



# Watson's Notes

Innovative Solutions  
for difficult problems

Published by:

**ISI** INVESTIGATIVE  
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INCORPORATED

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## **"You have recently been in Afghanistan, I perceive"**

*With these words was born the most famous team in detective fiction; Sherlock Holmes and his trusted comrade and biographer, Dr. John H. Watson.*

*In the spirit of Watson, who chronicled the exploits of Holmes, we have created this newsletter named "Watson's Notes".*

*In the pages of "Watson's Notes", modern day scribes document the discoveries, unusual cases and other news*

*of Investigative Science Incorporated, our scientific consulting firm in Burlington, Ontario, Canada.*

*Like Holmes, ISI is retained to conduct investigations into a range of seemingly intractable scientific problems. Also like Holmes, the ISI staff are first class scientists and masters of deduction. We hope you enjoy reading of our exploits through our own "Watson's Notes".*

*Please contact us if you have comments, and please read on.*

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### GETTING THE MOST OUT OF YOUR AUDITS

Over the course of our 5+ years of ISO 9001 registration, Investigative Science Incorporated has undergone 13 external audits conducted by our registrars, and have conducted more than 30 internal audits on our own operations, as well as numerous audits for our clients. From this experience, we have gleaned some hints on how to turn the process from an event to be endured, into a helpful learning experience.

#### Maximizing Your "Audit Credit"

We have a love-hate relationship with our external auditors. "Audit Credit" is a term we coined after one of those irritating days, when the auditor failed to appreciate the beauty of a system we had recently implemented, because our

records were not in an audit-friendly format. Since then we have learned several ways to solve this problem. Here are a few examples:

1. During audits of our management reviews, we would periodically be written up for failing to meet the quarterly commitments specified in our QAM, despite the fact that management routinely held meetings on the fly to solve problems as they arose. The latter were not documented in our standard management review format, but in our workbooks. The auditors assumed that quarterly management reviews meant that in any calendar year there should be records of four formal management reviews. We were not getting audit credit for our interim meetings.

To solve the problem, we changed the wording in our QA manual from "quarterly" to "approximately quarterly" and issued management with notebooks entitled

# ELEMENTARY MY

DEAR

WATSON

Sherlock Holmes and Dr. Watson go on a camping trip, set up their tent, and fall asleep. Some hours later, Holmes wakes his faithful friend.

"Watson, look up at the sky and tell me what you see."

Watson replies, "I see millions of stars."

"What does that tell you?"

Watson ponders a minute. "Astronomically speaking, it tells me that there are millions of galaxies and potentially billions of planets.

Astrologically, it tells me that Saturn is in Leo.

Timewise, it appears to be approximately a quarter past three.

Theologically, it's evident the Lord is all powerful and we are small and insignificant.

Meteorologically, it seems we will have a beautiful day tomorrow. What does it tell you?"

Holmes is silent for a moment, then speaks.

"Watson, you idiot, someone has stolen our tent."

"Management Review Book", to document the results of interim meetings. The auditors loved it.

There is also an added bonus to this approach. That is, if you actually miss a scheduled management review or need to defer it a month or so, the documentation of all of your interim mini-meetings provides audit friendly proof that management involvement is ongoing.

2. At ISI, we recognize that small problems, detected and documented using our non-conformance system, are often indicators of a larger potential problem lurking underneath. We have many times fixed the small problem and addressed the larger lurking problem, documenting it as long term corrective action on the same NCR form.

Unfortunately, our auditors don't recognize this as preventive action, because the actions were triggered by an actual problem. Does this sound familiar?

In order to get audit credit for preventive actions, it is necessary to break them out into an actual problem and a potential problem. We use a second NCR to address the potential component. It's the only way we have found to get recognition of our preventive action efforts triggered by the occurrence of a small actual problem.

## Avoid Needless Modifications to Your System

In the early days, we routinely responded to most non-conformances and audit findings with a modification to our Quality Management System. We naturally assumed that the system had failed and needed correction. One-day, while reading the definitions of "correction" and "corrective action" in ISO Standard 9000:2000, we realized that changes to the system, or corrective action, were only required when the root

cause of a problem was the system itself. All problems need "correction", that is, something done to eliminate a detected non-conformity, but only a small percentage were the result of anything wrong with the system itself.

One of our auditors suggested finding the root cause by asking the question "why" five times.

## Audits as Training Tools

Audits can be a great training ground for new staff or for experienced staff who are learning a new skill. Here's how we use them.

For a new staff member learning a new skill, a lot can be gained by inviting them to join the internal audit team to audit the process they are learning. This approach has two benefits: first, they must learn the written aspects of the procedure inside out in order to conduct the audit, and second, they have a chance to review the procedure with an experienced staff member in a structured framework.

In cases where an experienced staff member is having difficulty grasping the importance or significance of a procedure, they can be designated as the contact person for that procedure during an external audit. It's a bit of a dirty trick, but it works. Anyone, who has sweated through an external audit knowing you are on shaky ground, is generally not eager to repeat the experience.

## Getting the Most Out of Your Auditors

External auditors generally are not allowed to offer a consultancy service while they are employed by your registrar. Most however, are more than willing to help with specific problems so long as the questions don't put them in conflict with their prime directive: "Thou

shalt not consult". Don't forget that a typical auditor has seen dozens, if not hundreds, of examples of the implementation of the standard, and probably has a workable idea for you.

We have found that questions like "How else have you seen this done?" or "How do other companies handle this?" often lead to a useful response. Questions like "How do you suggest I do that?" or "What do you want me to do here?" may result in the "Sorry, I'm not allowed to consult" response.

### **In Summary**

We don't think anyone actually enjoys being audited. It is, however, a key component of our ISO 9000 systems and since we must do them, why not get the most out of the experience. The tips in this article are intended to help you do just that. Drop us a line if you have other tips that you would like to share with our readers.

## **ISO 9001:2000 – WHAT'S NEW**

As most of our readers are aware, the new ISO 9001:2000 Standard is now out, and will replace the 1994 version. By December 2003, all ISO 9000-registered firms will need to be 9001:2000 compliant. In this article, we review what's new in the 2000 standard.

### **No more 9002 or 9003**

The first difference you will notice is that the ISO 9002 and ISO 9003 standards are no longer. ISO 9003 is gone already and 9002 (same as 9001, but without the design component) will disappear with the 1994 standard in December 2003.

Under the new rules, companies will no longer be able to opt out of the design element, unless they actually don't do design or can demonstrate that excluding the element has no effect on the product. Under the 1994 rules, the choice of 9001 (with design) or 9002 (without design) was somewhat discretionary. For example, many laboratories which design and develop in-house methods for use on customer samples, have chosen to be registered to the 9002 standard.

### **More customer satisfaction data will be required**

Under new section 8.2.1, companies will now need to collect information to determine whether customers feel the product or service met their needs. This is a new requirement, not in the 1994 standard. Some firms are using questionnaires, others are using

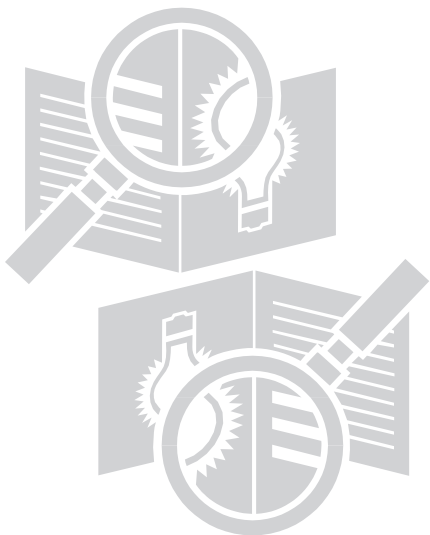
business indicators such as the frequency of repeat clients, some are using face to face meetings to collect this information. Be prepared to expend considerable energy getting a true sense of whether your customers are happy with you.

### **Must now document sequence and interaction of processes**

The need to define and document the processes needed for the Quality Management System is included in section 4.1 of the new standard. This was not formally required under the 1994 version, although some consideration had to be given to the issue in order to develop the QMS. The processes that the new standard refers to include management activities and processes for provision of resources, product realization and measurement. The sequence and interaction must be determined according to the new standard. Flow charts are a convenient way to demonstrate this. A table format may also work in some cases.

### **More monitoring of how your quality system is performing**

The 9001:2000 standard requires much more monitoring of the output of key systems such as non-conformance, internal audits, management reviews, in order to determine whether they achieve the expected results. For example, the number and type of non-conformances raised in-house can be monitored in order to identify where the problem areas are, or whether earlier corrective action was successful. Auditors have suggested to us that target levels, or "comfort"



levels should be set for each type of non-conformance. As well, it has been recommended that "percent achieved" values be assigned to policy objectives during management review, so that we can determine where to focus our efforts. No, we are not making this up!

### **What about the paperwork?**

Our auditors have cheerfully informed us that there are fewer documentation requirements in the 9001:2000 standard compared to 9001:1994. As most of the key elements (non-conformances, corrective action, management review, training, internal audit) are still present, but more monitoring of customer satisfaction and the quality system itself is required, we have yet to discover how the promised reduction in paperwork comes about. We are sure that three or four years of experience with the new standard, it will become clear, but for now, don't believe it!

### **Continual improvement**

The 9001:2000 standard now contains section 8.5.1 requiring that companies continually improve the effectiveness of their quality systems. Note that it does not say, "improve your product"!

We find that auditors have been nudging us toward this concept for several years, although there is no specific requirement in the 1994 standard to do so.

### **Revision control**

The 9001:2000 standard contains basically 5 large sections, replacing the 20 elements of the 9001:1994 system. This makes

revision control more difficult than before. Rather than using only 5 separate revision control sections, corresponding to the 5 major sections, we found it more convenient to use 31 revision control sections, corresponding to logical divisions among the minor sections. For example, we have broken out non-conformance and internal audit into their own sections as they were under our 1994 system. So much for the 9001:2000 standard being simpler!

### **Overall**

On the plus side, the wording is more friendly to the service industry compared to the 1994 version, which was clearly aimed at manufacturers. In fact, in the wording of the standard, "product" is interchangeable with "service".

Any claimed reductions in paperwork or effort though are not obvious to this writer. In fact, some of the new sections require considerable extra work. While some of the sections of your present 1994 version system can be directly used to meet the 2000 standard, others will need to be written from scratch. In particular, we found the new section 8.0: Measurement, Analysis and Improvement required a major rewrite.

The new standard is clearly more customer focussed than the 1994 version. In principle, this is a good thing, but will probably present the most difficult challenges in meeting the requirements of the 9001:2000 version.

## **ISI OFFERS NEW INTERNAL AUDIT SERVICE**

Are you looking for help with your ISO 9000 internal audits? If so, ISI's trained and experienced staff can conduct your internal audits for you, or manage your audits using your own staff as auditors.

Imagine an ISO 9001-registered internal auditor!

- We can provide the arms length independence you require.
- You can free up the valuable time of your staff to conduct your business.
- Your staff can learn the principles of internal auditing on the job while taking part in a professionally managed audit team.
- Complete audit report with back-up documentation provided

ISI is a Canadian consulting firm that has been registered to ISO 9001 since 1996. Our business is quality and, because we are registered ourselves, our work is continually checked by our registrars.

Does the idea fly with the registrars? Yes, ISO 9000:2000 (3.9.1) states that internal audits may be "conducted by, or on behalf of, the organization". Feel free to inquire with your own registrar. Then call ISI for more information.

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