革新的研究開発推進プログラム
ImPACT
Impulsing Paradigm Change through Disruptive Technologies Program

バイオニックヒューマノイド国際標準化の動向

鎮西　清行（産総研）

この発表は、JST ImPACT「バイオニックヒューマノイドが拓く新産業革命」の成果です

第27日本コンピュータ外科学会大会
COI開示

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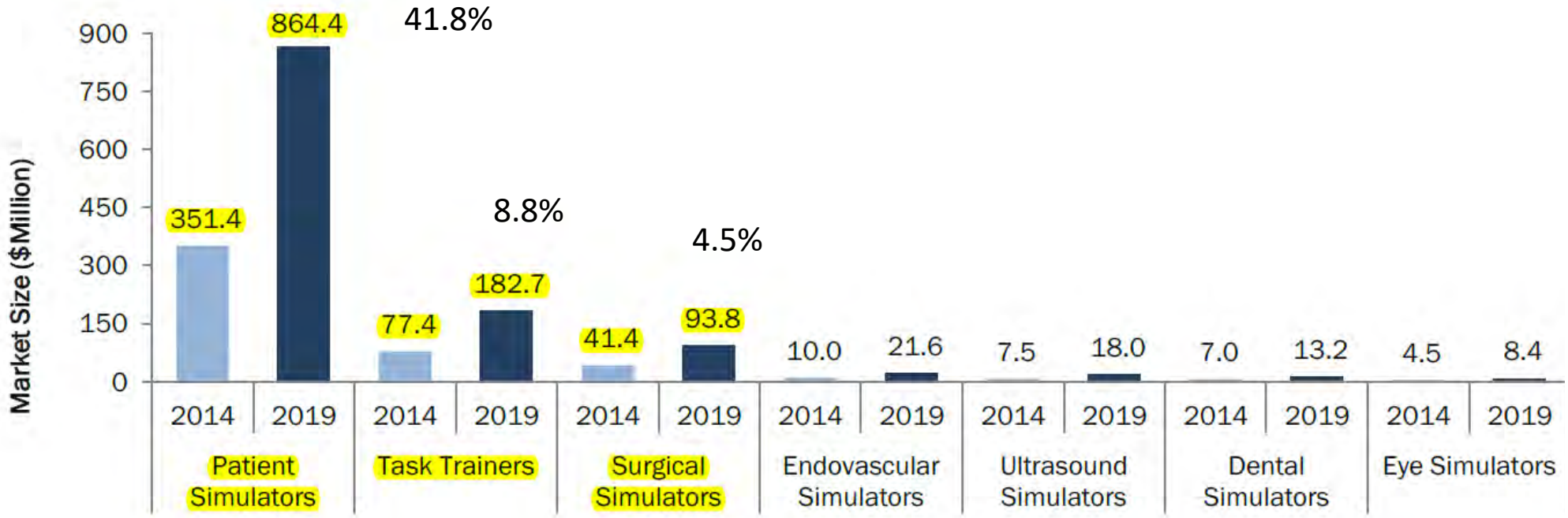
演題発表に関連し、開示すべきCOI関係にある企業等は（残念ながら）ありません。

バイオニックヒューマノイド

- 開発
- 性能評価・規制認証 → 規制当局の認知
- 教育・練習 → 医療界の認知

MANNEQUIN-BASED （臓器モデル）シミュレーション市場

FIGURE 5 GLOBAL MANNEQUIN-BASED SIMULATION MARKET, BY TYPE, 2014 VS. 2019 ($MILLION)



＜情報源＞

市場シェア分析（臓器モデル関係）

FIGURE 30 MARKET SHARE ANALYSIS: PATIENT SIMULATORS, BY KEY PLAYER, 2013

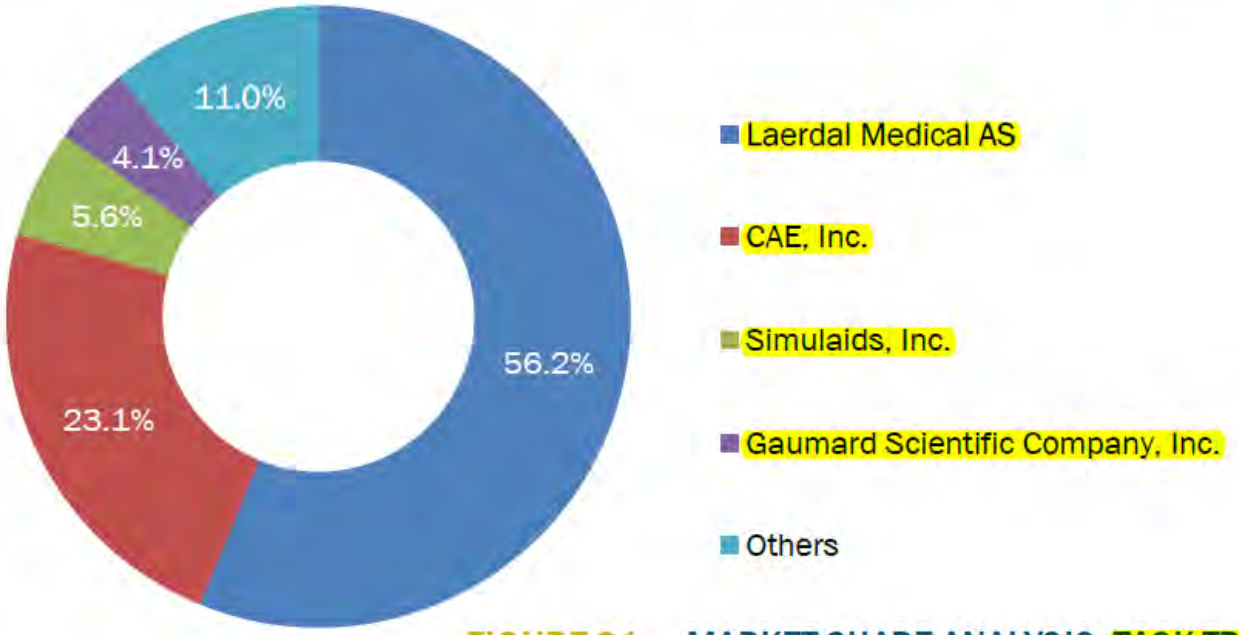
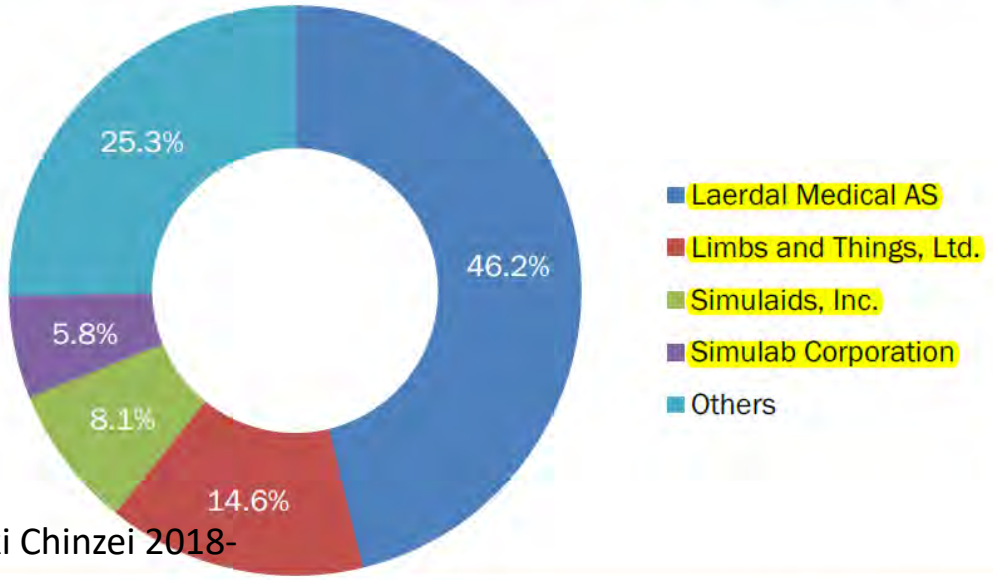


FIGURE 31 MARKET SHARE ANALYSIS: TASK TRAINERS, BY KEY PLAYER, 2013



＜情報源＞

BHと既存市場・ユーザ

差別化・キャッチアップ

- 先行企業のブランドに対抗
- 3Dプリンタの高性能・低価格化
- 価格競争に生き残る差別化

- **国際標準化と認証**
- **専門医制度と連携**
- **製造コスト／納期**

BH：コストと付加価値

- BHの製造
  - 労働集約的な生産工程：日数とコスト
- **労働集約では、日本は勝負できない**

- 3Dプリンタで全部を作れたら？
  - 現状では3Dプリンタだけではできない
    - 色々な膜
    - センサ・アクチュエータ統合
- **プリンターの導入・材料コストで価格が決定されてしまい，付加価値で勝負困難**

「臓器モデルの生体忠実度」提案

Proposal of a new standard:
Organ model – framework to establish biofidelity

Ver. 1709

Proposal for TC 150 'Implant for Surgery'

Kiyo Chinzei, Makoto Ohta

- ImPACT共同研究者の東北大・太田先生と ISO TC 150 (implants for surgery)に提案

Current art in TC 150/SC 5/WG 1

ISO 19213:2017 - Test methods for 3-D bone model

Published
July 2017
88 CHF

Scope

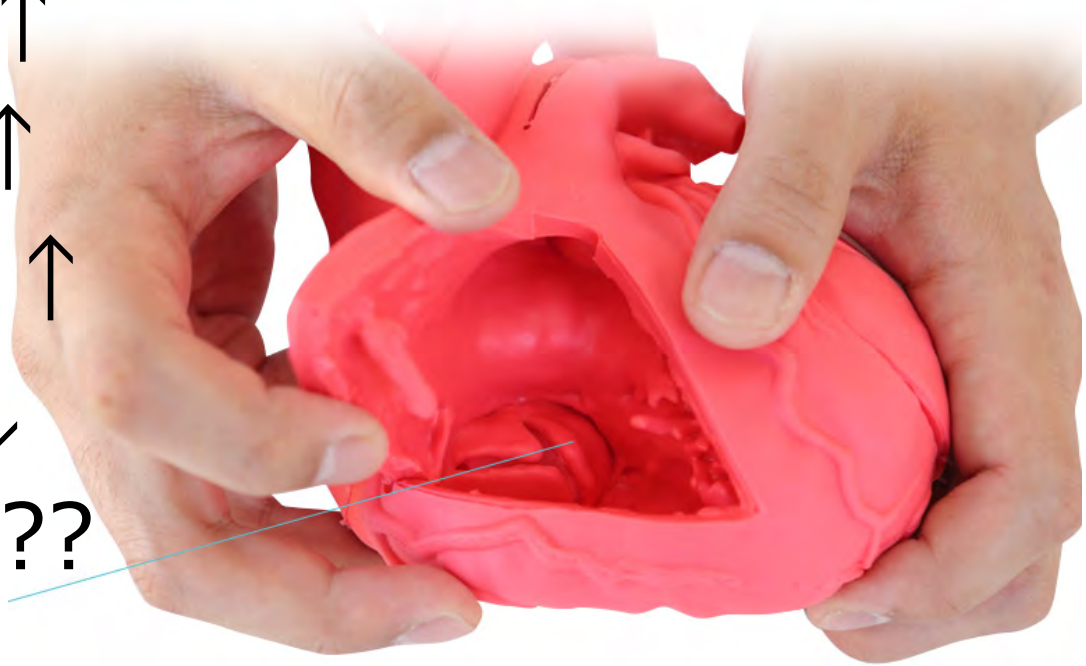
ISO 19213:2017 specifies mechanical test methods for characterizing cortical bone model materials for use as a standard model for performing mechanical tests for devices or instruments used in orthopaedic surgery, plastic surgery, neurosurgery, and oral and maxillofacial surgery.

From bone to other organs

No standard

Emerging technology: 3D printers

- Cosmetic reality ↑
- Shape accuracy ↑
- Material variation ↑
- Production cost ↓
- User satisfaction ??



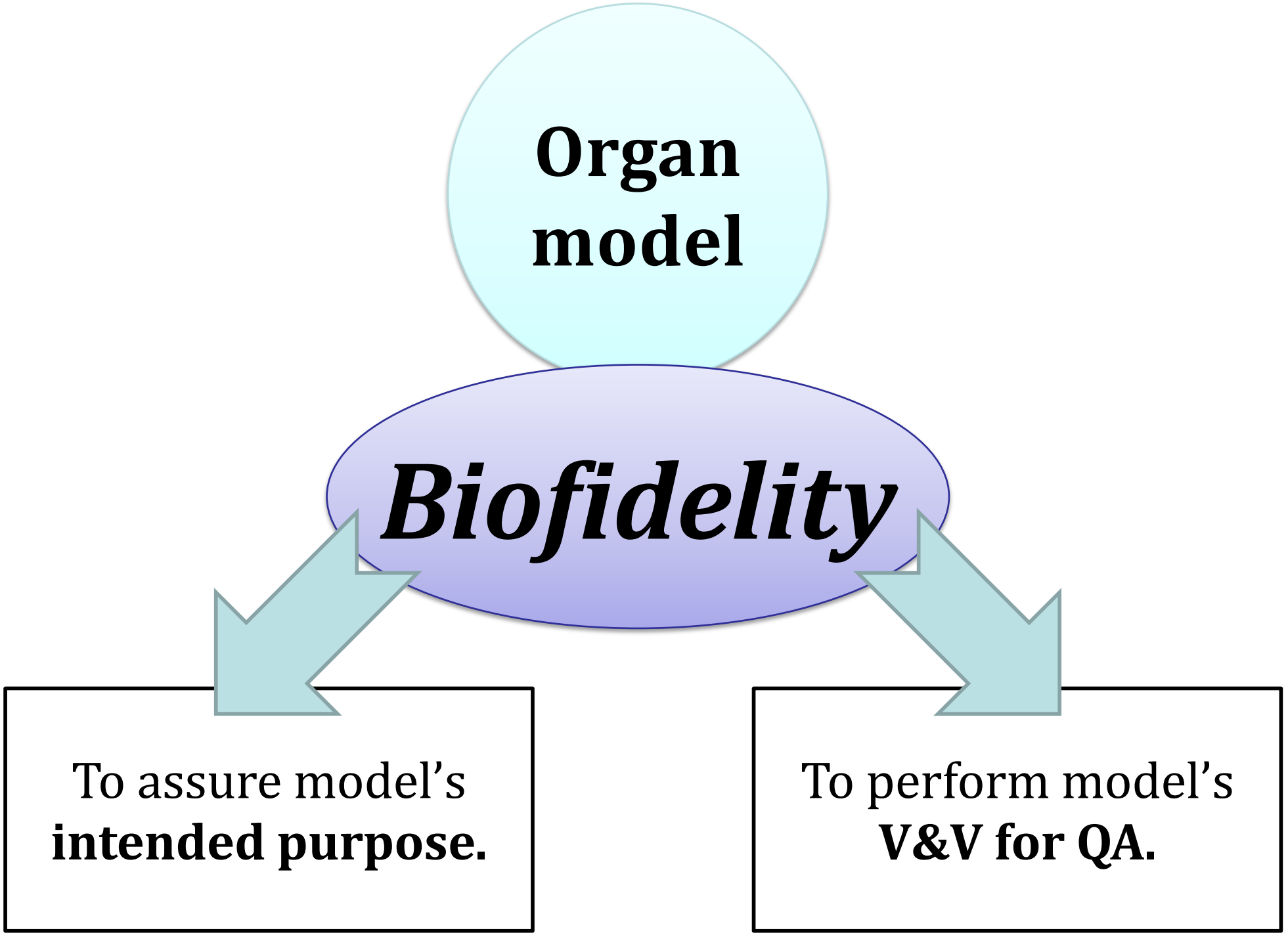
User may ask

- Does it accurate enough for my case?
- How product quality assured?

Why a new standard?

- To reduce animal/human subjects
  - Ethics concerns
  - Cost / Time
  - Repeatability
  - Objectiveness (→ sensor integrated model)

- To provide assurance
  - Regulatory assurance
  - User assurance
  - Quality assurance / QA methods



How other standards do…

- Biofidelity
  - ISO/TC 22 (Road vehicles) ISO TR 9790 Road vehicles -- Anthropomorphic side impact dummy -- Lateral impact response requirements to assess the biofidelity of the dummy

Biofidelity not defined

- Biomimetics
  - ISO/TC 266 (Biomimetics) ISO 18457, 58, 59

… solving practical problems through the function analysis of ***biological systems*** through the function analysis of ***biological systems***, their ***abstraction*** into ***models***, and the transfer into and application…

Biofidelity ≠ biomimetics

Definition of model, dummy, phantom

IEV 881-12-54
phantom (radiology)
a volume of material behaving in essentially the same manner as tissue of the same dimensions, with respect to absorption and scattering of the radiation in question, used for dosimetry or for the evaluation of radiographic images in diagnostic radiology and nuclear medicine

ISO/TC 173/SC 1 Wheelchairs

test dummy
device used to represent the mass and mass distribution of a human being, for the purpose of testing a wheelchair
ISO 7176-11:2012 *Wheelchairs — Part 11: Test dummies*, 3.7

ISO/TC 150/SC 4 - Bone and joint replacements

phantom
object that is used as a representative of an anatomical part
ISO 16 *and stereop ary migration of orthopaedic implants*, 2.15

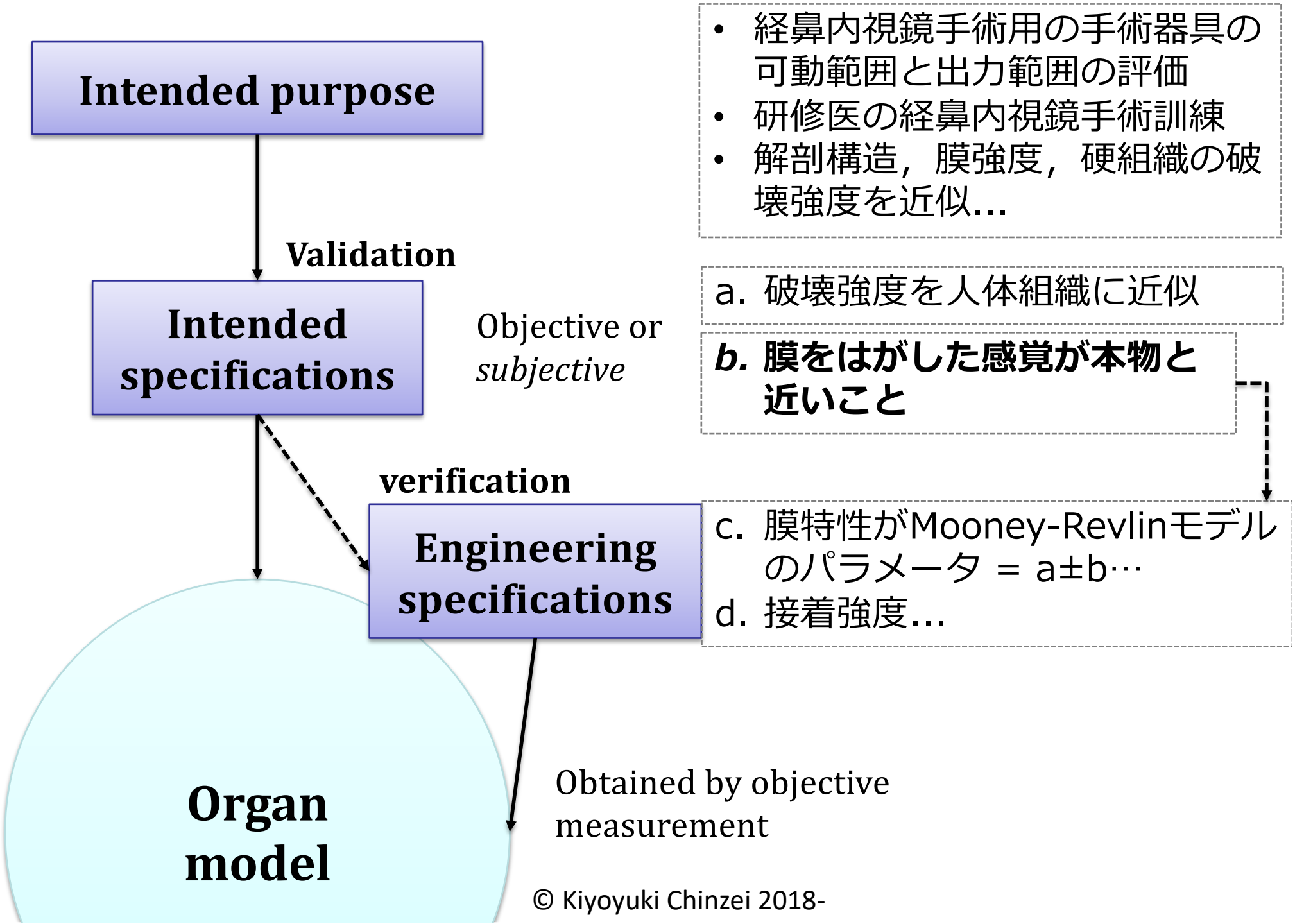
ISO/TC 85 Nuclear energy, nuclear technologies, and radiological protection

phantom
known reference object that is scanned to assess the performance of a CT system (3.15)
ISO 15708-1:2017 *Non-destructive testing — Radiation methods for computed tomography — Part 1: Terminology*, 3.5
(and many)

ISO/TC 94 Personal safety -- Protective clothing and equipment / Respiratory protective devices

dummy
test device or mechanically realizable human analogue model that simulates one or more of the anthropometric, ballistic and dynamic characteristics of man
ISO 5805:1997 *Mechanical vibration and*

- Model, dummy, phatomに関する規格は色々ある



ISO/TC 150 2017年総会に提案

- スコープがTC 150より（かなり）広い
- 数値計算モデルも含むのか

…

- TC 150各国による投票を経て，
- 2018年５月に賛成多数で承認
- 東北大学　太田先生をコンビナーに選出

ISO/TC 150/WG 14

- Title
  - **Models of tissues for mechanical testing of implants**

- Scope
  - This working group is intended to establish recommended specifications needed for models for use in mechanical testing of implants related to orthopedics, plastic surgery, and neurosurgery.

- インプラントの機械的試験法に限定されている
- 整形外科，形成外科，脳神経外科に限定されている

	2018	2019	2020	2021	2022
3D bone model (cortical)	NWIP	WD	CD	DIS	ISO
3D bone model (cancellous?)		NWIP	WD	CD	DIS
Soft tissue model (cardiovascular?)			NWIP	WD	CD
Tissue model (definition?)		NWIP	WD	CD	DIS

- Tissue modelの包括的規格の提案を先行

WG 14の今後の活動

- 鎮西がセクレタリに指名されました
- これから，エキスパートを増やす
  - TC 150の主なエキスパート
    - インプラント業界
    - 工学研究者
    - 規制当局
  - もっと集まって欲しい人々
    - バイオニックヒューマノイド，ダミー業界
    - 3Dプリンター業界
    - 医師，医学教育界
  - 既成勢力が存在しない，ブルーオーシャン