Global Harmonization Working Party
GHWP Towards Medical Device Harmonization

# Standard drives innovation of medical devices

## Sharing from recent CT new technology and standardization

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SIEMENS Healthineers

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# About Siemens Healthineers: who we are

## Market leader in majority of businesses

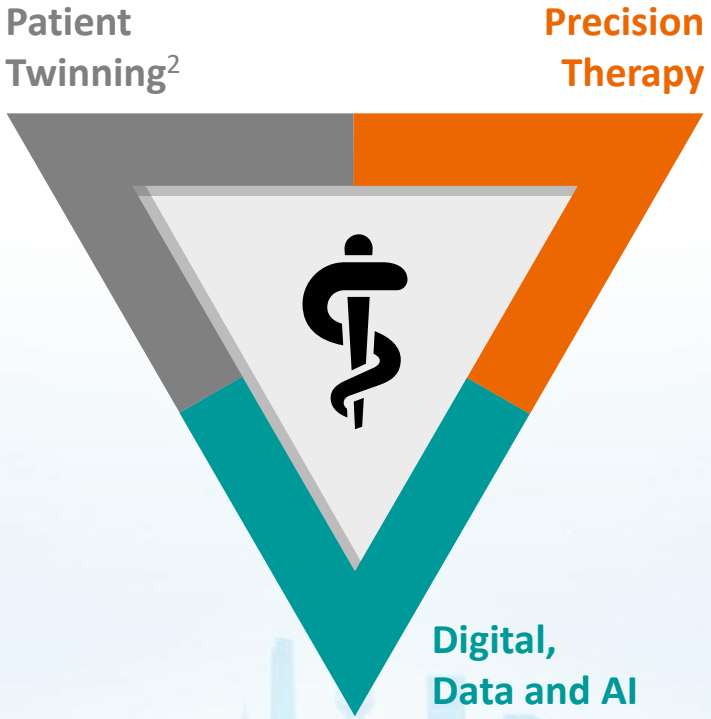
**>90%** of leading hospitals collaborate with us[3]

**>71,000**
highly skilled employees

**>70**
countries with direct presence

**€21,68bn**
revenue FY2023[1]

**24,000** technical IPRs,
thereof 15,000 granted patents




**84**
AI-supported product offerings

**42%** of revenues based on innovations introduced in last three years

**>70%** of critical clinical decisions are influenced by the type of technology we provide[4]

**>700,000**
installed base

**1** Revenue FY2023 Siemens Healthineers
**2** Patient Twinning is currently under development. It is not for sale. Its future availability cannot be guaranteed.
**3** Based on hospital rankings in the U.S., China, and Germany | **4** AdvaMedDX 'A Policy Primer on Diagnostics'

# Dimensions where standardization can drive innovation of medical imaging devices

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**Standard can enable product innovation by provide:**

- **Performance evaluation metrics and methodology for new imaging techniques**
- **Quantitative and objective evaluation for clinical outcomes**
- **Consensus and unified procedure for new technology integration or productization**

# Standard drives innovation of medical imaging devices

## Performance evaluation metrics and methodology for new imaging techniques

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### Trends of modality innovation for Computed Tomography

- Development of CT spectral imaging
- CT spectral imaging application stepping into routine
- Variant realization techniques including DECT and PCCT
- More and more CT product from almost all vendors

**Enhanced Visualization/Spectral Info:**
Virtual Monoenergetic Images
- Enrich the contrast level of tissues
- Optimum CNR @ corresponding keV
- Optimized tissue imaging surrounding metal implants/stents
- Tissue characteristics from spectrum curves

etc.

**Quantitative Imaging/analysis:**
Concentration of selected materials
- Iodine map (absorption), tissue property
- Tumor diagnostics/classification

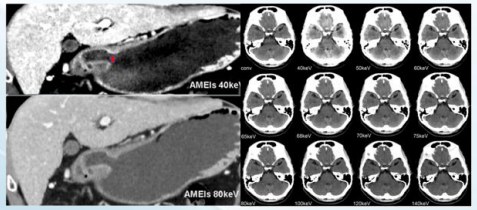
Virtual Non-Contrast (VNC)
- Scan workflow optimization, dose reduction

etc.

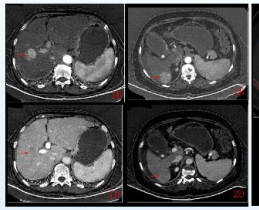
**Material identification/separation:**
Kidney stone
- Composition and therapy plans

Material separation/enhancement
- Gout
- Bone removal, calcium removal, VNC

etc.




早期胃癌诊断[1]（上海瑞金医院） Definition Flash



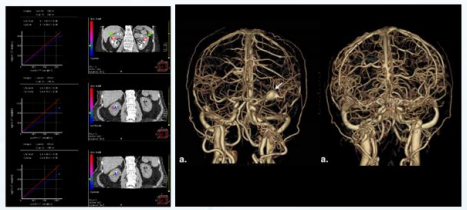
头颅平扫成像[2]（北京协和医院） IQcon



肝细胞癌分型[3]（陕西中医药大学附院） Discovery HD 750



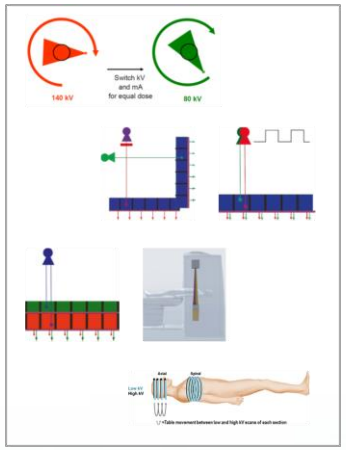
肺癌分型[4]（北京协和医院） SOMATOM Force



结石成分分析[5]（暨南大学一附院） Aquilion ONE



传统/双能量去骨[5]（重庆医大学一附院） LightSpeed VCT




FDA NEWS RELEASE

FDA Clears First Major Imaging Device Advancement for Computed Tomography in Nearly a Decade

For Immediate Release: September 30, 2021

Today, the U.S. Food and Drug Administration cleared the first new major technological improvement for Computed Tomography (CT) imaging in nearly a decade.

"Computed tomography is an important medical imaging tool that can aid in diagnosing disease, trauma or abnormality; planning and guiding interventional or therapeutic procedures; and monitoring the effectiveness of certain therapies," said Laurel Burk, Ph.D., assistant director of the Diagnostic X-ray Systems Team in the FDA's Center for Devices and Radiological Health. "Today's action represents the first major new technology for computed tomography imaging in nearly a decade and underscores the FDA's efforts to encourage innovation in areas of scientific and diagnostic progress."


[1] Cen Shi et al. Decreased stage migration rate of early gastric cancer with a new reconstruction algorithm using dual-energy CT images: a preliminary study. Eur Radiol. 2017; 27(2): 671–680.
[2] XM Zhao et al. Dual-layer Spectral Detector CT Monoenergetic Reconstruction Improves Image Quality of Non-Contrast Cerebral CT as Compared With Conventional Single Energy CT. Eur J Radiol. 2018 Jun;103:131-138.
[3] Chuangbo Yang et al. Dual energy spectral CT imaging for the evaluation of small hepatocellular carcinoma microvascular invasion. Eur J Radiol. 2017 Oct;95:222-227.
[4] X Xu et al. Clinical Utility of Quantitative Dual-Energy CT Iodine Maps and CT Morphological Features in Distinguishing Small-Cell From Non-Small-Cell Lung Cancer. Clin Radiol. 2019 Apr;74(4):268-277
[5] Zhaoxia Li et al. Evaluation of the chemical composition of nephrolithiasis using dual-energy CT in Southern Chinese gout patients. BMC Nephrol. 2019 Jul 19;20(1):273.
[6] Qi Li et al., Automated Subtraction CT Angiography for Visualization of the Whole Brain Vasculature: A Feasibility Study. Acad Radiol. 2013 Aug;20(8):1009-14.

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# Standard drives innovation of medical imaging devices

## Performance evaluation metrics and methodology for new imaging techniques

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**Key enabler of CT spectral imaging utilization**

**Standardization of imaging performance metrics and evaluation methodology**

- Important for future product and application development
- Important for product safety and effectiveness review and approval
- Important for wider and routing clinical usage

**Pilot in industrial standardization**

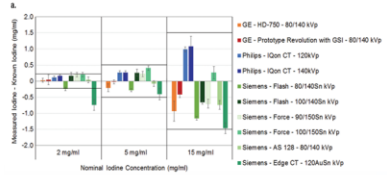
- DICOM 188 → basic terms/definitions
- YY/T 1766.3 – 2023 → First industrial standard for Dual energy CT and spectral application

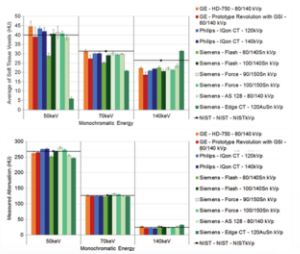


**For CT Industry:**
- Booming of CT Spectral Imaging Functionalities and Products in the market, and widely used clinically
- Standardization of imaging performance evaluation is essentially important for development for corresponding product and applications

**For product review:**
- Different CT Spectral Imaging technique / product may introduce differences on diagnostic image quality, patient dose, noise behavior and quantification accuracy
- Standardized/objective evaluation methods is also important for product safety/effectiveness review and approval

**For clinical usage:**
- Different clinical application would require different system imaging performance
- Standardized performance evaluation can serve as important references for choose right scan and diagnostic procedures
- Standardized description and terms are also important for CT Spectral Imaging for routine





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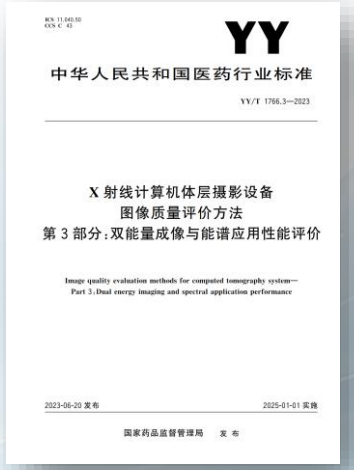


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## Performance evaluation metrics and methodology for new imaging techniques

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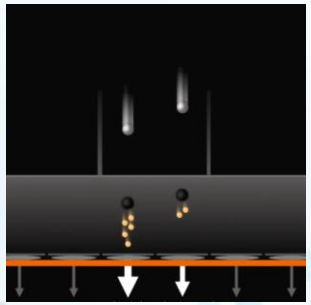
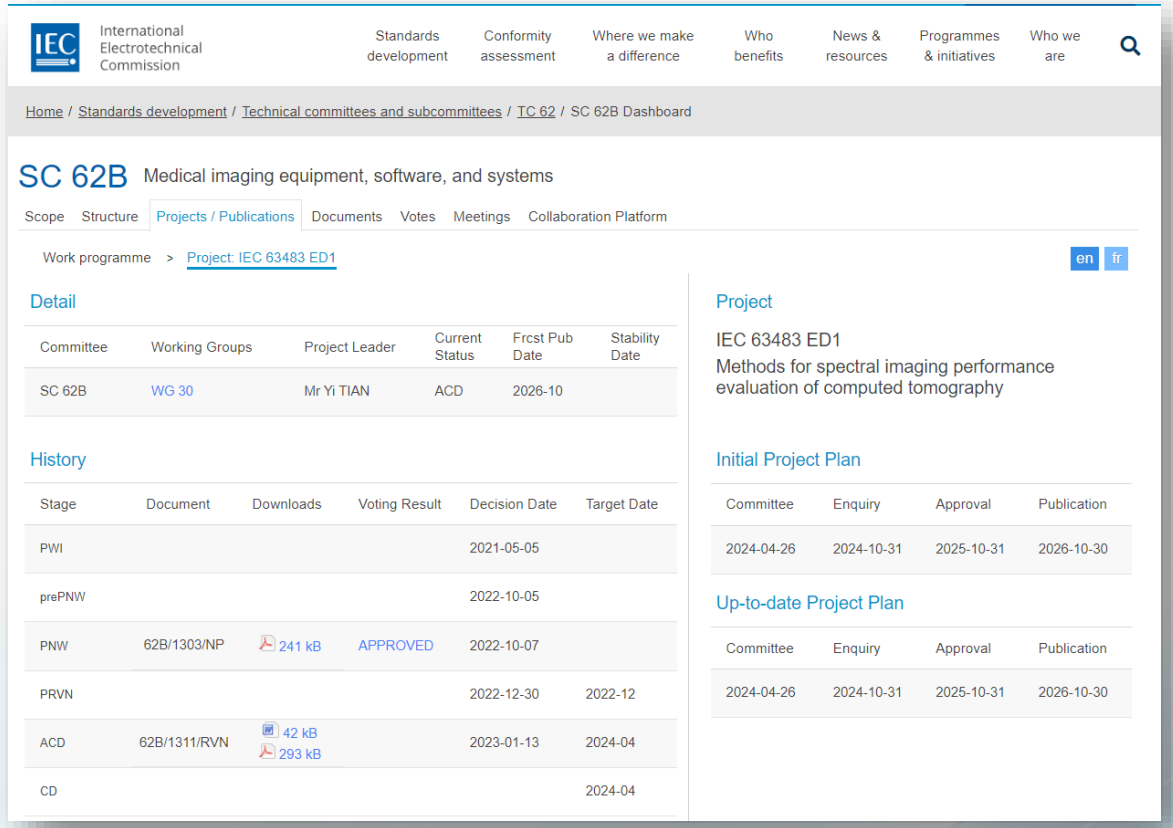
**On going activities and further steps in global standardization community**

- AAPM TG299
  → Quality control in use scenario (final review stage)
- CMDE CT Spectral Imaging Review Guidance
  → working in progress
- IEC 63483 Ed.1.
  →First IEC standard for Medical Imaging Modality proposed and led by Chinese expert
  →Consideration for Photon Counting technology





# Standard drives innovation of medical imaging devices

## Quantitative and objective evaluation for clinical outcomes

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**New CT dose reduction reconstructions technologies:**

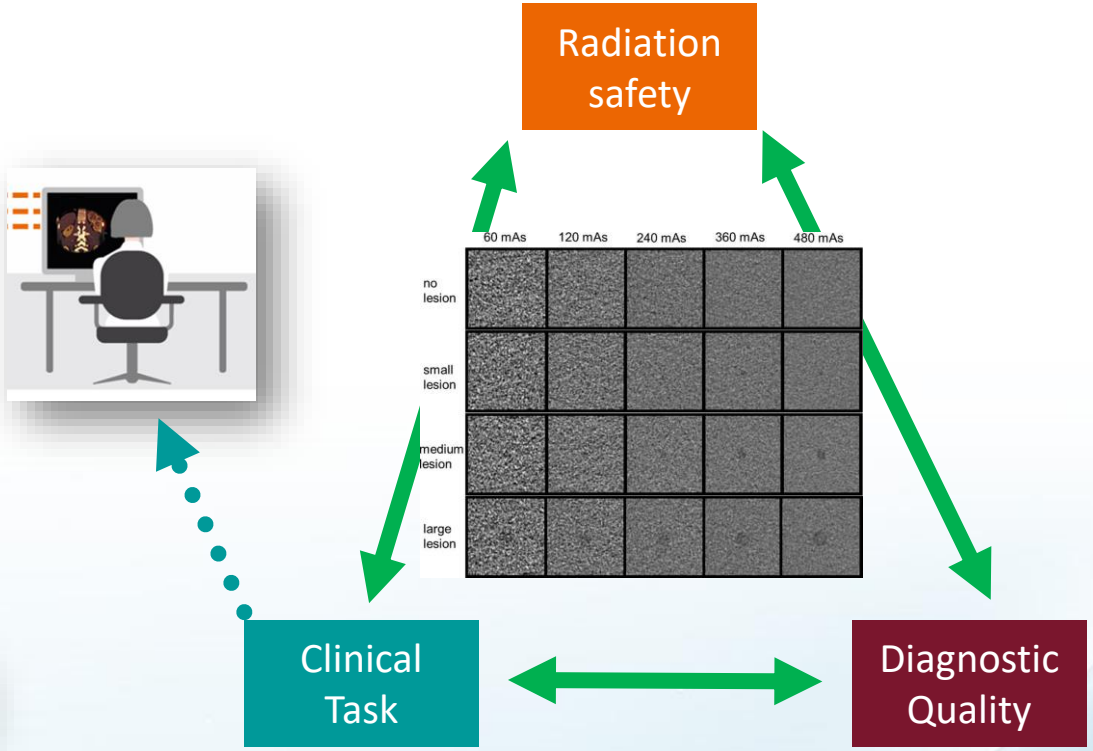
- Advanced algorithms to reduce noise for dose benefits
- Provided by all manufacture

**Challenge in assessment, evaluation and application**

- Complex claims
- Subjective Image quality

**New question for CT imaging dose**

- From “ALARA*” to “how low is too low”




ADMIRE Advanced Modeled Iterative Reconstruction

IMR

NDI+(NanoDose Iterative) 微剂量迭代重建

AIDR 3D integrated

**Sub-mSv imaging**

**Dose reduction up to 60%**

**Low dose as 40% of conventional**

*ALARA – As low as reasonably achievable

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## Quantitative and objective evaluation for clinical outcomes

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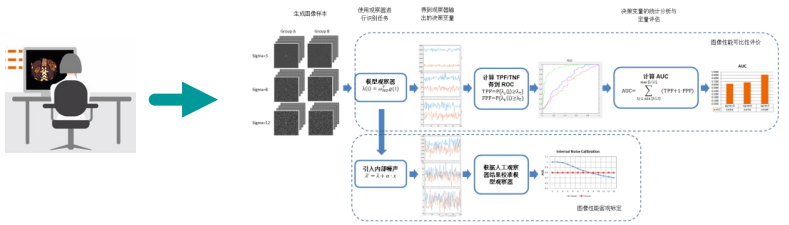
**New methods for image quality assessment[1]**

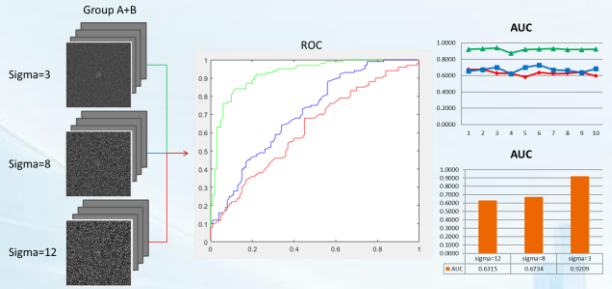
- Clinical task oriented
- Quantitative subjective reading – Human Observer
- Objective evaluation – Model Observer

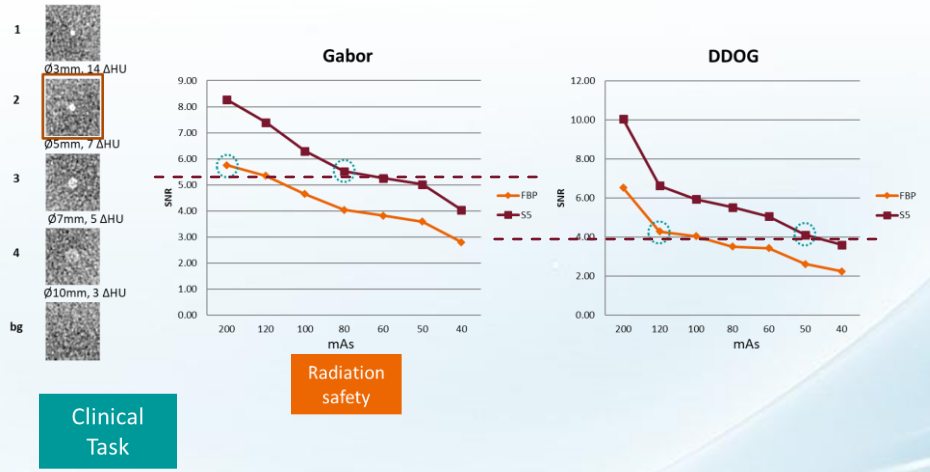
**Piloting in industrial standards**

- NEMA WP 1-2017
  →Phantom and general methods

- YY/T 1766.2 - 2021
  → Low contrast resolution to reflect clinical task
  → Objective evaluation + standardized model observer




[1] Prediction of human observer performance in a 2-alternative forced choice low-contrast detection task using channelized Hotelling observer: Impact of radiation dose and reconstruction algorithmsMed. Phys. 40 (4), April 2013

# Standard drives innovation of medical imaging devices

## Consensus and unified procedure for new technology productization

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### Trends of AI application in medical imaging devices and software

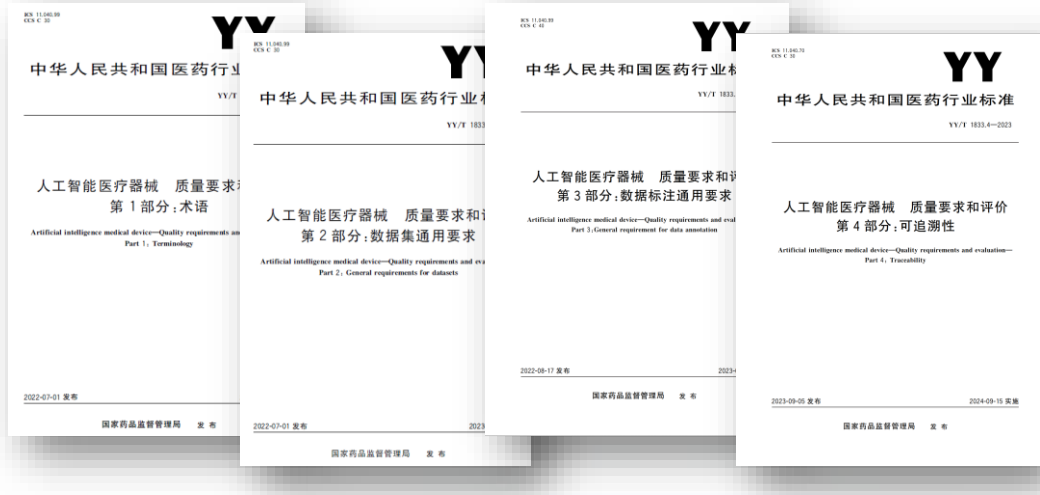
- Scan, workflow and processing automation
- Software as medical device – SaMD
- AI enabled medical device - AIMD

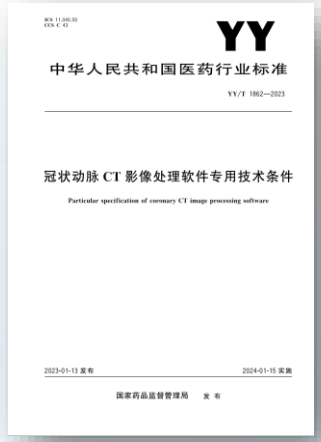

### Needs for standardization for AIMD

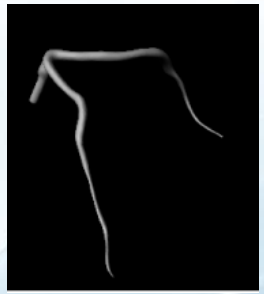
- Fundamental aspects for AIMD development
- Algorithm performance: metrics , methodology and requirements

### Piloting in industrial standards

- AI MD – general quality and evaluation:
  → YY/T 1833 part 1 to 4, Terminology, Datasets, Annotation, Traceability
- AI MD – application algorithm performance:
  → YY/T 1858, YY/T 1907, Pulmonary and CCTA
- SaMD – product performance
  → YY/T 1862 – 2023, CCAT postprocessing software, new practice with Digital Phantom as standardized evaluation tool



3D digital phantom (DICOM)

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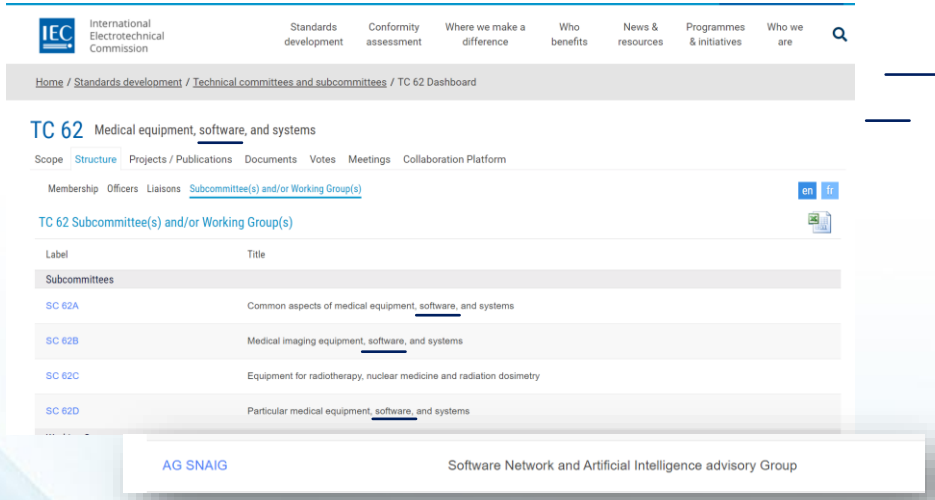
### On going activities and further steps in global standardization community

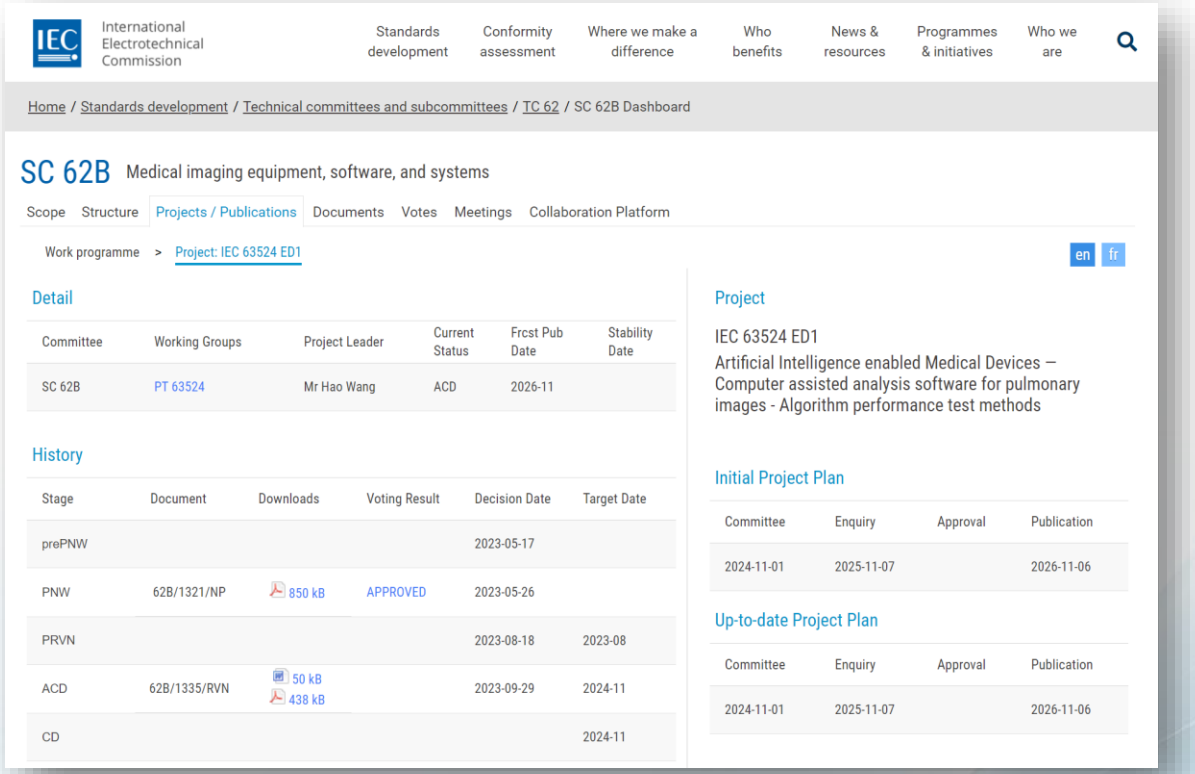
- **IEC TC62**




- **IEC 63524 Ed.1**

→First transition from YY/T AIMD standard to IEC standard, based on YY/T 1858-2022

→Proposed and led by Chinese expert



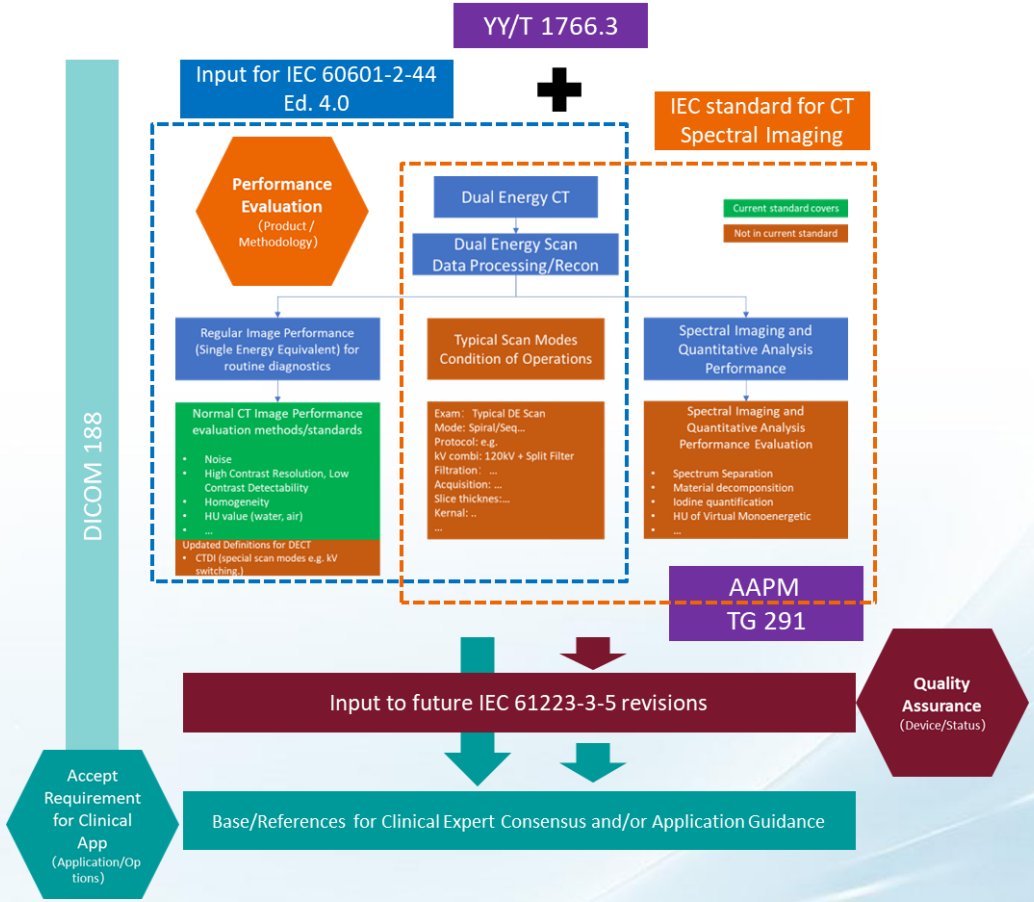
# Standardization drives Innovation of Medical Devices

## Expected roles of future standards



- **Standardization drives Innovation of Medical Devices**
- **Innovation of Medical Devices needs standardization**
- **Key enabler of success application with clinical and social benefits for innovative medical device**

→ **Example from CT Spectral Imaging standard**



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# Thank you for your attention and looking forward for further exchange

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- Sharing from recent CT new technology and standardization

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