

How to deal with inventoried repositories in the laboratory survey process

Several questions have been raised about how best to handle certain aspects of the clean sweep going on at NIH, in particular about step 5 which discusses how to deal with large inventoried repositories held at the NIH and by contractors. The following guidelines have been developed for the biospecimen (blood and other body fluids, tissues, nucleic acids, and other direct derivatives from human tissues) repositories which should be tracked using an inventory system that records the location and detailed information for every specimen in the repository. Expectations for tracking and storage of these specimens is spelled out in "Guidelines for Human Biospecimen Storage and Tracking within the NIH Intramural Research Program"

<http://sourcebook.od.nih.gov/oversight/BiospecimenGuidelines.pdf>

Other repositories with biological specimens to be used at BSL-1 levels such as cell lines, microorganisms, etc. should also be inventoried according to best practices in the laboratory:

1. It is not sufficient to state that the existence of an inventory guarantees that there are no adventitious (un-inventoried) pathogenic or toxic biological samples in the repository. Each IC should determine how best to assure that inventoried repositories are extremely unlikely to contain unexpected materials, including, but not limited to: a) randomly choosing several containers in the inventoried repository and confirming that their contents are as expected; b) if feasible, visually inspecting the contents of a substantial number of containers in the repository to be sure they hold vials of the expected type. Contractors should be asked to confirm the contents of their NIH repositories in a similar way. For extremely large repositories (over 1 million samples) the same principle holds but the proportionate number of samples that needs to be individually tested is smaller. NCI has proposed a statistically valid and rigorous sampling strategy to be used with these large repository collections (10,000 samples checked for a repository of 10 million samples), but other approaches are also possible. Attestations should indicate what procedure was used to survey the repository. These will be reviewed by DOHS and in some cases clarifications may be sought and/or additional steps may need to be taken.
2. For un-inventoried, stored samples, there is no alternative to examining each container and visually determining that the contents are labeled and in need of storage. Unlabeled samples and those that can be discarded should be double autoclaved if they might contain biological material. If you suspect you have an unregistered select agent, please contact DOHS: (301 496-2960) or the DOHS office at your campus.
3. For any select agent found, call the Select Agent Program at your campus. For agents requiring BSL-2 containment or higher (all human biospecimens and pathogenic microorganisms among others), please be sure they are inventoried using the attached spread sheet. The spreadsheets can then be uploaded into a centralized database. The URL is forthcoming. You will need to indicate what the nature of the samples is, how many samples you have, and where they are located.