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To whom it may concern

October 29, 2015

Impact of Firmware Update on Validation Status: Requirements for the Operation of the Next Generation RFID Tags in Agilent LC Instrumentation

Dear Valued Agilent Customer,

For many years, various Agilent LC Modules and assemblies have been equipped with RFID (radio-frequency identification) tag readers. Specifically in regulated industries, this has been a great tool to warrant chain of custody, when it comes to tracking and documenting the usage of, for instance, chromatographic columns or lamps in the detector.

As a result of the ongoing technological evolution, the very first generation of original RFID tags will eventually no longer be commercially available. We expect that this change will be implemented in the fourth quarter of 2015 and it implies that the affected Agilent LC modules and instruments need to be updated with the compatible firmware version. No additional changes in the hardware or software will be required. The new firmware will allow the use of both old and new RFID tag versions, so you will not have any problem in using supplies you still have in stock in your laboratory. The following assemblies will be changed to a new RFID tag version later in 2015.

- Lamps/Flow Cells in G1314D/E/F VWD, G1315C/D DAD, G1365C/D MWD, G4212A/B DAD and G7100A CE
- Pump Heads, Purge Valves, Mixers in G4204A, G4220A/B, G7104A, G7120A pumps
- Valve Pods in G1316C TCC
- Valve Pods in G1170A Infinity Valve Drive,
- Valve Pods in G4227A Flex Cube

To ensure a smooth transition, above assemblies will be shipped with a technical note (Agilent P/N: 01200-90130 Rev B) providing detailed technical information about the process.

The question remains whether the LC software, instrument hardware and analytical procedures or methods that have been qualified and validated with an **older** firmware version have to be qualified or validated again on the new firmware version or not. As a matter of fact, no changes are required on instrument driver and/or on the workstation or data system software, communicating with the driver. This applies to Agilent data systems as well as 3rd party instrument control via Waters Empower, Dionex Chromeleon or other software packages.

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In summary: It is our opinion that software and method revalidation is **not necessary** when updating the instrument drivers. However, we recommend updating the IQ document with the new firmware revision number and to conduct a system test, e.g., running a routine System Suitability Test (SST) or a quality control sample analysis.

Our reasoning for this opinion is as follows: Revalidation is required when either mechanical or firmware / electronic changes have an impact on the performance of the modules or instrument, on which the methods are validated or operated. For the Agilent 1100 Series, 1200 Series as well as the 1200 Infinity Series the following aspects are to be considered in the context of this firmware update:

1. Change in Specifications

   Specifications, which have an impact on the **analytical performance** of the module or instruments, will **not be changed**, i.e. there is no reason for a method revalidation due to change in chromatographic performance.

2. Mechanical Changes

   The **mechanical design** of the modules or instruments was **not changed**. Therefore this is not a reason for method revalidation.

3. Firmware Changes

   All 1100 Series, 1200 Series and 1200 Infinity Series modules need a compatible firmware revision in order to function with the new RFID tags. The firmware changes are minimal and it is our assessment that the use of the new firmware does not require revalidation of analytical methods or re-performing equipment operational qualification. However, firmware changes need to be documented accordingly. This is achieved through updating the IQ document with the new firmware revision number. The update should follow the company's change control SOP for firmware updates. After the update, the IQ document should be saved under a new version number.

Please note that our recommendation concerning revalidation is based on Agilent's knowledge and experience in this area. Nevertheless, as common practice in the regulated industry, the end user has ultimate responsibility for validation of methods and systems. Therefore, Agilent cannot accept any legal responsibility for the statements and assumptions made and explicitly points out that the final decision whether a revalidation has to be made or not is with the user.

For regulatory inspections we recommend keeping this letter as a documented justification for not revalidating your analytical procedures and methods.

Sincerely yours,

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Waldbronn, October 29, 2015

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