

Decontamination Program - Instrumentation and Accessories

Revision History

Version	Date	Author	Description
0	6.3.15	E. Cantas	New formal program developed – capturing response plan.
1	7/27/2017	R. Fiume	Periodic Review
2	8.13.18	E. Cantas	Updated training frequency to at least annually.
3	10/9/18	E. Cantas	Added records section.
-	11/12/2019	E. Honcharik	Periodic Review – No Changes
4	7/15/2020	E. Honcharik	Minor revision – added details pertaining to updating instrument manual link and customer care upon revision to decontamination form.
-	3/25/2021	E. Honcharik	Periodic Review – No Changes
-	3/18/2022	M. Freeman	Periodic Review- No Changes

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Doc Ref #	HSM_4_001	approval date	3/18/2022	Page 1 of 3			
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1.0 PURPOSE

This procedure is to be used for materials and instrumentation destined for return to PerkinElmer for repair, maintenance, warranty or trade-in or recycling purposes.

2.0 SCOPE

The health risks of handling and working with instruments and accessories received from the field are largely unknown. This dictates prudent actions be taken to insure returning equipment present no health hazard to those who come in contact with these products throughout the in-house processing cycle.

3.0 REFERENCES

Doc ref #	Document Description		
HSM_4_001_1	Response Plan for Equipment Returned Without Decontamination Certification		
HSM_4_001_2	Decontamination Certification Form		

4.0 GENERAL

Anyone authorized to return instrumentation or accessories to PerkinElmer are advised through the customer care department RMA process that all returns must be submitted with a completed Decontamination Certification Form.

This form must be completed by the shipper (i.e., customer) and attached to the outside of the box in a 'shipping docs' bag, or equivalent.

The following criteria are provided as guidance for shipper as to the proper decontamination of instrumentation and accessories:

- 1. The instrument or item to be returned must be cleaned of all visible residue and encrusted material.
- 2. Where there is the potential for hazardous non-visible chemical contamination, it may be necessary to verify that no contamination is present.
- 3. For items used in conjunction or in contact with radioactive materials, ensure that no radioactivity may be detected with survey equipment or incidental swipe tests.
- 4. Where infectious/bio-hazardous materials were used or suspected, disinfect all surfaces with material specific effective disinfectants.

DOCUMENT TITLE				Approved by	REV		
Decontamination Program				D. Hellerman	4		
Doc Ref #	HSM_4_001	approval date	3/18/2022	Page 2 of 3			
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5. When hazards have been successfully removed by decontamination, remove all hazard warning labels or signs.

PerkinElmer employees who receive instrumentation or accessories without a completed decontamination certification form must follow procedure HSM_4_001_1, 'Response Plan for Equipment Returned without Decontamination Certification.' Under no circumstances will uncertified returned equipment be allowed into the operations process. In-house decontamination procedure and/or equipment returns back to the shipper must be authorized by the Manufacturing Manager and EHS Manager, on a case by case basis.

The following link (containing the decontamination form) shall be updated upon changes to the decontamination form. This is the link that is provided to customers in various instrument manuals:

https://www.perkinelmer.com/content/technicalinfo/dts instrumentdeconprocedure.pdf

Additionally, Customer Care leadership must be notified of the revisions.

5.0 TRAINING

Affected personnel will receive training on this procedure and associated materials at least annually.

6.0 RECORDS

Shelton's return department will create copies of all decontamination certificates and hold in a file. Monthly, EHS personnel will collect the records for final recordkeeping.

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Doc Ref #	HSM_4_001	approval date	3/18/2022	Page 3 of 3			
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