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Not all ISO 9001:2000 certifications are alike

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Section 7.3 Design and Development
What does this mean for purchasers of custom electronic assemblies?

To reduce costs and focus on core capabilities, companies today routinely outsource the manufacturing of electronic modules and adapters. However, when companies require the modification of a standard module or a custom adapter design, suddenly you are outsourcing more than manufacturing; you are also outsourcing some or all of the electronic module design. How do you choose a supplier for both the design and production of your critical electronics?

Your supplier selection checklist for outsourcing production probably includes ISO 9001:2000 certification. (This ISO version is a relatively new standard; manufacturers who were certified under the previous ISO 9001:1994 standard had a deadline of December 15, 2003 to make the transition.) What a prospective supplier's ISO 9001:2000 certification tells you is that the company, at a minimum, has a documented and controlled process for consistent manufacturing.

ISO 9001:2000 ALLOWS SUPPLIERS TO EXCLUDE DESIGN AND DEVELOPMENT REQUIREMENTS.

The new set of ISO requirements is different from ISO 9001:1994 in that it allows for different levels of certification: meaning a manufacturer may choose to exclude part or all of Section 7 Product Realization* from their quality management system. Eliminating some sections does not preclude

ISO 9001:2000 certification, but it does change the scope of the manufacturer's certification.

One of the subsections included in Section 7.3 of the ISO 9001:2000 standard delineates the quality process for product design and development. However, this section is one that is often excluded in the scope of manufacturers' ISO certifications.

To understand the precise scope of a potential supplier's ISO 9001:2000 certification, you need to read carefully the certification document signed by the organization's ISO registrar. As an example, the scope of Ironwood Electronics' ISO 9001:2000 certification is described this way: "Design and Manufacture of Prototype and Production Adapters and High Speed Sockets Accommodating IC Packages for the Microelectronics Industry." This statement clearly says that Ironwood's quality system extends to both its design and manufacturing processes.

WHY SHOULD ELECTRONIC ASSEMBLY PURCHASERS CARE ABOUT AN ISO 9001 CERTIFIED DESIGN PROCESS?

The ISO 9001:2000 standard states as a general requirement that, "The supplier must establish and maintain documented procedures to control and verify the design of a product to ensure that the requirements are met." In other words,

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*Section 7 Product Realization includes the following: 7.1 Planning of product realization; 7.2 Customer-related processes; 7.3 Design and development; 7.4 Purchasing; 7.5 Production and service provision; 7.6 Control of monitoring and measuring devices.

the value of extending a quality system to the design and development process, ensures the component module or adapter produced, functions as specified and can be manufactured successfully in the volumes required.

The supplier whose quality system meets the design requirements of ISO 9001:2000's Section 7.3 can promise that their design process is the same every time, that the process contains reviews and plans at verification and validation points, and that prototype-build and production problems will be minimized or eliminated. To sum it up in two words, the reason to look for supplier design certification is "reduced risk." In any product development and production process, you want to reduce your risk and maximize your likelihood of success. The

Design Input

Fig. A

This sample supplier flow chart describes the steps and feedback loops for the design input phase.

ISO 9001:2000 design certification option helps to reduce the risks of misunderstood product requirements, uncertain development phases, unclear assignments of responsibility, and the related costs in both time and dollars.

WHAT DOES SECTION 7.3 DESIGN AND DEVELOPMENT REQUIRE?

The first subsection of the ISO 9001:2000 Design and Development section deals with planning the design and development process. To comply with this section's requirements, the supplier must document the design and development stages, design reviews, and the verification and validation to be completed at each stage. The supplier must also make clear the responsibility and authority of functional groups in the organization.

Once a plan is in place, a supplier is ready to take on the actual phases of design and development: Design Input, Design Output, Review, Verification, Validation, and Control of Design Changes. Here is a review of each of these phases in the design quality process:
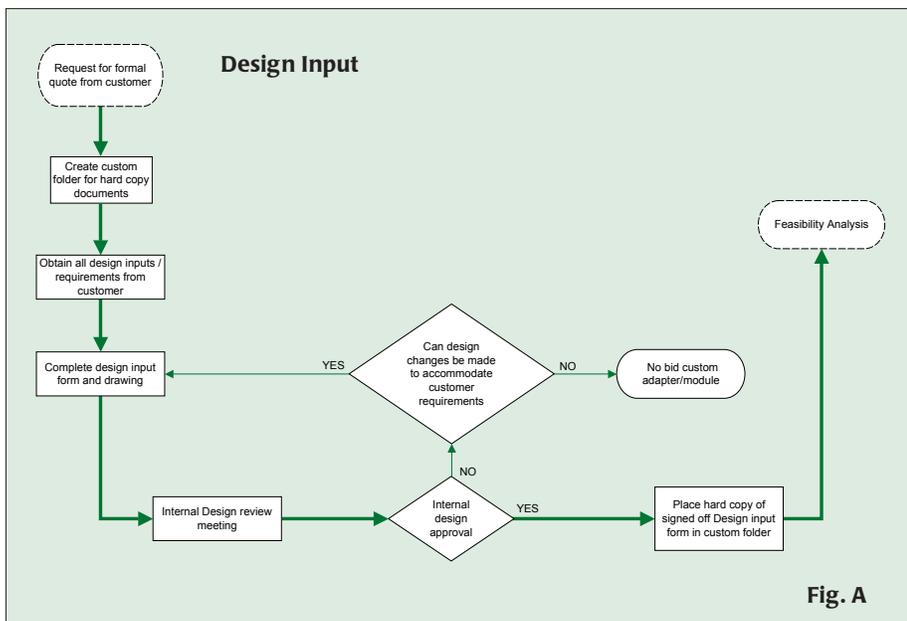
A. Design Input
When it comes to design and development planning, ISO 9001:2000 requires a documented process that defines who will do what in the design of a new product. That means identifying the organizational interfaces. This step addresses a big problem in many large organizations: new products are often driven by one function without consulting other groups in the organization, often groups that may have valuable knowledge to contribute. For example, the goal is to keep the new-product resources from Sales or Product Marketing, in close contact with Engineering, Manufacturing and Quality. All groups are enabled to work together to define requirements and examine relevant factors such as health, safety, environmental regulations, as well as market research, industry practices, and past experience.

The ISO auditors look for a full review of these criteria, as well as a discussion of any areas where information is ambiguous or incomplete. Figure A is a sample supplier

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flow chart that spells out the steps and feedback loops for this phase.

B. Design Output

The result of the *Design Input* activity is a set of design documents that fully describe the desired design relative to the identified inputs. This is where your requirements are turned into specifications, drawings, etc. The design documentation should be in quantifiable terms that can be verified as development proceeds. For instance, purchasing, manufacturing, and customer service functions must have enough information from this set of documents to do their jobs.
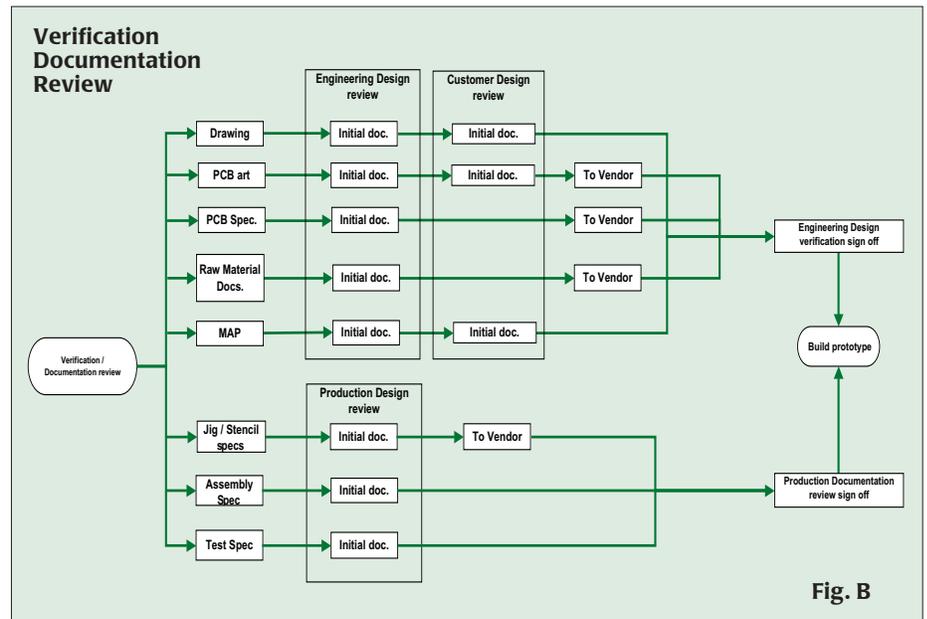
C. Design Review

ISO 9001:2000 design certification requires the supplier to keep records of periodic reviews of design progress, and that all relevant groups and functions are included in the process. The tasks at this point are to decide whether the design will meet the requirements, to identify problems, and to propose necessary actions.

D. Design Verification

When the design review is complete, the next step is design verification where the supplier and customer representatives come together, as laid out in the planning arrangements, to ensure that the product design outputs match the input requirements. This process is illustrated in Figure B. Upon completion, the verification documentation is signed off. If there are problems, then the process goes back to reviewing requirements.

After verification, a limited number of prototypes can be built from the documentation. Prototype production usually involves setting up a number of production processes along with specialized tooling — activities that may reveal potential manufacturing problems. When issues arise in this phase, they need to be looked at carefully to determine if the same issues will

Fig. B

Once the verification documents have been reviewed (as illustrated above) and both the customer and vendor have signed off on them prototypes can be built.

appear during volume production.

Rapid prototyping, or quick turn on initial samples for test, is very important to the success of many projects. A major criteria, then, is for your outsourcing partner to have the experience and track record of successfully fabricating functional prototypes in a matter of weeks (and perhaps days, depending on the complexity and budget). Using the methods of ISO 9001:2000 with design is especially helpful at the prototype stage. Having the requirements defined and the documentation package verified will eliminate expensive iterations of the design, because critical parameters are much less likely to be overlooked.

E. Design Validation

When the prototypes and pre-production units are built, the next step is to develop the criterion for testing and validation. A sample validation plan is shown in Figure C. The product undergoes final checkout and beta testing. Results of these validation tests are fed back to the design loop enable to enable necessary modifications. Once validation is complete, the product is ready to be released
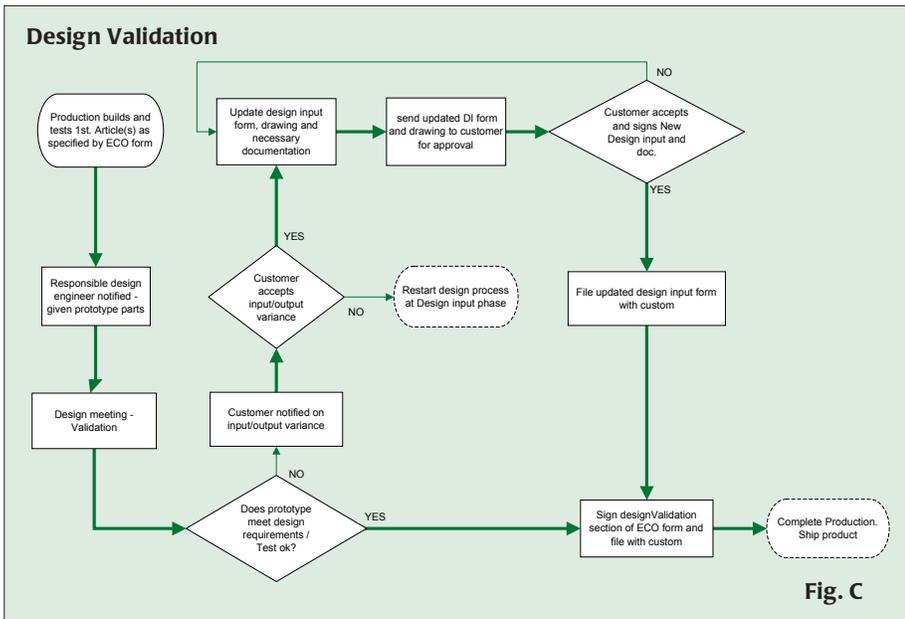
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Design Validation

Fig. C

A critical fork in the road occurs at Design Validation where it is decided whether the prototype meets the design requirements.

DOING IT RIGHT, FOR YOUR SAKE.

Relative to prior standards, the current ISO 9001:2000 standard is more customer-focused. It also deals more explicitly with the need for continuous improvement. Both of these new emphases are apparent in Section 7.3. Incorporating design and development processes into a quality management system provides a robust model for responding effectively and efficiently to your needs as the customer.

You gain assurance that your supplier can deliver a product that has gone through design considerations for possible risks, including life cycle, safety, testability, usability, dependability, durability, ergonomics, and environmental concerns. Equally important, these processes incorporate feedback loops that allow for correction and communication, and assure that any changes made are re-evaluated for feasibility, design concept, verification and validation.

All the processes and documentation required for an ISO 9001:2000 certification "with design" prove the old adage that, "Doing it right the first time is cheaper (and faster) than doing it over." That's the ultimate reason for you to insist that your critical component suppliers have earned an ISO 9001:2000 certification that includes the entire design and development process.

for volume production.

F. Design Changes
Electronic assemblies may have several design iterations over their production lifetime. An ISO 9001:2000 certified design-change process ensures that all changes are "identified, documented, reviewed, and approved by authorized personnel before their implementation." Following this standard avoids the situation in which one group makes changes unilaterally without informing other affected groups.

Ironwood Electronics offers a comprehensive line of sockets and adapters used to incorporate integrated circuits and printed circuit boards into higher-level products for prototyping, testing, and production applications. The company's line of standard products has grown out of extensive custom design work for major electronics manufacturers around the world. Ironwood is proud of its ISO 9001:2000 certification that includes design and development.

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