

10 Steps to Save ISO 9001

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Christopher Paris

VP Operations

Oxebridge Quality Resources

PART ONE:

HARD DATA, HARSH REALITY



The Players

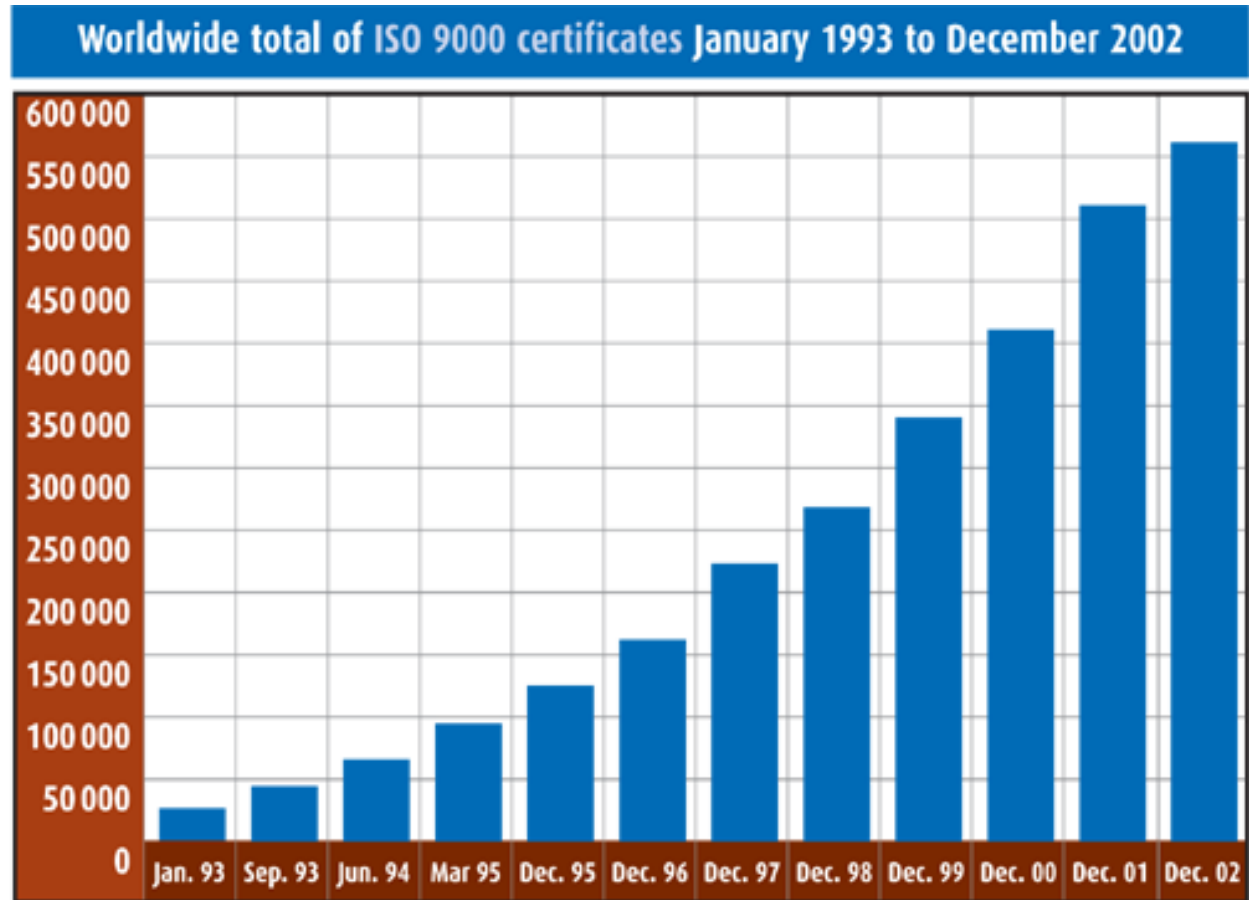


ISO 9001 in Crisis?

- NOT YET.
- There is more potential now for ISO 9001 growth than ever before.
- There is, however, huge room for improvement.

The Data, 2002

- Total # of certificates has increased
- Number of countries has increased
- Share by region has begun to equilibrate



Source: *The ISO Survey of ISO 9000 and ISO 14000 Certificates, 12th Cycle 2002*
Graphic © 2003 ISO

Sound Bites

- ISO Secretary-General Alan Bryden:

"... it is certainly gratifying to note another growth year for certification to ISO's management system standards that underlines their increasing importance and use worldwide for the development and promotion of quality and environmental protection, not only in industry, but also in services and the public sector."

Sound Bites

- American National Standards Institute (ANSI)

*“Certification to ISO 9000 and ISO 14000
Family of Standards Exhibits Strong Growth.”*

Sound Bites

RAB President Robert H. King, Jr.:

“Contrary to what alarmists with an interest in fueling controversy might say, ISO 9001 is still on the rise--and with good reason.”

... “Predictions of negative growth in ISO 9001 registrations seem misplaced.”

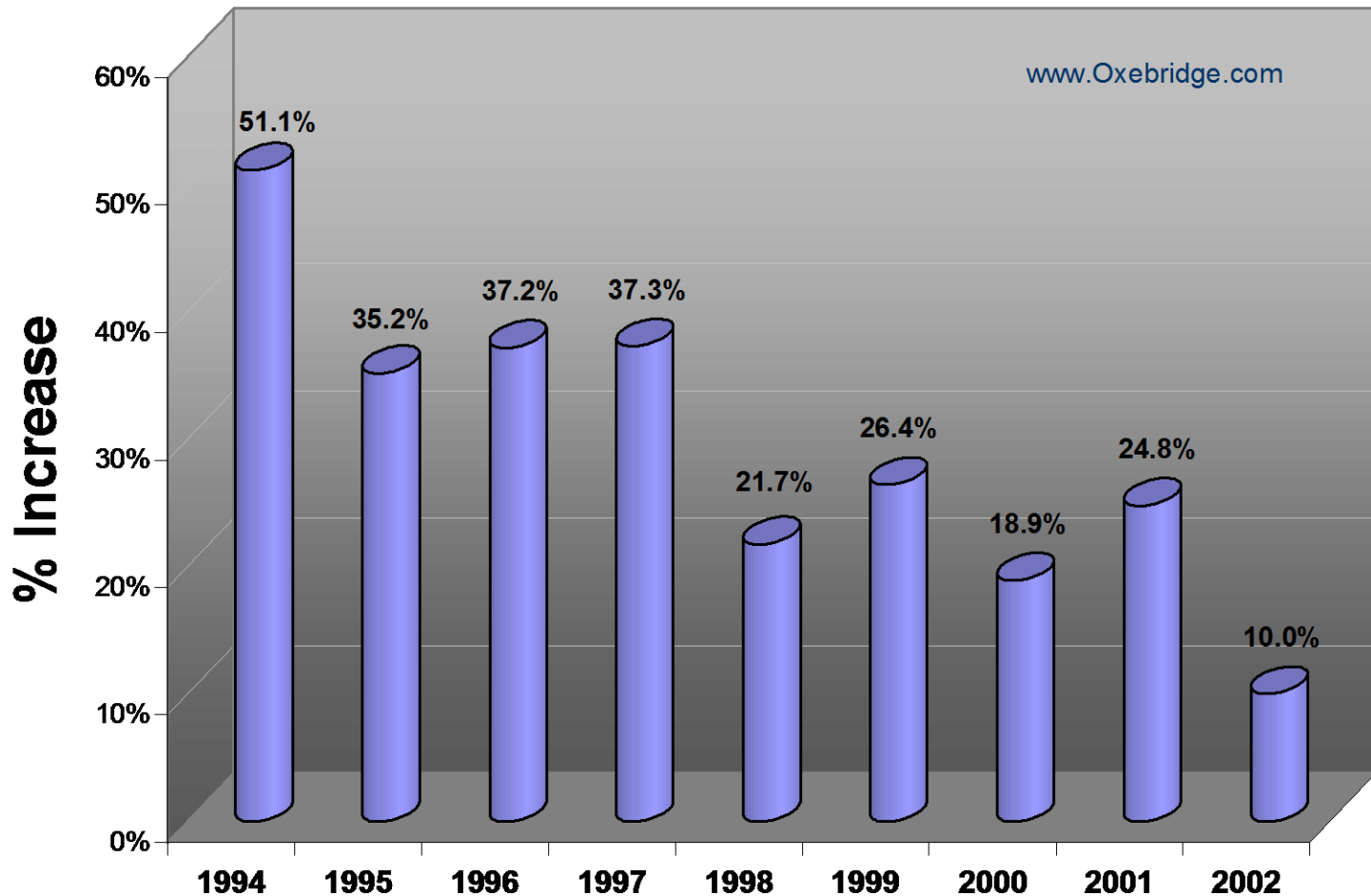
Source: *Quality Digest*, November 2003

http://www.qualitydigest.com/nov03/articles/04_article.shtml

The trouble is... it's not true.

ISO 9001 Registration Growth: Worldwide

Source: *The ISO Survey Twelfth Cycle 2002*, www.iso.ch



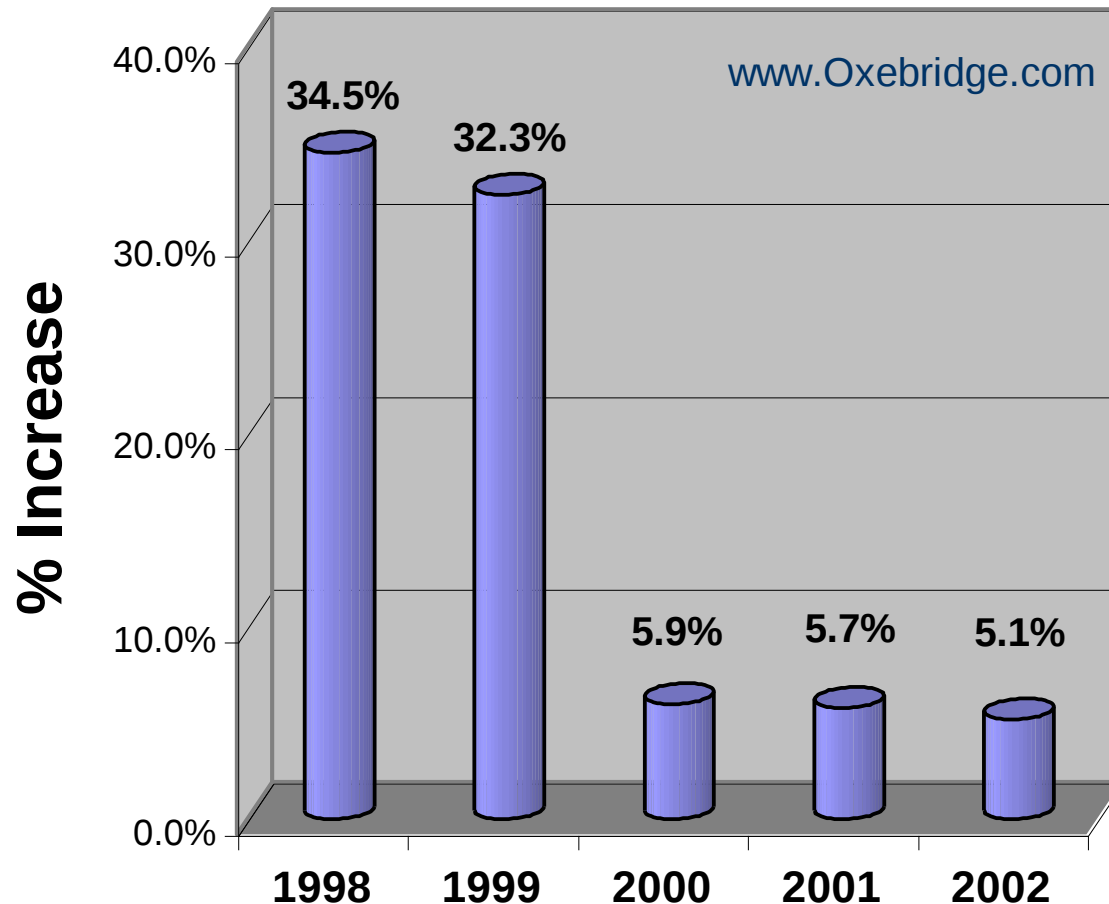
Reality

- Growth of ISO 9001 certificates is at the ***lowest it has ever been*** in sixteen years.
- 2002's growth rate was ***less than 1/3*** that of the average since 1994.
- Growth from 2001 to 2002 ***was cut in half***.

The U.S. Picture

ISO 9001 Registration Growth: US Only

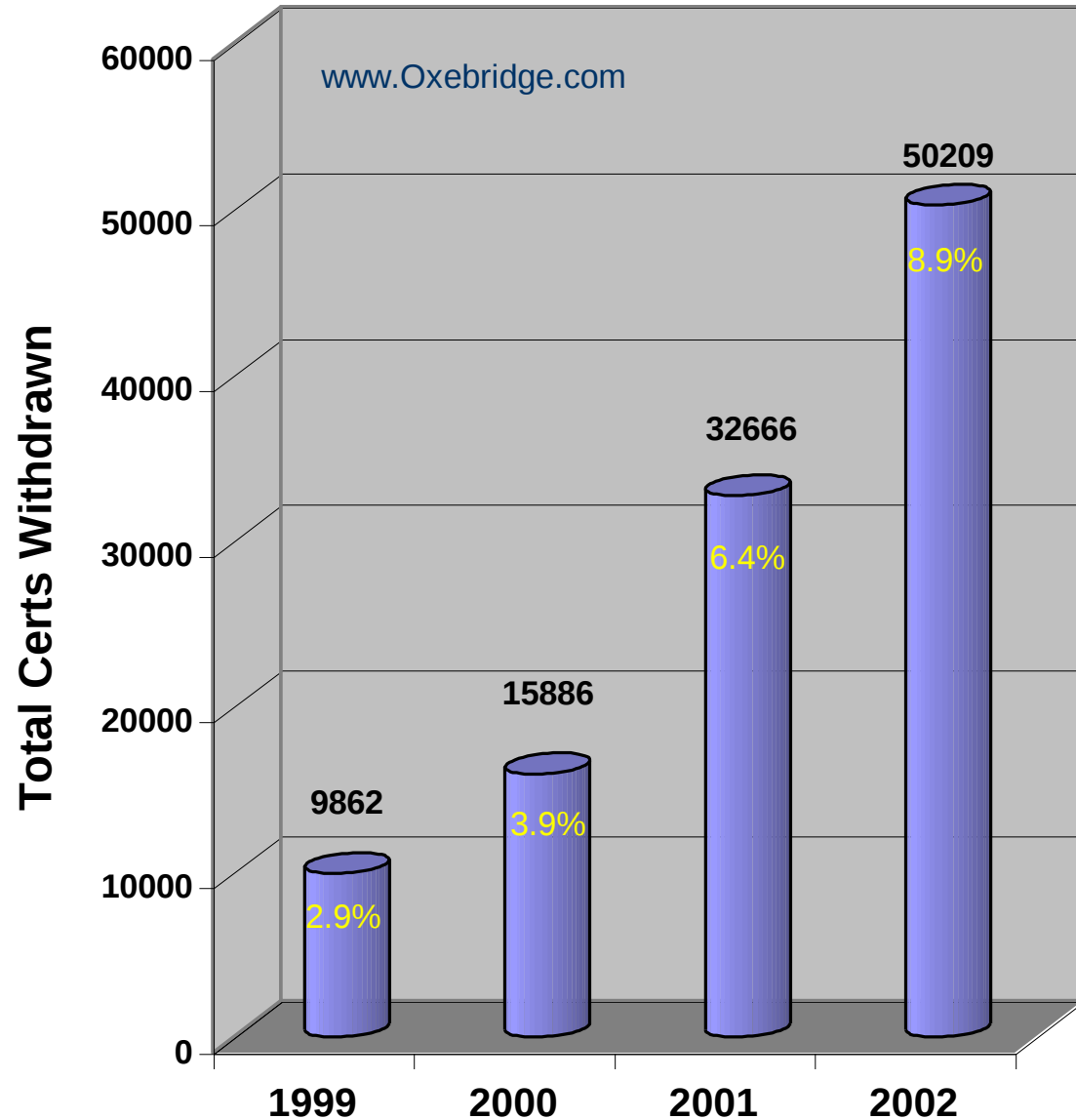
Source: *The ISO Survey Twelfth Cycle 2002*, www.iso.ch



Withdrawals

ISO 9001 Certificates Withdrawn

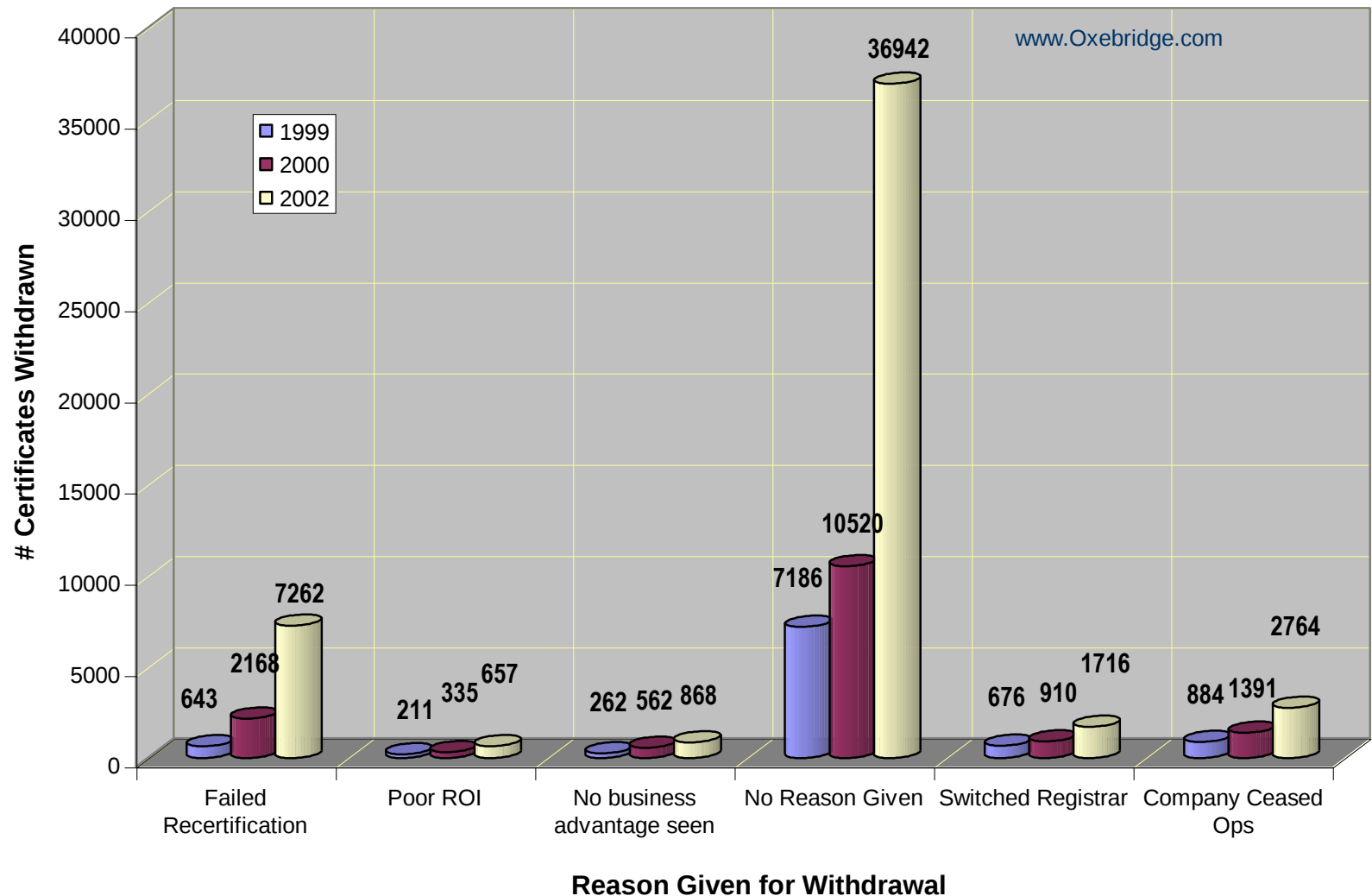
Source: *The ISO Survey 9th, 10th, 11th, 12th Cycles*



Reasons for Withdrawal

ISO 9001 Certificates Withdrawn, By Reason, 1999, 2000 & 2002

Source: *The ISO Survey 9th, 10th, 12th Cycles*



Sound Bitten

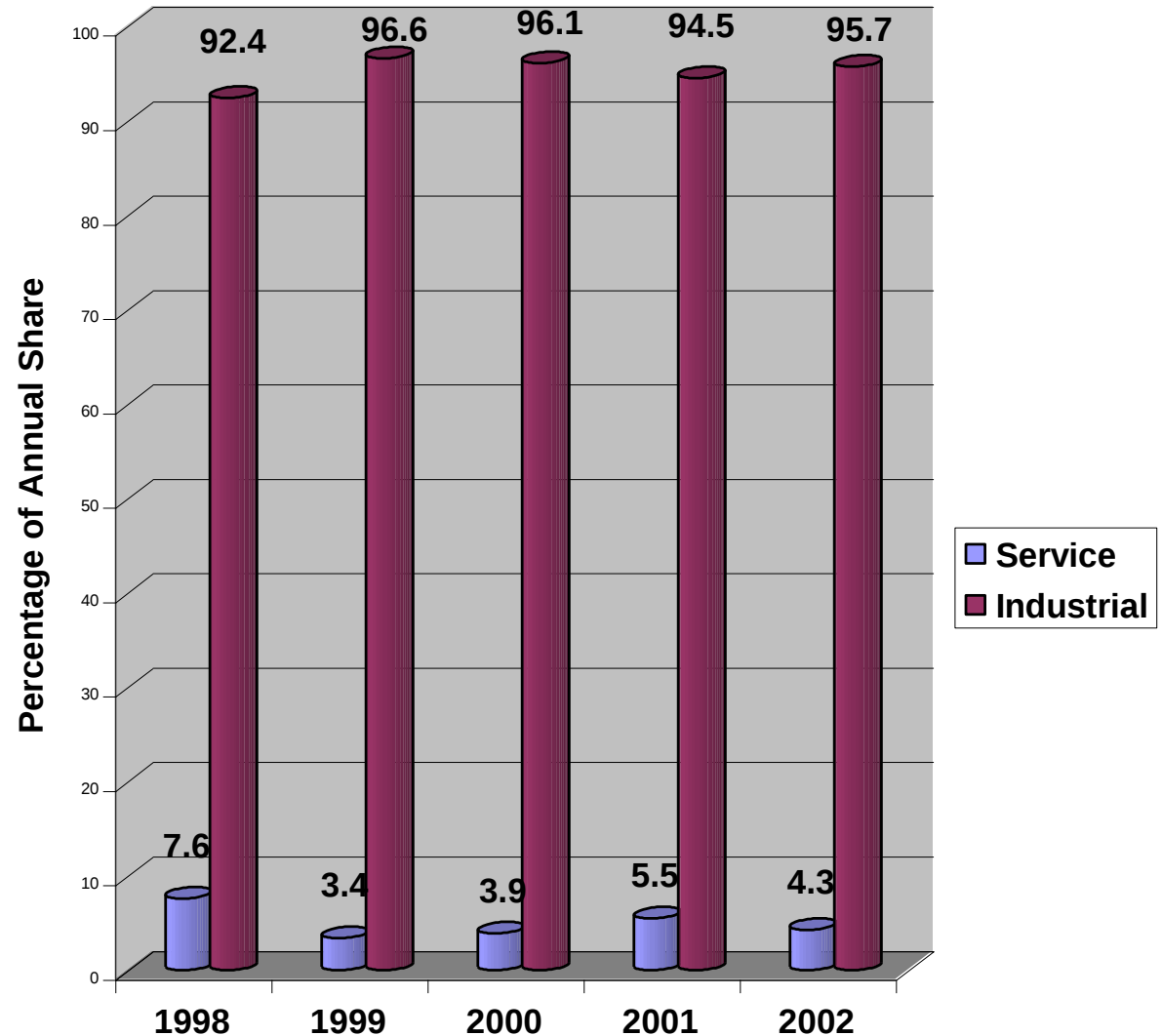
ISO Secretary-General Alan Bryden:

*"... it is certainly gratifying to note another growth year for certification to ISO's management system standards that underlines **their increasing importance** and use worldwide for the development and promotion of quality and environmental protection, **not only in industry, but also in services and the public sector.**"*

Not true! Service... still alienated

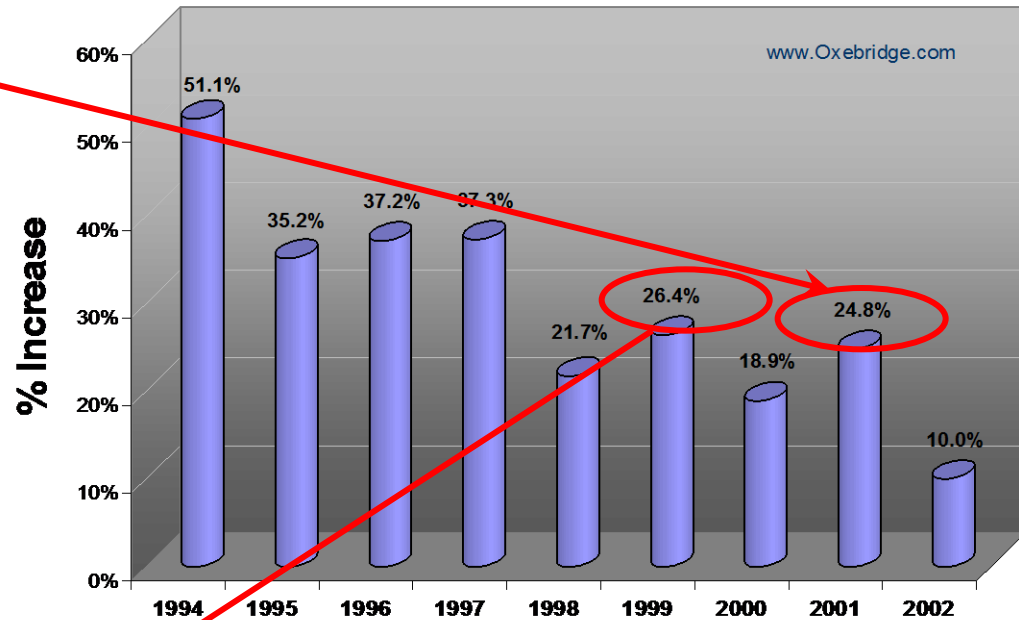
ISO 9001 Share by Sector

Source: *The ISO Survey Twelfth Cycle 2002*



According to ANSI, 24.3 > 26.4

"[2001] was an increase of nearly 25% since last year, making it the highest increase recorded by far in the survey's history."



Source: http://www.ansi.org/news_publications/newsstory.aspx?menuid=7&articleid=36

3 Key findings on ISO 9000

3.1 A country-by-country breakdown is shown in Annex A and you will find the key findings highlighted below.

3.2 The success of the ISO 9000 family of standards is still growing, and the number of countries where ISO 9000 is being implemented has increased. Up to the end of December 1999, at least 343 643 ISO 9000 certificates had been awarded in 150 countries worldwide. This is an increase of 71 796 ISO 9000 certificates (26,40%) over the end of December 1998, when the total stood at 271 847 for 141 countries.

3.3 The country breakdown remains unchanged in this edition, with the exception of the data for Curacao and

Sound Bitten

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“Contrary to what ***alarmists with an interest in fueling controversy*** might say, ISO 9001 is still on the rise--and with good reason.”

... ***“Predictions of negative growth in ISO 9001 registrations seem misplaced.”***

... “Media predictions of the decline and imminent failure of ISO 9000 help to fuel confusion. One unfortunate result is that ***some parties have exploited these misunderstandings to gain competitive advantage.***”

Source: *Quality Digest*, November 2003

http://www.qualitydigest.com/nov03/articles/04_article.shtml

Sound Bitten

ISO Management Systems editor Roger Frost:

“It seems more often to be the case that decisions are taken on the basis of beliefs – if not prejudices – or hunches (a hunch being a type of belief), or self-interest, or expediency, and then facts are selected to support the decision.”

“The fact is that ISO 9000 certification continues to rise. ...the number of certificates worldwide grew ... an increase of 101,985 certificates (+ 24,96%), the highest growth recorded in all 11 cycles of the survey carried out since January 1993. To persist in the face of such data in announcing the demise of ISO 9000 is a good example of the strength of belief – if not something else – over fact.”

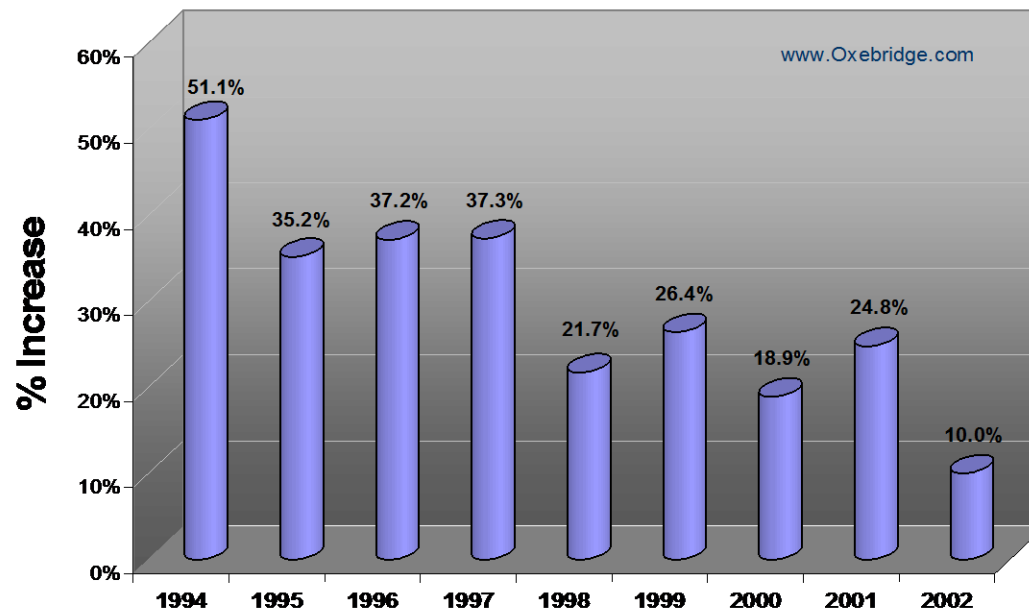
Statistician, Pareto Thyself

- Such statements are irresponsible and misleading.
- Negative growth is a reality, not a marketing tool.
- ISO 9001 promotes continual improvement by way of data analysis, but ISO itself does not employ these techniques, nor does it require any of the subordinate bodies to do so, regarding this data.

A test – is this okay?

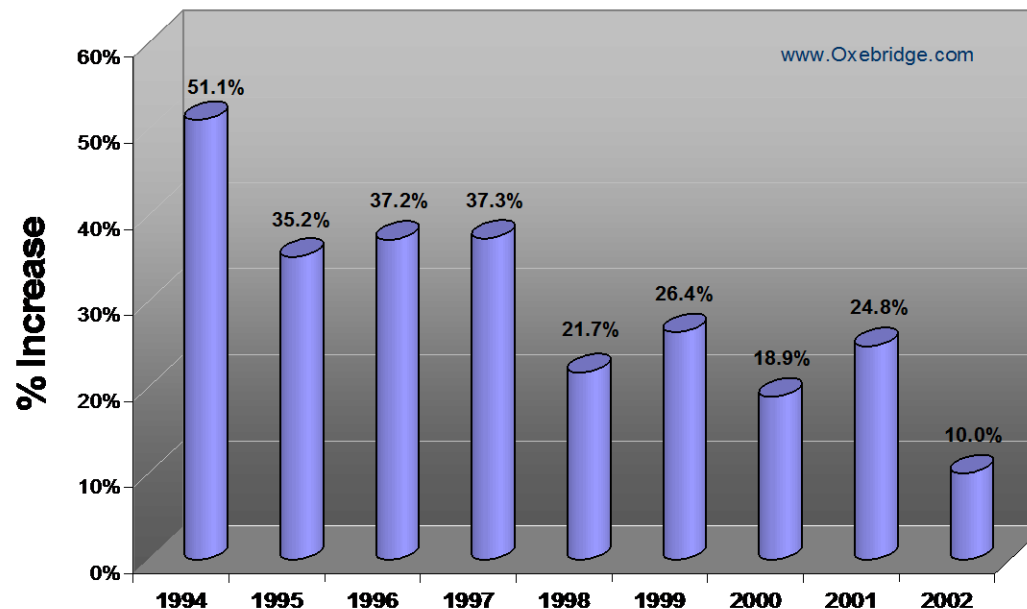
ISO 9001 Registration Growth: Worldwide

Source: *The ISO Survey Twelfth Cycle 2002*, www.iso.ch



A test – what about now?

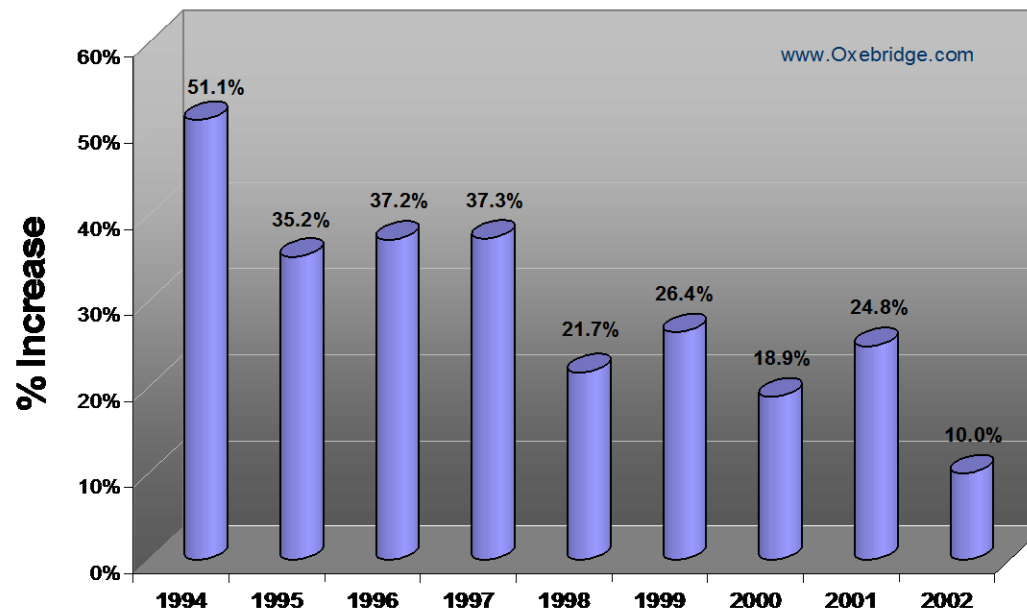
GENERAL MOTORS CORP. Annual Growth, 1994 - 2002



A test – and this?

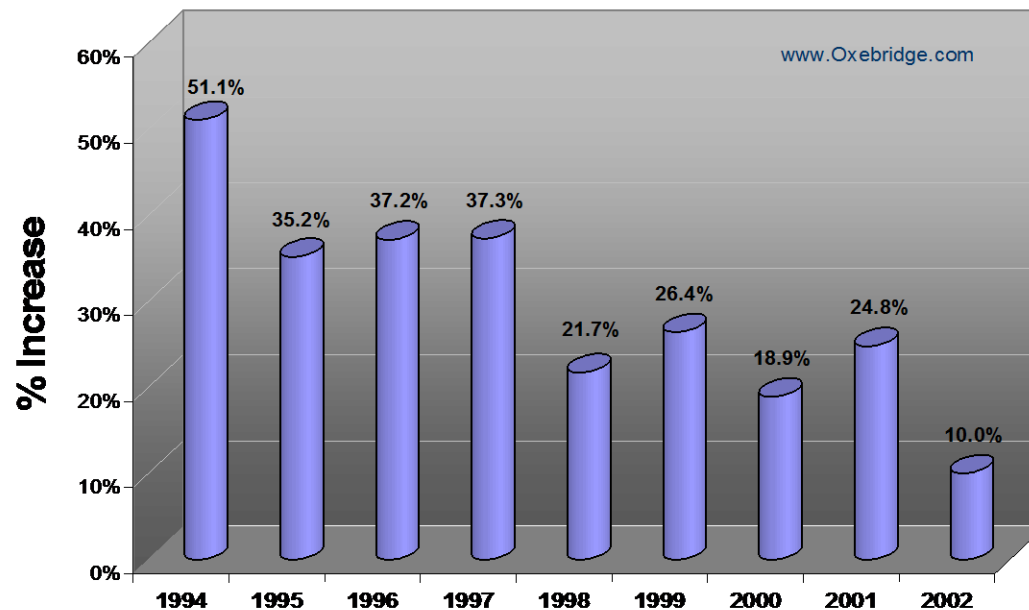
JANUS MUTUAL FUND PERFORMANCE

Annual returns



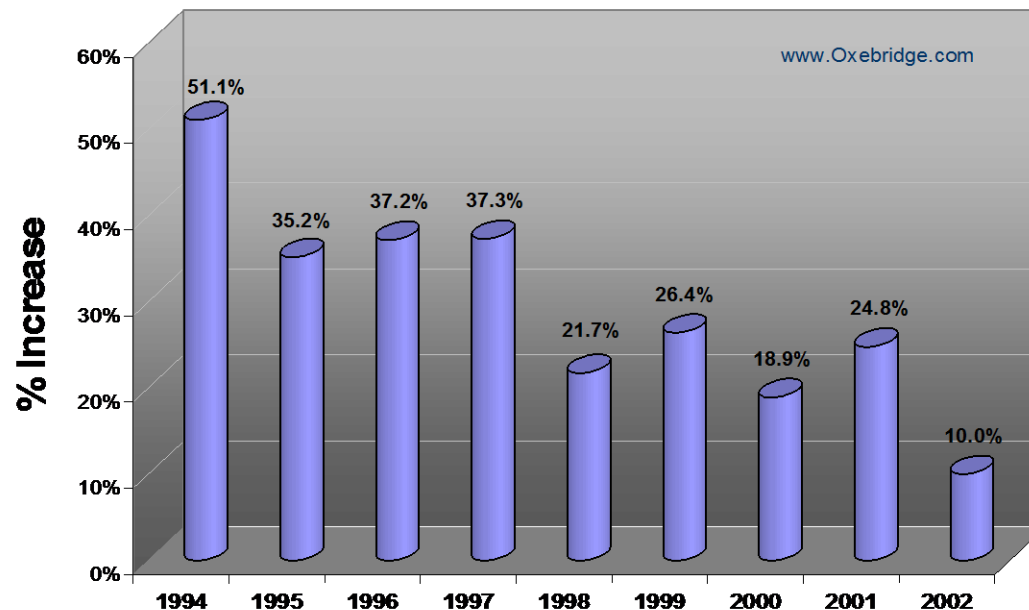
A test

UNITED STATES GROSS DOMESTIC PRODUCT (GDP), 1994 - 2002



A test – how about now?

YOUR SALARY



Possible Reasons

ISO 9001:2000 a turn-off?

- Too soon to tell
- Unlikely, based on current feedback

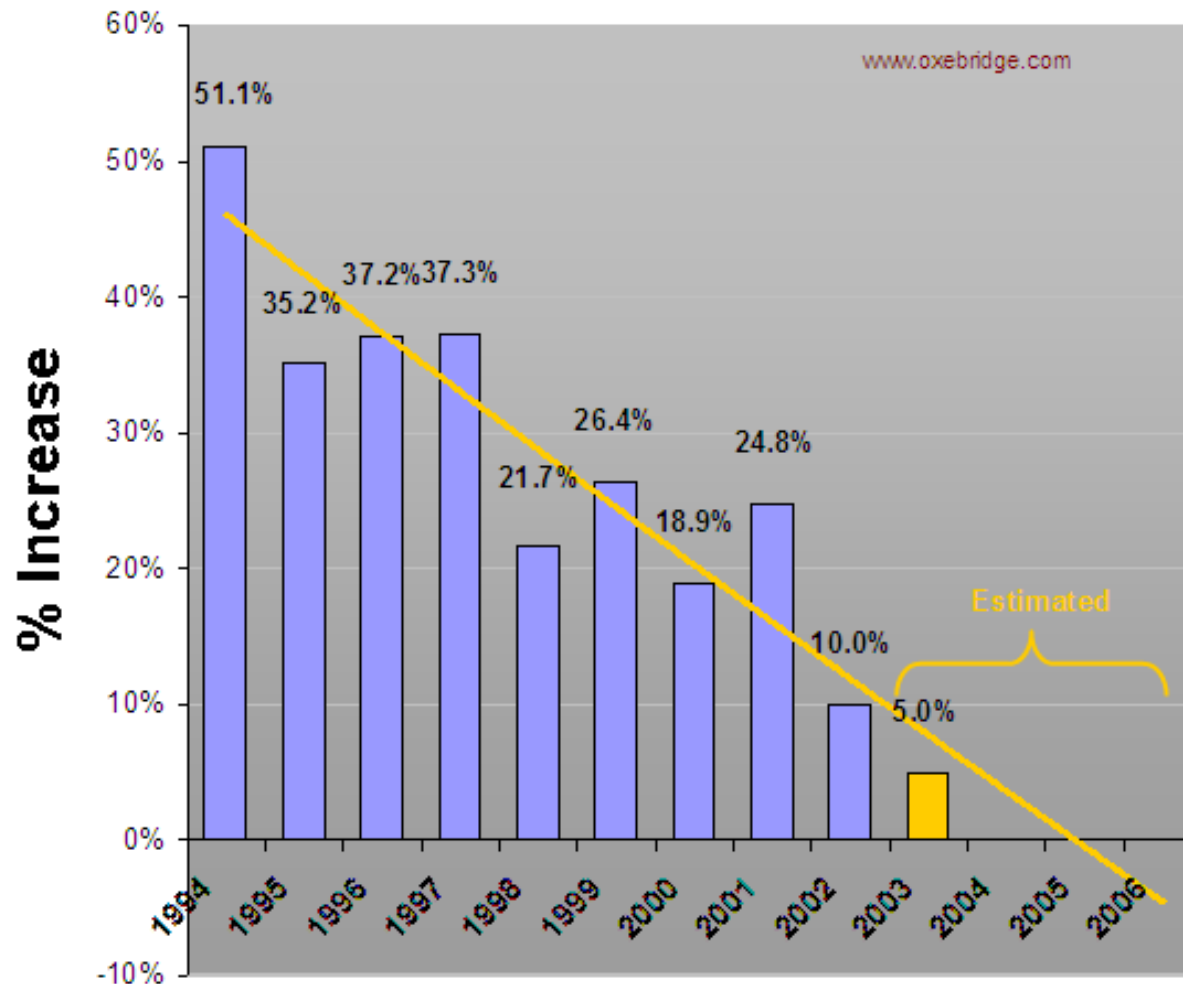
BUT:

- Registrars are reporting about 5-10% of certified. Companies are letting certification lapse.

Predicted Growth

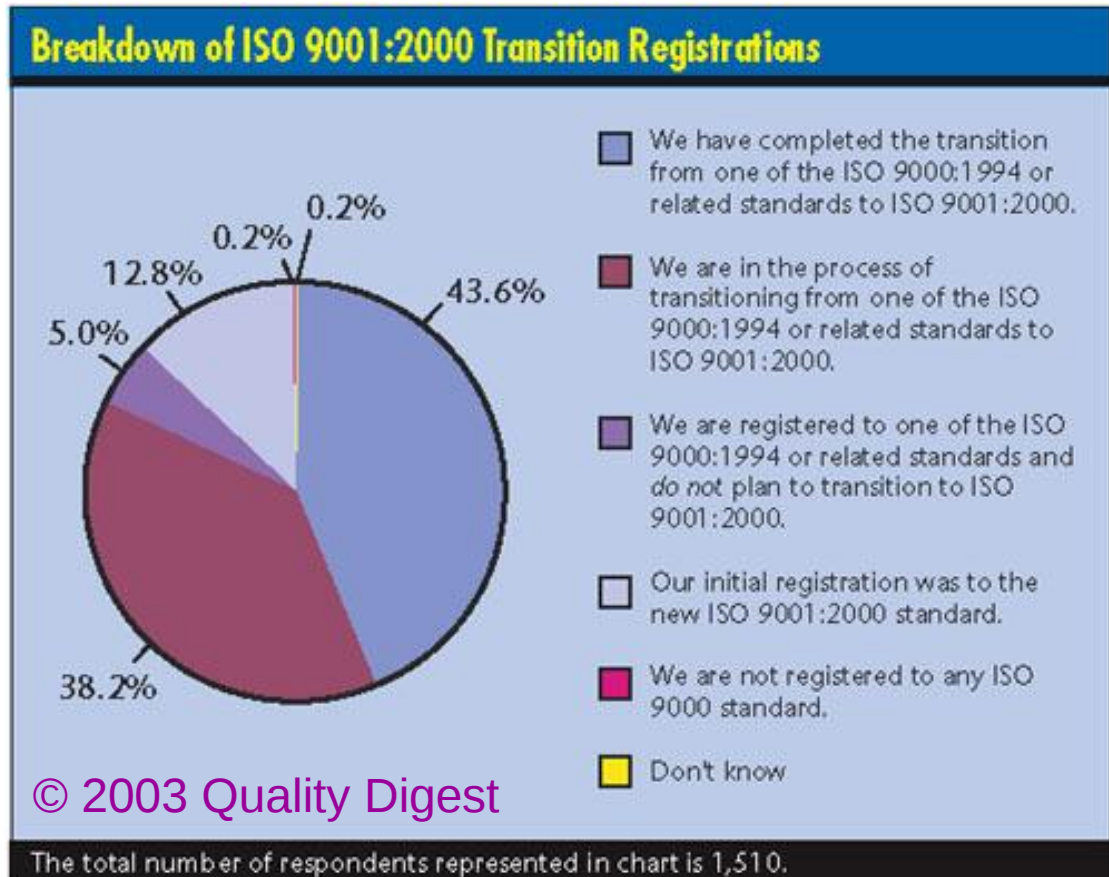
ISO 9001 Registration Growth: Worldwide

Source: *The ISO Survey: 9th, 10th, 11th & 12th Cycles*, www.iso.ch



Possible Reasons

Alternate
standards
to blame?



Possible Reasons

TC 176 goal: *"work towards minimizing the proliferation of standards in the field of quality management developed externally to TC 176 using a joint and cooperative approach with the ISO/IEC TCs and other bodies involved."*

Source: <http://www.tc176.org/About176.asp>

Alternate Standards

- ISO/TS 29001: oil and natural gas industry
- ISO/TS 16949: automotive manufacturing
- AS9100: aerospace manufacturing
- TL 9000: telecommunications
- ISO 13485: medical device
- ISO 10006: program management services

Possible Reasons

Registrant Pool Depleted?

- US 2000 census: over **5.6 million** unique companies in operation.
- ISO: total # US companies registered to ISO 9001 in 2002 was about 39,000, or **only 0.69% of potential companies.**

Summary of Problems

- TC 176 has failed in reducing the proliferation of standards.
- ISO 9001 has failed to make inroads into the service sector.
- Growth of certification is at an all-time low, and the 16 year trend is downward.
- The number of clients “dropping” ISO 9001 is at an all time high.
- Sixteen years later, ISO 9001 still hasn’t been received well enough in the US.

Summary of Problems

- No one is analyzing the data constructively. In fact, they are intentionally analyzing the results for a ***predetermined outcome***.
- Too much political spin has been put on the data, ***jeopardizing credibility***.

The Potential is Huge

- Partly due to the past sixteen years, the potential “market” for ISO 9001 is massive.
- The ISO 9001:2000 standard is a marked improvement over previous versions, and can be implemented in a variety of industries.
- “ISO 9000” is entering US consumer culture, albeit slowly.

PART TWO:

ROLL UP YOUR SLEEVES



Is ISO 9000 Worth Saving?

Positive impact on:

- Commerce
 - Increases competition
 - Improves quality
 - Streamlines operations
- Politics
 - Eases international trade
 - Sets minimum quality expectations

Is ISO 9000 Worth Saving?

Positive impact on:

- Society
 - Improves wages
 - Quality of products increases consumer confidence
 - Decreases distrust in corporations
- Jobs
- Health and safety

Three Core Requirements

- TRANSPARENCY
- CREDIBILITY
- IMPROVEMENT

TRANSPARENCY

- Arcane authoring process
- Closed door attitude
- Careerist influence

CREDIBILITY

- Certification scheme is based on trust.
- Credibility in the certificate must be improved
- Conflicts of interest abound

IMPROVEMENT

- ISO 9001:2000 made improvements, but too little too late.
- Service is still alienated
- Satellite standards abound
- Too many question the need for ISO 9001

Step # 1: Force more transparency on the ISO 9001 authoring process.

- Publish records of TC176 sessions, including any TAG sessions.
- Solicit opinions worldwide *prior* to DIS stage
- Publish the results of feedback polling throughout the process.

Step # 2: Open TC 176

- Publish how TC 176 members are selected
- Require a minimum set of credentials for membership
- Require membership to be statistically representative of potential ISO 9001 pool
- Open enrollment period, ***elections through ASQ***
- Publish a regularly-updated roster of delegates, with credentials and contact information.
- ANSI to cover expenses for (US TAG) TC 176'ers

Step # 3: Disallow Profiteering by TC 176 Members

- 5 year moratorium for all TC176 members that prohibits:
 - Any for-fee or for-profit speaking engagements
 - Any publication of activities on TC176 where funds go to the member
- But allows:
 - Speaking without fee or profit
 - Publication of articles in non-profit publications with the intent of public education

Step # 4: Disallow Registrar Consulting

- No “training” services... ***AT ALL.***
- No publication of “guidance documents,” or “implementation guides.”
- Enforce rules through the IAF MLA.
- ISO Guide 62 to clearly define “consulting” as ***including*** “training” or “guidance,” etc.
- Transfer the privilege of offering training courses to other bodies, such as ASQ.
- Impose sanctions on registration companies that show preference to any one consulting company.

Step # 5: ISO Guide 62 to Include Relationship Rules

- Clearer rules for interaction between:
 - Registrars and consultants
 - Registrars and contract employees
 - Registrars and client companies

Step # 6: Improve Auditor Training by Improving ISO 19011

- Overhaul ISO 19011 to include:
 - Auditing process
 - Auditing AS A process
 - Minimum behavioral requirements
 - Emphasis on objective evidence
- “Lead Assessor” status granted when compliance to ISO 19011 is shown, not compliance to an arbitrary curriculum established by accreditation bodies.

Step # 7: IAF to Publish an Official Interpretation Guideline on ISO 9001

- Must occur at IAF level, so all MLA signatories are held to it.
- Must be published widely, and made available to registrants.
- Again, rule out per-registrar interpretation publications.

Step # 8: Develop a Central ISO 9001 Registry

- Return the significance of being “registered”
- Registry must be updated biweekly, at a minimum.
- Lists companies that are registered, withdrawn, etc.
- Lists accredited registrars.
- Operated by ISO, based on information made a requirement of registrars.

Step # 9: ASQ Must Prioritize ISO 9001

- Focus on ISO 9001, instead of specific tools --- and potential money-makers --- as Six Sigma.
- Resist jumping on fad bandwagons.

Labeled the "Great 8+2," the 2001-02 ASQ fiscal year initiatives were as follows:

- E-Business Strategy
- Creating Value
- Member Awareness Initiative
- Member Unit Excellence
- Global Initiative
- Target Market Initiative
- Leveraging Six Sigma
- Measurement System
- AQP
- Staff Satisfaction

ASQ: GO PUBLIC!

- Educate the general public on ISO 9000

PART THREE:

STEP # 10: RE-IMAGINE ISO 9001



The Solution: A Management Maturity Model

- Like the SEI's Capability Maturity Model (CMM), ISO 9001 must adopt a graduated structure that allows for improvement in the maturity of the quality system of registrants.



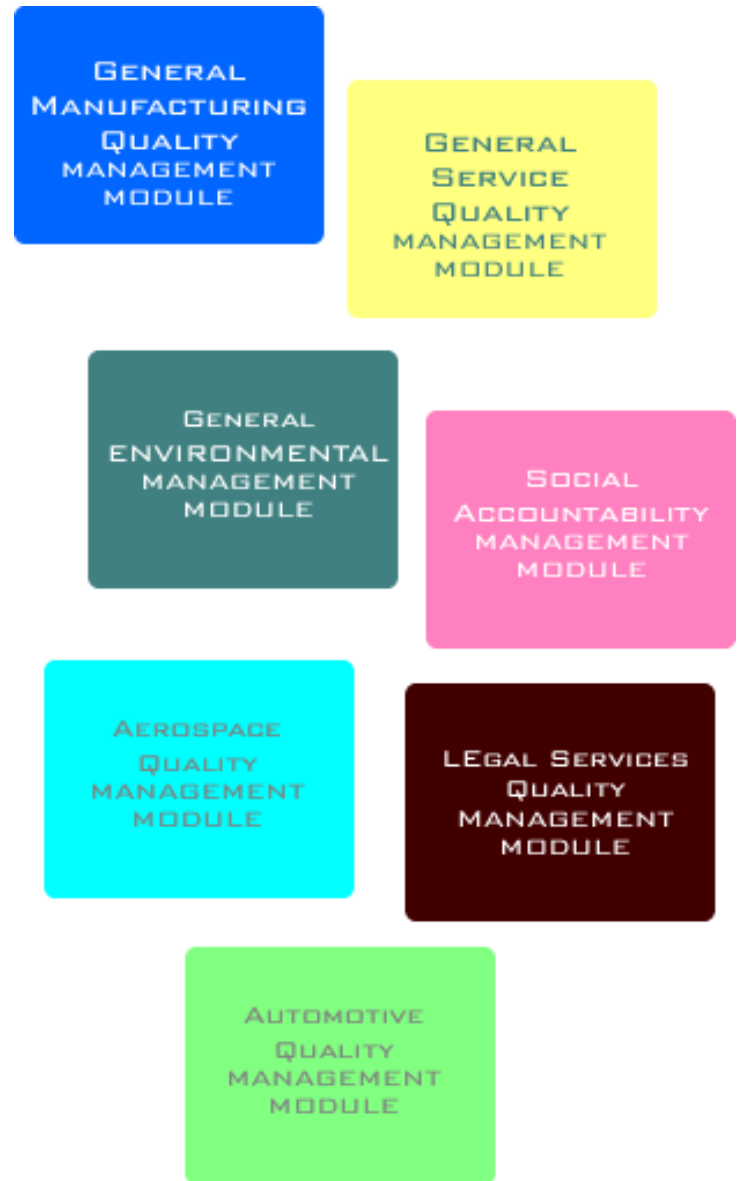
Goals of the M³ Initiative

- 1.) To revised the structure of ISO 9001 --- not the content --- to allow for better implementation in all companies, of all industries
- 2.) To allow for better integration with other standards.
- 3.) To allow new standards to be developed within the M3 framework, instead of in competition with it.

The M³ Schema

Modular Requirements.

Standards for different management concepts (e.g., "quality management," "environmental management") or sector-specific requirements (e.g., "automotive," "legal") shall be developed as modules that are subject to a standardized format.



The M³ Schema

Everything under M3 occurs on ***two maturity levels***. Level One is for companies with less mature systems, and Level Two is for companies with very mature systems.

For each level, a set of basic ISO 9001 rules would form the “Core Requirements” of any company being certified under the M3 Schema.

Additional levels could be added if desired, for such maturity levels as Baldrige-style “world class”

Management System Core Requirements: Level 1

- Management Responsibilities
- Policies
- Resource Management
- Evidence Controls
- Planning
- Verifications
- Corrective Action Measures
- Third Party Confirmations
- Internal Communication

Management System Core Requirements: Level 2

- Process Mapping
- Data Analysis
- Preventive Action Measures
- First Party Confirmations
- External Communication
- Satisfaction
- Continuous Improvement

Level 3 – Baldrige?

Management System
Core Requirements:
Level 3

BALDRIDGE AWARD
CRITERIA

Example of AS9100 Under the M³

Management System
Core Requirements:
Level 1

Management Responsibilities
Policies
Resource Management
Evidence Controls
Planning
Verifications
Corrective Action Measures
Third Party Confirmations
Internal Communication



AEROSPACE
QUALITY
MANAGEMENT
MODULE

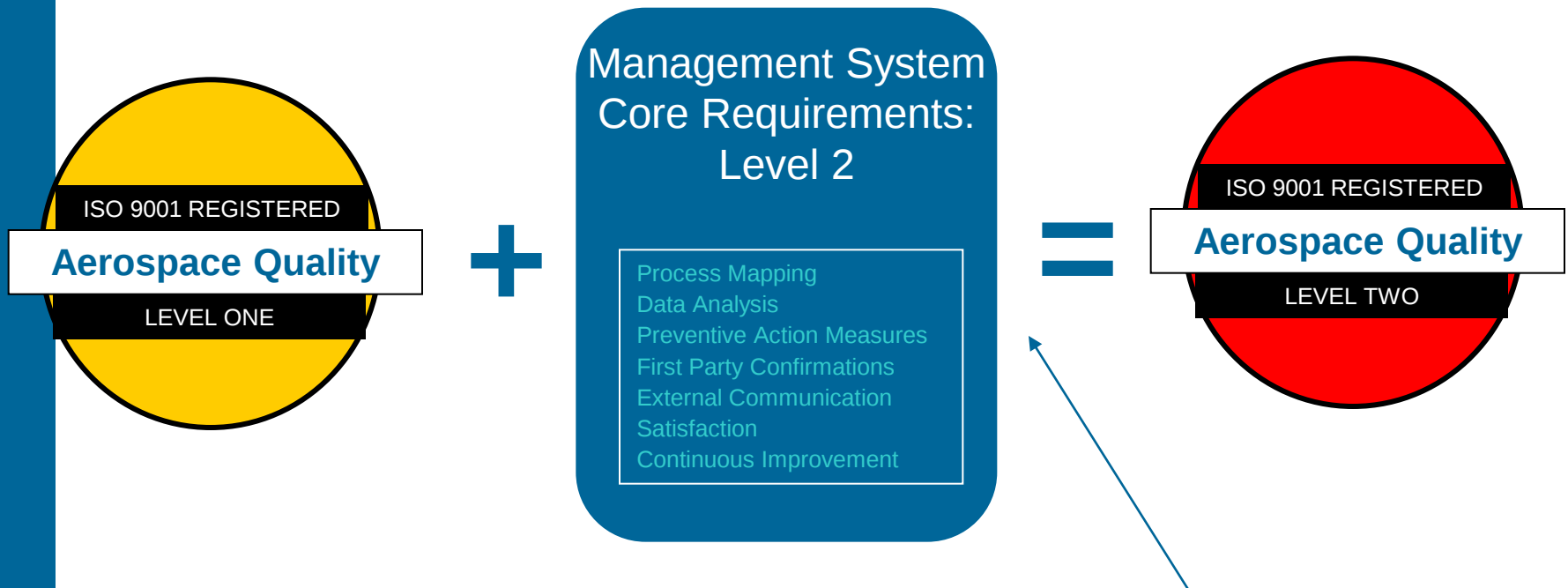


ISO 9001 REGISTERED

Aerospace Quality

LEVEL ONE

Example of AS9100 Under the M³



If Aerospace community desired, additional “more mature” requirements could also be added here.

Under M³:

- ALL management systems are certified to ISO 9001
- Additional certification “modules” are added on, without affecting universal, core requirements
- The maturity of a company can be assessed.
- Customers can require certain maturity levels of suppliers.

Under M³:

- Revisions to any part of the M3 schema do not affect the others.
- Additional maturity levels can be added as industry elects.
- Failure to maintain compliance at a higher level means reduction in level, not withdrawal of certificate.

CONCLUSION:

THE FUTURE OF ISO 9001



2005

- The ISO 9001:2000 standard will be revisited in 2005
- Discussion on these 10 Points must begin now
- ASQ is the best forum for this activity

Leadership Must Lead

The current “leadership of ISO 9001” must:

- LISTEN
- LEARN
- LEAD

Refusals on any of these three doom the standard

For more information

www.oxebridge.com