



# Healthcare Working Group Charter

## 1 PURPOSE

To improve healthcare delivery in the world by bringing together systems engineers and systems thinkers in healthcare system to identify, develop, and tailor best practices for the improvement of healthcare delivery. We will achieve that by

- Articulating the value and application of systems engineering to healthcare through simple examples and easily deployable guidelines, and
- Providing a forum for developing and sharing best practices, meeting world class experts in Systems Engineering and Healthcare (and across other industries).

*The creation of our group was driven by the fact that many if not most of the organizations in the biomedical and healthcare industries do not necessary recognize or understand the value of systems engineering and could thus benefit from the application of INCOSE principles.*

## 2 GOAL

Our ongoing goal is to aggregate information that articulates the value and application of systems engineering to the biomedical and healthcare industries and to provide an infrastructure for members and interested non-members to share relevant information.

### 5-year strategic objectives

- Increase individual and corporate membership in the biomedical/healthcare industry
- Collaborate with professional societies in the biomedical/healthcare industry
- Publish impactful information on systems engineering in the biomedical/healthcare industry
- Leaders in the biomedical/healthcare industry seek to raise the systems engineering competency of their workforce, in part by engaging INCOSE support and services
- Accelerate the transformation of systems engineering to a model based discipline

To reach the five year strategic objectives, our theme for each year is

- |        |   |                                   |
|--------|---|-----------------------------------|
| 2016   | Producing valuable pilot work products                  | } Building the INCOSE brand in HC |
| 2017   | Pilot using those products                              |                                   |
| '17    | Education and Hospital Partnering                       |                                   |
| '18    | Device Developers and Government/Policy Thought leaders |                                   |
| '18-19 | Scale up application of WG products                     |                                   |

### 2016 Annual objectives

#### **SE for Healthcare Education Strategy - Rachel Leblanc**

- Develop an education outreach strategy and form team
- Hold an SE Education for Healthcare Summit - Rachel Leblanc, Chris Unger
- Develop an education and certification strategy

#### **MBSE in Healthcare - Bob Malins, Ajay Thukral**

- Hold MBSE Workshop at IW2015, IW2016 - Bob Malins
- MBSE in Healthcare II with IBM/OMG - Ajay Thukral
- Develop reference model and user manual - Ajay Thukral
- Plan for a hospital department model based systems engineering example - Ajay Thukral



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- Develop an approach to integrating ISO safety related regulations into a healthcare SE approach – Bob Malins, *Michelle Lott, Bob Kenley*

Application of SE Principles to Healthcare - Chris Unger

- **Develop a strategy for a Healthcare SEBoK extension – Chris Unger**
- **Develop a strategy for defining Agile “Systems” (mixed HW/SW products) in Healthcare – Chris Unger/Mike Celentano**
- **VSE Checklists customized to Healthcare - Angela Robinson**
- Develop healthcare SE user personas definition
- Develop a strategy for a Healthcare SE competency model

**Develop practical Healthcare SE solutions - Mike Celentano**

- Develop a pilot US healthcare problem/solution database
- *Future: Develop a case study library*

Value Proposition / Outreach Strategy - Steve Badelt

- Grow regional Healthcare WG participation (Mike Celentano/Midwest, Steve Badelt/West, Tina Srivastava/Northeast, Gary Robert Smith/Europe, Edmund Kienast/Australia, Alan Ravitz/Chesapeake, Angela Robinson/Northstar)
- Develop a strategy for conferences and partnerships
  - Define a strategic partnering plan, aligned with WG deliverables. Develop relationships with 3 key partners
  - Execute ~3 events.
- Define value statement of Systems Engineering in the healthcare space
  - Define the Value ‘themes’ for SE in healthcare
  - Define marketing material strategy (and begin developing materials)
- Develop a response to the PCAST report, joint with AAMI (Multi-year project)

Working Group Operations - Bob Malins

- **Hold bimonthly Healthcare Systems Engineering Webinars - Ammon Wright**
- **Drive Biomedical / Healthcare track at IS2016 - Ammon Wright, Gary Smith**
- Social Media: Grow Linked in membership, increase the threaded discussion participation +10% - Ammon Wright
- Develop a publication/product summary (HC WG bibliography) – TBD
- **Grow the number of active members (members actively contributing to WG products) up 20% – Bob Malins**

Medical Device SE Deployment – Micha Coleman

- Survey the industry, develop initial needs assessment

*Academic/Research Challenges - Open*

- *Stretch: form a team, develop a strategy*



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### 3 SCOPE

The scope of our working group covers

- Manufacturers of devices and providers of services (Clinical and Research use only devices, in-vitro and in-vivo products, pharmaceuticals, and biologics),
- All points-of-care through the entire human life-cycle,
- Medical academic institutions,
- Regulatory agencies,
- Healthcare insurance providers, and
- Healthcare advocacy groups.

While these organizations may be served by other INCOSE working groups, it is believed that our working group will uniquely address the breadth of their needs.

### 4 SKILLS AND EXPERTISE REQUIRED

As an organization, this working group is expected to exhibit a broad range of expertise across the complete spectrum of the biomedical and healthcare industries. To support this goal, members should demonstrate one or more of the following skills:

- General systems engineering skills (ISO 15288, INCOSE SE Handbook, SDLC)
- Specific systems engineering skills (architecture, modeling, SysML, security, safety)
- Systems thinking ability (comprehensive understanding of basic to complex systems)
- Product or process development experience (e.g., medical devices, pharma, consulting)
- Regulatory or standards-based knowledge, including advocacy, training, or certification
- Active participatory skills (leading, mentoring, coaching, influencing)
- Good communication skills (writing, speaking, presenting)
- IT support for the problem/solution database

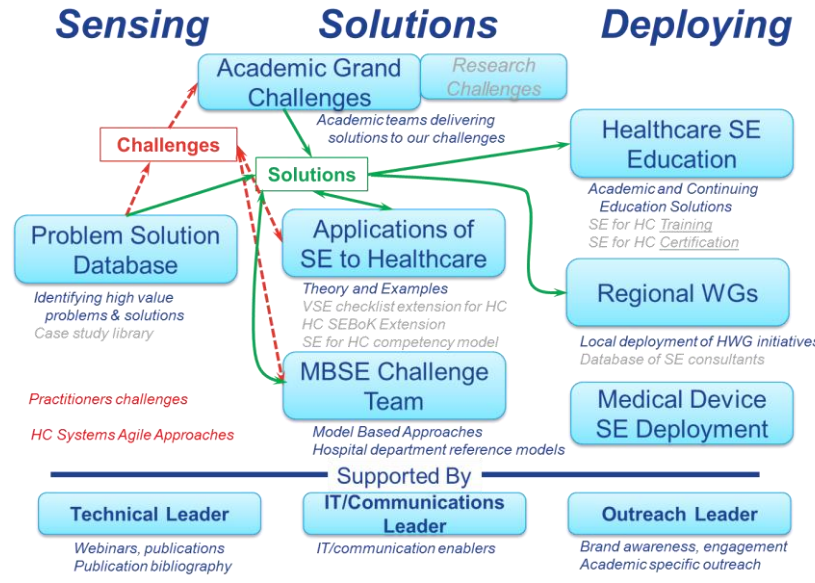
### 5 MEMBERS, ROLES AND RESPONSIBILITIES

#### INCOSE sponsors

- Tom Strandberg, Assistant Director of Industry Outreach Board
- Joe Marvin, Assistant Director for Industry

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## Overall WG Organizational Strategy



**Figure 1: HWG Organization as a system**

## Working group leaders

### Operations Leader: Bob Malins (WG Chair)

- Drive the WG execution to the roadmap, define and drive the WG metrics
- Run the WG operating mechanisms (team meetings, minutes, action item tracking)
- WG Member services (membership retention, increasing **active** participation)
- Manage the workstream execution and deploying the WG products
- Own the WG budget and checkbook

### IT/Communications Leader: Bob Malins

- Aggregate and publish working group materials on the INCOSE website
- Aggregate and publish relevant external information to working group members
- Curate and manage the INCOSE LinkedIn Group
- Manage the logistics of the webinars, including communications, meeting, posting materials, and facilitating a LinkedIn discussion thread after the meeting

### Medical Device SE Deployment Leader: Micha Coleman

- Identify critical SE improvement needs in medical device companies
- Increase deployment of SE best practices, especially INCOSE products, in medical device companies

Chapter (Regional) WG Leaders: Steve Badelt (West), Mike Celentano (Midwest), Tina Srivastava (Northeast), Alan Ravitz (Chesapeake), Yves Theriault (San Diego), TBD (Los Angeles)



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WG Architect: Chris Unger (WG Chair)

- Set the long term vision, Drive creation roadmap, WG priorities
- Own the technical content (Webinars, International Symposium, Publications)

Technical Program Leader: Ammon Wright

- Schedule knowledge exchange events on a bi-monthly basis (see Section 7 below)
- Organize cross-industry panels for the International Symposium

Outreach/Conferences Leader: Steve Badelt

- Develop and maintain a clear value proposition for the working group
- Develop and maintain collaborations with other professional organizations

Education Leader: Rachel Leblanc

- Develop a clear value proposition for SE in healthcare and healthcare education
- Gain wider adoption of SE in Healthcare Education
- Partner with recognized organizations to build credibility for INCOSE
- Longer term – Develop a suite of healthcare education products for use by industry

Academic Grant/Grand Challenge, Research Leader: **Open**

- Transform HWG gaps into challenge statements academics could work on
- Recruit partners to execute those projects

Sector Leaders: Gary Robert Smith (Europe), Edmund Kienast (Australia)

Workstream Leaders

- Healthcare MBSE Challenge – A. Thukral / B. Malins
- SE Applications to HC - C. Unger
- Healthcare SE problem database - M. Celentano

**Succession plan:**

Red is a critical open position. Names in Blue are potential candidates, but have not been contacted about their interest in the role.

<b>Role</b>	<b>Person</b>	<b>Backfill</b>
Operations Leader (WG Chair)	Bob Malins	<i>TBD</i>
WG Architect (WG Chair)	Chris Unger	<i>TBD</i>
Outreach/Conferences Leader	Steve Badelt	<i>Yves Theriault (2 years)</i>
<i>Europe</i>	<i>Gary Robert Smith</i>	
<i>Australia</i>	<i>Edmund Kienast</i>	
Academic Grant/Grand Challenge, Research Leader	<b>Open</b>	<i>TBD</i>
Technical Program Leader	Ammon Wright	<i>TBD</i>
IT/Communication Leader	Bob Malins	<i>Ammon Wright (1 year)</i>



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Medical Device SE Deployment Leader	Micha Coleman	<i>TBD</i>
HC SE Education Leader	Rachel Leblanc	<i>TBD</i>
Regional WG Coordination	<i>Open</i>	<i>TBD</i>
Workstream Leaders		
Applications of SE	Chris Unger	<i>TBD</i>
Practical Solutions	Mike Celentano	Bob Malins (6 months) David Vickery (1-2 years)
MBSE in Healthcare	Ajay Thukral	Bob Malins
2015 Healthcare Industry Ambassadors <i>Note: Ambassadors report to outreach director</i>	<b>Steve Badelt</b> Gary Robert Smith Meaghan O’Neill	<i>N/A</i>

### 6 OUTCOMES (PRODUCTS/SERVICES)

- Relevant information shared via regular (virtual) working group meetings (see Section 7 below)
- Relevant information shared via the INCOSE website
- Relevant presentations, panels, and roundtables at the International Symposium
- Specific work products (see Section 2 above)

### 7 APPROACH

- Regular communication meetings (virtual)
  - Working group meetings on a bi-monthly basis
  - Working group steering committee meetings on a bi-weekly or monthly basis
- Ad hoc meetings to discuss or work on specific working group activities (see Section 2 above)
- Annual attendance (in-person or virtual) at the International Symposium
- Annual attendance (in-person or virtual) at the International Workshop
- Participation or collaboration with other INCOSE working groups and professional partners

The working group intends for most working matters to be decided by the appropriate functional leader (see Section 5 above), without the need for a formal vote. However, for decisions that affect the operation of the group, a simple majority of the Steering Committee is required. For matters specific to a particular functional area, the majority vote must include the person responsible for that function. In cases where a majority vote is not possible (e.g., due to the unavailability of key members), both co-chairs must concur.

This approach will be revisited in the future as the working group matures.

### 8 MEASURES OF SUCCESS

- Active member participation in working group activities, defined as:
  - Stable, growing attendance at working group meetings
  - Stable, growing attendance at workshops and symposia



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- Growing active participation in developing WG products
- Attendance levels greater than 10% of the working group roster
- A functioning website (see Section 9 below)

## 9 RESOURCE REQUIREMENTS

- See the WG checkbook for the 2015 Budget request details
- Normal WG resources (tele-/web conferencing , INCOSE website, meeting rooms at IW & IS)

## 10 DURATION

This charter will be reviewed annually at the INCOSE International Workshop.

## 11 SIGNATURES

Enter the signature block of the submitter Date

### 1<sup>st</sup> Level of Approval

Technical Director, INCOSE Date

**2<sup>nd</sup> Level of Approval** (Note this will be added by the INCOSE Technical Director when deemed appropriate.)

Chairman, INCOSE Board of Directors Date

## Revision History

<u>Date</u>	<u>Revision</u>	<u>Description</u>	<u>Author</u>
April 2014	1.0	Initial draft	Tom Fairlie
September 2014	2.0	Updated with new roles, added backfill strategy	Chris Unger
January 2015	3.0	Updated for 2015...new roles (section 5), updated 105 deliverables (section 2)	Chris Unger
August 2015	3.1	Updated after International Symposium (changed "directors" to leaders", modified figure 1, added some leadership roles	Chris Unger Bob Malins
August 2016	3.2	Minor edits to header dates, correct logo.	Cary Bryczek