

**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 Multidisciplinary 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

IMRT White Paper

Practical Radiation Oncology (2011) 1, 190–195



Special Article

Safety considerations for IMRT: Executive summary

Jean M. Moran PhD^{a,*}, Melanie Dempsey MS^b, Avraham Eisbruch MD^a,
Benedick A. Fraass PhD^c, James M. Galvin DSc^d,
Geoffrey S. Ibbott PhD^e, Lawrence B. Marks MD^f

SBRT White Paper

Practical Radiation Oncology (2012) 2, 2–9



Special Article

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

Timothy D. Solberg PhD^{a,*}, James M. Balter PhD^b, Stanley H. Benedict PhD^c,
Benedick A. Fraass PhD^d, Brian Kavanagh MD^e, Curtis Miyamoto MD^f,
Todd Pawlicki PhD^g, Louis Potters MD^h, Yoshiya Yamada MDⁱ

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

Peer Review White Paper

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
- 1st Safety Stakeholders' Meeting (ASTRO, Nov. 2, 2010) organized by Vastagh and Fraass. Issues of continuing importance identified.
- 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

Benedick A. Fraass

Cedars-Sinai

ASTRO co-chair

Ellen Yorke

Memorial Sloan Kettering

AAPM Co-chair

Rajinder Dhada

Elekta

Industry Co-Chair

Stephen Vastagh

MITA

secretary

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)

QA WG

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

Working Definitions

Usability WG

- 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)**