Decontamination of instrumentation and associated sub-assemblies

PURPOSE

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

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.

Equipment can not be approved for return from the field until it is certified as "clean". A complete decontamination must be performed on all equipment suspected of being contaminated. The PerkinElmer customer/user certification form should be used to certify the equipment as "clean", or that the required decontamination process has been completed. The certification form should be signed off and attached to the outside of the box in a "shipping docs" bag. In the event questions arise regarding the applicability of the decontamination and certification process for returned parts and accessories, clarification by your PerkinElmer field representative will be provided.

Refer to Certificate of Decontamination form to complete documentation.

DECONTAMINATION CRITERIA

A determination must be made regarding the materials currently and previously used or stored in the instrument/equipment being returned. A visible examination must also be made to reveal any check for evidence of spills (such as damage to the inner surfaces of the instrument).

Those wishing to return instrumentation and associated materials are advised that all returned goods must be certified as clean and free from contamination.

The following minimum criteria are provided as guidance for the proper decontamination of instrumentation.

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. If contamination is suspected, the customer must initiate a material appropriate decontamination process.
3. For items used in conjunction or in contact with radioactive materials, insure 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.
5. When hazards have been successfully removed by decontamination, remove all hazard warning labels or signs.
6. The customer must complete a PerkinElmer LAS Decontamination Certification, designating the equipment as clean.
7. Regarding possibly contaminated equipment, the customer/user must verify the proper decontamination process was completed. The completed certification document must be sent to your PerkinElmer representative, with copies of the certification document accompanying all returned goods and hardware.

SPECIAL NOTICE

Return shipments of instruments and equipment not having decontamination certificates displayed on the exterior of the shipping container as herein described will be subject to rejection at the dock.

Any equipment or instruments that are accepted and are found not having proper decontamination certificates will be clearly labeled as a possible hazard and be placed on hold at the dock.

Under no circumstances will uncertified returns be transacted into the operations process. All uncertified returns will remain unopened, in a sealed condition, until a determination of decontamination is received.