>14</b>	<b>Scope</b>	<b>29</b>
14.1	Purpose or rationale	29
14.2	Normative or informative?	29
14.3	Mandatory, conditional or optional?	29
14.4	Numbering and subdivision	29
14.5	Specific principles and rules	29
<b>15</b>	<b>Normative references</b>	<b>30</b>
15.1	Purpose or rationale	30
15.2	Normative or informative?	30
15.3	Mandatory, conditional or optional?	30
15.4	Numbering and subdivision	30
15.5	Specific principles and rules	30
15.5.1	General	30
15.5.2	Introductory wording	31
15.5.3	Referencing	31
<b>16</b>	<b>Terms and definitions</b>	<b>31</b>
16.1	Purpose or rationale	31
16.2	Normative or informative?	32
16.3	Mandatory, conditional or optional?	32
16.4	Numbering and subdivision	32
16.5	Specific principles and rules	33
16.5.1	General	33
16.5.2	Rules for the development of terminological entries	33
16.5.3	Introductory wording	33
16.5.4	Permitted content	33
16.5.5	Terms	33
16.5.6	Definitions	34
16.5.7	Examples	35



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# WHAT'S CRITICAL?

Three elements are decisive for a good standard development and timely delivery:

1. New work item Proposal (NP)
2. Stakeholder representation
3. Convener





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# WHAT'S CRITICAL?

## Three critical elements:

### 1) New work item Proposal (NP)

- Reflects clear vision of intended deliverable
- Has solid justification for the effort to be made
- Is realistic about time needed
- Might refer to selected “Essential Principles”





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# WHAT'S CRITICAL?

Three critical elements:

## 2) Stakeholder representation



- Broad group of experts (*expertise, nationality, ...*)
- Collaborative attitude
- Preferably available for the entire project
- Ideally: mix of expertise tailored to project
- Often depends on experts “made available”



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# WHAT'S CRITICAL?

## Three critical elements:

### 3) Convener

- Consensus builder
- Must have ample time available
- Project manager, for timely completion
- Focus, preferably not too close to the subject





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# WHAT'S CRITICAL?

Sometimes, a convener must “borrow” from Darth Vader



Asteroids do not concern me, Admiral. I want that ship, not excuses.





- Good standards development is not difficult, but ...
- Many tools and support materials available
- Context for IEC/ISO standards: enhancing global trade and regulatory convergence
- Structure and format prescribed in Directives
- Good preparation (NP) critical for start-up
- Focus and dedication critical for timely delivery



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