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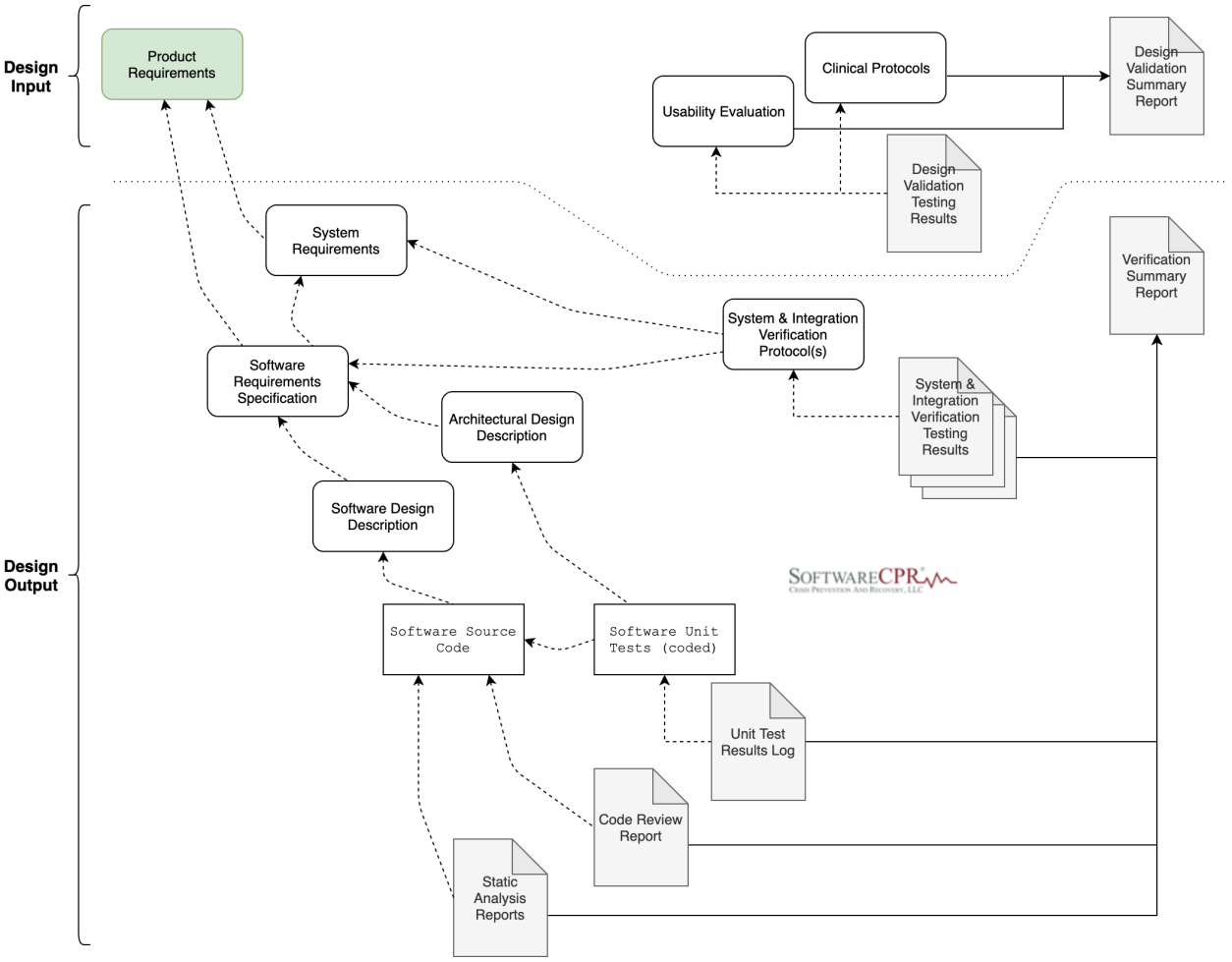

This job aid is intended to help understand how the requirements and specifications of medical device software "flow down" to the implementation, and how verification and validation relate to that flow down. This is just an example - there is great flexibility in how documentation is organized. However, the method chosen should be clear to the staff involved in design and development activities, and support delineation of design control activities.

One area that often causes confusion is determining what will be considered the "design input." We recommend that design input be limited to the intended use, medical/therapeutic requirements of the system. The design input should be the focus of "design validation" activities. Often the design input is captured in a document titled "Product Requirements."

This diagram maps well to the FDA premarket submission for software guidance[1] and IEC 62304.

[1] *Guidance for Industry and FDA Staff: Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices, Document issued on: May 11, 2005*.