Developing a new Machine Safety Specification Standard and an approach for upgrading existing machinery

Nancy Orr, CIH, CSP
Safety & Industrial
Hygiene Manager
Becton Dickinson & Co.
About BD

• A global medical technology company
• 107 years old
• $5.5+ billion in sales
• 25,000 employees worldwide
• Approx. 55 manufacturing sites in 50 countries
• Serves healthcare institutions, researchers, laboratories, industry and general public
BD makes…

- Diabetes syringes and glucose monitoring devices
- Drug delivery devices/pre-filled syringes and flush devices
- Blood collection systems
- Ophthalmic blades/ anesthesia needles
- Blood diagnostic equipment/plated media/reagents
- Catheters/ surgical kits
- Monoclonal antibodies
- Candidate drug toxicity screening kits
- Flu test kits
- Sharps disposal containers
- … And much much more
Syringes and safety engineered devices
Intravenous systems
Blood collection products- Vacutainer tubes
Blood collection systems
Ophthalmic blades
Sharps disposal systems
Why does BD worry about machine guarding?

- Huge quantities produced: Billions of pieces annually, 24/7 operations
- High speed production and highly automated assembly of small parts
- On-site packaging/robotics
- Multiple machine “systems”, many homegrown
- “Lean” workplace, hence operators are stretched
- Unique processes (sterilization, blades, rubber manufacturing) present special machine risks
Typical molding dept.
Assembly-significant lockout/guarding issues
Typical assembly-multiple access points
Product palletized prior to sterilization
Cobalt irradiator carrier system

Pressure sensitive mat

Sterilization Off Load Station
Injection molding press - garbage can size
Glass cane handling/ preheating
Tube forming and cutting
Glass forming- Vacutainer tubes
Rubber compounding
Rubber Milling

Mill – Rubber Molding
Clam shell press - open
Stopper press-clam shell

Press (closed) – Rubber Molding
Initial automated grinding- surgical blades
Final inspection and testing surgical of blades
BD machine specifications prior to 2004

• Emphasized performance criteria (cycles/sec)
• Focused on physical design issues (how big)
• Originated simultaneously from many manufacturing sites and locales
• Did not always spell out controls (barriers, guards, interlocks, control reliability)
• Relied on vendors to meet implied standards
Result…

• Not all new machines provided adequate protection or met existing standards.
• Inconsistent level of protection across company (among business segments and world regions).
• Created exposures that were both unacceptable and expensive to retrofit.
Goal

• Have a consistent, minimum standard for new machinery across all BD segments, worldwide.
• To include physical safety design, controls and instrumentation, and control reliability.
• To include a risk assessment process, especially when consensus standards are absent.
Development team for machine standard

- Internal design engineers
- Engineering Category Management Team Members
- Global Process and Automation Development Team (PAD)
- Paul Prince, NATLSCO (consultant)
- Additional design and process engineers throughout BD (worldwide)
- Corporate Risk and Law Group (reviewers)
- Corporate Safety (facilitators)
Source materials

- ANSI B11.19 standard and B11.TR3 guideline
- European Normative Standards
- Existing BD machine procedures
-Comparable standards by other companies
- Experience and common sense
The standard!

- Two and a half years, 9 drafts and 67 worldwide reviewers later…

we had a standard!
Scope of standard

- Applies to new and significantly rebuilt (>50%) machinery
- Does not supersede local or EN requirements, if applicable
- In absence of local or EN standards, BD standard to apply
Basic contents

• Objective/scope
• Designing for safety
  – Risk assessment
  – Hierarchy of controls
• General requirements for guards and control systems
• Category 3 system requirements
• Category 1 systems
• E stops
Contents (continued)

• Electrical safety design
• Safety resets
• Local energy disconnects
• Electrical safety disconnects
• Pneumatic and hydraulic disconnects
• Ergonomic considerations
• Start-up and authorization to run
Contents (continued)

- Appendices:
  - Definitions
  - Risk assessment scheme
  - List of pertinent EN and US standards and guidelines
  - Acceptance/Start-up checklist
What about all the old machines?

- BD also needed a strategy to address well recognized problems associated with existing machinery and systems
Priority scheme for upgrading existing machinery

- Wall-to-wall machine guarding assessments to identify gaps
- Plant level training (maintenance, engineers, facilities, designers) with local examples
- Excel spreadsheet tool developed to “quantify” risk of existing machines: completed by mechanics, operators, engineers
- Tool evaluates:
  - type and severity of risks
  - frequency and probability of exposures
  - remaining equipment life multiplier
  - resource requirements to upgrade
Provides:

- Relative ranking of risks associated with existing machinery
- Clarity for an action plan to address highest “scored” machines first
- Scope of upgrades necessary
Questions?