THE CURRENT STATE OF PLAY WITH THE REVISION OF ISO 23908

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ISO 23908 ‘OVEN-READY’?

- Draft has expanded from 12 to c 40 pages,
- New categories of needles are to be included in expanded ‘Scope’
- ‘Blood testing, Monitoring, Sampling, Medical Substance Administration:

- This might include needles fitted to devices currently not fitted with needle-safety mechanisms:-
- Central venous access/ monitoring.
- Peripheral & central arterial access/monitoring needles.
- Neuraxial drug delivery (spinal & epidural needles),
- Subcutaneous contraceptive implants.

- 2 new Normative Annexes, 3+ Informative Annexes (Including ZA)
- Six months of work, but not yet ready for public comment – still a ‘working draft’ not a ‘Committee Draft’

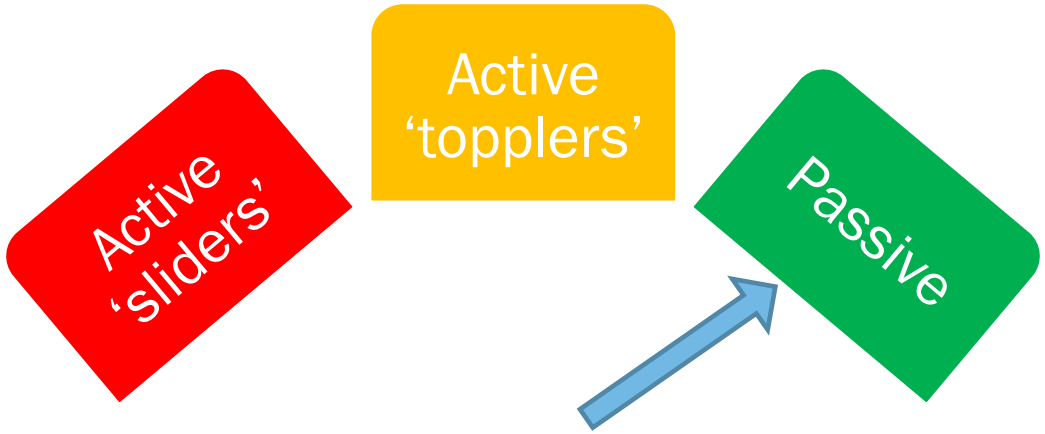
- A wish from the manufacturers to make this as ‘horizontal’ a standard as possible, to allow it cover all types of needle-containing devices (many thousands)
- Widely varied demographics of ‘end-users’
- Threshold values (measurable by third parties) for activation forces, minimum over-riding/ unlatching force of safety mechanism could be influenced by demographic, therefore difficult to specify ?

Vs

- A wish from end-users to have the needle safety mechanism on these devices perform consistently and predictably
- An expectation of those working in healthcare facilities to have the risk of a random injury from an unprotected ‘used sharp’ eliminated

MOVING THE 'NEEDLE OF DESIGN' TO AID PURCHASERS

- W. Tosini et al. **Infection Control & Hospital Epidemiology 2010; 31:402-407**
- =/>22 million SEDs purchased for study period (18/12 until Dec 2006), used in 61 French hospitals
- 453 SED-related NSIs documented = 2.05 injuries per 100,000 SEDs purchased
- Fully-automatic (passive) safety mechanisms least likely to result in an NSI
- Semi-automatic mechanism > Manual (active) 'toppling shield' > Manual 'sliding shield' (most likely to fail-to-protect)



WHAT PHYSICAL CHALLENGES TO THE SAFETY MECHANISM ARE ‘REASONABLY & FORESEEABLE’?

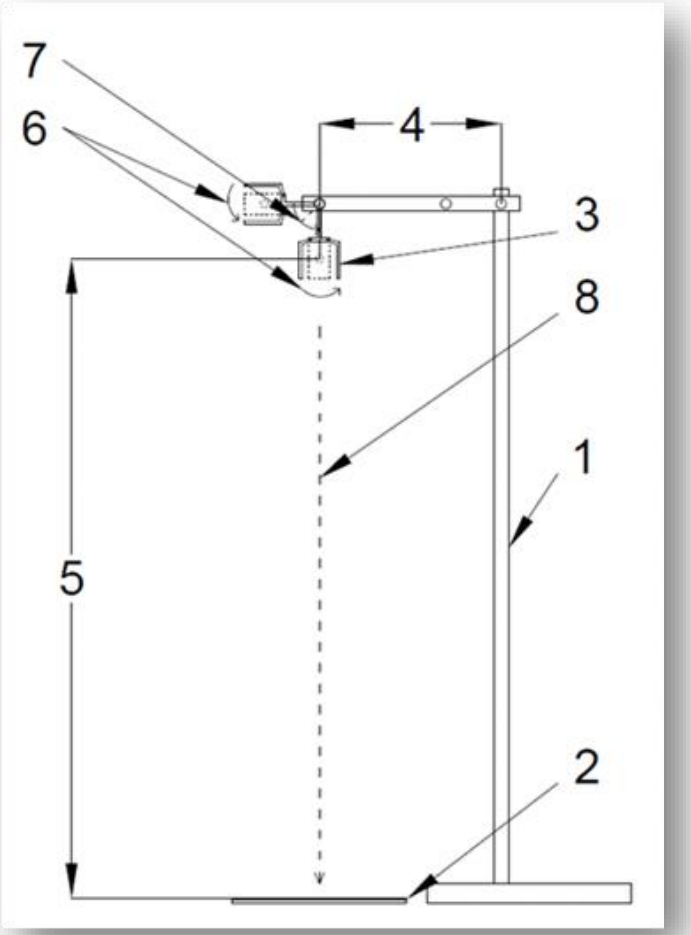
- Outside the manufacturers intended use. But ‘real world’ challenges
- An expectation that a safety mechanism should be capable of resisting as much physical stress as a multi-use sharps container is unreasonable (and impractical : cost, material, bulk)
- Nevertheless, the safety mechanism should be able to resist a fall onto a hard surface (how many times?)

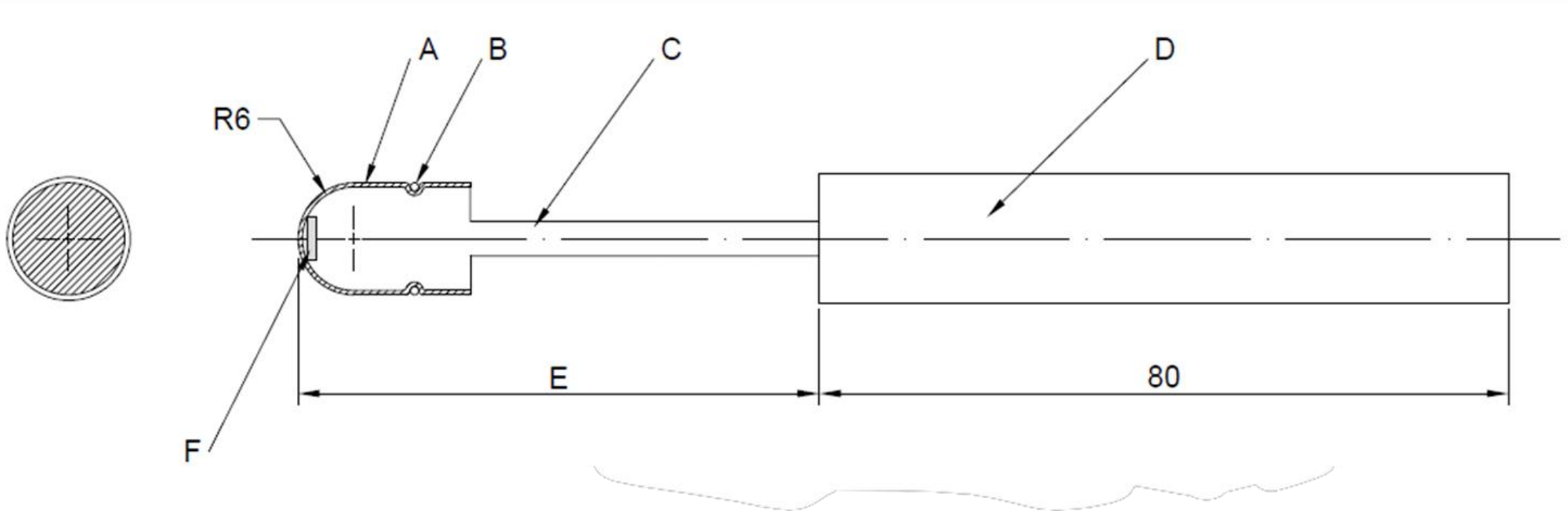
But then:-

- Simulated crush test?? E.g. a from simulated foot? How much force?
- Resistance to an attempt to ‘unlatch’/over-ride a safety mechanism? A measurable, defined force
- Are these **‘foreseeable accidents’** or **‘intentional abuse’?**

‘DROP’ (FREE-FALL) TESTING

- Agreed in principle by ‘New Tests’ Sub-group of TC84 WG8 on 21st June
- How many tests for each device?
- One test, single orientation vs several times, each test in a different orientations
- Should a pre-filled device be tested when full or empty?
- Should this test always be performed before any other test of the safety mechanism?





TESTING FOR UNINTENDED ACCESS TO A SHARP, ONCE THE SHARPS PROTECTION MECHANISM IS IN ‘SAFE MODE’ (BY USING AN ARTIFICIAL FINGER)

EUROPEAN FOREWORD & ANNEX ZA

- Comprehensively addresses the current state of the draft document
- M575 requirements for compliance with points 11.1 & 22.2 being addressed
- Non-integral safety mechanisms not covered - but by reference to IFUs
- Reference to currently-dated versions within cited ISO standards is made
- Need for machine-readable data on labelling, ‘tweaks’ to instruction for use

WORK STILL TO BE STARTED

- Revision of Informative ‘Annex A’ on ‘Simulated User’ studies, including the format of the reports
- Reports to focus on **reliability** of activation of safety mechanism rather than **usability** per se
- Benchmark failure levels to be determined: ? Up to 500 consecutive unit uses with no failures?

Thank you to all the subgroup members for their participation and to our WG8 convenor, Francois Thomassin, for all the scheduling and drafting work

THANK YOU
ANY QUESTIONS?