

Remain In Compliance After Major Repairs

With Agilent On-Demand Repair Qualification (RQ) Service



Instrument Repairs – Compliance Requirements

If an instrument in a regulated lab breaks down, the potential impact of the instrument failure on analytical results must be investigated and the instrument must be re-qualified before it can be returned to use. With Agilent on-demand Repair Qualification (RQ), the RQ work can be added to a repair call to minimize instrument downtime.

Agilent recommends USP <1058> as a framework for documenting the suitability of analytical instruments, which states¹:

“The relevant OQ or PQ test(s) should be repeated after the maintenance or repair to ensure that the instrument remains qualified”

Many labs use system suitability and/or PQ tests to verify instrument performance after replacement of consumable components, such as an injector needle. For replacement of non-consumable parts during repair, the appropriate Operational Qualification (OQ) tests must be performed.

Reduced downtime with minimal costs

Planned maintenance (PM) for lab instrumentation can reduce the number of repair events by up to 39% and repair cost by up to 34%².

For the re-qualification of HPLC, HPLC-MS, GC, and GC-MS after repair, performing the full suite of OQ tests is time consuming and not necessary. Only the qualification tests related to the components impacted by the repair need to be performed. For non-modular systems, a full Operational Qualification (OQ) is performed following the repair.

This is the basis of Agilent RQ service, which can be added as an on-demand option to a repair call to speed up return of the instrument to compliant use. The RQ test matrix is designed into the Agilent Automated Compliance Engine (ACE) software.

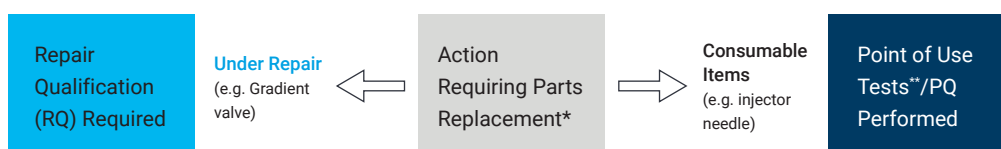
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From Insight to Outcome

Agilent on-demand RQ services ensures

- Add RQ to a Repair Call
- Consistent Qualification (between OQ and RQ)
- Integrated into Agilent ACE (Automated Compliance Engine)
- Lowest Cost RQ (only pay for what you need)
- Reduced Audit Risk (peace of mind)
- Reduced Instrument Downtime (Add RQ to a repair call)

* Suggested - action taken depends on company policy/SOP.

** In chromatography, point of use tests are referred to as System Suitability Tests.



Regulatory Non-Compliance Findings

Within regulated labs, Analytical Instrument Qualification is the highest area of concern³ (after data integrity). To help companies make informed choices about **instrument qualification**, Agilent worked with leading compliance expert Bob McDowall to produce Four White Papers on Different Aspects of USP <1058>⁴.

An Agilent RQ ensures that the testing performed before the instrument is returned to routine use is compliant and aligned with the Operational Qualification (OQ).



Agilent RQ On-Demand Services

To support laboratories with different requirements, Agilent offers the option of adding an RQ to your existing Agilent service (contract RQ)⁵. RQ On-Demand provides RQ services for an instrument for the lowest cost.

On-Demand RQ

“On-Demand” RQ service means an RQ can be conveniently added to an instrument that requires repair.

Note: This is a single RQ operation performed after the repair and does not include the initial OQ (RQ can only be performed on instruments that have had an Agilent OQ).

Features of Agilent On-Demand RQ Services

RQ On-Demand	
Service Components	Single visit (e.g. perform the necessary RQ tests after the repair)
Pre-Requisites	An Agilent OQ must have been performed in the last 12 months (to apply an RQ service)
Designed for	Adding RQ to a repair call
RQ Guarantee?	No (reserved for specific Agilent Contract RQ services [#])
Part Number:	PIERQ

See Reference 5

References

1. United States Pharmacopeia (USP) general chapter <1058>
2. 5-Year Study Substantiates Value of Agilent Preventive Maintenance, [5990-5938EN](#)
3. Preferences and Trends in Qualification Practices in Regulated Labs, [5994-5126EN](#)
4. USP General Chapter <1058>, Compilation of White Papers, [5994-1134EN](#)
5. Agilent Contract RQ Service – Agilent Publication [5994-2177EN](#)

Contact Agilent – to reduce your compliance risk

Compatible with Agilent flexible spend plans, contact your local Agilent representative to book an RQ on-demand.

To know more about Agilent Repair Qualification Services, please visit:

www.agilent.com/en/service-center-repair

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