Essential Design Output

The Quality System Regulation, QSR, has a requirement to identify essential design outputs. §820.30(d) says, "Design output procedures … shall ensure that those design outputs that are essential for the proper functioning of the device are identified." While QSR requires their identification, it doesn't require their use. QSR doesn't define essential design outputs, nor does the preamble discuss them.

QSIT

The Quality System Inspection Technique, QSIT, uses essential design outputs to help the Investigator determine important things to look at during an inspection. The excerpts below show the QSIT process, the inspectional objectives, and a portion of the narrative.

Design Controls – Inspectional Objectives
2. For the design project selected, verify that design control procedures that address the requirements of Section 820.30 of the regulation have been defined and documented.

Review the firm's design control procedures and verify that they address the specific requirements of the regulation. Determine if … the design output procedures ensure that those design outputs that are essential for the proper functioning of the device are identified.

5. Verify that the design outputs that are essential for the proper functioning of the device were identified.

[D]esign outputs which are essential for the proper functioning of the device must be identified. Typically a risk analysis tool such as FTA or FMEA is used to determine essential outputs. For the selected project, verify that essential outputs have been identified. In addition, review the firm's process for determining how the essential outputs were identified and determine if it was done in accordance with their design output procedures.

6. Confirm that acceptance criteria were established prior to the performance of verification and validation activities.

Review the documentation associated with a sample of verification activities and a sample of validation activities as determined using the Sampling Tables. If possible, select activities that are associated with outputs identified as essential to the proper functioning of the device.

7. Determine if design verification confirmed that design outputs met the design input requirements.

Review the documentation of the verification activities associated with a sample of inputs and outputs as determined using the Sampling Tables. If possible, select activities that are associated with outputs identified as essential to the proper functioning of the device. Confirm that design outputs met design input requirements.

15. Determine if the design was correctly transferred.

Sample the significant elements of the device master record using the Sampling Tables and compare these with the approved design outputs. These elements may be chosen based on the firm's previously identified essential requirements and risk analysis.

Production and Process Controls – Inspectional Objectives
2. Review the specific procedure(s) for the manufacturing process selected and the methods for controlling and monitoring the process. Verify that the process is controlled and monitored.

This verification must include a review of the purchasing controls and receiving acceptance activities regarding at least one component or raw material (preferably determined essential for the proper functioning of the device).

Essential Outputs Checklist
Looking at the requirements in QSR and the uses in QSIT, a checklist emerges.

- Design output procedures require identification of essential outputs

- Design output procedures define a process to identify essential outputs

- Essential outputs are identified

- The identification of essential outputs followed the defined process

- The essential outputs are comprehensive enough to allow for design verification

- The essential outputs are comprehensive enough to allow for design validation

- The essential requirements are among the significant elements of the Device Master Record (DMR)

Essential Design Outputs
Definitions can help determine the essential design outputs. The list below includes useful working definitions.

Essential Design Output means any design output that directly affects the device safety, effectiveness, or ability to meet a labeled performance specification.

Safety means freedom from unacceptable risk [ISO 14971:2007, 2.24]
    If the output were absent, the risk would go up, *i.e.,* a risk control measure.

Effectiveness means the ability of the device to satisfy its intended use.
    An effectiveness failure would require evaluation under Corrections and Removals and a potential recall.

Labeled performance specification means the requirements for device performance included in the labeling such as the instructions for use, marketing literature, *etc*.

> Failure to meet a labeled performance specification would require evaluation under Corrections and Removals and a potential recall.

Design verification, §820.30(f), requires confirmation "that the design output meets the design input requirements". A common methodology uses a trace matrix to link design output with design input, identify the design verification method, and the design verification results.

Use the trace matrix to classify the design output's impact on safety, effectiveness, and performance specification. If the design output impacts one or more of the three, based on the definitions, then it is an essential design output.

Internal Audit
QSIT provides a framework for internal audits. In design control, ensure the design output procedure requires the identification of essential design outputs and includes the method to determine them and to record them. For a design project, verify the identification of essential design outputs using the method in the procedure.

Trace the essential design outputs. Depending on how many the design project identified look at a sample, but ensure it represents the areas in the Device Master Record, DMR, and associated processes. This includes production process, validated processes, purchasing data, quality assurance procedures, packaging, labeling, installation, maintenance, and servicing.

Trace the essential design outputs from the DMR to the associated procedures, work instructions, and records.