

9K08 7.3.3 Design and development output

9K15 8.3.5 Design and development outputs

Big Changes

1. Removed: the requirement that outputs must be approved before release. Impact: nil.
2. Added: Outputs must be
 - a. Adequate for subsequent processes for provision of products/services, and
 - b. Specify characteristics essential for their intended purpose.
 - c. In other words, output must be complete - must include sufficient information and data to facilitate production and/or service delivery.
 - d. Impact: potentially significant.

Minor Changes

1. Output must include or reference monitoring and measurement requirements, "as appropriate." Impact: potentially significant.
2. Added: Records of design output must be kept. In the real world, design output (drawings, bills of material, instructions, programs, whatever) are retained for subsequent use, so requiring records seems a bit redundant. Impact: Nil.

What To Do

If your design processes have been thorough and robust already, nothing in these changes will be that big a deal. Just verify that your outputs take into account:

- a. Sufficient production / service delivery information;
- b. Fitness for intended purpose (especially where voice of the customer is involved)
- c. Monitoring and measuring requirements (specifications, tolerances, acceptance criteria).

30 Design: review, verification, validation

9K08 7.3.4 Design and development review

9K08 7.3.5 Design and development verification

9K08 7.3.6 Design and development validation

9K15 8.3.4 Design and development controls

Big Changes

1. 9K15 consolidated three sections from 9K08 and, in the process, shortened the requirements and made them less strict.
2. Previously, design validation had to consider "requirements for intended use, where known." The weasel term "where known" is now gone. So, design validation must always examine the capability of resulting product to meet requirements for intended use. Impact: