The Radiation Oncology Safety Stakeholders Initiative: A New Approach to Safety Issues

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CEDARS-SINAI

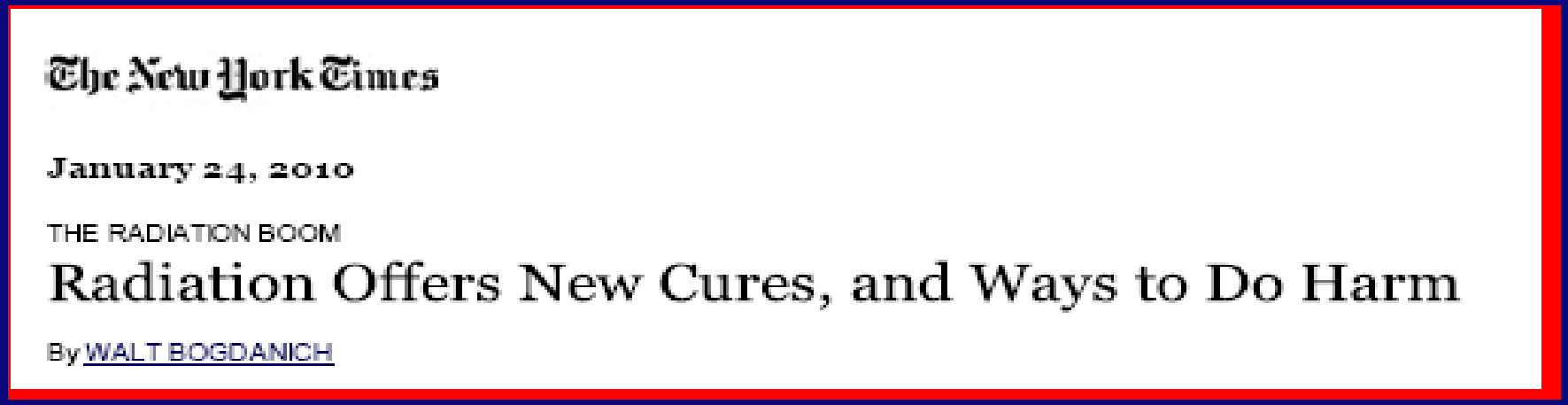
LEADING THE QUEST

Disclosures

- Member, Varian Patient Safety Council
- Previous research and/or travel funding:
  - Varian
  - Elekta
  - Sun Nuclear

Learning Objectives

- Understand the structure and mission of the RadOnc Safety Stakeholders' Initiative (RO-SSI)
- Learn how the clinical community and vendors are collaborating to help improve usability, quality, + safety of medical devices and clinical practice
- Understand safety risk management, the product lifecycle,+ how it applies to products + clinical practice
- Understand the basics of usability and its relationship to the safety of medical devices, including problems and recommended improvements with content + frequency of software error messages



The New York Times

January 24, 2010

THE RADIATION BOOM

Radiation Offers New Cures, and Ways to Do Harm

By WALT BOGDANICH

It's been 4+ years since the NY Times helped focus Radiation Oncology on safety and errors

Some Recent RadOnc Safety Efforts

2010: AAPM: Safety Summit in Miami

2010: FDA meeting w/ vendors and users, re-eval of 510K process, etc.

2011-14: ASTRO Safety White Papers

2012: ASTRO Meeting with FDA Commissioner

2013: IHE-RO Safety profile “QA with Plan Veto”

2014: ASTRO/AAPM Incident Learning System

2014: Strengthened RadOnc accreditation, new ASTRO accreditation process

2010: Radiation Oncology Safety Stakeholders Initiative

Radiation Oncology Safety Stakeholders Initiative

- A Brief History
- Goals and Motivations
- The (sic) Organization of RO-SSI
- Progress (So Far)
- Conclusions

Safety Stakeholder's Initiative

- FDA Public Meeting (6/10): During the discussion, many vendor-user issues identified
- AAPM Therapy Physics Committee (7/10): Industry presentation on two small safety initiatives
- Suggestions for safety initiatives collected by Fraass (8/10)

User-Requested Topics for First Meeting

Issues from Users and Vendors (~8 pages):

- 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

Safety Stakeholder's Initiative

- Held meeting at ASTRO (11/10), organized by Fraass + Stephen Vastagh (MITA), with room and time donated by MITA/AdvaMed
- Invited vendors, MITA, AdvaMed, ASTRO, AAPM, ASRT, ACR, physicists, physicians…
- Meeting was very well attended, successful in identifying issues, with many people interested in working on those issues
- This was first meeting of the "Radiation Oncology Safety Stakeholders Initiative, now with annual meetings at AAPM + ASTRO…

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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 by having everyone work together using a grass-roots bottom up collaboration

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RadOnc Safety Stakeholder's Initiative

Members from:

- Academic Centers
- Free-standing Clinics
- AAPM
- ASTRO
- Vendors
- AAMD
- ASRT
- MITA, AdvaMed
- SROA
- FDA

Members are:

- Physicists
- Physicians
- Therapists
- Dosimetrists
- Administrators
- Vendors
- Regulators

Safety Stakeholder's Initiative: an Ad-Hoc Self-Governing Collaborative Effort

Co-chairs:

Alf Siochi	**University of Iowa**
Rajinder Dhada	**Elekta**
Benedick A. Fraass	**Cedars-Sinai**

Safety Stakeholder's Initiative

Working Groups

1. Error Messages: Art Olch + Christina Negrut
2. QA: Jim Galvin + Clif Ling
3. Training: Jean Moran + Joel Goldwein
4. Usability: Gig Mageras + Geoff Dalbow

5? Risk Assessment: Tim Prosser, Jean Moran, Jim Schewe


Radiation Oncology Safety Stak...
http://info.radoncssi.org
Radiation
Oncology
Safety
Stakeholders
Initiative
Search this site
Home
About
Working Groups
Publications
Minutes
Contact Us
Members
Home
Mission Statement
To recommend and facilitate safety improvements in radiotherapy through a common, independent and impartial vision broadly based on diversity of experience and knowledge among radiation oncology professionals.
Internal Links
About - a brief description of the organization.
Publications - a list of all approved documents.
Contact Us - Leave us a message.
Membership - Become a RO-SSI member.
Leadership - Contact information and org structure.
Our Next Meeting
TBD - TCON - 12/2013
News
New Publications We have two documents that have just been published! They are from the Error Messages Working Group and discuss the Appropriate Frequency of Error Messages and Error and Message Dialogs ...
Posted Aug 9, 2013, 10:49 AM by Sa Rossi
Showing posts 1 - 1 of 1. View more »
Thanks to Alf Siochi
Questions about this site? Contact the webmaster and domain administrator ralfredo-siochi@uiowa.edu
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Leadership

Organization

RO-SSI has three co-chairs that manage the operations and help provide vision for the group.

There are currently four Working Groups. Each working group has two co-chairs.

Leadership is represented by radiation oncology professionals and manufacturers.

Co-Chairs

Dick Fraass
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Rajinder Dhada
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WG Chairs

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Joel Goldwein
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QA

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Clif Ling
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Minutes

Showing 9 items

Date	Place	Minutes Link
Sort	Sort	Sort
September 24, 2013	ASTRO meeting, Atlanta, GA	RO-SSI 9-24-2013 ASTRO Minutes
August 6, 2013	AAPM, Indianapolis, IN	ROSSI 08062013 AAPM Minutes
October 30, 2012	ASTRO, Boston, MA	ROSSI_10302012_ASTRO_Minutes.pdf
July 31, 2012	AAPM 2012, Charlotte, NC	ROSSI_07312012_AAPM_Minutes.pdf
February 1, 2012	Teleconference	TCON 02012012
October 4, 2011	ASTRO, Miami, FL	ROSSI 10042011 ASTRO Minutes
August 2, 2011	AAPM, Vancouver, British Columbia, CA	ROSSI 08022011 AAPM Minutes
June 2, 2011	MITA TCON	MITA TCON 06022011
November 2, 2010	ASTRO, San Diego, CA	ROSSI 11022010 ASTRO Minutes

Showing 9 items

Publications

Document Lifecycle

Documents are managed through commenting and revision cycles, first by the workgroup, then by the membership. After approval, they are publicly available for comment. Comments will be used to plan revisions.

Endorsements

Click here to see the endorsers for various publications.

Commenting

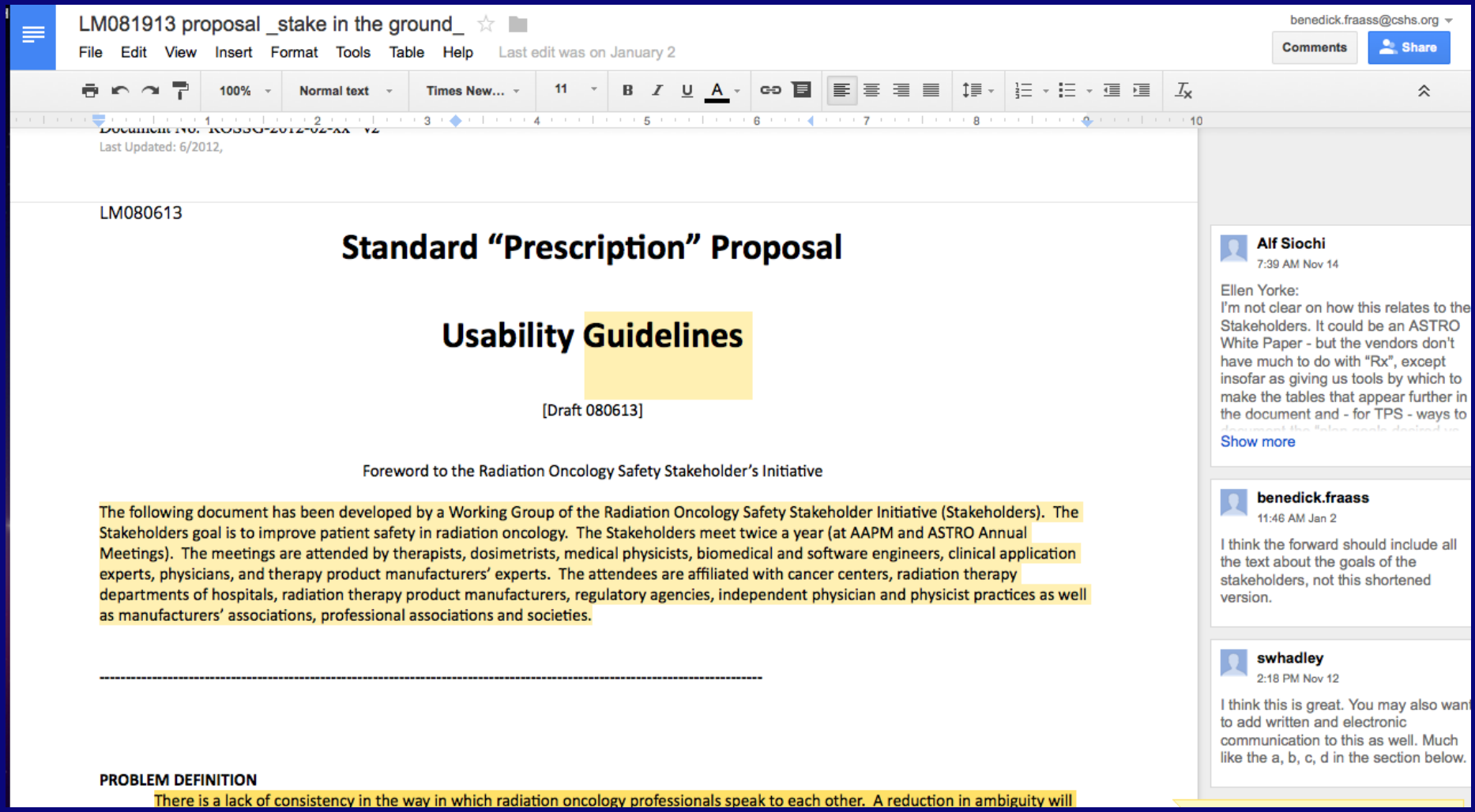
1. Click on the link to the google doc.
2. Highlight the text to be commented.
3. Right-Click to open a menu.
4. Select the "Comment" menu item.
5. Type the comment in the textbox.
6. Click the button labeled "Comment."

Showing **2** items

Working Group	Number	Google Doc
Sort	Sort	Sort
Error Messages	RO-SSI-EM-P002-2013-06-16	Appropriate Frequency of Error Messages
Error Messages	RO-SSI-EM-P001-2013-06-15	Error and Message Dialogs Content Usability Guidelines

Showing **2** items

Shared Document Editing+Commenting: Google-Docs



Safety Stakeholder's Initiative: Output

- Documents posted on the RO-SSI website
- Educational symposium talks on safety-related topics
- Internal vendor discussion and/or use of RO-SSI guidance
- Manuscripts submitted to scientific and organizational publications
- Anything else you can think of

RadOnc Safety Stakeholders: Document Review Process

- WG approves document by consensus, with individual authors listed
- Review by all Safety Stakeholders
- Revision by WG
- Released after vote by Safety Stakeholders (majority)

RadOnc Safety Stakeholders: Document Life-cycle

- Main release: 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
- Documents will be versioned, and updated often (we hope)

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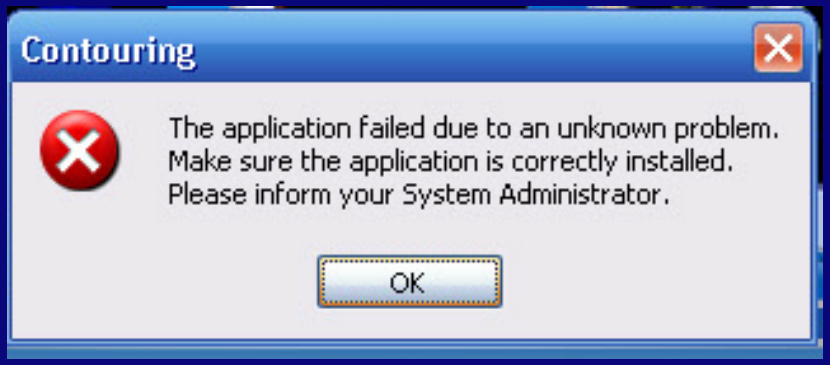
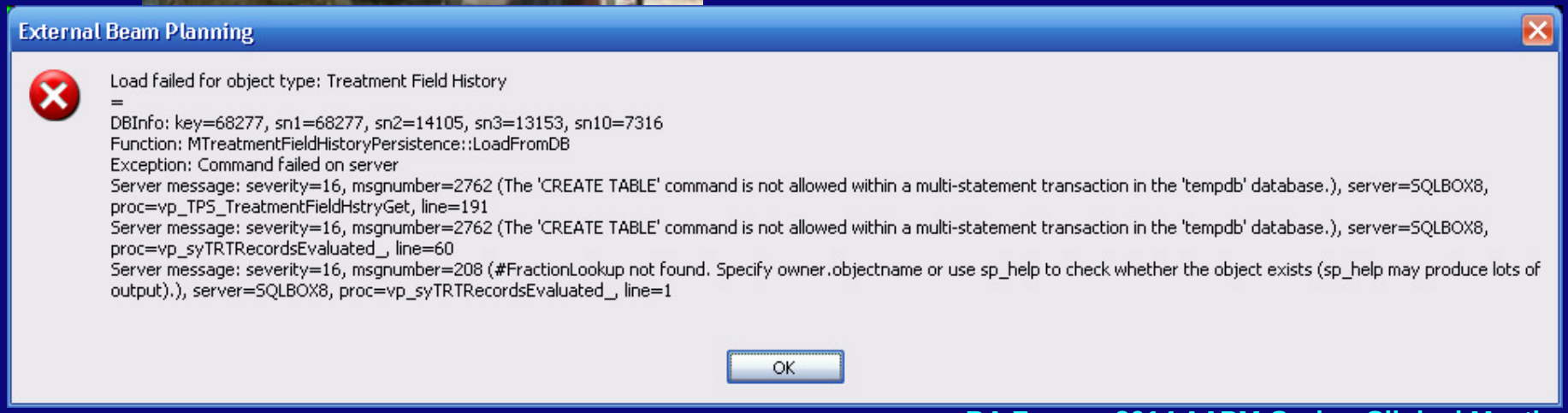
Error Messages WG





Error Messages WG

Radiation Oncology Safety Stakeholders Initiative
Error Messages Working Group
Subcommittee of the Frequency of Error Messages

Document No. RO-SSI-EM-P002-2013-06-16

Appropriate Fre

Alf Siochi (1), Scott Hadley
G
Freq
Error M
Radiation Oncol

1 University of Iowa, 2 University of

Radiation Oncology Safety Stakeholders Initiative
Error Messages Working Group
Content Subcommittee

Document No. RO-SSI-EM-P001-2013-06-15

ERROR AND MESSAGE DIALOGS
Content Usability Guidelines

Cristina Negrut (1), Nzhde Agazaryan (2), Julie Clift (3), Niklas Hardenborg (4), Denise Monks (5), Arthur Olch (6), Jim Schewe (7), Alf Siochi (8)

Content Subcommittee,
Error Messages Working Group,
Radiation Oncology Safety Stakeholders Initiative

1 Accuray Incorporated, 2 UCLA School of Medicine, 3 Varian Medical, 4 Elekta, 5 Beth Israel Deaconess Medical Center, 6 Children's Hospital Los Angeles, 7 Philips Medical, 8 University of Iowa

QA WG

- **Examine QA processes now in place, make recommendations on how they can be updated to improve patient safety.**
- **Particular emphasis on timely development + dissemination of QA procedures for new RT products**

Steps for Developing QA Procedures for New Radiation Oncology Technologies

Stakeholders QA Working Group

Jim Galvin[1], Clifton Ling[2], Alan Cohen[3], Ellen York[4], Eric Klein[5], Bruce Curran[6], Geoff Dalbow[7], Sonja Dieterich[8], Jose Luis Dumont[9], Eric Ford[10], Craig Hust[9], Paco Hernandez[11], Todd Holmes [2], Chuck Lindley[12], Moyed Miften[13], Mark Pepelea[14], Kellie Russell[15], Christof Schadt[16], Seth Rosenthal[17], Raymond Wynn[18]

[1]Thomas Jefferson Univ, [2]Varian, [3]Accuray, [4]MSKCC, [5]Wash U St. Louis, [6]Brown Univ., [7]Oncology Owl, [8]UC Davis, [9] Elekta, [10]Univ. Washington, [11]Siemens, [12]IBA, [13]Univ. Colorado, [14]Philips, [15]Nucletron, [16]BrainLab, [17]Radiological Assoc Sacramento, [18]UPMC

QA WG

Recommendations:

- **Need adequate resources: both effort + equipment**
- **Accelerate QA protocols for new technologies:**
  - **Clinical partners work with vendors to propose guidelines for initial clinical QA process**
  - **Vendors forward QA procedures to AAPM, and AAPM establish a mechanism to review QA info and procedures for new devices so they are available when device is available**
- **Complete system end-to-end test as a safety net**

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

Training WG:

in multiple

of Training in

Roles and Challenges of Industry in Safety Training

Joel Goldwein, MD

Published Errors, Human Factors and Training

Addressing Clinical Problems: The Roles of Individuals and Training

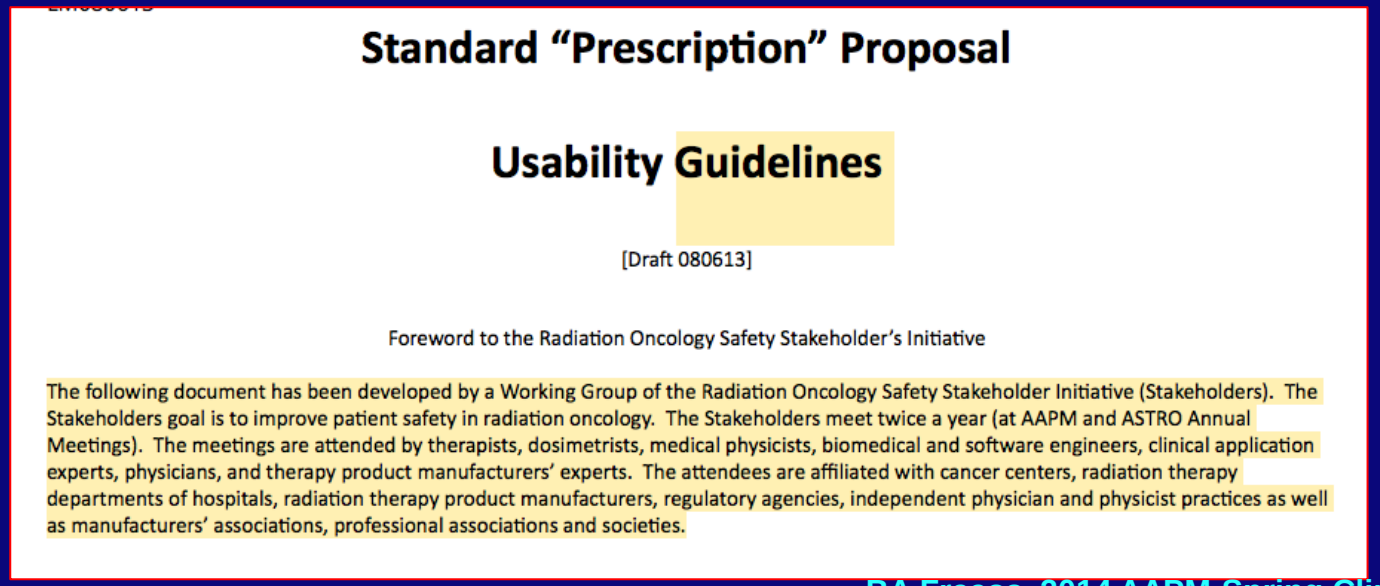
Jean Moran, PhD
Associate Professor and
Associate Division Director of Clinical Physics
Department of Radiation Oncology, University of Michigan

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**
- **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
- Treatment Management Systems



Standard "Prescription" Proposal

Usability Guidelines

[Draft 080613]

Foreword to the Radiation Oncology Safety Stakeholder's Initiative

The following document has been developed by a Working Group of the Radiation Oncology Safety Stakeholder Initiative (Stakeholders). The Stakeholders goal is to improve patient safety in radiation oncology. The Stakeholders meet twice a year (at AAPM and ASTRO Annual Meetings). The meetings are attended by therapists, dosimetrists, medical physicists, biomedical and software engineers, clinical application experts, physicians, and therapy product manufacturers' experts. The attendees are affiliated with cancer centers, radiation therapy departments of hospitals, radiation therapy product manufacturers, regulatory agencies, independent physician and physicist practices as well as manufacturers' associations, professional associations and societies.

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Conclusions

- The Stakeholder's Initiative is an ad hoc group which is creating its own process, deciding on problems to address at the working group level
- The group is attempting to work by consensus, in a very democratic, grass-roots way
- The group is trying to avoid the huge barriers to formal approval by all the participating organizations (vendors, regulators, purchasers, users…)
- If we're successful, RO-SSI recommendations will affect future developments

Conclusions

- The unique vantage point of the Stakeholders is a useful complement to all the standard organizational efforts toward safety and QA
- Both mechanisms have their place – with very different problems to address
- Progress with either mechanism takes lots of care and feeding – to avoid bureaucratic inertia, organizational dynamics, and other political type issues that can derail useful efforts and progress