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

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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

BA Fraass, 2014 AAPM Spring Clinical Meeting
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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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
http://info.radoncssi.org

Thanks to Alf Siochi

Questions about this site? Contact the webmaster and domain administrator ralfredo-siochi@uiowa.edu
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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WG Chairs

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Clif Ling
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BA Fraass, 2014 AAPM Spring Clinical Meeting
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<tr>
<th>Date</th>
<th>Place</th>
<th>Minutes Link</th>
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<td>September 24, 2013</td>
<td>ASTRO meeting, Atlanta, GA</td>
<td>RO-SSI 9-24-2013 ASTRO Minutes</td>
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<td>August 6, 2013</td>
<td>AAPM, Indianapolis, IN</td>
<td>ROSSI 08062013 AAPM Minutes</td>
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<td>October 30, 2012</td>
<td>ASTRO, Boston, MA</td>
<td>ROSSI 10302012 ASTRO Minutes.pdf</td>
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<tr>
<td>February 1, 2012</td>
<td>Teleconference</td>
<td>TCON 02012012</td>
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<td>October 4, 2011</td>
<td>ASTRO, Miami, FL</td>
<td>ROSSI 10042011 ASTRO Minutes</td>
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<tr>
<td>August 2, 2011</td>
<td>AAPM, Vancouver, British Columbia, CA</td>
<td>ROSSI 08022011 AAPM Minutes</td>
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<td>June 2, 2011</td>
<td>MITA TCON</td>
<td>MITA TCON 06022011</td>
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<tr>
<td>November 2, 2010</td>
<td>ASTRO, San Diego, CA</td>
<td>ROSSI 11022010 ASTRO Minutes</td>
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# 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.

## 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."

## Endorsements

Click [here](#) to see the endorsers for various publications.

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<th>Working Group</th>
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<td>RO-SSI-EM-P002-2013-06-16</td>
<td><a href="#">Appropriate Frequency of Error Messages</a></td>
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<tr>
<td>Error Messages</td>
<td>RO-SSI-EM-P001-2013-06-15</td>
<td><a href="#">Error and Message Dialogs Content Usability Guidelines</a></td>
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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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PROBLEM DEFINITION

There is a lack of consistency in the way in which radiation oncology professionals speak to each other. A reduction in ambiguity will
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

External Beam Planning

Load failed for object type: Treatment Field History

Exception: Command failed on server

Server message: severity=16, msgnumber=2762 (The 'CREATE TABLE' command is not allowed within a multi-statement transaction in the 'tempdb' database.), server=SQLBOX8, proc=vp_TPS_TreatmentFieldHstryGet, line=191

Server message: severity=16, msgnumber=2762 (The 'CREATE TABLE' command is not allowed within a multi-statement transaction in the 'tempdb' database.), server=SQLBOX8, proc=vp_syTRTRTRecsEvaluated_line=60

Server message: severity=16, msgnumber=208 (#FractionLookup not found. Specify owner.objectname or use sp_help to check whether the object exists (sp_help may produce lots of output).), server=SQLBOX8, proc=vp_syTRTRTRecsEvaluated_line=1

BA Fraass, 2014 AAPM Spring Clinical Meeting
Error Messages WG

Appropriate Frequency

Alf Siochi (1), Scott Hadley (2), George Levin (3), Gary Pitman (4), Carl Gross (5), Brian Louie (6), Carlos De Sa (7), Alf Siochi (8)

1 University of Iowa, 2 University of California, Los Angeles, 3 Varian Medical, 4 Elekta, 5 Beth Israel Deaconess Medical Center, 6 Children’s Hospital Los Angeles, 7 Philips Medical, 8 University of Iowa

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
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 Galvin¹, Clifton Ling², Alan Cohen³, Ellen York⁴, Eric Klein⁵, Bruce Curran⁶, Geoff Dalbow⁷, Sonja Dieterich⁸, Jose Luis Dumont⁹, Eric Ford¹⁰, Craig Hust⁹, Paco Hernandez¹¹, Todd Holmes ², Chuck Lindley¹², Moyed Miften¹³, Mark Pepelea¹⁴, Kellie Russell¹⁵, Christof Schadt¹⁶, Seth Rosenthal¹⁷, Raymond Wynn¹⁸

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

Roles and Challenges of Industry in Safety Training

Joel Goldwein, MD
Senior Vice President of Medical Affairs, Eikon
Pennsylvania State University

Published Errors, Human Factors and Training

Jennifer L. John
Senior Medical Physicist
Department of Radiation Oncology
M.D. Anderson Cancer Center

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 is the ease of use and learnability of a human-made object. It can apply to software app, machine, process, or anything a human interacts with. It 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

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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