

Part One

Before the Audit

In this part of the book, I give you all the background information you need on the decisions you must make and the procedures you must follow prior to your first audit.

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1 The Changes: Issue 5 to Issue 6

If you are new to the Global Standard, then this chapter may be only of passing interest and you may want to skip to Chapter 2. However, for those who have been involved before or if you are just interested in the history, here is a look at the key headline changes in the Standard from Issue 5 to Issue 6.

Reasons for Change

There were four big issues with the stakeholders for the review this time around:

- (1) Firstly, it had been felt for some time that too great a proportion of the audit time was being spent by the Auditor looking at documents and becoming trapped in the office when they should be where the action is: in the factory. Indeed, some were saying that audits were not picking up issues of housekeeping or building and plant fabric because not enough time was spent in production. Furthermore, it was felt that potential weak points in production such as shift changes and product changes should be audited, and that the Auditor should aim to be present at those times.
- (2) Secondly, there was disappointment in the low uptake of the unannounced audit scheme, which for Issue 5 attracted less than 100. They were looking for a change to encourage more to try unannounced but thankfully drew back from making it compulsory.
- (3) Thirdly, there was a desire to see more new companies going for the Standard, especially in developing countries, which might be put off by some of the Requirements.
- (4) Fourthly, there was a desire to nail the terms ‘high care’ and ‘high risk’ and bring better understanding of these terms.

Other changes were made this time as a result of the wide consultation with CBs and interested parties in industry.

Two-Part Auditing: Increased Focus on GMP

The challenge was how to allow the Auditor to spend more time in the factory. The answer was to have an overall aim of audit time being split 50:50 between production areas and document review in the office and to achieve this by both the review itself and the resulting format of the Standard and by training. *In my opinion, this is the most significant change for Issue 6 and will result in a different feel to the audit for all involved.*

To help with this, we have now a Standard where the Requirements are divided by colour coding to indicate to the Auditor that which should be audited in each place. In general, GMP aspects will be audited during the site tour (see Chapter 10).

There is also a significant aspect of training in this idea, and the official training courses for Auditors will now include emphasis on spending more time interviewing staff, collecting evidence in the factory, observing product change times and so on (see Chapter 10).

Vertical Audits

To add to this change, we now have more emphasis on what we term as a vertical audit. This will be done in parallel to the traceability challenge carried out by the Auditor. It will be a document review but will take in all the process records related to the traceability exercise being done. Furthermore, it will include all related issues starting with raw material specifications and supplier approval right through to dispatch and finished product release, taking in any relevant training records etc. on the way. In this way, this will be a complete vertical slice through what you do and a valuable way for the Auditor to sample much of your documentation.

Unannounced Audits

We now have two options. The first is mostly as before with some changes, mostly relating to timing and dating. The new Option 2 means that you can opt for an audit that is part unannounced, part announced. The unannounced part will be a GMP audit of your site, mostly spent in the factory. The second part will be *announced* and take place before the due date as usual. It is hoped that this will encourage more to choose an unannounced option. I am interested in your views, so email me (ronkill@micron2.com).

Enrolment Programme

Essentially, this idea is to encourage new starters to join the scheme with no fear of 'failure'. There will be no stigma of failing to achieve a grade but rather a score given that can indicate progress towards certification. As a consequence, this is now the entry point for all companies into the Standard and we will no longer apply the term 'initial audit'. However, a company may stay in the Enrolment Programme for as long as necessary. One incidental result is that there is now no 90-day grace for resolving a

major nonconformity at an initial audit. The thinking being that if you cannot correct a nonconformity in 28 days, you will be un-certificated and remain in the Enrolment Programme or rather the continual development phase (see Chapter 5).

The Protocol itself is also now in two parts, the second of which details the options for the format of audit now available to companies.

High Care and High Risk

New definitions of these terms have been written into the Standard but on the basis of areas or zones in the factory, not the product. The Standard now has an Appendix (2) of five pages covering all levels of risk as applied to the factory areas. There are also some new and rewritten Requirements as a consequence (see Chapter 7).

New Report Format

A new style of report has been developed, with less detail on each clause but a better summarising of each section. There is also more useful detail in the front pages of the report on the company (see Chapter 18). It is hoped that this will be more readable and it will certainly be better for the Auditor to write.

Other Protocol Changes

No more Grade D

The term 'No Grade' will be used instead in the appropriate grade box on the report and 'Not certificated' in the audit result field as before.

No factored goods

Only products made at the site can be included in your scope.

Root cause

For every nonconformity, you will not only have to submit evidence of your immediate corrective action, but analysis of the root cause of any issue and plans to address it. This includes nonconformities from your standard audit and from any internal issues identified. For more details on root cause analysis, see Chapters 4 and 19.

Head office audits and multiple locations

There is now a system for separate audits of head office functions, where appropriate. There are also new requirements for the auditing of multiple sites and off-site storage areas (see Chapter 16).

Changes to Requirements

There are numerous changes to the Requirements.

Many clauses have been merged, so there appears to be fewer than last time. The total is down from 325 to 284, including SOIs. Do not be fooled; there is plenty of material there. One of the reasons for merging some of the old clauses was to even out the weighting of clauses. A consequence is to make it more appropriate for a minor nonconformity to be given when a certain issue is not complied with.

Some clauses have fallen by the wayside and in one case an entire subject: *customer focus* has been removed, for example. No one was sorry to see that one go.

Many clauses have been extended to be more prescriptive and easier to understand. Thus, more clauses have lists of specific points to meet.

Other changes include greater emphasis on prerequisite programmes in HACCP and more reference to agency workers in personnel.

Statements of Intent

SOIs have been revised and almost all have been rewritten so that they truly are objectives and not specific requirements in their own right.

Note: Appendix 2 of this book gives details on where all the Requirements of Issue 5 have gone and Appendix 3 gives new clauses for Issue 6.