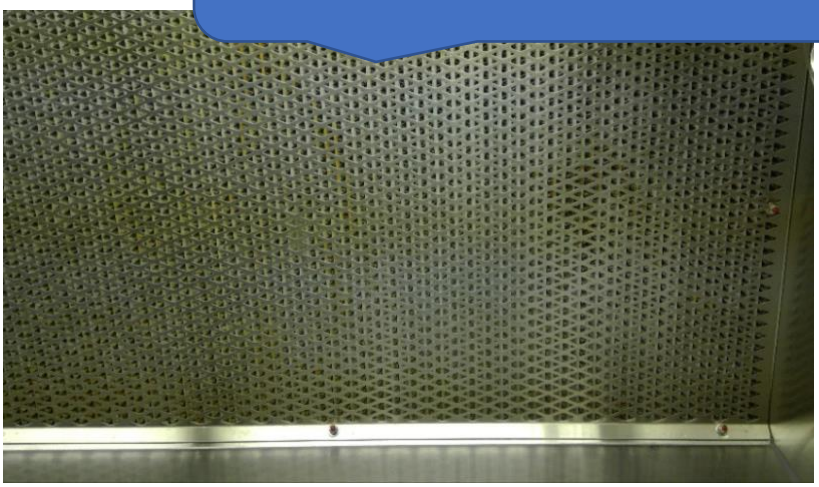
There are actually TWO issues with this very common picture of a LAFW HEPA filter and protective screen assembly taken in a sterile compounding facility.



The HEPA filter is stained with overspray from the compounding operation. While there are no tests that a certifier will conduct that tend to demonstrate that this staining is problematic, the FDA has made it clear through their published observations, 483s, that this is not acceptable. A quick review of the FDA's citations unearthed many notices of insanitary conditions for this. The only solution is to replace the HEPA filter.

The "Lip" at the base of the HEPA filter protective screen is also problematic and must be accounted for. The lip can be worked around, but the operator must know that it creates a problem and must set up the work accordingly. USP Chapter <797> mandates that a dynamic airflow smoke pattern test be performed on all unidirectional airflow ISO Class 5 devices. This test will demonstrate that there is no "first air" at the work surface. Syringes and IV bags placed on the work surface will not be considered in unidirectional airflow. All items that require placement in first air will need to be positioned above the lip and out of the turbulent flow.

Many of the LAFWs with turbulent flow zones are not equipped with diffuser screens. Baker and Nuaire for example have only been including diffuser screens as standard items since about 2015. The diffuser screen pictured to the right creates a backpressure which spreads the air evenly across the entire work zone, from side to side and top to bottom. In addition to elimination of turbulent flow zones, the diffuser screen provides better protection to the HEPA filter.

It is recommended that:

- **Diffuser screens are added to older LAFWs if not so equipped; and**
- **All future LAFW purchases include airflow diffuser screens.**