Summary of
ASTRO Safety White Papers
and
the RadOnc Safety Stakeholders’ Initiative

Benedick Fraass
ASTRO Safety White Papers

• With a week of the first NY Times article about RT errors, ASTRO Board asked the Multidisplinary QA Subcommittee to organize short fast white papers on safety for the following:
  • IMRT: Intensity Modulated Radiation Therapy
  • IGRT: Image-Guided Radiation Therapy
  • SBRT: Stereotactic Body Radiation Therapy
  • HDR: High Dose Rate Brachytherapy
  • Peer Review
ASTRO Safety White Papers

• Writing groups include MDs, PhDs, RTTs, CMDs
• **Goal**: a comprehensive overview of all issues relevant to safe patient treatments
• Small groups to work quickly
• 2 sets of reviews:
  • Expert review from individuals (and other orgs)
  • Public posting comments
• Eventual formal approval by ASTRO, and endorsement by AAPM, ACR, AAMD, ASRT, ABS
Special Article

Safety considerations for IMRT: Executive summary

Jean M. Moran PhD, Melanie Dempsey MS, Avraham Eisbruch MD, Benedick A. Fraass PhD, James M. Galvin DSc, Geoffrey S. Ibbott PhD, Lawrence B. Marks MD
Special Article

Quality and safety considerations in stereotactic radiosurgery and stereotactic body radiation therapy: Executive summary

Timothy D. Solberg PhD, James M. Balter PhD, Stanley H. Benedict PhD, Benedick A. Fraass PhD, Brian Kavanagh MD, Curtis Miyamoto MD, Todd Pawlicki PhD, Louis Potters MD, Yoshiya Yamada MD
IGRT White Paper

Assuring Safety and Quality in Image-guided Delivery of Radiation Therapy

D Jaffray, K Langen, G Mageras, L Dawson, D Yan, R Adams, AJ Mundt, BA Fraass

Posted for public comment - now
May 28 – to ASTRO Board
HDR White Paper

Status of Guidance for Safety, Quality Management and Practice for High Dose-Rate Brachytherapy

Bruce Thomadsen, Beth A. Erickson, Patricia Eifel, Joe Hsu, Rakesh Patel, Daniel Petereit, Benedick Fraass, Mark Rivard

Post for public comment – in a couple weeks
May 28 – to Board
Already approved by ABS
Enhancing the Role of Case-Oriented Peer Review to Improve Quality and Safety in Radiation Oncology

LB Marks, R Adams, T Pawlicki, A Blumberg, D Hoopes, M Brundage, BA Fraass

Post for public comment – in a couple weeks?
May 28 – to Board
Do we need more white papers?

My vote for the next white paper is Treatment Management Systems.
Safety Stakeholder’s Initiative

• FDA Public Meeting, June 2010
• Industry presentation to AAPM Therapy Physics Committee, July 2010
• B. Fraass collected suggestions for safety initiatives, Aug-Sept. 2010
• 2nd Safety Stakeholders’ Meeting (AAPM, Aug. 2, 2011)
• 3rd Safety Stakeholders’ Meeting (ASTRO, Oct. 4, 2011)

Moral of this story: Learn to keep your mouth closed!
User-Requested Topics for First Meeting

• Speed of Vendor Responses to Problems
• Vendor Responsibilities (QA, Training…)
• Testing and QA Guidelines
• New Safety-related Tools
• Error Messages, Warnings
• Feedback from Vendors to Users
• How should this process continue?
# Safety Stakeholder’s Initiative: an Ad-Hoc Self-Governing Effort

<table>
<thead>
<tr>
<th>Name</th>
<th>Affiliation</th>
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<tbody>
<tr>
<td>Benedick A. Fraass</td>
<td>Cedars-Sinai ASTRO co-chair</td>
</tr>
<tr>
<td>Ellen Yorke</td>
<td>Memorial Sloan Kettering AAPM Co-chair</td>
</tr>
<tr>
<td>Rajinder Dhada</td>
<td>Elekta Industry Co-Chair</td>
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<td>Stephen Vastagh</td>
<td>MITA secretary</td>
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Safety Stakeholder’s Initiative

Initial goal: talk!

Then, organize working groups to address issues:

• Try to identify problems which can be addressed
• Try to reach consensus on solution(s)
• Publish (journals, web)

Goal: try to avoid all the potholes in having everyone work together using a grass-roots bottom up collaboration
Safety Stakeholder’s Initiative

Volunteer Working Groups

1. Error Messages
2. QA
3. Training
4. Nomenclature
5. Usability
Error Messages WG

Art Olch, USC, co-chair
Christina Negrut, Accuray, co-chair

Werner Baer, Seimens
Ulrich Beifuss, Brainlab
Julie Clift, Varian
Scott Hadley, U. of Michigan
Miklas Hardenborg, Nucletron
Colleen Heelan, Elekta
Annmarie Ison, Elekta
Stan Mansfield, Varian
Tim McGregor, Elekta

Julie Misfeldt, Varian
Michael O’Hara, FDA
Jim Schewe, Philips
George Sherouse, Vassar Bros. Hosp.
Alf Siochi, U. of Iowa
ERROR MESSAGES
Content Usability Guidelines

The two main goals of this document are: 1) to present in a concise manner the best practices and design guidelines for good message dialogs, and 2) to illustrate these design guidelines with specific examples from the field of radiation oncology. Unless specifically called out, these guidelines apply to all categories of error messages identified by the Terminology subcommittee (e.g. critical error, warning, system status, informational, routine interlock messages).

Cristina Negrut, Accuray (Lead)
Niklas Hardenborg, Nucletron
Jim Schewe, Philips
Julie Clift, Varian
Olch, Arthur, Children’s Hospital Los Angeles
Nzhde Agazaryan, UCLA School of Medicine
Denise Monks, Beth Israel Deaconess
Alf Siochi, University of Iowa
QA Work Group:  
“Steps for Developing QA Procedures for New Radiation Oncology Technologies”  

Clinical Chair: Jim Galvin (Thomas Jefferson)  
Industry Chair: Alan Cohen (Accuray)

Ellen Yorke (MSKCC),  
Eric Klein (Wash Univ),  
Bruce Curran (RI/Brown U),  
Geoffrey Dalbow (Cirvco),  
Sonja Dieterich (Stanford),  
Jose Luis Dumont (Elekta),  
Eric Ford (Johns Hopkins),  
Paco Hernandez (Siemens),  
Todd Holmes (Varian),

Craig Hust (Elekta),  
Chuck Lindley (IBA),  
Moyed Miften (U. Colorado),  
Mark Pepelea (Philips),  
Kellie Russell (Nucletron),  
Christof Schadt (BrainLab)
Primary Aim

Guarantee Patient Safety for New RT Products by Providing QA Methodologies and Test Equipment at the Time of New Product Release

Secondary Aims

Protect Manufacturers’ Proprietary Information
Respect Manufacturer’s Timelines
Professional Societies to Provide Expert Review and Feedback on QA Procedures to Manufacturers
Professional Societies to Provide Information to Users for Possible Expansion or Amendment of Manufacturer Recommended QA Procedures
Safety Stakeholders: Training Working Group

Joel Goldwein, Elekta, Co-chair
Jean Moran, U. of Michigan, Co-chair

Al Blumberg, ACR
Bruce Curran, Rhode Island Hospital
Michelle Etzel, ASRT
Kim Gehrin, Elekta
Paco Hernandez, Siemens
Jon Hollon, Varian
Andrea Jesson, Siemens
Jennifer Johnson, MDACC

Stan Mansfield, Varian
Derek Olender, Accuray
Patrick Ploc, Philips
Kellie Russell, Elekta
Jasmine Schirmer, Brainlab
Christof Schadt, Brainlab
Training WG: What’s the Issue?

- Training – for new equipment and processes, was a major issue identified by users and vendors at the June 2010 FDA meeting
- Everyone is dissatisfied with the way training works
  - Users: Vendors don’t train well
  - Vendors: Users don’t pay attention or even come to training
Harmonized Nomenclature WG

User Co-Chair: Ellen Yorke, MKSCC
Industry Co-Chair: Peter Hoban, Accuray

Thalia Mills, FDA
Walter Bosch, Wash Univ. St. Louis
Marissa Johnson, UT Southwestern
Catherine Large, Philips
Anja Leibl, Brainlab
Stan Mansfield, Barian
Lara Marco, Az CA Specialists

Mike Mills, U. of Kentucky
Nicholas Rowlands, Elekta
Kellie Russel, Nucletron
Alf Siochi, U. of Iowa
Johannes Stahl, Siemens
Stephen Vastagh, MITA
Ping Xia, Cleveland Clinic
Ellen Yorke, MSKCC
RT System Usability

Clinical Co-Chair: Radhe Mohan, MD Anderson
Industry Co-Chair: Geoffrey Dalbow, CIVCO

Todd Pawlicki, UC San Diego
Geoff Ibbott, MD Anderson
Bruce Curran, Rhode Island Hospital
Lawrence Marks, UNC
Gig Mageras, Memorial Sloan Kettering
Randy Holt, ICAD
Jeff Simon, Sun Nuclear
Julie Clift, Varian
Alf Siochi, University of Iowa
Usability WG Members

• Radhe Mohan M D Anderson (Chair)
• Sean Frigo Philips
• Geoffrey Dalbow CIVCO (Chair)
• Bruce Curran, Brown University
• Geoffrey Ibbott M D Anderson
• Todd Pawlicki UCSD
• Andrew Brenner Siemens
• Joel Goldwein Elekta
• Niklas Hardenborg Nucletron
• Paco Hernandez Siemens
• Annmarie Ison Elekta
• Gig Mageras MSKCC
• Stan. Mansfield Varian
• Tim.Mcgregor Elekta
• C. Negrut Accuray
• Carsten Raupach Brainlab
• Christof Shad Brainlab
• Stephen Vastagh MITA-NEMA
• Filip Vojan Varian
Usability is the ease of use and learnability of a human-made object.

Can apply to software app, machine, process, or anything a human interacts with.

Includes principles behind an object's perceived efficiency or ease of use.

Studies the clarity with which the humans interact with a machine or program.

Is connected to safety in the sense that products that are easier to learn and easier to use are less prone to error or can be designed to expose errors or near misses.
Usability WG

- Hardware – Medical accelerators
- Brachytherapy Devices
- Software – Treatment Planning
- R&V Systems
  - they meant Treatment Management Systems
Safety Stakeholders: Document Review Process

• WG approves document by consensus, individual authors listed (i.e., not from institutions, from individuals as part of the WG)
• Review by all Safety Stakeholders
• Revision by WG
• Released after vote by Safety Stakeholders (majority)
Safety Stakeholders
How Do Documents Get Released?

• Main release is posting on Stakeholders’ website
• We hope organizations (and individuals) will support the documents – by posting their support on the website
• Documents will be sent to organizations asking for support – after release by Stakeholders
• Propose use of MITA to support website, links to other organizations websites (and vice versa)
• Documents will be versioned, and updated often (we hope)