

NPUAP S3I Lifespan Evaluation Working Group

Draft Minutes

Meeting Date: Thursday, January 10, 2002

Annex A Membership Roster

1.0 Roll Call

Ann Avery (M)

Dave Ardis (M)

John Asturius (M)

Kathleen Baldwin, Chair (R)

Robin Basset (HP)

Lydia Biggie, Vice-chair (M)

Ron Dzedziula (M)

Chuck Gokoo (M)

John Holder (M)

Tricia Karg (R)

Tom Krouskop (R)

Ronald Motherwell (M)

Co-Consumer, Cl-Clinician, HP-Healthcare provider, G-government, M-Manufacturer, R-researcher

2.0 Adoption of Agenda

There was no formal agenda for this meeting

3.0 Acceptance of Minutes

There are no prior meeting minutes

4.0 Numbering of Documents

No documents were numbered

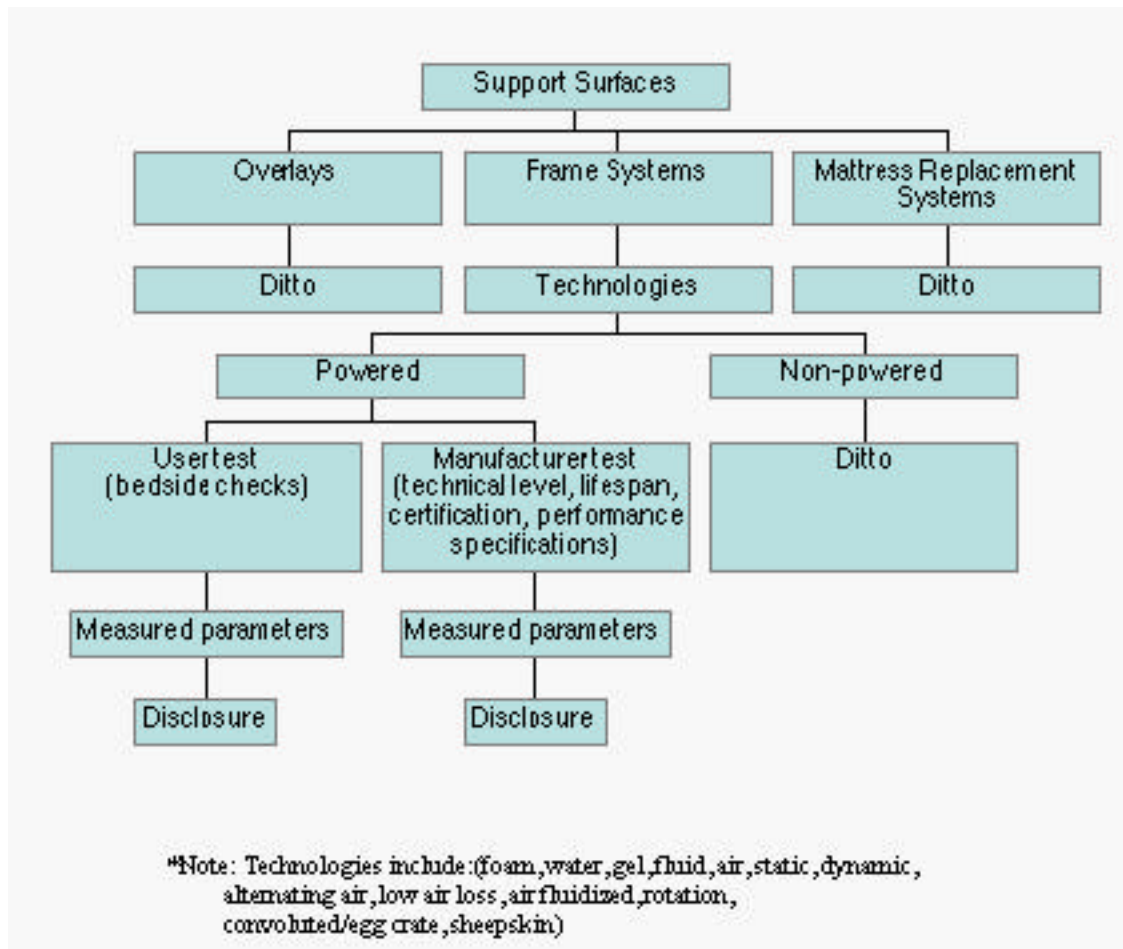
5.0 Review of Membership

Group discussed those not present at meeting and how to fill out membership.

Action: NPUAP to email or mail minutes and invitation to participate and add Mediq, UHS, Apria, and EAR to list.

6.0 General Discussion

6.1 To get our hands around the scope of our task and what our objective was the group first broke down the products being addressed into categories and sub-categories. The following graphic summarizes the discussions.



6.2 The group then brainstormed about what types of measures would be made. There was consensus that the guideline would include both laboratory testing and bedside checks to measure characteristics that indicate when a product fails to perform adequately. The following topics were discussed:

- Adequate user instructions that included use within the proper weight limit, check system is plugged in, mattresses that overlays should be used with...etc.– list contraindications and limitations
- Foam - change in stiffness (e.g., 30%) indicates when life over
- Handchecks
- Breathability with washing/cleaning
- Securing to bedframe
- Differentiation of pressure in air cells
- Noise and heat may be failure indicators
- Infection
- Does it still provide pressure reduction? Shear reduction?
- Measure Life-cycle cost
- Is product still delivering LAL benefit over time?
- Potential for entrapment
- How long after cleaning does it maintain its antimicrobial? Fire retardancy?

- How long does product continue to meet its initial product specifications?

7.0 Discussion of Name, Objective and Scope

7.1 Name

The group consensus was to remove “safety” from the name of the working group because of the connotations of the term. Instead the group would be called the Lifespan Evaluation Working Group.

7.2 Objective

Consensus was to define the objective of this working group as to, “Identify key parameters and test methods to assess whether support surface systems continue to perform as designed.” The group thought about using wording such as “continues to meet initial design specifications” or “...meet performance specifications.”

7.3 Scope

Scope defined as:

“This guideline will specify test methods to assess whether support surface systems continue to perform as designed. It will apply to overlays, mattress replacement systems, and frame systems. This will address powered and non-powered technologies. It will also contain disclosure and labeling requirements.”

The group intentionally used “guideline” rather than “standard” and chose not to include safety measures. The reference to disclosure refers to required disclosure in pre-sale literature, user manuals and instructions.

8.0 Tasks

8.1 Applicable “safety” documents

The group discussed the existence of regulations or guidelines that address so called “safety” issues with support surfaces, for example, electrical standards, FDA draft guideline on entrapment. It was decided to collect relevant documents and compile a list. This part of the guidelines may require disclosure of whether meet or do not meet specified regulations/guidelines.

Action: Ron Dziejzula to compile a list of all applicable “safety” documents

8.2 Literature search and compilation

Action: Kathleen to compile a list of references. Chuck G. and Ron D. and others to forward their collections by Feb. 14. Both published and unpublished.

8.3 Literature review

Action: Kathleen to divide literature by three types of systems. Robin B. to review overlay literature. Ann A. to review rotation and air-fluidized literature. John to do mattress replacement systems literature. Kathleen and Ann to review frame systems. Will report at next meeting.

8.4 Product specifications

Action: Start to define performance specifications for the various technologies. Everyone to forward product literature to following people by February 14, 2002:

Ann Avery – air-fluidized

John A. – foam and gel

Lydia – air

Ann, John and Lydia to review and bring list of specifications to next meeting

9.0 Task Schedule

Task	Target Date	Person(s) Responsible
Compile safety documents	June meeting	Ron D.
Literature search	Feb 14	Kathleen B.
Forward literature to Kathleen	Feb 14	All
Literature review	June meeting	Robin B., Ann A., John H.
Forward product literature to appropriate person (see 7.4)	Feb 14	All
Begin to define product specs	June meeting	Ann A., John A., Lydia B.

10.0 Future Meetings

Prefer in conjunction with SAWC, prefer meeting before, meeting for 1.5 days, spend half day on each type of support surface system (overlays, mattress replacement, frame systems)

11.0 Adjournment

Meeting adjourned at 4 p.m. for full committee meeting and report