# The ISO Survey - 2004

### ISO and The ISO Survey

SO is the world's largest developer of voluntary international standards for business, government and society. Its portfolio in mid-July 2005 comprised 15 250 standards that provide practical solutions and achieve benefits for almost every sector of economic activity and technology.

Of these, the ISO 9000 quality management system and ISO 14000 environmental management system standards are among ISO's most well-known and widely implemented ever. They are used worldwide by businesses and organizations large and small, in public and private sectors, manufacturers and service providers, in all sectors of activity.

Many users decide to have their management systems independently audited and certified as conforming to the standards. Certification is not a requirement of the standards themselves, which can be implemented without certification for the benefits that they help user organizations to achieve for themselves and for their customers. Nevertheless, many thousands of organizations have chosen certification because of the perception that an independent confirmation of conformity adds value.

ISO itself does not perform certification to its standards, does not issue certificates and does not control certification performed independently of ISO by other organizations. However, it frequently receives requests for information on the number of certificates and this led the organization to undertake *The ISO Survey*, which is now in its 12<sup>th</sup> year. ISO provides the basic results free-of-charge as a public information service on its Web site www.iso.org.

The collection and compilation of data for the 2004 survey was out-sourced to the market research firm ACNielsen, of Vienna, Austria.

#### **About ACNielsen**

ACNielsen is the leading global provider of marketing research information services, analytical systems and tools, and professional client services that help clients win in the market-place. The clients of ACNielsen include the world's leading manufacturers and retailers of consumer packaged goods, as well as companies that market many other types of consumer products and services. Clients work with ACNielsen to measure their market performance, to analyze market dynamics, to diagnose and solve marketing and sales problems, and to identify and capture growth opportunities. ACNielsen's operations span more than 100 countries. Founded in 1923 by Arthur Charles Nielsen, Sr., ACNielsen in the USA, the Austrian office was opened in 1961, initially carrying retail measurement. In 1990, consumer research was added to the range of services offered by the Austrian office.

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# **Highlights of The ISO Survey – 2004**

This edition of the survey gives the worldwide panorama of certification to ISO management system standards at the end of 2004. The principal standards covered are ISO 9001:2000 and ISO 14001.

In addition, for the first time, the survey includes certification data on two ISO standards that include the requirements of ISO 9001:2000, plus sectorspecific requirements: ISO/TS 16949:2002 (automotive sector) and ISO 13485:2003 (medical device sector).

### The essentials

The ISO Survey – 2004 confirms the thorough integration of ISO 9001:2000 and ISO 14001 with the world economy.

The worldwide total of ISO 9001:2000 certificates was 670 399, an increase of 35 % over the previous year and 64% over 2000, the year before the transition to the improved, more rigorous ISO 9001:2000 version began. The standard is now implemented in 154 economies.

If the number of certifications to the ISO 9001:2000-based specific quality requirements published by ISO for the automotive industry and the medical device sector is added to the above total for ISO 9001:2000 then the aggregate total is 683 523.

With 90 569 ISO 14001 certificates, an increase of 37 %, in 127 economies, ISO's environmental management system standard confirms its global progression.

The service sectors now account by far for the highest number of both ISO 9001:2000 and ISO 14001 certificates in both cases, about 31% of the total.

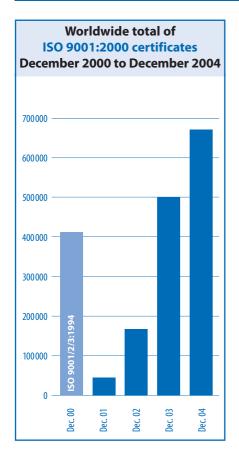
### ISO 9001:2000, Quality management systems

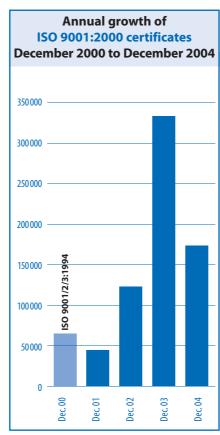
The current version of the standard was published on 15 December 2000, replacing three earlier versions - ISO 9001/2/3:1994. According to a joint policy agreed by ISO and the International Accreditation Forum (IAF), organizations were given three years until 15 December 2003 to make the transition to the improved, more rigorous ISO 9001:2000 version which is the only ISO 9000 standard recognized by ISO and the IAF for approved certification. For a variety of reasons given in *The ISO Survey – 2003*, not all organizations were able to meet the deadline and the transition continued into 2004. Therefore, The ISO Survey – 2004 is the first that allows a complete perspective of the transition, as follows:

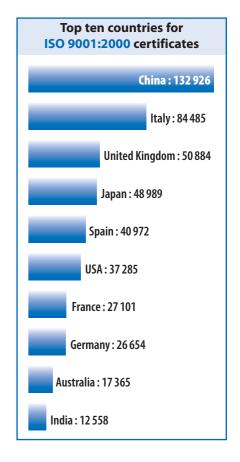
- Up to the end of December 2004, at least 670 399 ISO 9001:2000 certificates had been issued in 154 countries and economies.
- The 2004 total represents an increase of 172480 (+35%) over 2003, when the total was 497 919 in 149 countries and economies.
- The 2004 total represents an increase of 261 768 certificates (+64%) over the end of 2000, just after the release of ISO 9001:2000, when the world total of ISO 9001/2/3:1994 and ISO 9001:2000 certificates combined was 408631 in 157 countries and economies.

### ISO 9001:2000 principal results

World results	Dec. 2000	Dec. 2001	Dec. 2002	Dec. 2003	Dec. 2004
World total	<b>408 631</b> ISO 9001/2/3:1994	44388	167 210	497 919	670 399
World growth			122 822	330 709	172 480
Number of countries/ economies		98	134	149	154







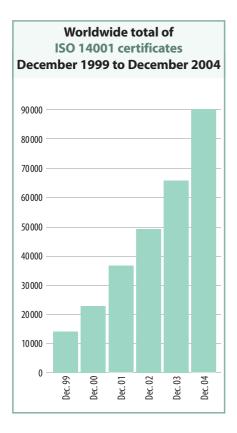
## ISO 14001, Environmental management systems

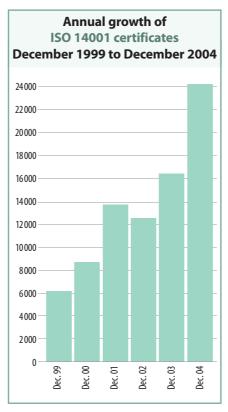
ISO published a new, improved version of ISO 14001 on 15 November 2004, replacing ISO 14001:1996. According to a joint ISO/IAF policy, organizations have been given 18 months until 15 May 2006 to make the transition to ISO 14001:2004 certification from the 1996 version. Given the short period between the release of the new version and closure of this edition of the survey, no attempt was made to obtain separate figures for the two ISO 14001 versions. Eight years after the standard was first released, the worldwide certification picture of ISO 14001 is as follows:

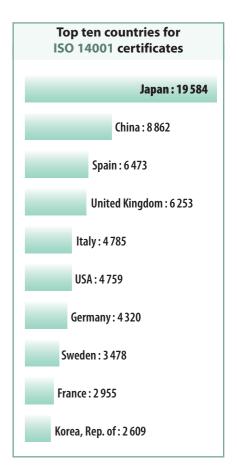
- Up to the end of December 2004, at least 90 569 ISO 14001 certificates had been issued in 127 countries and economies.
- The 2004 total represents an increase of 24 499 (+37 %) over 2003, when the total was 66 070 in 113 countries and economies.
- The increase in the number of certificates in 2004 is the largest so far recorded in the ten surveys in which ISO 14001 has been included.

### ISO 14001 principal results

World results	Dec. 1999	Dec. 2000	Dec. 2001	Dec. 2002	Dec. 2003	Dec. 2004
World total	14 106	22 897	36 765	49 449	66 070	90 569
World growth	6219	8 791	13 868	12 684	16 621	24 499
Number of countries/ economies	84	98	112	117	113	127







## ISO/TS 16949:2002, Quality management systems – Particular requirements for the application of ISO 9001:2000 for automotive production and relevant service part organizations

The potential worldwide market for ISO/TS 16949:2002 certificates is estimated to be 30 000. Not all data sources were able to provide figures, but the first time that the survey has included certificates to the international automotive industry's ISO 9001:2000-based quality requirement, the results was as follows:

- Up to the end of December 2004, at least 10 056 ISO/TS 16949:2002 certificates had been issued in 62 countries and economies.

#### ISO/TS 16949:2002 principal results

World results	Dec. 2004
World total	10 056
World growth	
Number of countries/ economies	62



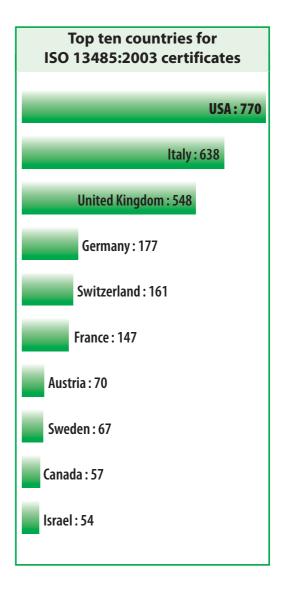
## ISO 13485:2003, Medical devices – **Quality management systems –** Requirements for regulatory purposes

This was the first time that the survey included certification to the medical device industry's ISO 9001:2000-based quality requirement and the findings were as follows:

- Up to the end of December 2004, at least 3068 ISO13485:2003 certificates had been issued in 56 countries and economies.

### ISO 13485:2003 principal results

World results	Dec. 2004
World total	3 068
World growth	
Number of countries/ economies	56



# ISO 9001:2000 certifications worldwide

## Growth from end of 2001 to end of 2004

Africa/				
West Asia	Dec. 2001	Dec. 2002	Dec. 2003	<b>Dec.</b> 2004
Afghanistan	1			3
Algeria	6	16	43	126
Angola		5	1	2
Bahrain	3	2	30	99
Bangladesh		6	49	182
Benin				1
Botswana		2	11	8
Cameroon			2	9
Central African Rep.				212
Côte d'Ivoire		4	9	
Egypt	18	222	754	810
Ethiopia				2
Gabon		1	2	3
Ghana			9	17
India	544	2 247	8 3 6 7	12 558
Iran	37	16	470	3 000
Israel	33	408	5 0 1 9	7 280
Jordan		34	112	278
Kenya	8	11	29	158
Kuwait	11	7	25	101
Lebanon	14	27	62	154
Libyan Arab Jamihiriya	1	2	4	6
Madagascar				3
Malawi		2	6	2
Maldives			1	1
Mauritius	3	32	93	212
Morocco	14	46	64	296
Mozambique		2	3	9
Namibia			15	23

Africa/West Asia	Dec. 2001	Dec. 2002	Dec. 2003	<b>Dec.</b> 2004
Nigeria		3	49	99
<b>Oman</b>	25	32	86	250
Pakistan	96	186	464	695
Palestine		13	18	29
Qatar	13	11	17	94
Rwanda				1
Saudi Arabia	6	131	247	394
Senegal		9	10	29
Seychelles		2	4	9
South Africa	87	401	2 3 5 6	2 486
Sri Lanka	1	34	90	148
Sudan	2	9	26	118
Swaziland		8	17	13
Syrian Arab Rep.	4	38	215	240
Tanzania			2	5
Tunisia	10	30	119	123
Uganda	7	31	120	47
United Arab Emirates	112	407	892	819
Yemen		4	6	29
Zambia		1	11	17
Zimbabwe	2	2	14	109

Total				
Africa/West Asia	1 058	4 444	19 943	31309
Share in percent	2,39	2,66	4,01	4,67
No. of countries/ economies	25	39	44	49

ISO 9001:2000 certifications worldwide (continued)

Central				
and South America	Dec. 2001	Dec. 2002	Dec. 2003	<b>Dec.</b> 2004
Argentina	203	710	1790	4 149
Bahamas				5
Barbados			8	11
Belize	2	2	2	
Bermuda			1	1
Bolivia		10	40	88
Brazil	182	1 582	4 012	6 120
Cayman Islands (United Kingdom)			1	1
Chile	15	92	340	924
Colombia	87	728	2 222	4 120
Costa Rica	5	23	63	105
Cuba		3	3	218
Dominican Rep.			1	22
Ecuador	2	8	29	57
El Salvador	1	3	7	34
Grenada			1	1
Guatemala	3	7	18	25
Guyana		1	3	11
Honduras		5	9	9
Jamaica	1	1	3	12
Netherlands Antilles (NL)		1	35	38
Nicaragua		6	9	28
Panama	4	13	44	69
Paraguay	4	21	37	44
Peru	16	82	141	205
Puerto Rico		2	26	33
Saint Lucia			4	2
Surinam			1	
Trinidad/Tobago		6	52	60
Uruguay	41	116	200	325
Venezuela	14	47	201	299

Total				
Central and South America	580	3 475	9303	17016
Share in percent	1,31	2,08	1,87	2,54
No. of countries/ Economies	15	24	30	29

North				
America*	Dec. 2001	Dec. 2002	Dec. 2003	Dec. 2004
Canada*	704	2 125	8 454	9 286
Mexico*	79	265	1 437	3 391
IISA*	1 104	4 587	30 294	37 285

Total				
North America*	1 887	6 977	40 185	49 962
Share in percent	4,26	4,18	8,07	7,45
No. of countries/ Economies	3	3	3	3

<sup>\*</sup> Data received from Quality Systems Update

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Europe	Dec. 2001	Dec. 2002	Dec. 2003	Dec. 2004		
Albania		1	2	6		
Andorra		3	1	1		
Armenia		1	16	26		
Austria	700	1879	2 809	3 839		
Azerbaijan			2	203		
Belarus		16	102	447		
Belgium	119	1 285	3 167	4 471		
Bosnia and Herzegovina	1	8	47	209		
Bulgaria	38	246	842	1 685		
Croatia	30	194	580	966		
Cyprus	10	160	314	573		
Czech Rep.	320	1125	2 5 6 5	10 781		
Denmark	36	447	935	1 050		
Estonia	66	167	261	438		
Finland	282	643	1861	1784		
France	2 194	6 5 2 9	15 073	27 101		
Georgia		3	7	20		
Germany	2338	10811	23 598	26 654		
Gibraltar (United Kingdom)		1	28	47		
Greece	31	540	1615	2 5 7 2		
Hungary	1349	4446	7 750	10 207		
Iceland		6	25	28		
Ireland	248	494	1132	1 683		
Italy	1974	14733	64 120	84 485		
Kazakhstan	21	16	174	229		
Kyrgyzstan		4	5	6		
Latvia	15	33	73	484		
Liechtenstein	14	38	69	71		
Lithuania	29	158	324	487		
Luxembourg	5	41	110	108		
Malta	25	122	204	230		
Moldova		6	16	26		

Europe	Dec. 2001	Dec. 2002	Dec. 2003	Dec. 2004
Monaco		5	45	22
Netherlands	750	2 803	9 9 1 7	6 402
Norway	75	405	1171	1368
Poland	232	914	3 216	5 753
Portugal	188	965	3 417	4733
Romania	87	767	2 052	5 183
Russian Federation	35	314	962	3 816
San Marino, Rep of				18
Serbia and Montenegro			103	696
Slovakia	144	768	1 148	2 008
Slovenia	34	330	465	1811
Spain	808	8 872	31 836	40 972
Sweden	145	833	3 107	4 687
Switzerland	1931	5060	8 3 0 0	11 549
The Former Yugoslav Rep. of Macedonia	1	7	47	133
Turkey	72	911	3 248	5 009
Ukraine	26	181	308	934
United Kingdom	8 501	9 3 0 1	45 465	50 884
Uzbekistan			2	

## Total

Europe	22 888	76 678	242 636	326895
Share in percent	51,57	45,86	48,73	48,76
No. of countries/ economies	38	48	50	50

#### ISO 9001:2000 certifications worldwide (continued)

Far East	Dec. 2001	Dec. 2002	Dec. 2003	<b>Dec.</b> 2004			
Brunei Darussalam	4	13	36	46			
Cambodia		5	5	5			
China	7 413	40997	96 715	132 926			
Hong Kong, China	547	1338	2 683	3 252			
Macau, China	6	10	58	80			
Chinese Taipei	634	1316	2 991	5 676			
Fiji	2	2	2	2			
Indonesia	161	308	1318	3 134			
Japan	3 650	16 813	38 751	48 989			
Korea, Democratic People's	106	130	63	1352			
Korea, Republic of	1 156	2 942	10 640	12 416			
Malaysia	257	1119	3 076	4337			
Mongolia		1	4	7			
Myanmar			3	346			
Nepal		4	6	25			
Papua New Guinea				1			
Philippines	43	270	456	1108			
Singapore	333	1953	3 341	3 964			
Thailand	89	938	1675	5 955			
Tuvalu			1	1			
Vietnam	33	354	1237	1598			

Total				
Far East	14434	68 513	163 061	225 220
Share in percent	32,52	40,98	32,75	33,60
No. of countries/ economies	15	18	20	21

Australia / New				
Zealand	Dec. 2001	Dec. 2002	Dec. 2003	<b>Dec.</b> 2004
Australia	3 442	7 024	19 975	17 365
New Zealand	99	99	2 816	2 632

Total				
Australia/ New Zealand	3 541	7 123	22 791	19 997
Share in percent	7,98	4,26	4,58	2,98
No. of countries/ economies	2	2	2	2

### ISO 9001:2000 certifications

World results	Dec. 2001	Dec. 2002	Dec. 2003	Dec. 2004
World total	44 388	167 210	497 919	670 399
World growth		122 822	330 709	172 480
Number of countries/ economies	98	134	149	154

# ISO 14001 certifications worldwide

## Growth from end of 1999 to end of 2004

Africa/						
West Asia	Dec. 1999	Dec. 2000	Dec. 2001	Dec. 2002	Dec. 2003	Dec. 2004
Afghanistan	1	4	4			4
Algeria						3
Bahrain	2	2	2	2	3	13
Bangladesh			2	3	4	7
Botswana			2	2	2	2
Cameroon			2	1	1	1
Egypt	35	78	100	101	195	289
Ghana						4
India	111	257	400	605	879	1250
Iran	12	12	34	54	88	400
Israel	25	60	75	112	163	247
Jordan	8	16	10	14	39	33
Kenya		2	3	1	1	16
Kuwait			3	3		7
Lebanon	4	5	5	5	6	7
Madagascar						1
Malawi				3		
Mauritius	3	4	5	5	1	11
Morocco	1	4	6	11	6	21
Namibia	1	4	4	4	4	3
Niger				1	2	2
Nigeria		1	5	4	8	11
Oman	1	2	3	6	2	4
Pakistan	2	4	10	21	26	38
Palestine		1	1	1	1	5
Qatar	1	1	1	1		9
Saudi Arabia	3	6	6	5	10	17
Senegal				2		3
Seychelles					1	1

Africa/West Asia	Dec. 1999	Dec. 2000	Dec. 2001	Dec. 2002	Dec. 2003	Dec. 2004
South Africa	82	126	169	264	378	393
Sri Lanka		2	2	5	11	13
Sudan				1		
Swaziland						3
Syrian Arab Republic	2	3	5	8	34	48
Tanzania, United Rep.						3
Tunisia	1	3	7	13	18	30
Uganda					3	2
United Arab Emirates	36	48	49	92	104	87
Zambia	2	2	2			
Zimbabwe	4	4	6	5	7	19

Total						
Africa/ West Asia	337	651	923	1355	1 997	3 007
Share in percent	2,39	2,84	2,51	2,74	3,02	3,32
No. of countries/ economies	21	25	29	31	28	37

ISO 14001 certifications worldwide (continued)

Central						
and South America	Dec. 1999	Dec. 2000	Dec. 2001	Dec. 2002	Dec. 2003	Dec. 2004
Argentina	84	114	175	249	286	408
Barbados	3	3	3	3		
Belize			2	2	2	
Bolivia		1	3	4	7	14
Brazil	165	330	350	900	1008	1800
Chile	5	11	17	55	99	312
Colombia	13	21	41	69	135	217
Costa Rica	7	20	14	38	38	52
Cuba						1
Dominican Republic		1	1		1	1
Ecuador	1	1	2	1	1	11
El Salvador						3
Guatemala	1	2	2	1	1	3
Guyana			3	3	4	3
Honduras		2	2	2	6	5
Jamaica			4	1	1	4
Netherlands Antilles						1
Nicaragua						1
Panama			1	1	2	2
Paraguay		1	1	4	3	3
Peru	7	13	15	25	31	41
Puerto Rico	4	4	4	3	4	6
Saint Lucia	1	2	2	1	1	1
Trinidad & Tobago	1	1	1	7	9	7
Uruguay	10	22	29	32	32	42
Venezuela	7	7	9	17	20	17

Total						
Central and South America	309	556	681	1 418	1 691	2 955
Share in percent	2,19	2,43	1,86	2,87	2,56	3,26
No. of countries/ economies	14	18	22	21	21	24

North						
America *	Dec. 1999	Dec. 2000	Dec. 2001	Dec. 2002	Dec. 2003	Dec. 2004
Canada *	276	475	801	1064	1274	1 492
Mexico*	63	159	254	369	406	492
USA*	636	1042	1645	2 620	3 553	4759

Total						
North America *	975	1676	2 700	4 053	5 233	6743
Share in percent	6,91	7,32	7,35	8,20	7,92	7,45
No. of countries	3	3	3	3	3	3

<sup>\*</sup> Data received from Quality Systems Update

#### ISO 14001 certifications worldwide (continued)

Europe	Dec. 1999	Dec. 2000	Dec. 2001	Dec. 2002	Dec. 2003	Dec. 2004
Albania						1
Andorra		2	2	2		
Austria	156	203	223	429	500	549
Azerbaijan				3	5	32
Belarus			2	1	4	42
Belgium	74	130	130	264	391	642
Bosnia & Herzegovnia				1	3	10
Bulgaria			6	10	17	26
Croatia	8	8	19	35	53	84
Cyprus	3	4	4	21	40	56
Czech Republic	60	116	174	318	519	1 288
Denmark	320	532	620	711	486	711
Estonia	4	18	24	47	74	86
Finland	470	508	687	750	1 128	882
France	462	710	1092	1 467	2 3 4 4	2 9 5 5
Germany	962	1 260	3 380	3 700	4 144	4320
Greece	20	42	66	89	126	173
Hungary	121	164	340	640	770	882
Iceland	2	2	2	3	3	5
Ireland	115	163	247	289	218	294
Italy	243	521	1 295	2 153	3 066	4785
Kazakhstan			1	1	4	7
Latvia		4	4	20	3	78
Liechtenstein	19	19	20	20	22	22
Lithuania	1	10	21	33	72	155
Luxembourg	6	9	9	17	32	39
Malta		2	2	3	4	4
Monaco	2	3	3	3	1	1
Netherlands	403	784	942	1073	1162	1150
Norway	133	227	298	278	350	441
Poland	72	66	294	434	555	709
Portugal	28	47	88	137	248	404
Romania	1	5	15	45	96	361

Europe	Dec. 1999	Dec. 2000	Dec. 2001	Dec. 2002	Dec. 2003	Dec. 2004
Russian Federation		3	12	23	48	118
San Marino						1
Serbia and Montenegro					12	46
Slovakia	24	36	73	70	165	184
Slovenia	19	88	136	149	205	338
Spain	573	600	2 064	3 228	4860	6 473
Sweden	851	1370	2 070	2730	2330	3 478
Switzerland	543	690	762	1052	1155	1348
The Former Yugoslav Rep. of Macedonia			1	1		5
Turkey	66	91	91	135	240	338
Turkmenistan				1	1	
United Kingdomraine			1	4	7	36
United Kingdom	1 492	2534	2722	2917	5 460	6253

# Total

Europe	7 3 6 5	11 021	18 243	23 316	31 997	39812
Share in percent	52,21	48,13	49,62	47,14	48,43	43,96
No. of countries/ economies	32	36	41	44	42	44

ISO 14001 certifications worldwide (continued)

Far East	Dec. 1999	Dec. 2000	Dec. 2001	Dec. 2002	Dec. 2003	Dec. 2004
Brunei Darussalam		2	4	3	3	4
Cambodia					1	1
China	222	510	1 085	2803	5 064	8 862
Hong Kong, China	51	105	165	208	262	349
Macau, China	1	1	1	70	10	15
Chinese Taipei	216	421	999	1024	1337	1 463
Fiji				1	1	
Indonesia	55	77	199	229	297	373
Japan	3 015	5 5 5 6	8 123	10 620	13 416	19 584
Korea, Democratic People's Republic of		26	38	84		202
Korea, Republic of	309	544	880	1065	1 495	2 609
Malaysia	117	174	367	367	370	566
Myanmar			1	1		2
Nepal					1	2
Papua New Guinea					1	
Philippines	39	46	120	124	174	261
Singapore	87	100	298	441	523	616
Thailand	229	310	483	671	736	966
Vietnam	9	9	33	33	56	85

Total						
Far East	4350	7881	12 796	17 744	23 747	35 960
Share in percent	30,84	34,42	34,81	35,88	35,94	39,70
No. of countries/ economies	12	14	16	16	17	17

Australia / New						
Zealand	Dec. 1999	Dec. 2000	Dec. 2001	Dec. 2002	Dec. 2003	Dec. 2004
Australia	708	1 049	1370	1485	1 250	1 898
New Zealand	62	63	52	78	155	194

Total						
Australia/ New Zealand	770	1 112	1 422	1 563	1 405	2 092
Share in percent	5,46	4,86	3,87	3,16	2,13	2,31
No. of countries	2	2	2	2	2	2

## ISO 14001 certifications

World results	Dec. 1999	Dec. 2000	Dec. 2001	Dec. 2002	Dec. 2003	Dec. 2004
World total	14 106	22 897	36 765	49 449	66 070	90 569
World growth	6 2 1 9	8 791	13 868	12 684	16 621	24 499
Number of countries/ economies	84	98	112	117	113	127

# ISO/TS 16949:2002 certifications worldwide

## At the end of 2004

Africa/	
West Asia	Dec. 2004
Egypt	1
India	225
Iran	35
Israel	12
Morocco	6
South Africa	134
Sri Lanka	1
Tunisia	3

Total	
Africa/West Asia	417
Share in percent	4,15
No. of countries/ economies	8

Central and	
South America	Dec. 2004
Argentina	83
Brazil	299
Colombia	1
Costa Rica	5
El Salvador	1
Puerto Rico	2
Uruguay	3

Total	
Central and South America	394
Share in percent	3,92
No. of countries/ economies	7

North America*	
	Dec. 2004
Canada*	258
Mexico*	566
USA*	3 693

Total	
North America*	4517
Share in percent	44,92
No. of countries/ economies	3

<sup>\*</sup>Data received from Quality Systems Update

Europe	Dec. 2004
Austria	77
Belarus	1
Belgium	74
Bosnia and Herzegovina	2
Bulgaria	2
Croatia	1
Czech Rep.	307
Estonia	1
Finland	2
France	126
Germany	1 043
Greece	1
Hungary	95
Ireland	7
Italy	173
Luxembourg	4

Europe	Dec. 2004
Netherlands	16
Norway	13
Poland	77
Portugal	54
Romania	4
Russian Federation	5
Serbia and Montenegro	7
Slovakia	34
Slovenia	83
Spain	526
Sweden	21
Switzerland	77
Turkey	98
United Kingdom	318

Total	
Europe	3249
Share in percent	32,31
No. of countries/ economies	30

(continued overleaf)

Far East	
	Dec. 2004
China	459
Hong Kong, China	30
Chinese Taipei	71
Indonesia	10
Japan	169
Korea, Democratic People's	37
Korea, Republic of	366
Malaysia	22
Philippines	14
Singapore	117
Thailand	18
Vietnam	1

Total	
Far East	1314
Share in percent	13,07
No. of countries/ economies	12

Australia / New Zealand	
	Dec. 2004
Australia	163
New Zealand	2

Total	
Australia/New Zealand	165
Share in percent	1,64
No. of countries/ economies	2

ISO 16949 certifications	
World results	Dec. 2004
World total	10 056
World growth	
No. of countries/economies	62

# ISO 13485:2003 certifications worldwide

### At the end of 2004

Africa / West Asia	
	Dec. 2004
India	9
Israel	54
Morocco	2
Pakistan	4
Seychelles	2
South Africa	3
Swaziland	24

Total	
Africa/West Asia	98
Share in percent	3,19
No. of countries/ economies	7

Central and South America	Dec. 2004
A .:	DCC. 2004
Argentina	5
Brazil	5
Puerto Rico	10
Uruguay	3

Total	
Central and South America	23
Share in percent	0,75
No. of countries/ economies	4

North America*	
	Dec. 2004
Canada*	57
Mexico*	23
USA*	770

Total	
North America *	850
Share in percent	27,71
No. of countries/ economies	3

<sup>\*</sup> Data received from Quality Systems Update

Europe	
Luiope	Dec. 2004
Austria	70
Belgium	13
Bulgaria	2
Croatia	1
Czech Republic	18
Denmark	10
Estonia	2
Finland	6
France	147
Germany	177
Greece	5
Hungary	15
Iceland	2
Ireland	19
Italy	638

Europe	Dec. 2004
Latvia	1
Netherlands	15
Norway	12
Poland	21
Portugal	1
Russian Federation	2
Serbia and Montenegro	1
Slovakia	3
Slovenia	3
Spain	1
Sweden	67
Switzerland	161
Turkey	12
United Kingdom	548

Total	
Europe	1 973
Share in percent	64,31
No. of countries/ economies	29

Far East	
	Dec. 2004
China	14
Hong Kong, China	3
Chinese Taipei	16
Indonesia	1
Japan	21
Korea, Republic of	28
Malaysia	4
Nepal	1
Philippines	10
Singapore	17
Thailand	3

Australia /	
New Zealand	Dec. 2004
Australia	4
New Zealand	2

Total	
Australia/New Zealand	6
Share in percent	0,2
No. of countries	2

Total		
Far East	118	
Share in percent	3,85	
No. of countries/ economies	11	

ISO 13485:2003 certifications		
World results	Dec. 2004	
World total	3 068	
World growth		
No. of countries/economies	56	

# How The ISO Survey is carried out

The ISO Survey has been carried out 14 times since the first in January 1993. The survey is now published on an annual basis by ISO Central Secretariat (ISO/CS). The data is provided by a variety of sources including ISO national member institutes, accreditation and certification bodies and certification databases. ISO/CS would like to thank all sources for their participation and assistance.

ISO/CS is well aware that the certification bodies which contribute data are commercial competitions. For this reason, the data supplied is not connected in the survey to the certification body which supplied it in order to avoid it being used by competitors as "business intelligence". The data is treated by ISO/CS in strict confidentiality and requests to identify market share, or "the top 10 certification bodies in the world", are turned down.

The responsiveness of certification bodies to requests for data varies. Not all submit data. Among those who do, the quantity and quality varies. In some cases, estimates have to be made. From time to time, mistakes come to light and the figures are adjusted accordingly in subsequent surveys.

In addition, the responsibility for collecting figures within different countries and organizations may be transferred and with it, the methods for calculating totals. As a result, country totals given in previous surveys may be revised retrospectively and totals may not, therefore, always tally up from one survey to another.

A number of joint assessment arrangements are in operation by certification bodies. These are taken into account when known, but a small degree of double counting no doubt occurs. Again, when double counting becomes apparent, totals are adjusted.

As pointed out above, the survey is carried out once a year and ISO/CS does not maintain a database or running total which would allow it to meet requests for updates between publications of the survey.

It should be noted too that the data supplied is of the numbers of certificates – the individual organizations which hold certificates are not identified. Therefore, ISO/CS cannot satisfy requests for lists of certified organizations in a particular country or business sector.

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ISBN 92-67-10410-1 © ISO, 2005-09/1800 Printed in Switzerland