


**Notification date:** October 17, 2019  
**Notification reference number:** CN-RPII-BFNH5E

## Change Notification – Pre-Notification

<b>Purpose</b>	Notification of change by Pall's supplier of the polypropylene (PP) raw material used in certain Pall products.
<b>Affected products</b>	Specific direct flow filters for liquid and gas (reference Table 1) Reference Appendix 1 for list of affected filter part numbers
<b>Change to fluid or air contact component (s)?</b>	Yes
<b>Change process stages</b>	Pre-notification: This document Final notification: January 2020 Target date for implementation: November 2020
<b>Pall manufacturing plants impacted</b>	Ilfracombe, United Kingdom; Fajardo, Puerto Rico; Cortland and Timonium in the USA.
<b>Customer action required</b>	We cannot assess individual end-user requirements and use of these products. Please refer to the following information to assess the impact on your specific operations
<b>Pall point of contact</b>	Please email inquiries to: <a href="mailto:customernotification@pall.com">customernotification@pall.com</a>
<b>Authorized by</b>	 Mark Baree Quality Director Biotech Consumables

**Description of change**

The change is to the PP raw material used in filter media or hardware cores and bonding material for certain filter products shown in the table below.

The current raw material is made by a manufacturing process that uses a catalyst incorporating phthalate compounds. Because of a move to a phthalate free catalyst in their manufacturing process, the vendor is discontinuing the current raw material and is offering a replacement that is manufactured with a phthalate-free catalyst.

Extensive qualification studies are underway to demonstrate that the material change will not result in change to form, fit, or function of the finished products that you have been receiving from Pall. There is no change to Pall’s suppliers of the materials used for construction of the products, or in the established product specifications.

The validation summary plan is provided in Appendix II.

**Table 1**

Impacted filter families, applications, and affected components.

<b>Filter families</b>	<b>Application</b>	<b>Component</b>
HDC® II and HDC B	Prefiltration, Clarification	Filtration Media
Preflow™ UB	Prefiltration	Core Component
Mustang® S and Mustang Q	Chromatography	Core Component
Emflon® PFR, Emflon HTPFR	Gas filtration	Support Material
Profile II™, Profile® Star, Starclear®	Prefiltration, Clarification	Filtration Media, Core Component

**Reason for the change**

This change is driven by our raw material supplier.

**Initial preliminary qualification plan for the change**

The preliminary qualification plan is contained in Appendix 2. A full validation package will be available on request at the time of final notification.

**Additional information**

This information is being provided to you to serve as an advance notification so that you can begin to assess the potential impact on your receipt and incoming inspection operations. If anyone else within your organization should be made aware of this notification, please forward them a copy of this letter or advise us accordingly. Please email your inquiries about this change to: [customernotification@pall.com](mailto:customernotification@pall.com)

This notification has been cleared for release by Pall Quality Assurance.

We appreciate your continued use of Pall products.

**Appendix I – Affected Part Numbers List**

Part Number	Part Number	Part Number	Part Number
158872	609-17N	AB05J0457PH4	AB1A7007PH4
160026	609-17V	AB05J0602PH4	AB1A9007PH4
6036813	609-17X	AB05PFR2PVH	AB1BC7PH4
6040258	609-25B	AB05PFR2PVH1	AB1BP7PH4
5090-0371N	609-27B	AB05PFR2PVH4	AB1FR7PSH4
5090-0444Q	609-37A	AB05PFR2PVH4SSA	AB1FR7PSJ
5090-0545M	609-44E	AB05PFR2PVJ	AB1H2157PH4
5090-0815M	609-52K	AB05PFR3PVH4	AB1HAZ7PH15
509-1013	609-69U	AB05PFR7PVH4	AB1HAZ7PH4
509-2066	609-95J	AB05PFR7PVJ	AB1HAZ7PJ
509-2456	639-53X	AB1A0103H1	AB1HTPFR7PVH
509-2483	639-98M	AB1A0107PH1	AB1HTPFR7PVH1
509-599	6450-0442Z	AB1A0107PH4	AB1HTPFR7PVH4
509-62	7090-1084U	AB1A0157H4	AB1J0063PH4
509-671	7090-1084V	AB1A0157PH4	AB1J0067H4
5190-0881J	739-55Z	AB1A0157PJ	AB1J0067J
52.012017.05.12.01	7430-0528F	AB1A0307J	AB1J0067PH1
52.012018.07.12.01	7430-0528K	AB1A0307PH4	AB1J0067PH4
529-0654	7430-0828G	AB1A0307PH4NPL	AB1J0067PJ
529-0655	AB01A10014J	AB1A0307PJ	AB1J0123H15
5EC4888629BC	AB01A20014J	AB1A0507H1	AB1J0123PH4
6090-0355C	AB01A40014J	AB1A0507J	AB1J0127H4
6090-0473Y	AB01Y20018J	AB1A0507PH4	AB1J0127PH1
6090-0477C	AB01Y40018J	AB1A0507PH4BAX	AB1J0127PH4
6090-0479V	AB05HAZ2PH4	AB1A0507PJ	AB1J0127PJ
6090-0479X	AB05HTPFR2PVH	AB1A1007H1	AB1J0128H4
6090-0517X	AB05HTPFR2PVH1	AB1A1007H4	AB1J0257H4
6090-0566U	AB05HTPFR2PVH4	AB1A1007J	AB1J0257PH4
6090-0632J	AB05HTPFR2PVJ	AB1A1007PH4	AB1J0457PH1
6090-0648P	AB05HTPFR7PVH4	AB1A1007PJ	AB1J0457PH13
6090-0913E	AB05J0062PH4	AB1A1507PH4	AB1J0457PH4
609-00A	AB05J0122PH4	AB1A2007PH4	AB1J0458H1
6090-1164C	AB05J0122PJ	AB1A4007J	AB1J0458PH1
609-11H	AB05J0452PH4	AB1A4007PH4	AB1J0607H4
609-16N	AB05J0452PH4NPL	AB1A4007PJ	AB1J0607J

Part Number	Part Number	Part Number	Part Number
AB1J0607PH1	AB1PFR7PVJ	AB1Y0707PH	AB2HAZ7PH4
AB1J0607PH4	AB1PFR8PVH4	AB1Y0707PH4	AB2HTPFR7PVH1
AB1J0607PJ	AB1UB7PH1	AB1Y1007H4	AB2HTPFR7PVJ
AB1J0608PH4	AB1UB7PH4	AB1Y1007PH4	AB2J0067PH4
AB1J1007H	AB1UY0207J	AB1Y1009J	AB2J0067PJ
AB1J1007H4	AB1UY0207PH4	AB1Y2007PH4	AB2J0127PH1
AB1J1007J	AB1UY0457H4	AB1Y4003PH1	AB2J0127PH4
AB1J1007PH1	AB1UY0457PH4	AB1Y4007PH4	AB2J0127PJ
AB1J1007PH13	AB1UY0603H4	AB1Y7007PH4	AB2J02528PH4
AB1J1007PH4	AB1UY0607H4	AB1Y9007PH4	AB2J0257PH4
AB1J1007PJ	AB1UY0607J	AB1Y9009J	AB2J0257PJ
AB1J1008H4	AB1UY10007J	AB2A0107PH4	AB2J0457PH4
AB1J2007H4	AB1UY10007PH4	AB2A0157H4	AB2J0458H4
AB1J2007PH1	AB1UY1003H	AB2A0157PH4	AB2J0607PH4
AB1J2007PH4	AB1UY1007H4	AB2A0307J	AB2J1003H4
AB1J2007PH432	AB1UY1007J	AB2A0307PH4	AB2J1007H4
AB1J4007H4	AB1UY1007PH4	AB2A0307PJ	AB2J1007PH4
AB1J4007PH4	AB1UY1007PJ	AB2A0507H1	AB2J1007PJ
AB1J4007PH424	AB1UY2007H4	AB2A0507J	AB2J2007PH4
AB1J4007PJ	AB1UY2007J	AB2A0507PH4	AB2J2007PJ
AB1J7007H4	AB1UY2007PH4	AB2A1007H1	AB2J4007PH4
AB1J7007PH4	AB1UY4007H4	AB2A1007H4	AB2J4007PJ
AB1J7007PJ	AB1UY4007PH4	AB2A1007J	AB2J4008H1
AB1PFR2PVH4	AB1UY7007H4	AB2A1007PH4	AB2J7007H4
AB1PFR3PVH	AB1UY7007PH4	AB2A1007PJ	AB2J7007PH4
AB1PFR3PVH4	AB1Y0037PH4	AB2A2007J	AB2J7008H4
AB1PFR3PVJ	AB1Y0053H4	AB2A2007PH4	AB2PFR3PVH4
AB1PFR7PVH	AB1Y0057PH4	AB2A4007J	AB2PFR7PVH
AB1PFR7PVH1	AB1Y0057PJ	AB2A4007PH4	AB2PFR7PVH1
AB1PFR7PVH4	AB1Y0107PH4	AB2A7007J	AB2PFR7PVH4
AB1PFR7PVH424	AB1Y0108PH4	AB2A9007PJ	AB2PFR7PVJ
AB1PFR7PVH4BAX	AB1Y0207PJ	AB2BN7PH4	AB2PFR7PVJSST
AB1PFR7PVH4NPL	AB1Y0307PH4	AB2FR7PSH4	AB2PFR8PVH4
AB1PFR7PVH4SSA	AB1Y0503PJ	AB2FR7PSJ	AB2UB7PH1
AB1PFR7PVH4SU	AB1Y0507PH4	AB2HAZ3PH4	AB2UB7PH4

Part Number	Part Number	Part Number	Part Number
AB2UY0207PH4	AB3A0307PH4	AB3PFR7PVJ	AB3Y2007H4
AB2UY0457H4	AB3A0307PJ	AB3PFR8PVH4	AB3Y4007H4
AB2UY0457J	AB3A05018J	AB3PFR8PVJ	AB3Y4007J
AB2UY0457PH4	AB3A0503PH4	AB3UB7PH1	AB3Y4007PH4
AB2UY0457PJ	AB3A0507H4	AB3UB7PH4	AB3Y7007PH4
AB2UY0607PH	AB3A0507PH4	AB3UB7PJ	AB4A0507PH4
AB2UY0607PH4	AB3A0507PH412	AB3UY0207H4S	AB4HAZ7PH4
AB2UY10007J	AB3A1007PH15	AB3UY0207PH4	AB4J0127PH4
AB2UY1003H4	AB3A1007PH4	AB3UY0207PJ	AB4J1007PH4
AB2UY1007H4	AB3A2007PH4	AB3UY0453H	AB4PFR7PVH4
AB2UY1007PH4	AB3A2007PJ	AB3UY0457J	AB4UY1007PH4
AB2UY2007H	AB3A4007J	AB3UY0457PH4	AB4UY1008J
AB2UY2007PH4	AB3A4007PH4	AB3UY06018J	AB4Y0107PH4
AB2UY4007H4	AB3A4007PJ	AB3UY0603H4	AB4Y0509J
AB2UY4007PH4	AB3A9007PH4	AB3UY0607H4	AB4Y050B7PH4
AB2Y0057PH4	AB3HAZ3PH4	AB3UY1007H4	AVF021A050J
AB2Y0077PH4	AB3HTPFR7PVH4	AB3UY1007J	BYA015P6
AB2Y0107H	AB3HTPFR7PVJ	AB3UY1007PH4	BYA030P6
AB2Y0107PH4	AB3J0067PH4	AB3UY2007PH4	BYA050P6
AB2Y0307H4	AB3J0127H4	AB3UY7007J	BYA2008J
AB2Y0307PH4	AB3J0127PH4	AB3UY7007PH4	BYY010P6
AB2Y0309J	AB3J0257PH4	AB3Y0037PH4	BYY050P6
AB2Y0503H4	AB3J0457PH4	AB3Y00520H4	BYY100P6
AB2Y0507PH4	AB3J0607H4	AB3Y0057PH4	C2PFRP1B
AB2Y0707PH4	AB3J0607PH4	AB3Y0057PH496	C3J012P1
AB2Y1007PH4	AB3J1007PH1	AB3Y01028J	CM05PFRP1
AB2Y1008J	AB3J1007PH4	AB3Y0107PH4	DFA3001FRP
AB2Y2007PH4	AB3J2007PH4	AB3Y0107PH496	DFA3001J025P
AB2Y3007H4	AB3J4007PH4	AB3Y03020H4	DFA3001J045P
AB2Y4007H4	AB3J7007H4	AB3Y0307PH4	DFA3001J200
AB2Y4009J	AB3PFR2PVH4	AB3Y05020H4	DFA3001J400P
AB2Y7007PH4	AB3PFR3PVH4	AB3Y0507J	DFA3001J700
AB3A0107PH4	AB3PFR7PVH1	AB3Y0507PH4	DFA3001J700P
AB3A0157H1	AB3PFR7PVH15	AB3Y1007PH1	DFA3201FRP
AB3A0157PH4	AB3PFR7PVH4	AB3Y1007PH4	DFA3201J006P

Part Number	Part Number	Part Number	Part Number
DFA4001FRP	KA1J025P2	KA2J100P1	MACWA1008J
DFA4001J025P	KA1J025P3	KA2J100P2	MCS1001CH030H13
DFA4001J060P	KA1J045P1	KA2J200P1	MCS1001CH100H
DFA4201FRP	KA1J045P12	KA2J200P1G	MCY1001A030J
DFA4201Y010	KA1J045P2	KA2J200P2	MCY1001A050H2
DVF1A030NW25H4	KA1J060P1	KA2J400P1	MCY1001A100H2
DVF1A030NW32H4	KA1J060P2	KA2J400P6	MCY1001A100H4
E602Y200	KA1J060P3	KA2PFRP1	MCY1001A100J
E604YB	KA1J100P1	KA2PFRP16	MCY1001A200J
FA71RPPFP1H15	KA1J100P2	KA2PFRP2	MCY1001J006J
FA71RPPFP1J	KA1J100P6	KA2PFRP6	MCY1001J006PH4
FA72RPPFP1J	KA1J200P1	KA3A050P1	MCY1001J012H4
FA73RPPFP1H15	KA1J200P1G	KA3J006P1	MCY1001J012J
FFGFR00P1A	KA1J200P2	KA3J012P1	MCY1001J012PH4
FLF6001J012P	KA1J400P1	KA3J012P6	MCY1001J025J
FLF6001J060P	KA1J400P2G	KA3J025P1	MCY1001J025PH4
FLF6001J100	KA1PFRP1	KA3J025P6	MCY1001J045PH4
FTKGB	KA1PFRP1SU	KA3J045P1	MCY1001J100H4
FTKJ200	KA1PFRP2	KA3J045P6	MCY1001J200PH4
FTKJ400	KA1PFRP6	KA3J060P1	MCY1001J200PJ
FTKPFR	KA2J006P1	KA3J060P6	MCY1001J400H13
GC508300	KA2J006P2	KA3J100P1	MCY1001J400PH4
GC589100	KA2J012P1	KA3J100P6	MCY1001Y020H13
HFU620CAS010JUW	KA2J012P2	KA3J200P1	MCY1001Y100H13TIM
HFU620UY200J	KA2J025P1	KA3J400P1	MCY1001Y200H13
HFU620UY400J	KA2J025P2	KA3PFRP1	MCY1002A100H2
HFU660UY700J	KA2J025P3	KA3PFRP6	MCY1002A150J
HLB3J60P02	KA2J025P4	KA4A050P1	MCY1002H5-40PJ
J06014225	KA2J045P1	KA4A100P1	MCY1002HAZJ
J10014225	KA2J045P2	KA4J006P1	MCY1002Y030H13
J20014225	KA2J045P3	KA4J012P1	MCY1003A030J
KA02PFRP3	KA2J045P4	KA4J045P1	MCY1003A050J
KA1J012P1	KA2J045P6	KA4J100P1	MCY1003A200J
KA1J012P2	KA2J060P1	KM292HP	MCY1003A900J
KA1J025P1	KA2J060P2	KV1PFAPV8	MCY1003J012H13

Part Number	Part Number	Part Number	Part Number
MCY1003J100PJ	MCY4463J060PH4	NP6MSTGQP1	NP8A100P1G
MCY1003Y030H13TIM	MCY4463J100PH4	NP6MSTGSP1	NP8HAZP1G
MCY1004A400J	MCY4463J200PH4	NP6PFRP1	NP8J012P1G
MCY1110J060PH4	MCY4463J400H13	NP6UBP16G	NP8J012P1S
MCY1110PFRPH4	MCY4463J400PH4	NP6UBP1G	NP8MSTGQP1
MCY2220J012PH4	MCY4463PFRPH	NP6UBP6G	NP8PFRP1
MCY2220J200PJ	MCY4463PFRPH1	NP6UY045P1G	NP8PFRP1A
MCY2230J045JNPL	MCY4463PFRPH4	NP6UY045P6G	NP8UBP1G
MCY2230PFRPH	MCY4463PFRPJ	NP6UY100P1G	NP8UBP6G
MCY2230PFRPH4	MCY4463PFRPJ24	NP6Y005P1G	NP8Y003P1G
MCY2230PFRPJ	MCY4463PFRPVH4	NP6Y005P6G	NP8Y005P1G
MCY3330PFRPH4	NL07932	NP6Y010P1G	NP8Y050BP1G
MCY4440J012PH4	NP5LJ012P1G	NP6Y010P6G	NP8Y100P6G
MCY4440J012PH4NPL	NP5LJ045P1G	NP6Y050BP1G	NT6A030P1G
MCY4440J025PH4	NP6A010P1G	NP6Y050P1G	NT6A050P1G
MCY4440J045PH4	NP6A015P1G	NP6Y050P6G	NT6A100P1G
MCY4440J045PH4NPL	NP6A030P1G	NP6Y150P16G	NT6A200P1G
MCY4440J060PH4	NP6A030P6G	NP7A015P1G	NT6A400P1G
MCY4440J100PH4	NP6A050P1G	NP7A050P1G	NT6A400P1S
MCY4440J100PJ	NP6A050P6G	NP7J012P1G	NT6HAZP1G
MCY4440PFRPH	NP6A100P1G	NP7J045P1G	NT6J006P1G
MCY4440PFRPH1	NP6A100P6G	NP7J100P1G	NT6J012P1G
MCY4440PFRPH4	NP6A200P1G	NP7J200P1G	NT6J400P1G
MCY4440PFRPH4MR	NP6A200P6G	NP7MSTGQP1	NT6PFRP1
MCY4440PFRPJ	NP6A400P1G	NP7MSTGSP1	NT6UBP1G
MCY4463A050J	NP6HAZP1	NP7PFRP1	NT6UBP1S
MCY4463A100J	NP6HAZP1G	NP7UBP1G	NT6Y005P1G
MCY4463J006H4	NP6J006P1G	NP7UBP6G	NT6Y005P1S
MCY4463J006PH4	NP6J012P1G	NP7Y005P1G	NT6Y010P1G
MCY4463J012PH4	NP6J025P1G	NP7Y005P6G	NT6Y050P1G
MCY4463J012PJ	NP6J045P1G	NP7Y050BP1G	NT6Y050P1S
MCY4463J025PH4	NP6J060P6G	NP8A030P1G	NT6Y100P1G
MCY4463J045H13	NP6J100P1G	NP8A030P6G	NT6Y100P1H1G
MCY4463J045PH4	NP6J200P1G	NP8A030P6S	NT7A015P1G
MCY4463J060H	NP6J700P6G	NP8A050P1G	NT7A030P1G

Part Number	Part Number	Part Number	Part Number
NT7A050P1G	NT8Y100P1G	RM298F020H21	SLK7002J100P
NT7A100P1G	NT8Y100P1H1G	RM298F150H21	SLK7002J200
NT7A200P1G	PCF1Y050B08	RM2F030H21	SLK7002J200P
NT7A400P1G	PCF1Y050N04NPL	RM2F050H21	SLK7002J400
NT7J012P1	PCF1Y200B08	RM2F150H21	SLK7002PFRP
NT7J025P1G	PCF1Y400B08	RM2F700H21	SP0401600U001
NT7J400P1G	PUY1J025J	RM3F050H21	TAY11A050B
NT7J700P1G	PUY1J060J	RM3F100H21	TAY11A100B
NT7UB1H1G	PUY1J100H4	RM3F1200H21	TAY11Y005D
NT7UBP1G	PUY1J100J	RM3F400H21	TAY11Y050B
NT7UBP1S	PUY1J700J	RM4F010H21	W103A050J
NT7Y005P1G	PUY1UY020H4	RM4F050H21	YA71B3600A
NT7Y010P1G	PUY1UY200H4	RM4F100H21	
NT7Y030P1G	PUY1UY400J	SBF1J012PH4	
NT7Y0501H1G	PUY2J012H13	SBF1J012PJ	
NT7Y050P1H1GA	PUY2J060J	SBF1J045PH4	
NT7Y050P1S	PUY2J100Y1	SBF1J060PH4	
NT7Y100P1G	PUY2UY1000J	SBF1PFRPJ	
NT7Y100P1H1GA	PUY2UY100H	SCF3111J012	
NT8A015P1G	PUY2UY300H	SKA3PFRP1	
NT8A030P1S	PY2BB	SLK7001J012P	
NT8A050P1G	PY2DA	SLK7001J012PSU	
NT8A100P1G	R05F030	SLK7001J045P	
NT8HAZP1G	R09F010	SLK7001J100P	
NT8J200P1S	R09F900	SLK7001J200	
NT8PFRP1	R1F070	SLK7001J200P	
NT8UB1H1G	R2F050	SLK7001PFRP	
NT8UBP1B1G	R2F200	SLK7001PFRPNPL	
NT8Y005P1G	R3F020	SLK7002FRP	
NT8Y005P1GA	R3F030	SLK7002J012P	
NT8Y005P1S	R3F050	SLK7002J012PSU	
NT8Y010P1G	RLS2FPS200	SLK7002J025P	
NT8Y050P1G	RM1F050H21	SLK7002J045P	
NT8Y050P1GA	RM1F100H21	SLK7002J060P	
NT8Y050P1S	RM1F700H21	SLK7002J100	

## Appendix 2 - Validation Performance Qualification Summary

Test Type	Description & Acceptance Criteria	Status
USP Class VI test	The new material must meet the requirements of USP Biological Reactivity tests ( <i>in vivo</i> ) for Class VI – 121 °C plastics and a MEM Elution test assessing cytotoxicity.	Results will be available at the time of final notification.
Steam life	Filters manufactured with the new material are subjected to multiple steam sterilization cycles. The effect of this procedure will be evaluated by either Bubble Point tests or Forward Flow tests, dependent on the filter part number tested. The filters (Profile Star AB1A1007PH4, Emfon HTPFR AB1HTPFR7PVH4, HDC II AB1J0067PH4) should withstand steam cycles according to the claim to be found in Pall publications for the specific filter media. The results are compared to the results achieved with filters made with incumbent material.	Results will be available at the time of final notification.
Particulate retention testing	Representative filters (Profile Star AB1A1007PH4 and HDC II AB1J1007PH4) made with new material are tested using PTI Fine Test Dust suspended in water to obtain liquid removal performance of filters. The results are compared to liquid removal performance of incumbent filters.	Results will be available at the time of final notification.
Testing for Pall's Certificate of Test for Pharmaceutical Grade filters	Filter lots manufactured with filter media containing the new PP are required to meet all the applicable lot release tests and thus the criteria for Pall's Certificate of Test for Pharmaceutical-Grade filters. These tests may include, depending on the filter part number: <ul style="list-style-type: none"> <li>• Fabrication integrity</li> <li>• Effluent quality <ul style="list-style-type: none"> <li>○ Cleanliness (particulates)</li> <li>○ Total Organic Carbon (TOC) and Water Conductivity</li> <li>○ Oxidizable Substances</li> <li>○ pH shift</li> <li>○ Endotoxins/Pyrogens</li> <li>○ Bacterial Retention (AB1HTPFR7PVH4 only)</li> </ul> </li> </ul>	Results will be available at the time of final notification.

Test Type	Description & Acceptance Criteria	Status
Extractables testing	<p>Representative filters (Profile II, part number AB1Y0057PH4) in which the filter PP hardware and filter PP media are impacted by the change will be manufactured using new PP material and extractables results compared to incumbent filters.</p> <ul style="list-style-type: none"> <li>• Filters to be tested separately post-autoclave or post-gamma irradiation (50 kGy)</li> <li>• Water, 50% ethanol/water, and 95% ethanol extracts (24 hours at 40 °C) to be tested for total non-volatile extractables (NVR) and Fourier Transform Infrared (FTIR)</li> <li>• 50% ethanol/water extracts (24 hours at 40 °C) to be analyzed by liquid chromatography/mass spectrometry (LC/MS), by gas chromatography/mass spectrometry (GC/MS) and by inductively coupled plasma mass spectrometry (ICP/MS) for inorganic ions.</li> </ul> <p>Representative filter hardware impacted by the change will be manufactured using new PP material and extractables results compared to incumbent filters.</p> <ul style="list-style-type: none"> <li>• Filter hardware to be tested separately post-autoclave or post-gamma irradiation (50 kGy)</li> <li>• Water, 50% ethanol/water, and 95% ethanol extracts (24 hours at 40 °C) to be tested for total non-volatile extractables (NVR) and Fourier Transform Infrared (FTIR)</li> <li>• 50% ethanol/water extracts (24 hours at 40 °C) to be analyzed by liquid chromatography/mass spectrometry (LC/MS), by gas chromatography/mass spectrometry (GC/MS) and by inductively coupled plasma mass spectrometry (ICP/MS) for inorganic ions.</li> </ul>	Results will be available at the time of final notification.