放疗质量管理风险分析方法

_TG-100解读

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放射物理技术科

2019.01.19

汇报内容

- 背景介绍
- TG100方法
- 应用实例
- 总结

山 东 省 肿 瘤 医 院
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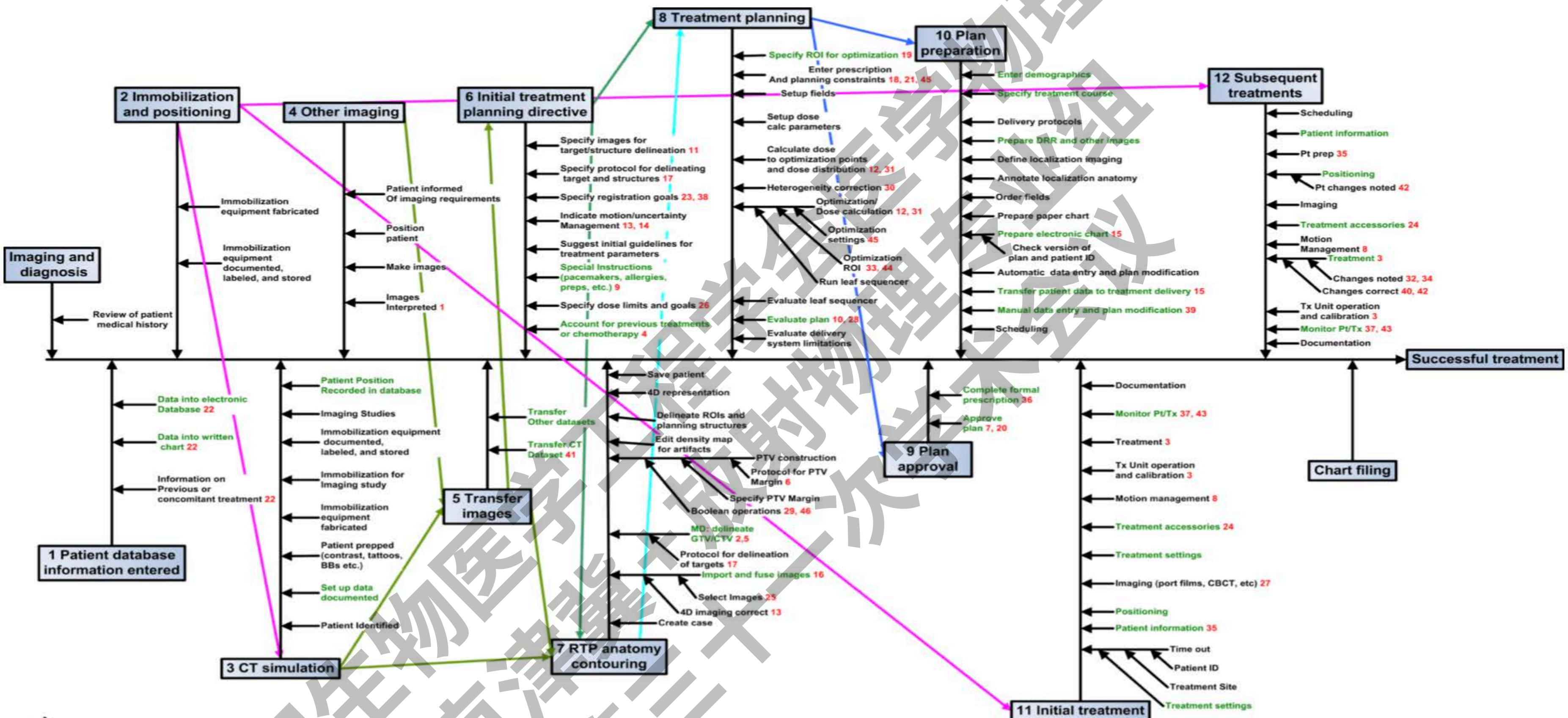


a)

放疗环节错综复杂，每一步差错可能影响患者接受精确的治疗！

千里之堤 毁于蚁穴

Huq M S, Fraass B A, Dunscombe P B, et al. The report of Task Group 100 of the AAPM: Application of risk analysis methods to radiation therapy quality management.[J]. Medical Physics, 2016, 43(7):4209-4262.

技术特征：

- CT/MR/CBCT
- 治疗计划系统
- 网络传输系统
- 计算机控制系统
- ……

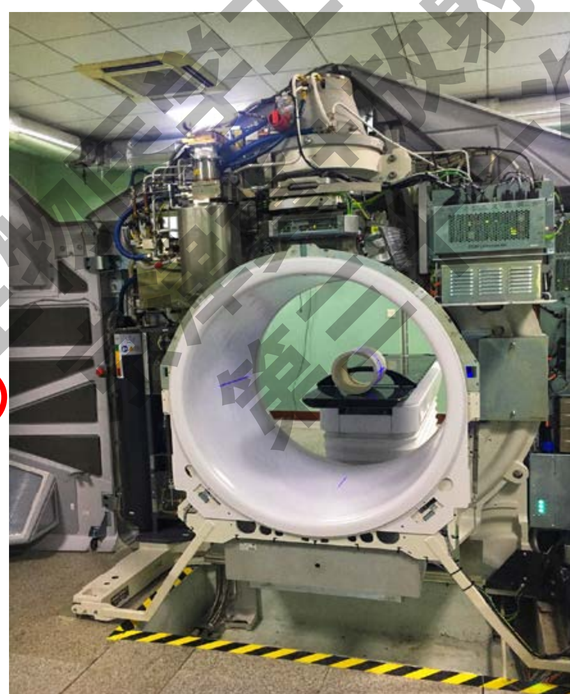
特殊治疗：

- VMAT：高效率治疗
- SBRT：大剂量少分次治疗
- ABC/DIBH治疗
- 4DRT：MLC Tracking
- ……

Catalyst
（运动管理）

Unity
(MR图像)

Halcyon
（高速机架叶片）



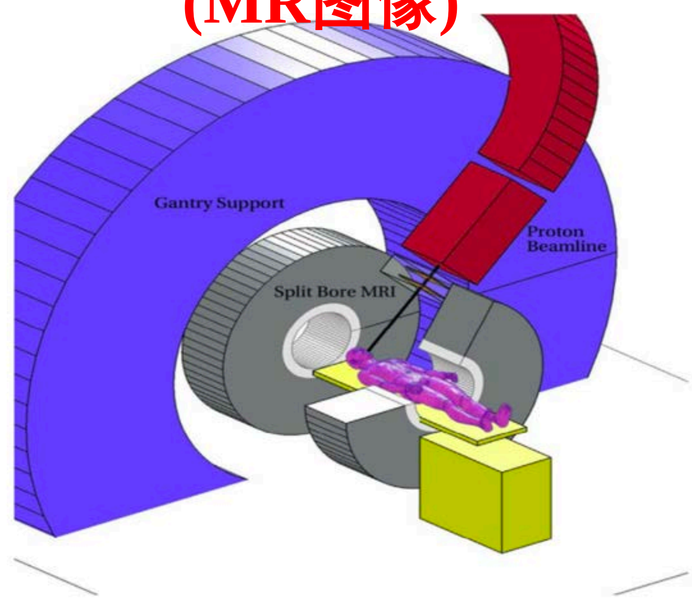
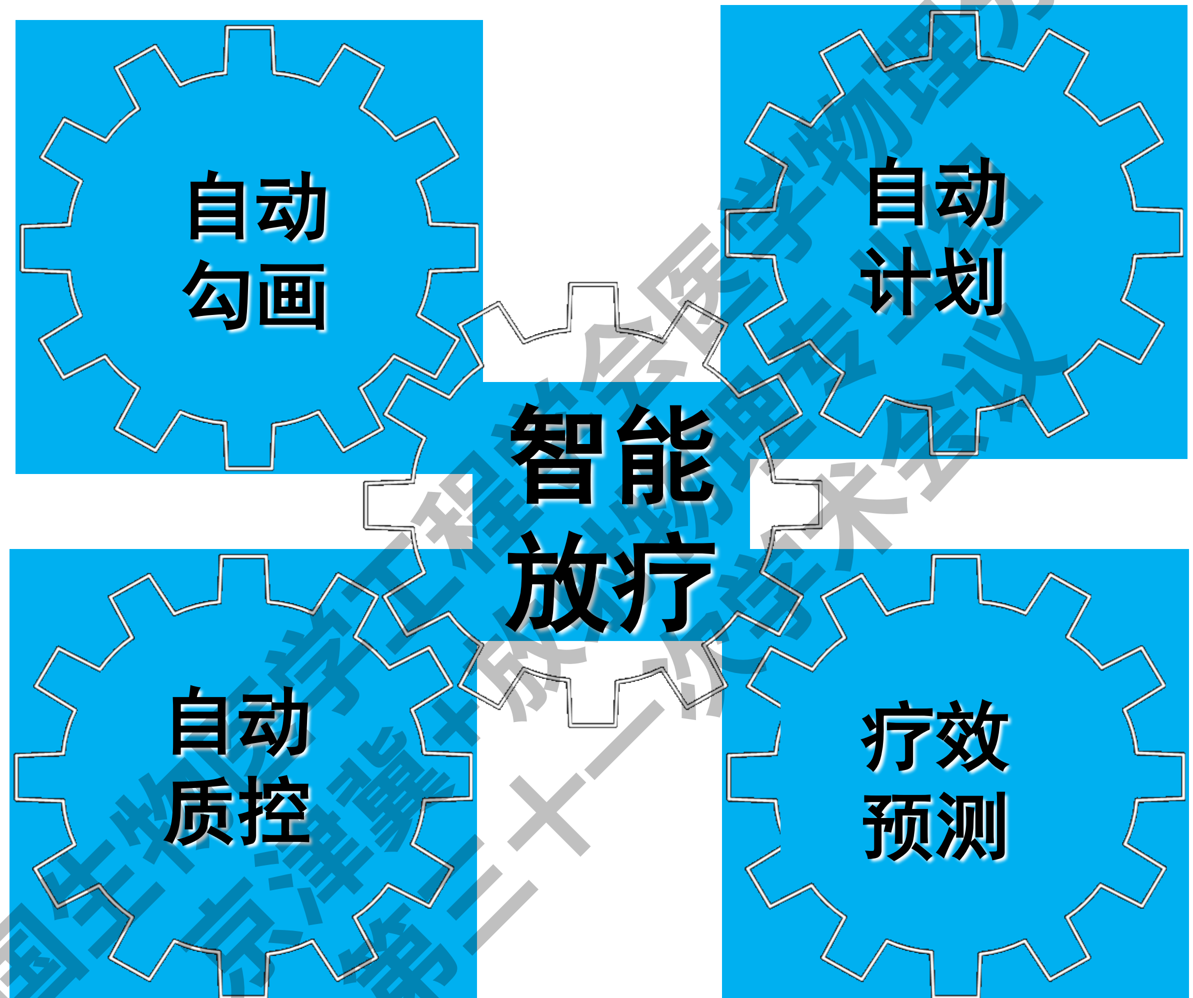


Fig 3. Artist's impression of a future MRIg proton therapy facility.


自动
勾画
自动
计划
智能
放疗
自动
质控
疗效
预测

Scott Jerome-Parks

cludes all parameters for treatment, the actual fluence
calculated, the generated digital reconstructed radiographs
and MLC control points (where each leaf should be posi-
tioned and for the number of MUs). During this process, the
1 planning workstation hung (which they frequently do) and
the only way to get further was to reboot the computer. To
save time, as the patient and family members were in the
waiting area, the planner brought up the patient on another
2 work station. The plan was reviewed and approved and the
patient was called to the treatment unit where the patient
file was opened with the new plan. The patient was treated
with this new plan. He mentioned that the treatment did
not not feel the same and he had nausea. After the third
fraction, on 16 March, the physicist carried out patient-
3 specific quality control according to the local procedures.
This was repeated several times (three times) as the results
4 were startling; the fraction dose measured was 13 Gy
instead of the prescribed 2 Gy. What the physicist saw was
horrifying; the MLC, which was supposed to move to pre-
cisely deliver the wanted IMRT to his tumour, was wide
open. Consequently, the patient was informed about this
dreadful situation and the remaining treatments were
5 cancelled. The patient lived for about 2 years with severe
side-effects until he died in February 2007 [11,17].

警钟长鸣！

Lessons Learnt from Past Incidents and Accidents in Radiation Oncology

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技术革新推动放疗质量提升，安全性依赖质量管理方式：

- 对过往差错的数据统计，利用聚类分析来确定差错易发生环节，再对其实施质量控制

- 基于流程风险分析方法(失效模式与影响分析, FMEA)，预测流程中高危环节，优化及改进质量控制方案

山 东 省 肿 瘤 医 院
山东省肿瘤防治研究院

过往差错的回顾性统计：

- 依赖数据的广泛性和可靠性
- 新技术应用时间短、数据匮乏

安大略癌症中心10年数据

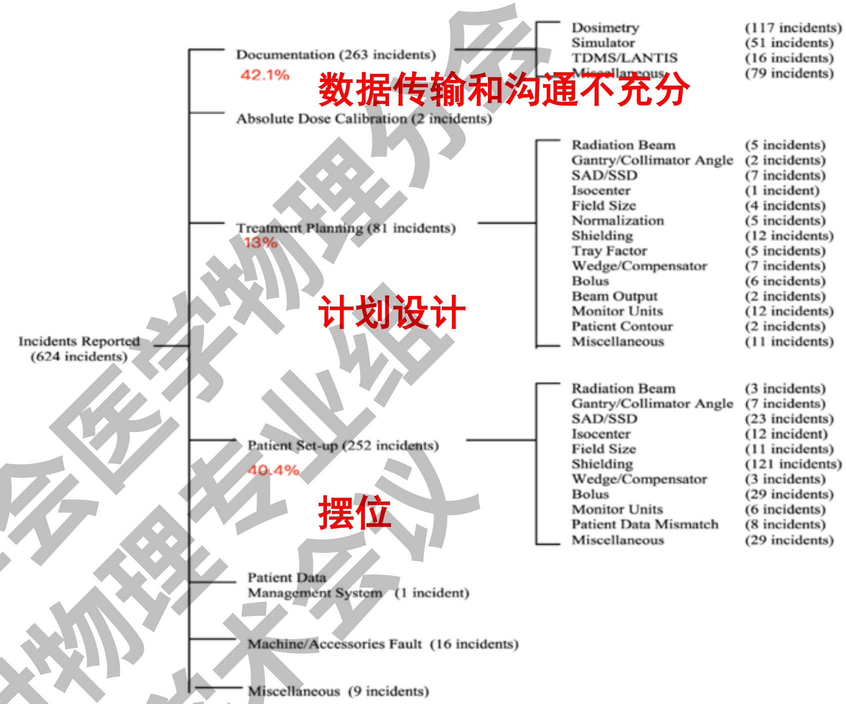

Fig. 2. Classification of incidents according to their source of error.

Radiotherapy and Oncology 74 (2005) 601－607

隆德大学、5年101中心

ROSIS 1074

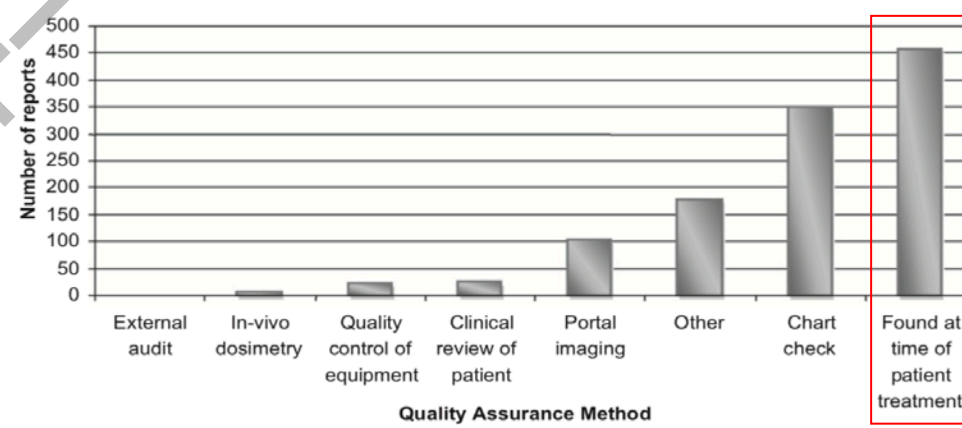

Fig. 2. Quality assurance method by which the incident was detected.

Radiotherapy and Oncology 97 (2010) 601－607

流程风险分析：

- 全流程的系统性分析
- 前瞻性预测差错易发生环节

The report of Task Group 100 of the AAPM: Application of risk analysis methods to radiation therapy quality management

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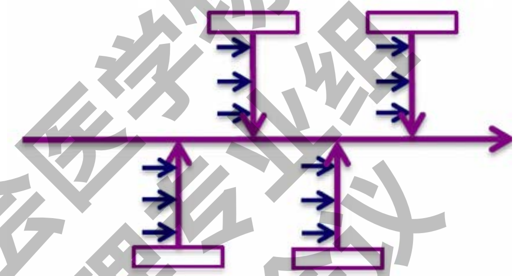
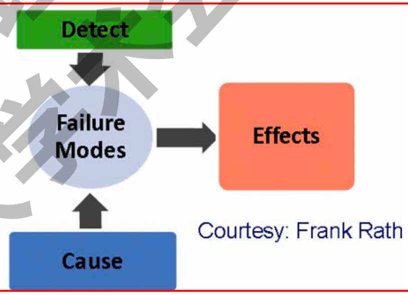
- **10章节**
- **54页**
- **11图示**
- **2016MP**

风险评估工具

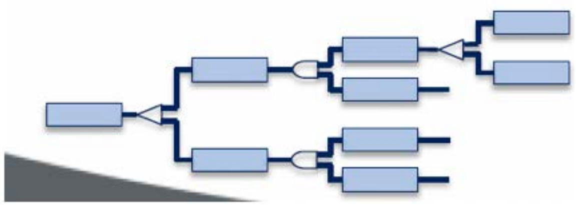
- 流程树



- 失败模式与效应分析



- 失败树

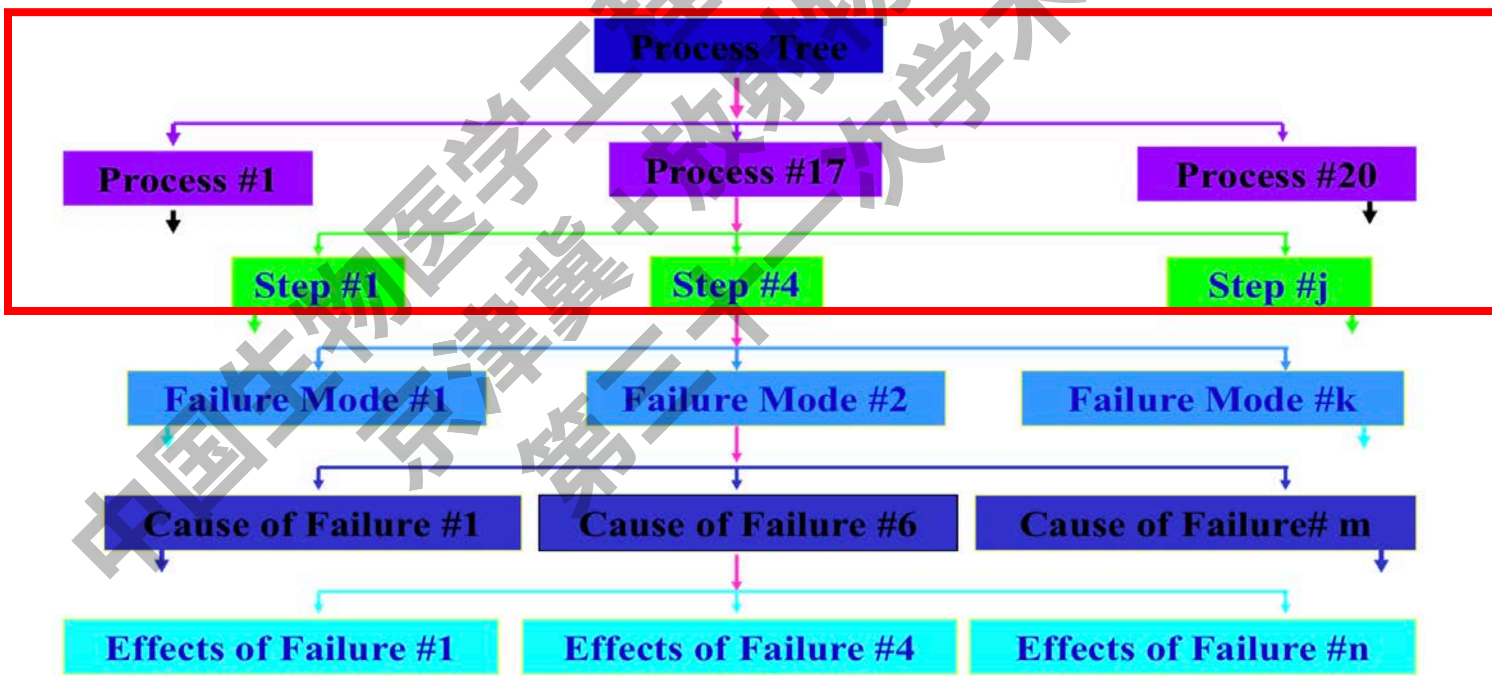


PT(1/3)

Process Tree

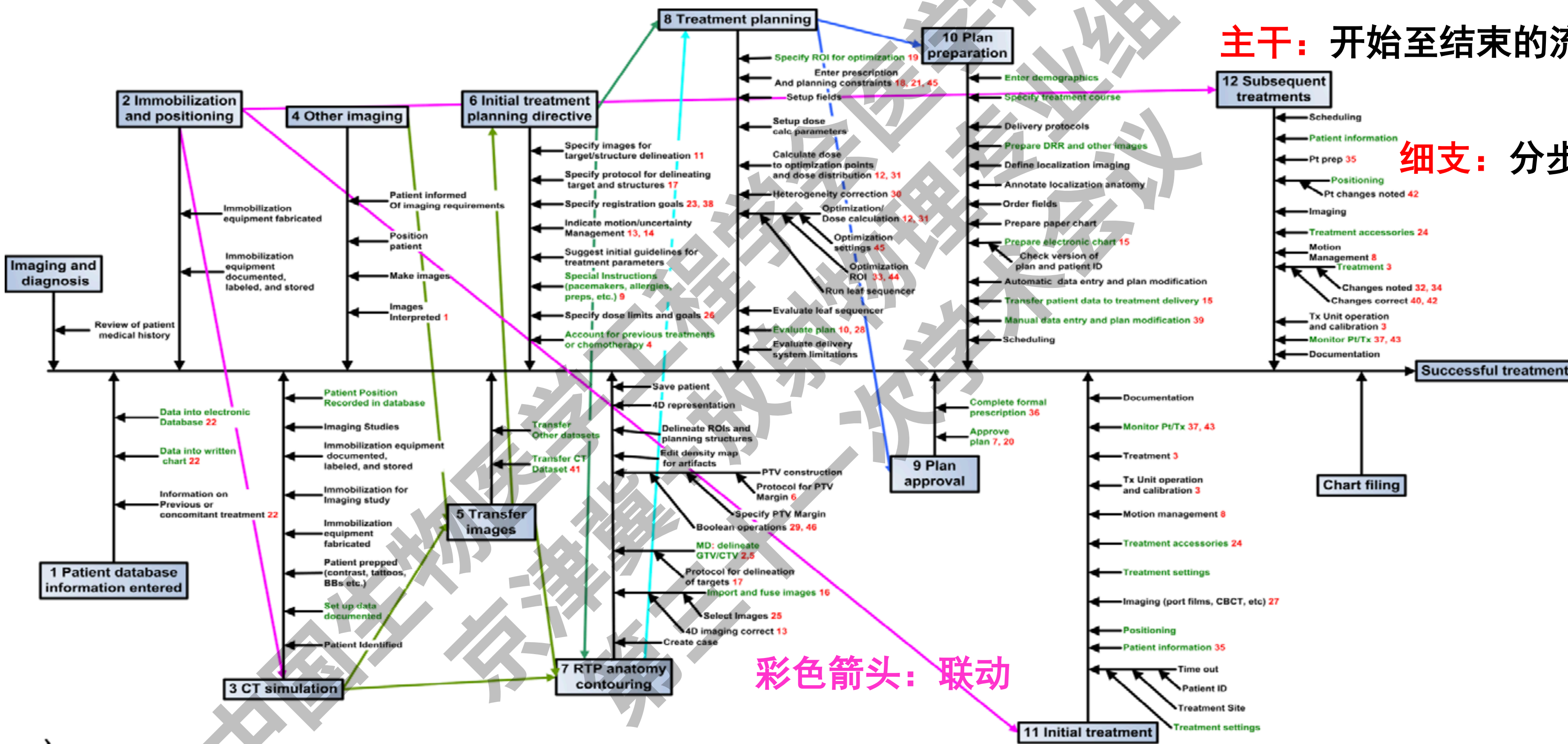
流程树(图)绘制：描述整个流程从开始到结束的步骤

整个流程各发生事件时空展开的视觉展示



PT(2/3)

Process Tree



主干：开始至结束的流程

细支：分步骤

彩色箭头：联动

PT(3/3)

Process Tree

丰富细节！

绿色分支：　临床影响较大
红色数值：　危险等级排列

FMEA(1/4)

Failure Mode and Effect Analysis

失败模式与效应分析

明确每个步骤中所有潜在的可能发生的失败模式(Failure Mode, FM)，分析发生原因及实际发生对临床的影响，以期消除或拦截可能发生在治疗中的错误。

FMEA(2/4)

Failure Mode and Effect Analysis

量化

- 失败模式发生概率（Occurrence, O）
- 临床影响严重程度(Severity, S）
- 检出概率(Detectability, D）

FM的预警值计算：

（Risk Priority Number, RPN=O*S*D，每项各1-10 分）

FMEA(3/4)

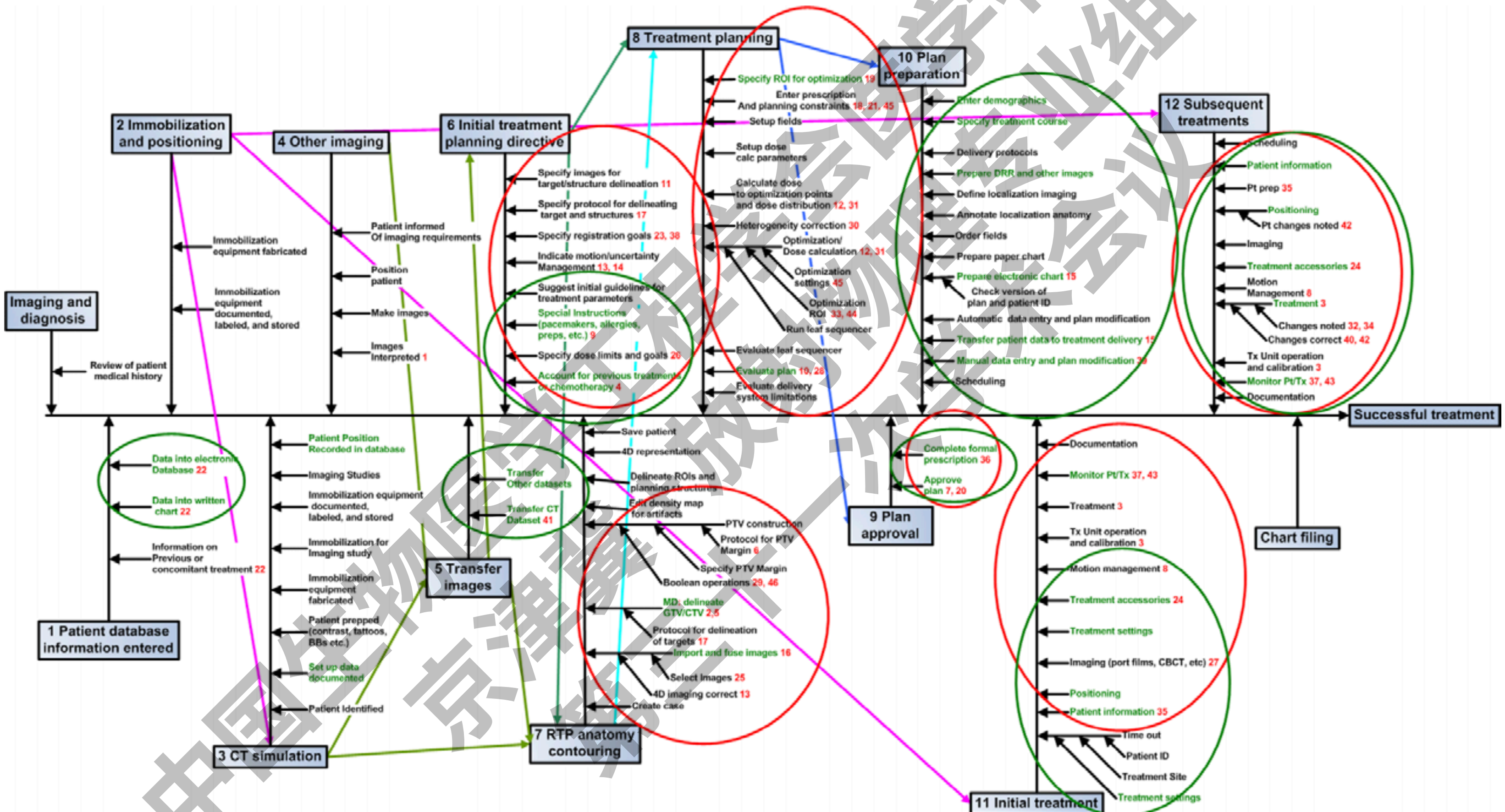
Failure Mode and Effect Analysis

量化

Table 4–3. Descriptions of the O, S, and D values used in the TG–100 FMEA

Rank	发生概率 Occurrence (O)		严重程度 Severity (S)		不被检出概率 Detectability (D)
	Qualitative	Frequency	Qualitative	Categorization	Estimated probability of failure going undetected
1	几乎不可能 Failure unlikely	0.01%	No effect 无影响		0.01%
2		0.02%	Inconvenience	Inconvenience	0.2%
3	Relatively few failures	0.05%			0.5%
4		0.1%	Minor dosimetric error	Suboptimal plan or treatment	1.0%
5		<0.2%	Limited toxicity or tumor underdose	Wrong dose, dose distribution, location or volume	2.0%
6	Occasional failures	<0.5%			5.0%
7		<1%	Potentially serious toxicity or tumor underdose		10%
8	Repeated failures	<2%			15%
9		<5%	Possible very serious toxicity or tumor underdose	Very wrong dose, dose distribution, location or volume	20%
10	必然出现 Failures inevitable	>5%	灾难性后果 Catastrophic		>20%

FMEA(4/4)



红色圆圈：高发生概率(O)步骤
绿色圆圈：高影响程度(S)步骤

FTA

Failure Tree Analysis

失败树分析

- 对高危失效模式展开分析(抓重点)
- 明确其在放疗流程中的传播途径和发生原因
- 据此针对性设计和改进质量控制方法

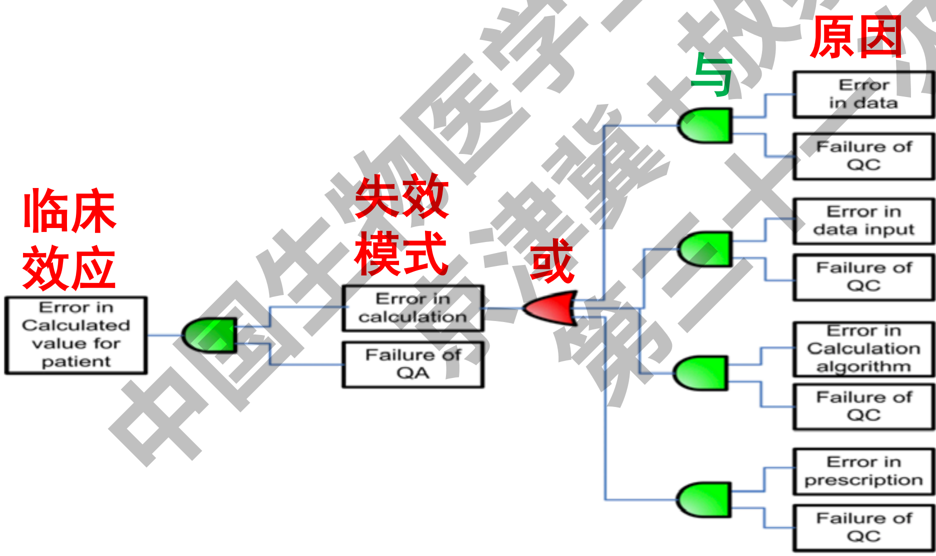


TABLE XI. Most common classifications for the possible causes for the failure shown in the IMRT fault tree analysis in Appendix E (Ref. 141).

Category		Occasions
Human failures	人为失误	230
Lack of standardized procedures	标准程序缺失	99
Inadequate training	培训不足	97
Inadequate communication	沟通不当	67
Hardware/software failure	软硬件故障	58
Hardware		9
Software		44
Hardware or software		5
Lack of staff		37
Inadequate design specifications		32
Inadequate commissioning		18
Use of defective materials/tool/equipment		12

Table X. The ten highest average RPN steps and the corresponding potential failure modes, potential causes of failure, and potential effects of failure from the TG100 FMEA.

Rank (process tree step#)	Subprocess #_description	Step description	Potential failure modes	Potential causes of failure	Potential effects of failure	Avg. *O*	Avg. *S*	Avg. *D*	Avg. RPN
1 (#31)	4—Other pretreatment imaging for CTV localization	6—Images correctly interpreted (e.g., windowing for FDG PET)	Incorrect interpretation of tumor or normal tissue	Inadequate training (user not familiar with modality), lack of communication (inter-disciplinary)	Wrong volume	6.5	7.4	8.0	388
2 (#58)	7—RTP anatomy	Delineate GTV/CTV (MD) and other structures for planning and optimization	1—>3*sigma error contouring errors: Wrong organ, wrong site, wrong expansions	Lack of standardized procedures, hardware failure (defective materials/tools/equipment), inadequate design specification, inadequate programming, human failure (inadequate assessment of operational capabilities), human failure (inattention), human failure (failure to review work), lack of staff (rushed process, lack of time, fatigue)	Very wrong dose distributions, very wrong volumes	5.3	8.4	7.9	366
3 (#204)	12—Day *N* treatment	Treatment delivered	LINAC hardware failures/wrong dose per MU; MLC leaf motions inaccurate, flatness/symmetry, energy—all the things that standard physical QA is meant to prevent	Poor design (hardware), inadequate maintenance, software failure, lack of standardized procedures (weak physics QA process), human failure (incorrectly used procedure/practice), standard Linac performance QM failure (not further considered here), inadequate training	Wrong dose, wrong dose distribution, wrong location, wrong volume	5.4	8.2	7.2	354
4 (#48)	6—Initial treatment planning directive (from MD)	Retreatment, previous treatment, brachy etc.	Wrong summary of other treatments. Other treatments not documented	Lack of staff (rushed process, lack of time, fatigue), human failure (inattention), lack of communication, human failure (reconstructing previous treatment), human failure (wrong info obtained), information not available	Wrong dose	5.3	8.6	7.3	333

RPN=333

第六步骤：既往剂量考量

流程树

高危失败模式（既往治疗错误总结和数据缺失）
患者可能因此接受错误的剂量
工作人员时间紧张、缺乏沟通、获取错误信息

失败树分析

失效模式和效应分析

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测验1

以下不属于AAPM-TG100报告推荐的放疗流程评估工具的是（单选）：

A. 流程树（Process Tree）

B. 预警值（Risk Priority Number）

C. 失败模式和效应分析（Failure Mode and Effect Analysis）

D. 失败树分析（Failure Tree Analysis）

测验2

失败树分析的目的是（单选）：

A. 对高危FM开展分析

B. 明确高危FM在放疗流程中的传播途径和发生

C. 设计和改进当前质控方法的依据

D. 以上三项都是

汇报内容

- 背景介绍
- TG100方法
- 应用实例
- 总结

Practical Implementation of Failure Mode and Effects Analysis for Safety and Efficiency in Stereotactic Radiosurgery

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SRS

Validating FMEA output against incident learning data: A study in stereotactic body radiation therapy

F. Yang,[a)] N. Cao, L. Young, J. Howard, W. Logan, T. Arbuckle, P. Sponseller, T. Korssjoen, J. Meyer, and E. Ford
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SBRT

RADIATION ONCOLOGY PHYSICS
WILEY

Failure modes and effects analysis (FMEA) for Gamma Knife radiosurgery

Andy Yuanguang Xu[1] | Jagdish Bhatnagar[1] | Greg Bednarz[1] | John Flickinger[1] | Yoshio Arai[1] | Jonet Vacsulka[2] | Wenzheng Feng[3] | Edward Monaco[2] | Ajay Niranjan[2] | L. Dade Lunsford[2] | M. Saiful Huq[1]

GammaKnife

Medical Physics
The International Journal of Medical Physics Research and Practice

Failure mode and effects analysis and fault tree analysis of surface image guided cranial radiosurgery

Ryan P. Manger, Adam B. Paxton, Todd Pawlicki, and Gwe-Ya Kim

SGRT

FMEA of manual and automated methods for commissioning a radiotherapy treatment planning system

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Risk assessment of a new acceptance testing procedure for conventional linear accelerators

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应用实例1_TPS

计划系统Commissioning：

FMEA of manual and automated methods for commissioning a radiotherapy treatment planning system

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(Received 18 October 2016; revised 1 March 2017; accepted for publication 12 March 2017; published 28 July 2017)

Purpose: To evaluate the level of risk involved in treatment planning system (TPS) commissioning using a manual test procedure, and to compare the associated process-based risk to that of an automated commissioning process (ACP) by performing an in-depth failure modes and effects analysis (FMEA).

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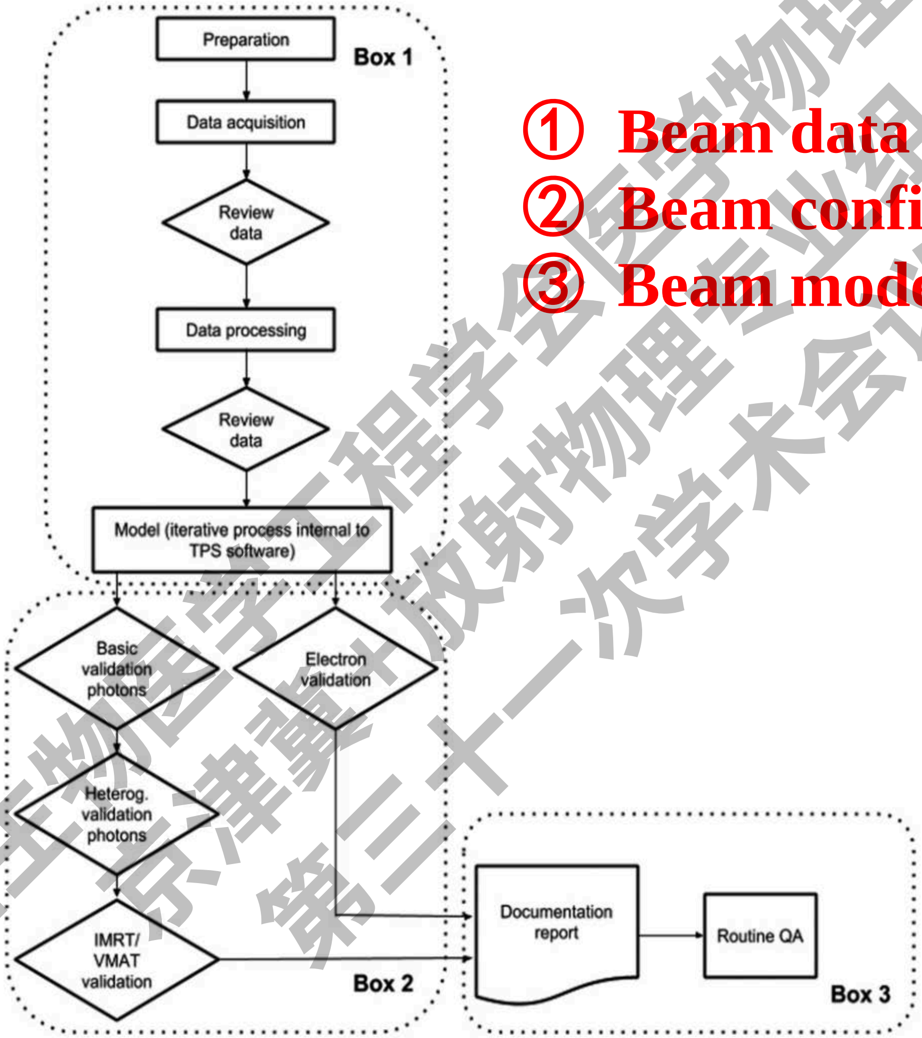

① Beam data collection
② Beam configuration
③ Beam modeling

Validation test

Report and routine QA

	Manual commissioning failure mode	RPN_m
1.	Incorrect choice of measurement equipment	640
2.	Film processor error, incorrect delivery (gantry, MU incorrect)	512
3.	Insufficient treatment plan evaluation	448
4.	Beam data misinterpreted by incorrect data selected	432
5.	Beam data misinterpreted by format mismatch	378
6.	Treatment plan parameters partially corrupted upon being uploaded to treatment unit	360
7.	Poor beam modeling	336
8.	Beam data not sufficiently reviewed	288
9.	Independent dose calculations of basic dosimetry parameters not performed	288
10.	Beam data not analyzed correctly	270

测量设备选择

计划文件部分传输

射束模型欠佳

主要失败模式

Table III. MTP recommended tests and examples of failure.

MTP test categories	Example test	Examples of failure
Data processing	All data used in the modeling process must be reviewed and validated after entry into the planning system	The physicist does not identify problems with the acquired data
Data modeling & analysis	The dose distribution calculated in planning system is >2% from the commissioning tests	The physicist does not review, validate and compare the data after the modeling to reference data provided by the vendor
Dose algorithm validation	Off-axis MLC shaped field, with maximum allowed leaf over travel	Measurement equipment not setup correctly Dosimeter used for absolute dose is not calibrated Wedge not inserted properly
Heterogeneous correction validation	Scan Hetero phantom at CT scanner and create the CT-density table by entering into the TPS.	The CT to density curve was not constructed correctly
Dose validation	Verification of sm field PDD & sm field output. Clinical cases be planned and measured with ion chamber, film, or array	Leaf transmission not set correctly Leaf gap offset not set correctly Equipment is not set up correctly QMP does not properly review the results of Dose Validation Test for commissioning of IMRT/VMAT modality

采集数据错误

绝对剂量标定错误

CT值电子密度曲线不对应

叶片参数设置错误

应用实例2_Linac

加速器验收测试：

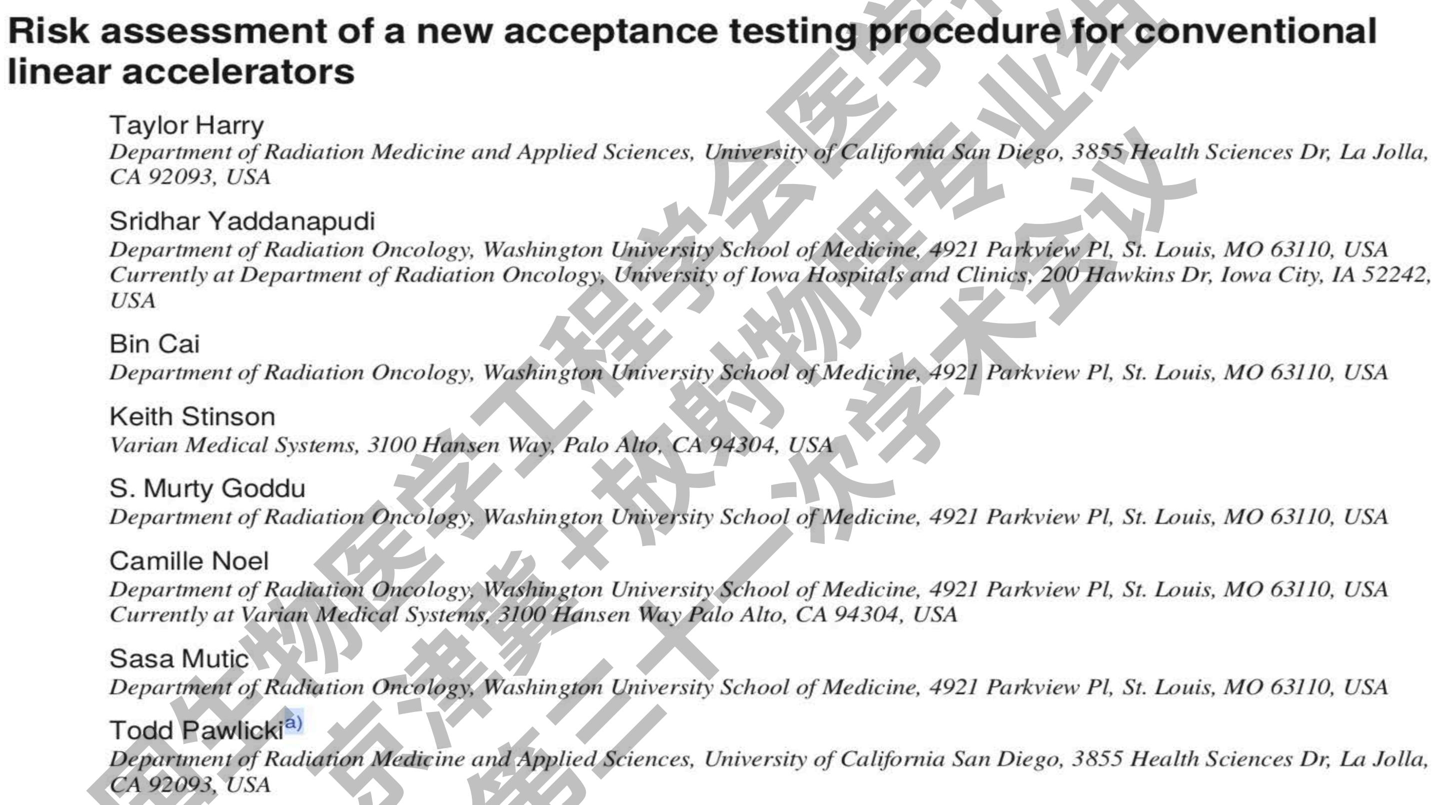
Risk assessment of a new acceptance testing procedure for conventional linear accelerators

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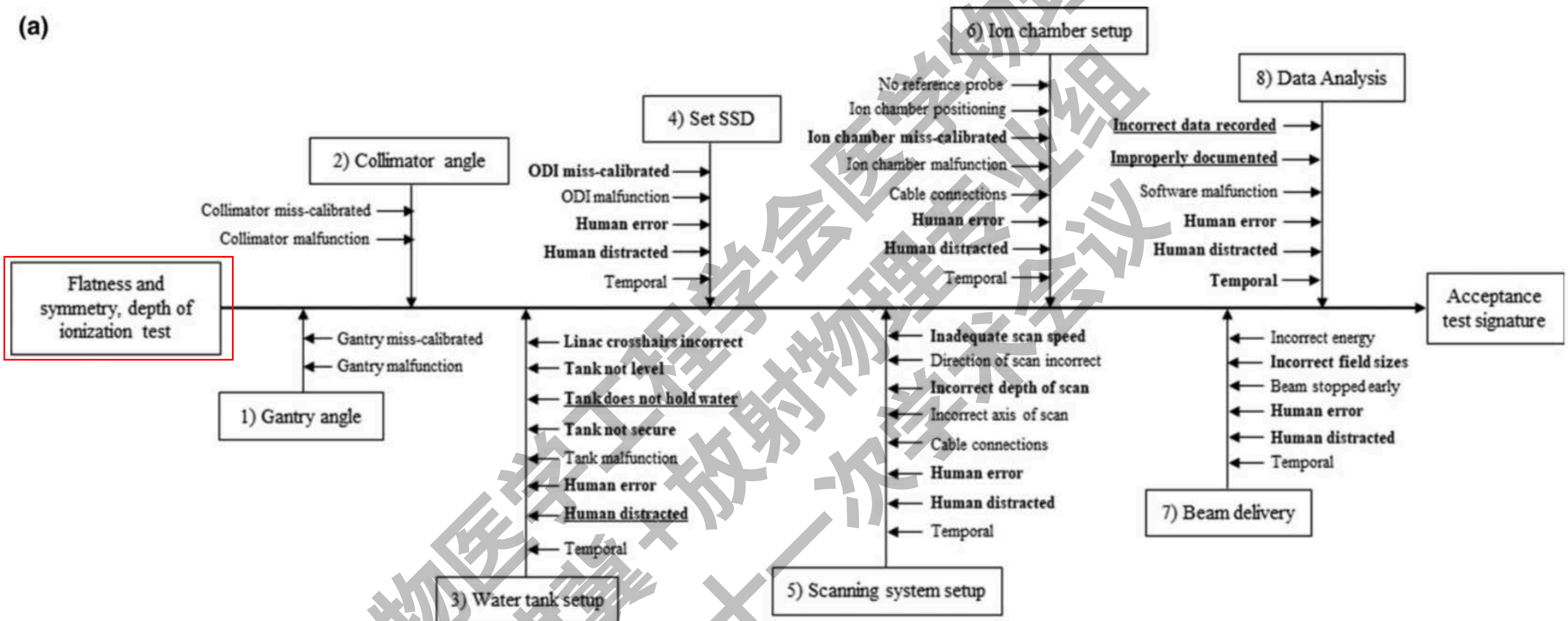
TABLE I. ATP tests evaluated.

ATP test	Purpose
Front pointer distance alignment verification (FPDAV)	Verify the front pointer measured distance meet specifications
Crosshair alignment and jaw parallelism (CAJP)	Verify that the radial and transverse crosshair lines parallelism alignment with the jaws and multi leaf collimator leaf banks meet specifications
Jaw position readout (JPR)	Verify that the projected light field and digital positional field readout meet specification
Coincidence of light field vs. x-ray field (LvR)	Verify the light vs. radiation field coincidence meet specification
Multileaf collimator static leaf position and static repeatability test including coincidence of light vs. x-ray field (MLC SLPA LR)	Verify planned MLC positions vs. physical MLC positions meet specification. Verify the light vs. radiation field coincidence meet specification
Photon field flatness and symmetry and depth of ionization (MV FS DOI)	Verify that the radial and transverse beam profiles meet specification. Verify the photon depth of ionization meets specification
Electron Field Flatness Symmetry and Depth of Ionization (MeV FS DOI)	Verify that the radial and transverse beam profiles meet specification. Verify the electron depth of ionization meets specification
MV/kV imager positioning unit Vrt/Lat/Lng/Iso cal (MVD/kVD PRO)	Verify that actual translational positions and displayed digital readout meet specifications
kV source positioning Vrt/Lat/Lng (kVS PRO)	Verify that actual translational position and displayed digital readout meet specification
MV image quality (MV IQ)	Verify that resolution, noise and contrast, gray scale linearity, and uniformity meet specification
kV gray scale and contrast (kV GSC)	Verify that, noise and contrast, gray scale linearity, and uniformity meet specification
MV dosimetry integration and uniformity/noise (MV DIUN)	Define the linearity of pixel counts relative to dose and uniformity and noise
kVp, HVL, Air Kerma test accuracy (kV HVL AK mAs)	Verify that kVp, mA, ms accuracy and Air Kerma meet specifications
Pixel sensitivity map (PSM)	Define response and intrinsic noise of the EPID

(a)



Photon field flatness and symmetry and depth of ionization (MV FS DOI)	Verify that the radial and transverse beam profiles meet specification. Verify the photon depth of ionization meets specification

① 八个步骤
② 四个预警值(RPN)>200的分步骤

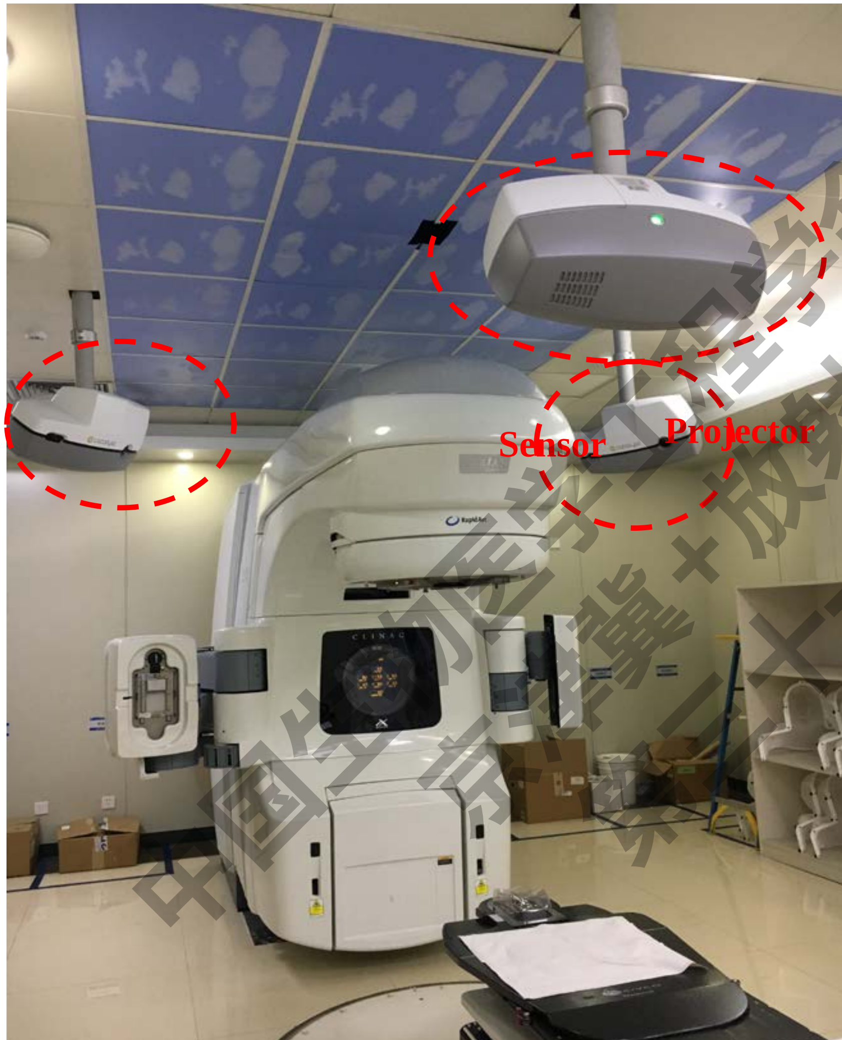
ATP test/process step	Failure mode or failure pathway	O	S	D	RPN
(a)					
Photon field flatness and symmetry, depth of Ionization					
Water tank/phantom setup and alignment to linac isocenter	Tank does not hold constant water level	5	7	6	210
	Human distracted	6	7	5	210
Scanning system setup	Incorrect depth of scan	5	9	4	180
Analysis of data. Documenting and recording results	Incorrect data recorded	4	9	7	252
	Improperly documented	4	9	7	252

水箱摆位操作

数据分析和后处理

三维水箱使用频率低，采集数据前的培训和技术指导是必要的！

应用实例3_Catalyst



三种光源：蓝光405nm，扫描物体并被摄像头所探测并成像
绿光528nm和红光624nm，分别用于提示皮肤实际位置与标准位置的偏差

① 摆位和监控
② 门控治疗

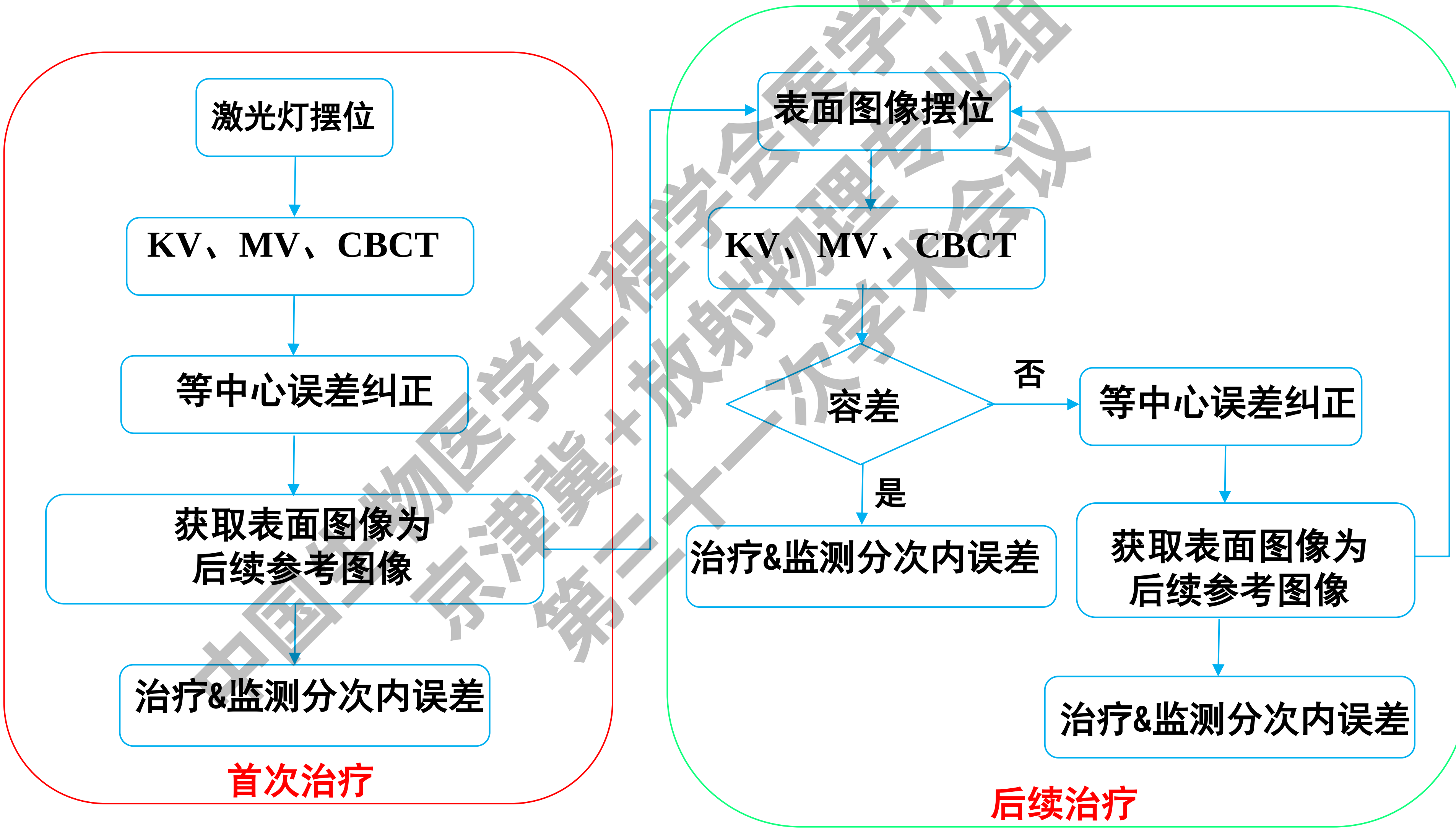
1974cc

4175cc

山 东 省 肿 瘤 医 院
山东省肿瘤防治研究院

Catalyst

摆位模式：



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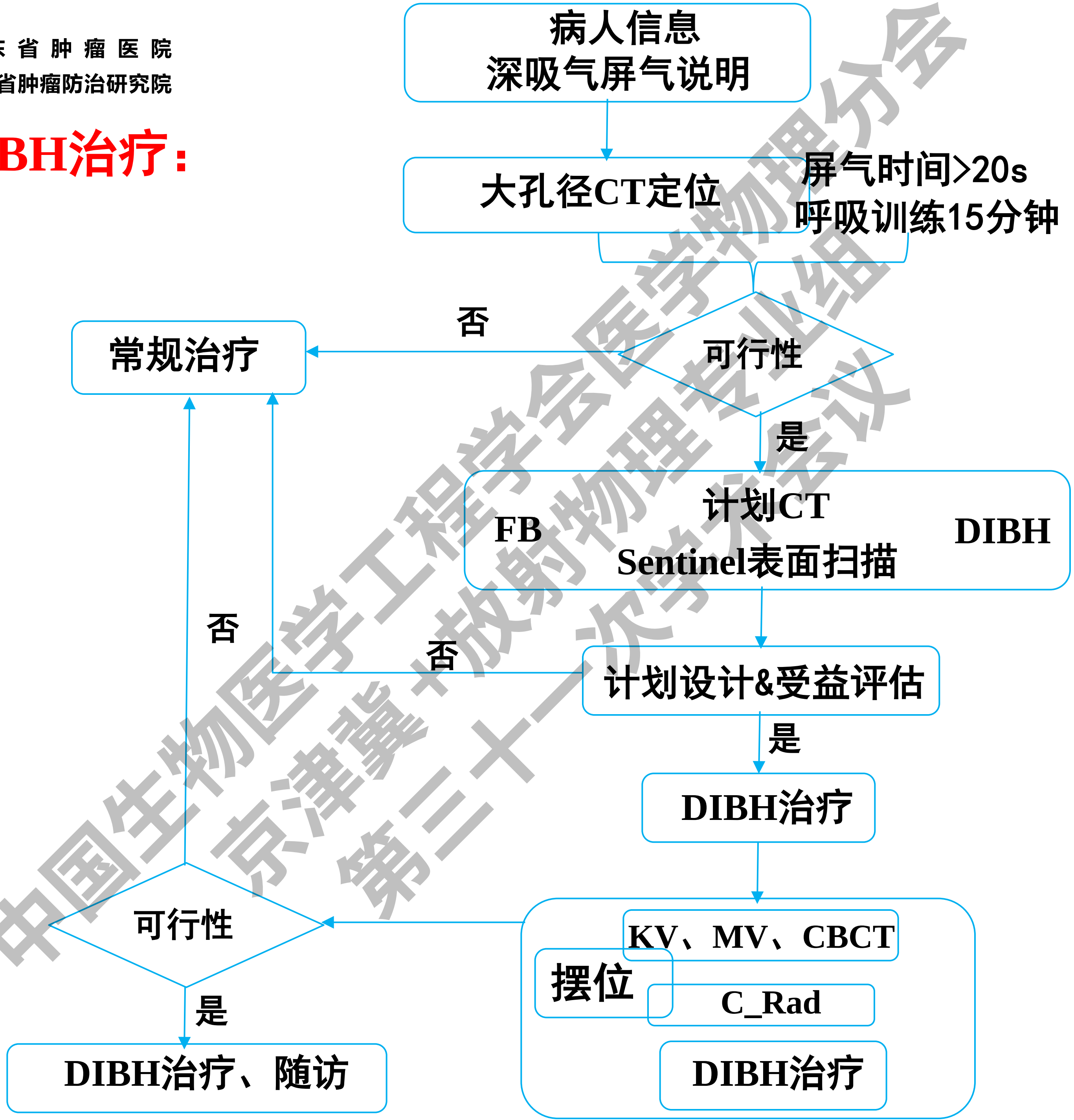
山东省肿瘤防治研究院

DIBH治疗：



高危FM

- 沟通：物理师与医师(呼吸训练的重要性)
  物理师与物理师(执行效率，两套计划)
  物理师与技术员(什么时间治疗)

- AR眼镜添加屏气时间提醒、呼气量的阈值警示语句

山东省肿瘤医院
山东省肿瘤防治研究院

汇报内容

- 背景介绍
- TG100方法
- 应用实例
- 总结

山东省肿瘤医院
山东省肿瘤防治研究院

总结

- 质量控制方法应以设备性能指标为重心转移到以多人员参与的信息传递流程为重心

- 基于PT、FMEA、FTA的风险分析方法，是深刻理解和预测放疗全过程的高危环节，优化质控方法，提高治疗精度的有力工具

- 放疗流程差异大，流程质量管理需要放射肿瘤团队各成员间长期紧密的沟通合作(医师、物理师、剂量师、治疗师等等)不断优化完善新技术和规范(最优化和特异化)。

谢 谢