

DSc 2005 Congress

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MDD and ISO13485:2003 Compliance - An Integrated Approach

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Standards

■ ISO9001:2000

Quality Management

- Customer satisfaction
- Process driven
- Continual Improvement
- Limited procedure requirements (six)
- Now 8 sections vs. 20 clauses
- ISO9000:1994 obsolete in Dec 2003

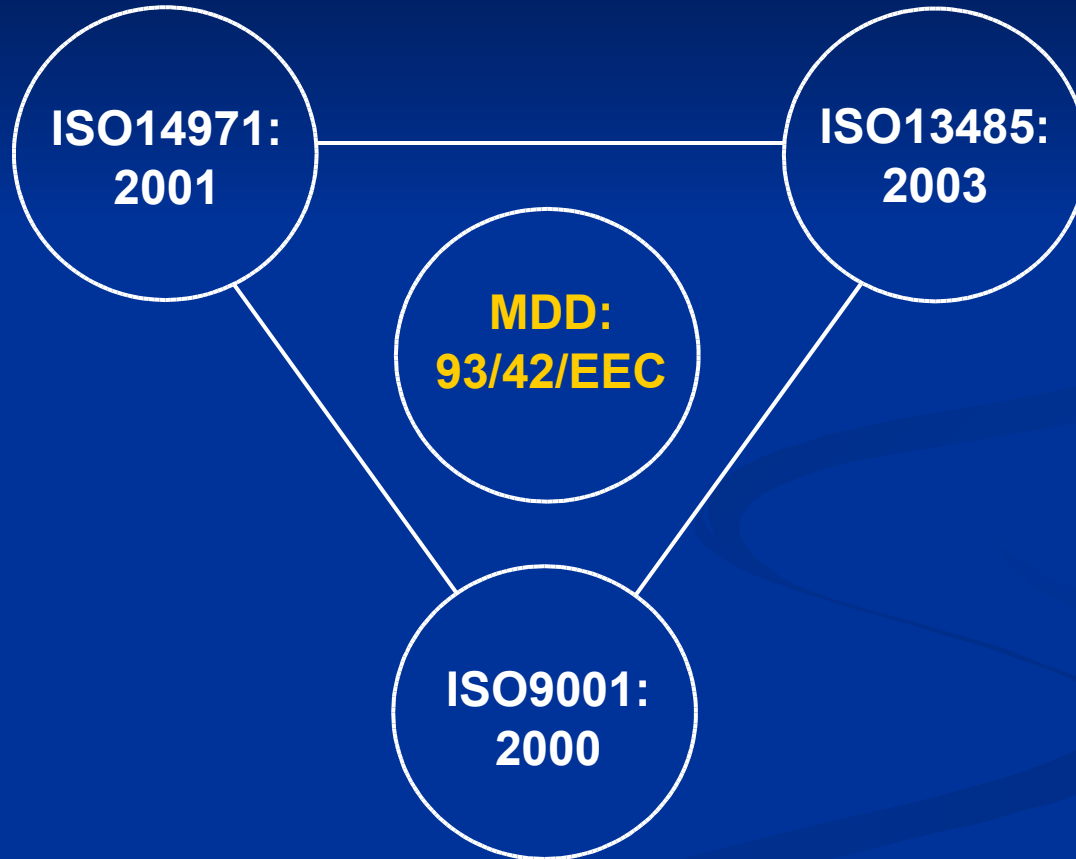
■ ISO13485:2003

Medical devices

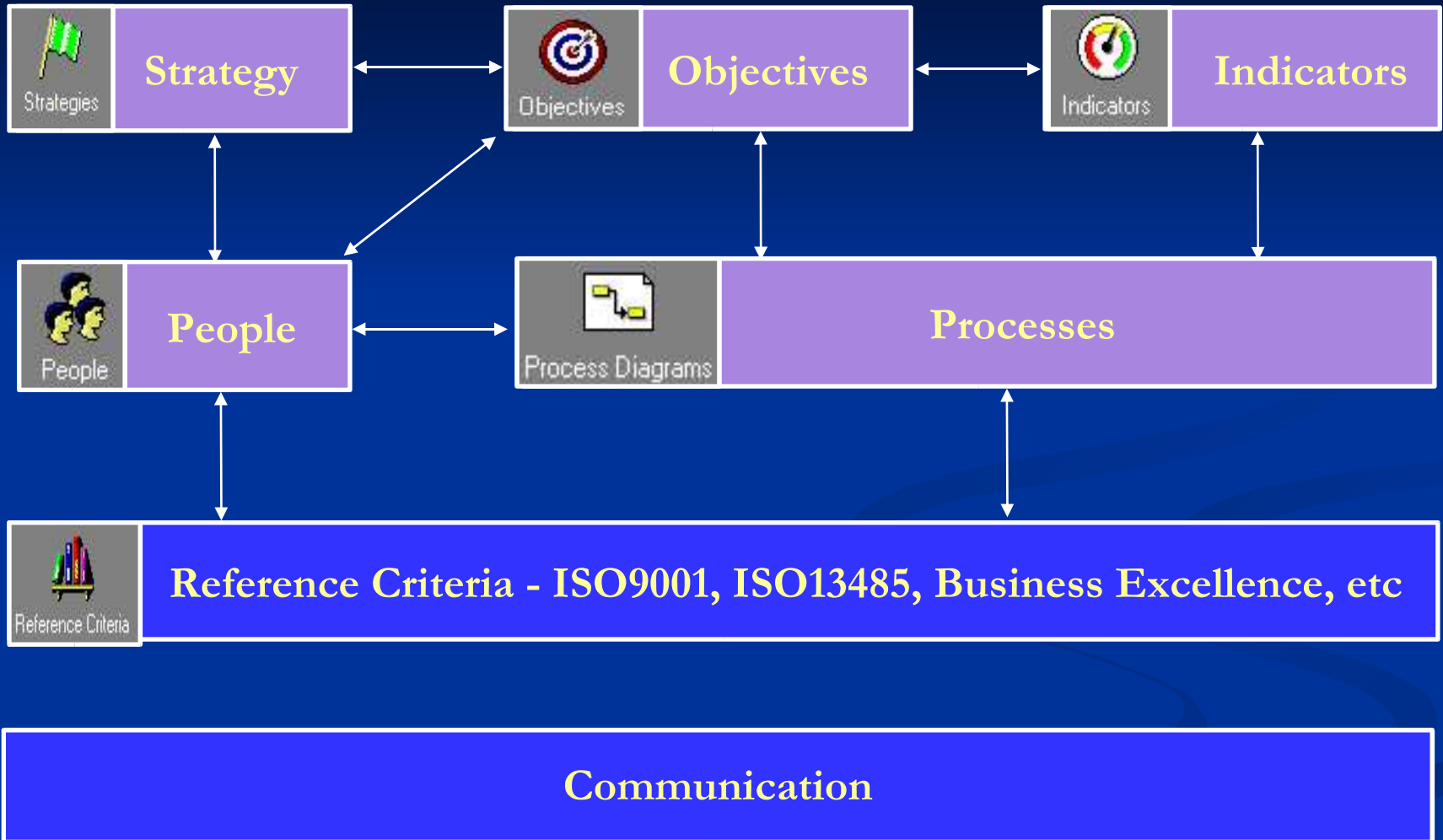
- ISO9001:2000 structure with significant differences
- Stand alone
- Additional requirements for medical devices
- ISO13485/88:1996 becomes obsolete by 15th July 2006.

■ ISO14971:2001 Risk Management

SSD Standards



Performance Building Blocks



Case Study
BMI Sterile Services (Glasgow)

Demonstration

Deliverables

Design Principles

ISO specific

Easy to use technology

Time efficient

Visible

Management control

Scalable and flexible

Flexible data import

+

Business fit

Tailored & bespoke

Supported

Not complex or costly

Business case proven

+

Benefits

One stop shop

Eases assessment

Flexibility

Integration

Brings ISO & processes
to life

Reduced maintenance

Multiple Applications

- ISO9001:2000
- Medical Devices
- Environmental
- Health & Safety
- Business Excellence Model (EFQM)
- Balanced Scorecard
- All of the above!!!
- Etc, etc

UKAS Requirements

(of 23/05/2002)



- QMS to be fully integrated into normal business operations
- Emphasis on measurement, analysis and results not compliance with procedures
- Top Management must demonstrate that the QMS works for them and how they meet customer requirements & expectations on a continuing basis
- External auditors to establish that QMS is actually effective and that all processes and interfaces have been assessed
- External audit records gained from a transition implementation over a period of time should collectively contain the same information as if it were a new assessment