

Index

Page numbers in italics refer to tables and figures.

```
accreditation 12
                                                functional (generic) 176-177
  defined 8, 12
                                               honesty in 175-176
  generic process 18, 19
                                               indicators
  national schemes 13-14
                                                  best practice 173
  ongoing commitment to quality 22-23
                                                  choice of 171
  own processes 23
                                                  efficiency 173
  process 18, 19
                                                  financial 174
    external assessment 10, 12-13, 21
                                                  laboratory operations 174
     recommendations 21-22
                                                  laboratory performance 104-105,
    self-assessment 12-13, 18-21
                                                    172-173
                                                  programme performance 172
  standards
    features 12
                                                  sentinel 170
     operational areas 20-21
                                               internal 176
  see also ISO standards
                                               reference populations 174–175
Accu-Beads 107
                                             best practice indicators 173
accuracy 111-112
                                             bioterrorism 52
ACHS 13
adverse events 51, 170-171
                                             calibrators 107
                                             Canadian Council on Health Service
Alpha 135
                                                    Accreditation (CCHSA) 13
andrology EQA schemes 117
                                             Canadian Fertility and Andrology Society
anthrax bioterrorism 52
AS/NZS 4360 46, 145, 154, 155
                                                    (CFAS) 13
                                             CAP 14, 91
audit 119
Australia, accreditation schemes 13
                                             CCHSA 13
Australian Council on Healthcare
                                             certification 9
       Standards (ACHS) 13
                                             CFAS 13
                                             Clinical Pathology Accreditation (UK)
bar codes 82, 81-83
                                                    Ltd. (CPA) 14
benchmarking 169–177
                                             CO2 incubators
  adverse events 51, 170-171
                                               choice of 185, 186, 190, 191,
  competitive 176
                                                   193-199
```



CO ₂ incubators (cont.)	disaster planning 52
CO ₂ recovery after opening 194	documentation, poor 51
troubleshooting example 141–144	document control systems
College of American Pathologists (CAP)	forms 114
14, 91	naming of electronic files 114-115
consequence for risks 123	requirements 113, 112-114
control charts 101, 101–105, 103, 104	SOP review and reissue 113, 114
control limits 102	documents, classifying 116, 116
control mean 102	double-witnessing 50, 79–81
warning limits 102	duty of care 32
see also process control, charts	
controlled documents see document	earthquakes 52
control systems	education of staff 36–37, 76–77,
Cook IVF 177, 196	202–203
MINC incubator see MINC incubator	efficiency indicators 173
Coombs, Ann 42	electrical power failure 50
counting errors 109, 110	electronic files, naming conventions
CPA 14	114–115
credentialing 9	embryo disposal 155–157
criticality scores 121	embryologists, recruitment of 201-202
cryobank management, risk	embryology work stations 184
minimization 146-147	air quality requirements 187-190
cryopreservation buffers 183-184	cabinet styles 184–185, 186
cryostorage packaging 164, 161-166	gassed enclosures 185, 186
culture media, choice of 190-193	pros and cons summarized 188
availability 193–194	warmed stages 185, 186
cost 195	employee issues see human resources
delivery and cold chain 194–195	employment regulations 11
efficacy 196–197	EPCoT Systems 83
quality control 196	EQA (external quality assurance) 117
suitability 195	equipment
culture oil, factors influencing use	maintenance and monitoring 50
197	selection 179-180
gassing and pH 194, 198-200	errors
prevention of evaporation 197	random 110
temperature stability 197–198	sampling 109, 110
customer expectations 33	systematic 110
•	system flows 166
Deming (PDCA) cycle 124, 126	ethics 32–33
Deming, W. Edwards 25	European Union (2004) 17, 187
Department of Health (2001) 187	European Union Tissues and Cells
detection-based mentality 42, 42	Directive 17–18, 187, 217



external assessment 21	career path 206, 207, 208, 209
external audit 119	delegation 206–208
external quality assurance (EQA) 117	rewards 204–206
• •	other factors 208–209
Failure Modes and Effects Analysis	salaries 204
(FMEA) 52–53	staffing issues in risk analysis 48-49
cryostorage packaging example 164	staff involvement and commitment
diagrammatic overview 120	37–38
flow chart 121	staff motivation 204–205
steps 122, 123, 120–124	teamwork 38–39, 201
uses 120	training 36–37, 47, 76–77, 202–203
FertAid 117	
fertilization rates, troubleshooting	ICSI, top-down process map 65, 66
example 138–141	IDEF0 63, 68, 67–68, 132–133
financial indicators 174	implantation rates 172
FIPS PUB 183 67-68	incident reports 51
fire, risk management example 149,	indicators used in benchmarking see
148–150	benchmarking: indicators
flow charts 63, 64	information management accreditation
FMEA see Failure Modes and Effects	20
Analysis	information technology accreditation 20
forms 114	inspection 9, 118–119
frozen embryo disposal 155–157	internal audit 119
, 1	ISO standards
governance of organizations,	development principles 14–15
accreditation of 20	ISO 9000 family 15–16
	for laboratories 16–17
"hand-offs" or "hand-overs" 80	IVF centers, structure and organization 3
hazardous materials, regulations for use	4, 2–4, 5, 207, 208, 209, 212
11	IVF Chamber 186, 188
honesty in reporting results 175–176	,
human error 125	JCAHO 14
human resources 201–209	Joint Commission on Accreditation of
accreditation 20	Healthcare Organizations
basic principles 166	(JCAHO) (USA) 14
education 36–37, 76–77, 202–203	Juran, Joseph M. 25
embryologists 201–202	,, ,
leadership 35–36	Kemeter, Peter 159–161, 160, 162–163
motivation, external 205	K-Systems cabinets 186, 188
motivation, internal 206	, ,
protecting staff from litigation 166	labeling in IVF laboratories 78, 77–79, 82
retention of staff 204	157



laboratories	oil see culture oil, factors influencing
"high risk" 48–52	use
ISO standards 16–17	oocyte retrieval 160, 158–161, 162
"out of control" 6	organization chart
well-run see well-run laboratories	generic company hierachy 207
laboratory operations indicators 174	ideal IVF lab
laboratory performance indicators (LPIs)	defined roles 209
104–105, 172–173	generic 208
laboratory services, accreditation of 21	IVF Center 3
labor relations 11	large 3
laminar flow cabinets, vertical 188	"market-in" 212
legal aspects 33	"product-out" 212
licensing process	small 4
defined 8–9	IVF lab, large 5
IVF 10–11	
likelihood of risks 122	Pareto methodology 123
litigation, protection of staff from	PDCA 124, 126
166–167	Percoll 46
	Peter principle 208
"market-in" company 212	Plan-Do-Check-Act (PDCA) cycle 124,
measurement, uncertainty of 109,	126
107–109	power failure 50
MedCalc software 102	pregnancy rates 172
meteor strikes 52	problems
methods	conceptual approaches to 136
design 86–87, 88, 106, 179	dealing with 135
implementation and validation 106	reactive approach 135-136
calibrators 107	see also troubleshooting
need for accuracy 111-112	process analysis 74, 75–76
reference materials 107	process control 74–75, 101
statistical issues 108, 110, 109-111	charts
uncertainty of measurement 109,	generic process 101, 101–102
107–109	laboratory performance monitoring
selection 179	example <i>104</i> , 104
microscopy, temperature control 185, 186	recalculation of control limits 102,
MINC 1000 incubator 185, 186, 190, 193	<i>103</i> , 103–104
mouse embryo assay (MEA), reliability	scenarios requiring action 102-103
196	software 102
	processes
NATA 13	as components of systems 55, 54-55
National Association of Testing	defined 54
Authorities (NATA) (Australia) 13	development for individual centers 23
New Zealand IVF accreditation 13	generic 55



process management software 83	management systems (QMS)
process mapping 55–72	defined 27
benefits 68-69, 84-85	manager 27
"dinner party" illustration 56–57	manual 27
intrinsic and extrinsic factors 56	in medicine 25–26
IVF laboratory systems 58, 59, 60, 61,	objective 27
62, 80	ongoing commitment to 22–23
map creation	planning 27
"bottom–up" approach 70	policies 27
as the process is performed 69	systems 27
recommended procedure 70–72	terminology 26–27
"top-down" approach 69-70	total 31
principle 55–56	
tools 59	radio frequency identification devices
approaches compared 63	(RFIDs) 82, 83
flow charts 63, 64	random errors 110
IDEF0 63, 68, 67–68	RCA see Root Cause Analysis (RCA)
swim lanes 65, 67	reactive oxygen species in sperm
top-down maps 64, 65, 66	preparation 181
"product–out" company 212	reference materials 107
professional responsibility 49, 81, 151	reference populations 174–175
	registration 8, 9
quality	regulation of IVF 10-12, 33
in action, example 27–29	regulations, defined 8–10
assurance (QA) 26, 29	Reproductive Technology Accreditation
defined 26	Committee (RTAC) (Australia)
external 117	13
concepts of 24-25	resistance
control (QC) 26, 29	active 41
defined 26	passive 41
cycle 26, 29, <i>30</i>	to change 40–41, 41
defined 26	resource issues 49–50
defined 24–25	responsibility see professional
improvement (QI)	responsibility
continual 29–31	RFIDs 82, 83
defined 26	risk 45
management	acceptance/retention of risk 147
defined 25–26	avoidance of risk 146
history 25	consequence rating 123
tools 118	elimination of risk 146
see also specific management tools;	likelihood rating 122
Total Quality Management	reduction/minimization of risk
(TQM)	146–147, 150



risk analysis of IVF laboratories 48	flow chart 126
organizational issues 50-51	implications of 166
resource issues 49–50	sperm preparation example 129, 133,
risk management issues 51-52	128-134
staffing issues 48–49	performing 127, 124–128
risk compensation behavior 81	see also troubleshooting
risk management 145–168	RTAC 13
basics 46	
benefits 46-47, 151-152	sample identification/verification
consequences of non-implementation	bar codes <i>82</i> , 81–83
47	double-witnessing 50, 79–81
disaster planning 52	labeling 78, 77–79, 157
examples 153	radio frequency identification device
cryostorage packaging 164,	<i>82</i> , 83
161–166	system failure 79, 80
fire, multi-faceted approach 149,	sampling errors 109, 110
148–150	self-assessment in accreditation 12-13,
frozen embryo disposal 155-157	18–21
labeling of OPU tubes 157	semen analysis 180–181
off-site sperm collection 154-155,	sentinel indicators 170
156	service contracts 90, 87-90, 91
Percoll use 46	Shewhart (PDCA) cycle 124, 126
sperm processing in parallel 157,	silos 73, 72–74
158	slack 49, 211
temperature control during oocyte	SmartDraw 64
retrieval 160, 158-161, 162	SOPs see standard operating procedures
importance for IVF centers 45	(SOPs)
professional responsibility 151	sperm collection off-site 154-155,
program development 152-153, 154,	156
155	sperm preparation
protection of staff from litigation	example SOPs 95, 96
166–167	in parallel 157, <i>158</i>
standard for 46	reactive oxygen species in 181
summarized 46	troubleshooting using RCA 129, 133,
tools 52–53, 118	128–134
see also specific tools	staff issues see human resources
transfer of risk 147	standard operating procedures (SOPs)
risk matrices 123	90–100
risk registers 153, 155	considerations when writing
risk reduction 150	75–76
Root Cause Analysis (RCA) 52-53,	deviation from 50–51, 203
124–125 , <i>127</i>	electronic manuals 91



examples of good and poor versions	third-party services 90, 87–90, 88–89,
<i>95</i> , <i>96</i> , 94–100	91
guidelines/requirements 90-91,	Tomcat catheters 51, <i>182</i> , 181–182
92	top-down process maps 63, 64, 65, 66
inadequate 95	Total Quality Management (TQM) 31
review and reissue 113, 114	defined 27
summary protocols 93	diagrammatic overview 32, 31–32
value of 93–94	implementation 34–40
see also top-down process maps	education and training 36–37,
standards	76–77, 202–203
accreditation see accreditation:	employee involvement and
standards	commitment 37–38
defined 9–10	importance of organization 34
IDEF0 67-68	leadership 35–36
risk management 46, 154, 155	measurement and feedback 39-40
SOP requirements 90–91, 92	requirements summarized 34-35
see also ISO standards	teamwork 38–39, 201
surveys for accreditation	tools and techniques 37
process 10, 13, 21	in IVF
recommendations 21–22	customer expectations 33
swim lane process maps 63, 65, 67	duty of care 32
systematic errors 110	ethics 32–33
systems	legal obligations 33
defined 54	liability 33–34
importance of understanding 84	medical and scientific standards 32,
systems analysis 55, 54–55	31–32
see also process mapping	responsibility 32
systems specification 178–200	ongoing process 40
general principles 178	origin of concept 25
practical examples 184–200	reasons for failure 40
CO ₂ incubator, choice of 185, <i>186</i> ,	resistance to change 40–41
190, 191, 193–199	"toxic workplace" 42–44
cryopreservation buffers 183	terminology 26–27
culture media, choice of 190–197	"toxic workplace" 42–44, 211
work station, choice of <i>188</i> , 184–190	training of staff 36–37, 49, 76–77,
culture oil, use of 197–200	202–203
selection of methods or equipment	troubleshooting 135–144
179–180	being reactive 135
1,7 100	CO ₂ incubator incident 141–144
teamwork 38–39, 201	conceptual approaches to problems
temperature control, oocyte retrieval 160,	136
158–161. 162	fertilization rates example 138–141
1.70-101, 104	ICI UHZAUOH TAUS EXAIIDIE 1.70-141



232 Index

troubleshooting (cont.) warmed microscope stages 185, 186 flow diagram of process 137 well-run laboratories 210-217 sperm preparation example 129, 133, benefits 216-217 Lab Director's role 215 128-134 see also Root Cause Analysis (RCA) organization charts 212 requirements 210-213 UK, accreditation schemes 14 road map to establishment 213, uncertainty of measurement 109, 214-215 107-109 scientists' roles 215 USA, accreditation schemes 14 WHMIS 11 user requirement specifications (URS) Workplace Hazardous Materials 86–87, 88 Information System (WHMIS) 11 work stations see embryology work vertical laminar flow cabinets 188 stations