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# **Quality Assurance Challenges**

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**Joann I. Prisciandaro, Ph.D.**

*The* **Department of Radiation Oncology  
University of Michigan**



# Outline

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- **Why is QA a necessary component of radiation therapy?**
- **What are the available resources to develop QA programs?**
- **What challenges do we face when developing a QA program?**
- **Conclusions**



# Why is QA necessary in RT?

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**“Every patient with cancer deserves to receive the best possible management to achieve cure, long-term tumor control or palliation.”**

- Goal of QA is to give high confidence that patients will receive the intended dose/treatment correctly.
- Requires a commitment to quality throughout the entire treatment process.
- Requires organizational structure, defined responsibilities, procedures, processes and resources for assuring the quality of patient management.

“Radiation oncology in integrated cancer management,” Report of the Inter-Society Council for Radiation Oncology (1986).

B. Thomadsen, *Int. J. Radiation Oncology Biol. Phys.*, 71 (1), S166–S169 (2008).

AAPM TG-40



# How do we setup a QA program?

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- **Need to set quality standards – accepted criteria against which quality can be assessed**
- **In the past, these quality standards have been established from:**
  - 1. Consensus recommendations**
  - 2. Learning from past errors**

**D.I. Thwaites, B.J. Mijnheer, and J.A. Mills, Radiation Oncology Physics: A handbook for teachers and students, chapter 12, IAEA (2007).**



# 1. Consensus Recommendations

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- **There are a number of resources available that provide QA guidance**
  - **AAPM Task Group Reports**
  - **ASTRO White Papers**
  - **NCRP Reports**
  - **NRC Regulations (requirements for by-product material)**
  - **ICRU Reports**
  - **IAEA publications**

# Map Standard 3D Treatment Process (TG Reports Only)

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- **Consultation**
- **Simulation**
  - TG 66 (CT QA)
- **Treatment planning**
  - TG 53 (QA of tx planning system)
  - TG 65 (Tissue Inhomogeneity Corrections)
  - TG 114 (MU verification non-IMRT)
- **Pre-Treatment Imaging**
  - TG 58 (EPID)

# Map Standard 3D Treatment Process (TG Reports Only)

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- **Treatment delivery**
  - TG 21 & 51 (photon and electron dosimetry)
  - TG 25 & 70 (electron dosimetry)
  - TG 106 (accelerator beam commissioning),
  - TG 40 (comprehensive QA) & TG 142 (linac QA)
  - TG 50 (MLC QA)
- **(This list is not exhaustive)**

# Complex Tx Require Additional Scrutiny and QA



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- **IMRT**
  - Ezzell *et al.* IMRT guidance document
  - TG 119 (IMRT commissioning)
  - TG 120 (IMRT measurements)
  - Moran *et al.* ASTRO White Paper (in review)
- **IGRT**
  - TG 104 (kV for setup and localization)
  - TG 75 (imaging dose)
- **SBRT/SRS**
  - TG 42 (SRS)
  - TG 101 (SBRT)



# Complex Tx (Cont.)

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- **Respiratory management - TG 76**
- **TBI - TG 29**
- **TSET - TG 30**
- **Brachytherapy**
  - **TG 43 (Dose calculation)**
  - **TG 56 (Code of Practice)**
  - **TG 59 (HDR)**
  - **TG 152 (Electronic)**
  - **Etc.**



## 2. Learning from Past Errors

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- By examining past errors, we can direct our attention to specific aspects of a procedure that may pose the greatest risk.

B. Thomadsen, *Int. J. Radiation Oncology Biol. Phys.*, 71 (1), S166–S169 (2008).



## 2. Learning from Past Errors (Cont.)

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- **Ostrom *et al.* reported seven by-product related misadministrations between 1991 – 1992.**
- **Root cause analysis:**
  - **lack of policies or procedures**
  - **lack of oversight and supervision**
  - **Ill defined authority and responsibilities of involved individuals**
  - **inadequate training and experience**

L.T. Ostrom *et al.*, *Int. J. Radiation Oncology Biol. Phys.*, 34 (1), 227-234 (1996)



## 2. Learning from Past Errors (Cont.)

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- **Root cause analysis (cont):**
  - lack of communication
  - errors in judgment and interpretation
  - changes in routine, unique conditions
- **Furthermore, each of the events involved more than one direct cause.**



## 2. Learning from Past Errors (Cont.)

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- The IAEA has provided summaries of incidents and accidents related to the therapeutic use of ionizing radiation
  - External beam, brachytherapy, and nuclear medicine
- Cases typically involved patients, but there were some examples of exposure of medical staff or general members of the public



## 2. Learning from Past Errors (Cont.)

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- **Root cause analysis:**
  - **Insufficient staffing**
  - **Human factors**
    - **Lack of communication between staff members**
    - **Inattention to details, lack of awareness**
    - **Ill defined authority and responsibilities of involved individuals**
  - **Insufficient training, especially how to respond to unusual situations**

**IAEA Safety Reports Series No. 17, Lessons learned from accidental exposures in radiotherapy (2000)**  
**IAEA Prevention of Accidental Exposure in Radiotherapy modules**



## 2. Learning from Past Errors (Cont.)

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- **Root cause analysis (cont):**
  - **Insufficient communication**
    - Between staff members and between staff and patients
  - **Equipment issues**
    - Equipment failure (small fraction of reported events)
    - Issues with human-machine interactions (understanding errors and responding appropriately)
  - **Insufficient documentation**



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# Lessons learnt from accidents

Accidental  
Overexposure  
of  
Radiotherapy  
Patients  
in San José,  
Costa Rica



INVESTIGATION OF AN  
ACCIDENTAL EXPOSURE  
OF RADIOTHERAPY  
PATIENTS IN PANAMA

Report of a Team of Experts, 20 May-1 June 2001



Accidental Overexposure  
of Radiotherapy  
Patients in Białystok



**International Atomic Energy Agency: *Lessons learned from accidental exposures in radiotherapy.* IAEA Safety Reports Series No. 17 (2000)**

**International Commission on Radiological Protection: *Prevention of Accidental Exposures to patients undergoing Radiation Therapy* ICRP Publication 86. Annals of the ICRP 30 (3) 2000**



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January 24, 2010

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By [WALT BOGDANICH](#)

January 27, 2010

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## F.D.A. to Increase Oversight of Medical Radiation

By [WALT BOGDANICH](#) and REBECCA R. RUIZ



# Why is QA challenging?

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- **Numerous guidance documents**
  - **>100 AAPM TG reports and numerous NCRP, ICRP, and IAEA publications**
  - **Some very LENGTHY documents**
  - **Provides a thorough list of recommendations, but overwhelming and can be prohibitively time consuming.**

**J. Palta, Chihray, L., and J. Li, Int. J. Radiation Oncology Biol. Phys., 71 (1), S13–S17 (2008).  
B. Thomadsen, Int. J. Radiation Oncology Biol. Phys., 71 (1), S166–S169 (2008).**



# Why is QA challenging?

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- Numerous guidance documents (cont.)
  - QA guidance documents may be interpreted by regulatory bodies as requirements.
    - This can hinder CQI, leaving little room to modify QA programs to accommodate changes in radiotherapy practice.
  - Need timely reports

J. Palta, Chihray, L., and J. Li, *Int. J. Radiation Oncology Biol. Phys.*, 71 (1), S13–S17 (2008).  
B. Thomadsen, *Int. J. Radiation Oncology Biol. Phys.*, 71 (1), S166–S169 (2008).



# Why is QA challenging? (Cont.)

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- Complexity of treatments
- Variation in clinical practice
- Level of automation
  - Technology has increased our capabilities, but has also created new kinds of failure modes.
- Clinical pressures – staffing, resources, and time to allot to develop in-house QA programs

J. Palta, Chihray, L., and J. Li, *Int. J. Radiation Oncology Biol. Phys.*, 71 (1), S13–S17 (2008).  
A. Gawande, *The Checklist Manifesto – How to get things right*, Metropolitan Books (2009).



# Why is QA challenging? (Cont.)

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- **Guidelines are living documents**
  - **Must be regularly reviewed and updated**



# What can we do?

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- The current process of developing consensus recommendations for prescriptive QA remains valid for many applications but...
  - QA guidance is incomplete and/or out of date.
  - This approach not practical for:
    - non-routine procedures
    - complex procedures
    - new and emerging procedures/technology
- Fresh approaches to quality and safety management are needed.



# What can we do?

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- The current process of developing consensus recommendations for prescriptive QA remains valid for many applications but...
- **A prescriptive QA paradigm is ineffective and/or cost prohibitive**
  - **“Effective QA needs to consider procedures, rather than just equipment, and the human actions and interactions required for safe execution.”**

**J. Palta, Chihray, L., and J. Li, Int. J. Radiation Oncology Biol. Phys., 71 (1), S13–S17 (2008).**

# Failure Modes and Effects Analysis (FMEA)

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- Create a workflow diagram of a process
- Identify what can go wrong at various stages of the documented process – failure modes

# Failure Modes and Effects Analysis (FMEA)

- For each failure mode estimate and score:
  - O, frequency (1-10)
    - 1 – unlikely, 10 – highly likely
  - S, severity (1-10)
    - 1 no harm, 10 lethal/catastrophic
  - D, “un”-detectability of failure mode (1-10)
    - 1 undetected <0.01% of time, 10 undetected < 20% if time

# Failure Modes and Effects Analysis (FMEA)

- Calculate risk probability (RPN)
  - $RPN = O * S * D$
  - Larger number, the greater the risk
- However, “[TG 100] is grappling with the values of RPN that should be of concern in medicine.”
- Requires brainstorming of team members
  - Need buy in – administration, physicians, dosimetry, therapists, nursing, etc.
  - Requires time and dedication

M.S. Huq *et al.*, *Int. J. Radiation Oncology Biol. Phys.*, 71 (1), S170- S173 (2008)  
R.A.C. Siochi, RAMPS Chapter Meeting





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<b>Primary Employment</b>	<b>Percent %</b>
Private or Community Hospital	33
Medical School or University Hospital	28
Medical Physics Service Group	10
Cancer Center	9
Medical (Physician) Group	7
Industrial or Commercial Firm	5
Self-employed Consultant	3
Government Hospital	2
Non-medical College or University	1
Government (Non-hospital)	1
Other	1

**John Sweet, Chair of the Professional Survey Subcommittee, AAPM**



# What can we do?

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- The current process of developing consensus recommendations for prescriptive QA remains valid for many applications but...
- A prescriptive QA paradigm is ineffective and/or cost prohibitive
- **Develop minimum standard guidelines**



# Subcommittee on Practice Guidelines

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- **Formally approved by AAPM in November 2007**
  - Chair: Maria Chan
  - Vice Chair: Joann Prisciandaro
- **Specific Charges:**
  - Receive requests for medical physics assistance from other groups relative to their practice or facility accreditation programs or professional certification programs.
  - Evaluate the requests for appropriateness and assign them to the appropriate Committee, Sub Committee or Working Group.
  - Receive drafts or comments from the AAPM groups and compose an official response or position to submit to the AAPM Board of Directors.



## SPG (Cont.)

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- **Specific Charges (Cont.):**
  - Evaluate all draft TG reports to determine whether a Clinical Implementation Guide would be appropriate and of benefit to AAPM members.
  - For TG reports in need of a Clinical Implementation Guide, generate and publish the Guide through a collaborative effort with the originating TG.



## SPG (Cont.)

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- **Saturday, March 21, 2009 SC met in NYC to review our charge**
  - **We should not be attempting to rewrite TG reports, but assist in identifying minimum, standardized tests for the community to implement.**
    - **These documents should boil down the TG suggestions so that it may be applied directly to clinical practice.**
  - **Some TG reports are too all encompassing.**
    - **Authors trying to cover all bases but very difficult for clinical physicist to distill the most important items.**
    - **Shall vs. should?**
    - **A number of TGs members, although experts in the field, are typically not performing the tests.**



## SPG (Cont.)

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- **Saturday, March 21, 2009 SC met in NYC to review our charge**
  - **Concerns:**
    - **Will we be perceived in an adversarial position.**
    - **Will medical physics community choose to review the short, concise document rather than take the time to review the TG report, which would be a disservice to our community and the TG authors.**
- **Following meeting, we approached the AAPM with suggestions on how to begin the MPG initiative – Not ready**



## SPG (Cont.)

- Initial charges were good intentioned but not well received....
  - Receive requests for assistance .... relative to their practice or facility accreditation programs....
  - Evaluate the requests for appropriateness and assign them to the appropriate Committee, SC or WGs.
  - Receive drafts or comments from the AAPM groups and compose an official response or position to submit to the AAPM Board of Directors.
  - Evaluate all draft TG reports for regulatory interpretation.
  - For TG reports in need of a Clinical Implementation Guide, generate and publish the Guide through a collaborative effort with the originating TG.



“... [SPG will soon] fulfill their charge of drafting Medical Physics Practice Guidelines (MPPGs), **pending direction** from ExCom. MPPGs, ...will signify a major change in our association – to that of a practice guidance setting organization and as such is being approached enthusiastically **yet cautiously** by Professional Council.”



## SPG (Cont.)

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- **18 members (3 new additions in 2011)**
  - **We have bright, passionate, and ambitious members**
  - **We have the expertise**
  - **But, how to we get the word out?**
  - **We need to be empowered!**



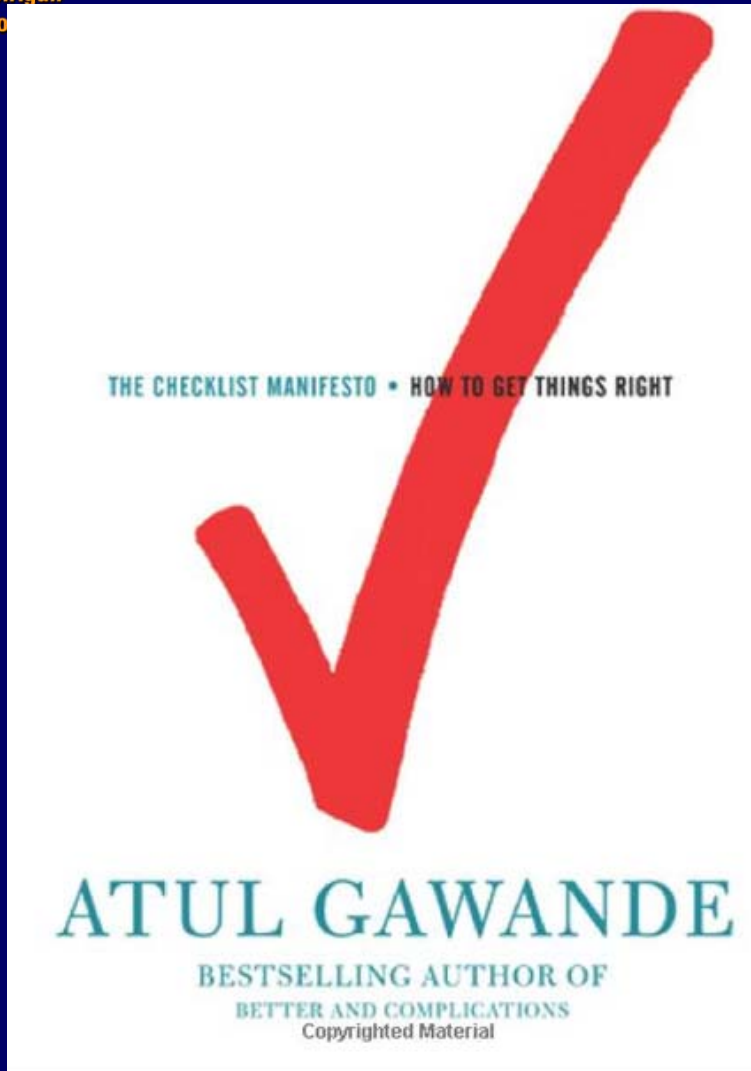
# What can we do?

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- The current process of developing consensus recommendations for prescriptive QA remains valid for many applications but...
- A prescriptive QA paradigm is ineffective and/or cost prohibitive
- Minimum guidelines
- **Develop checklist**



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# Benefits of Checklists

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- Take advantage of our experience and knowledge and makes up for human fallibility
- Intended to catch mental flaws
  - Memory lapses
  - Inattention to detail
- Checklists ensure the simple, but critical stuff is not overlooked.
  - Needs to be short and concise

**A. Gawande, The Checklist Manifesto – How to get things right, Metropolitan Books (2009).**



# Benefits of Checklists (Cont.)

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- **However, checklists are not for all situations**
  - **Insufficient for complex or non-routine situations**
- **Furthermore, a “checklist must not become ossified mandates that hinder rather than help.”**
  - **Need to be reviewed and revised periodically**

**A. Gawande, *The Checklist Manifesto – How to get things right*, Metropolitan Books (2009).**



# Benefits of Checklists (Cont.)

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- **It takes a village**
  - **Going back to the aviation analogy, “too much airplane for one person to fly”**
  - **Should be generated by a team**
  - **However, do physicists at small practices have the resources to develop these lists?**
  - **Must be cautious of checklist fatigue!**

**A. Gawande, The Checklist Manifesto – How to get things right, Metropolitan Books (2009).**



# What can we do?

---

- The current process of developing consensus recommendations for prescriptive QA remains valid for many applications but...
- A prescriptive QA paradigm is ineffective and/or cost prohibitive
- Minimum guidelines
- Develop checklist
- **Develop internal and national database for reporting**
  - **Information hard to obtain for fear of litigation and publicity**



# Lessons from the Aviation Industry

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- Industry has evolved from concentrating on reactive safety initiatives to a proactive process – focus on identifying potential hazards.
- Aviation Safety Action Partnership (ASAP) programs were developed to provide a vehicle to report hazards or near “hits” without fear of retaliation or disciplinary action.
- The FAA benefited by learning of system breakdowns before they resulted in an accident and could work with the operator to ensure the hazard or hazards were mitigated sufficiently.

T. Logan, *Int. J. Radiation Oncology Biol. Phys.*, 71 (1), S178–S181 (2008).



# What can we do?

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- The current process of developing consensus recommendations for prescriptive QA remains valid for many applications but...
- A prescriptive QA paradigm is ineffective and/or cost prohibitive
- Minimum guidelines
- Develop checklist
- Develop internal and national database for reporting
- **Take advantage of external audits**
  - ACR accreditation
  - RPC TLD program
  - Private audit
  - **These audits will not solve all issues, but it gives us an outside perspective and second set of eyes.**

# Conclusion – How do we approach QA challenges?

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- **Generate timely, clinically relevant task group reports.**
  - Diversify the membership of TGs (more clinical representation) and recruit the next generation of physicists
- **If FMEA is the newly embraced QA paradigm, provide more guidance and sample documents to support this approach.**
  - Impractical to expect small practices to perform a thorough systems analysis



# Conclusion (Cont.)

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- **Support the development of AAPM/ASTRO/ACR endorsed practice guidelines**
  - AAPM must support and empower C, SC, and WG, such as SPG to develop these guidelines.
  - If we do not develop these guidelines, someone else will!
  - Improve communication between different groups so that we are not duplicating efforts.
- **Utilize checklist**
  - Examples extremely valuable, especially to small practices



# Conclusion (Cont.)

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- **Support the creation of internal and national database for reporting**
  - **To Err is Human, lets learn from past mistakes**
- **Take advantage of external audits**
- **Additional take home points:**
  - **Support continuing education and training**
  - **Encourage the AAPM to develop and publish staffing guidelines**
  - **Encourage team mentality in clinics**



**If we want to promote a culture of safety in our clinics, we need to adhere to the adage that “patient safety is everyone’s responsibility.”**