

Re: Programmed device – labelling requirements?

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- *From:* Greg Neff <greg@xxxxxxxxxxx>
 - *Date:* Mon, 09 May 2005 21:15:56 –0400
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On 9 May 2005 11:10:52 –0700, "LeaUK" <lea@xxxxxxxxxxxxxxxx> wrote:

>Hi all

>

>I need some advice about requirements for labelling of programmed
>devices and wondered if someone can point me at documentation
>(FDA/ISO/IEC/BS) that identifies the exact labelling information
>required.

>

>Some background:

>

>I want to implement a PCB/programmed component labelling system across
>company that treats all programmable devices equally (EEPROMS, uC,
>PLDs, FPGs...etc) whether they are programmed on or off PCB.

>

>I've read certain parts of the FDA 820 and BS EN 60601 (my company is
>medically based) but the only info defining labelling requirements I
>found was MIL–STD 130/129. This document appears to provide some
>light.

>

>

>Our corporate systems allow full batch traceability but my argument for
>device labelling is simply based on gut feel that 'you can't beat a
>label!' Of course my presumption assumes that human readable info on
>programmed devices assists the field service personnel (and anyone else
>come to think of it) identify it's content but to assist me I need to
>point at a document saying "thou shall label all programmed devices
>with the following information:". This makes my life much easier in
>the convincing certain departments of this route.

>

>Some questions:

>

>What are the minimum identification markings for a device label – part
>number, firmware version, date of programming?

>

>What happens to the device when a user upgrades the firmware – the
>label's firmware number is now invalid.

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>How does industry label devices too small to affix labels?

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- >How does industry cope with batch programming and labelling at a latter
- >date?
- >
- >Does industry really need a label on programmed devices at all –
- >what's the real purpose?
- >
- >
- >Thanks for any input chaps.
- >Lea

As a general rule, we solder programmable parts to the board unprogrammed, and program them using JTAG or a parallel interface. We avoid pre-programmed parts like the plague, but we still have some to deal with.

We don't label parts that are blank at board assembly. The file to program a part is maintained with the assembly build configuration. The file is not permitted to change once it's in build configuration. If a change in the file is required, then this is treated like a component change. In this case a new assembly part number is generated and a new complete build configuration documentation (and file) set is produced for the new assembly part number. Therefore, all we need to identify the file(s) in any given assembly is the part number of the assembly. We don't rev assemblies.

When a part has to be programmed ahead of time then we treat this as an assembly itself. We have a build configuration documentation and file set for the programmed PROM. This includes all programming and labeling instructions. All we really need on the label is our part number, but we will provide additional information on the label if there is room. Again, if a file change is required then this would force a new programmed PROM part number, and then this would in turn force a new PCB assembly part number for the PCB where it is used. This protocol ensures that the exact file can be traced from the top level assembly in all cases.

We allow some flexibility during initial prototype debug and verification. While there are only a few assemblies that are under our control we permit changes to the assembly (or PROM) without forcing the generation of new part numbers. Once the design is released to production it is then frozen, and no more changes are permitted.

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- **References:**

- ◆ **Programmed device – labelling requirements?**

- ◆ *From: LeaUK*

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