Inspections, Compliance, Enforcement, and Criminal Investigations

Evaluation of Production Cleaning Processes for Electronic Medical Devices - Part 1, Contaminants

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DEPT. OF HEALTH, EDUCATION, AND WELFARE PUBLIC HEALTH SERVICE FOOD AND DRUG ADMINISTRATION *ORA/ORO/DEIO/IB*

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In electronic applications the effectiveness of the production cleaning process can directly affect the reliability of the finished device. For example, a clean surface is necessary to ensure good bonding and coating, chemical contaminants can cause corrosion, and particulate matter may provide conductance paths resulting in current leakage or electrical short circuits. These are usually time related failure mechanisms that occur after the device has been put into use.

In order to evaluate the effectiveness of a cleaning process, some of the first things you must know are the nature of the contaminants introduced during manufacture and the solvents and cleaning methods that can be safely used to effectively eliminate or reduce these contaminants. This ITG and ITG numbers 27 and 28 have been written to provide information in these areas. The discussions refer primarily to the manufacture of electronic medical devices but can be applied to all medical devices which use alcohol, fluorinated and/or chlorinated cleaning processes. Non-electronic medical devices that are cleaned using these processes include bone implants, catheters, syringes, disposable blood filters, orygenators, dental tools, surgical tools, optical lenses and heart valves. This ITG is concerned with surface contaminants which have been proven to degrade electronic device reliability and does not address sterility.

There are two types of contamination commonly introduced during the manufacture of a device - polar and nonpolar Polar contaminants dissociate into ions in the presence of water and can be removed with water or solvents containing water, alcohol or acetone. Polar contaminants are inorganic and include deposits from flux activators and finger salts. Nonpolar contaminants include deposits from materials such as rosin, and oils and greases. These are no soluble in water unless a detergent or saponifier is added. Nonpolar contaminants are usually removed with chlorinated or fluorinated solvents.

Ionic contaminants in the presence of moisture can provide ionic activity through which dendritic growth or metallic migration can occur across insulators or between conductors providing conductance paths which may degrade operation or cause a device to fail. This type of failure mechanism has resulted in pacemaker failures and subsequent extensive recalls for more than one manufacturer. For those electronic devices which operate in a high humidity environment, such as implants, it is especially important that all ionic contaminants are removed. Ionic contamination can occur through plating, etching, handling, fluxing, or soldering operations and airborne sources.

In the manufacture of electronic products, solder fluxes are one of the most common contaminants which contribute to circuit failure. Solder flux is used to improve wettability (reduce surface tension) and to remove oxides, sulfides and tarnishes from metals or connections to be joined by solder. This is done so that a clean active surface is exposed to the molten solder to promote better solder adherence.

Pure rosin, activated rosin and water soluble fluxes are the commonly used fluxes. It is generally agreed that pure rosin fluxes will not degrade electrical assemblies if properly removed by the cleaning process. If rosin residues are

not removed, ionic contaminants can become trapped by the rosin flux residues. Also, rosin may form an invisible insulating film making a soldered connection intermittently or continuously open even though it looks good through a microscope. Activated rosin fluxes have come into common use because they can remove oxides better than the pure rosin acids. The more active the flux the easier a solder connection can be made and the fewer rejects that occur. However, if not properly removed after soldering, active fluxes can lead to corrosion and electrical failures.

Water soluble fluxes use a wetting agent instead of rosin to reduce surface tension and to promote improved soldering. They also use the same acid activators as the activated rosin fluxes only in higher concentration. They ar inherently more corrosive than rosin itself, and all residues must be completely removed with water. Most manufacturers presently use rosin based fluxes principally because the water soluble ones leave higher ionic residues

In addition to fluxes in solution, fluxes may also be contained within the core of the solder. The type of flux within the solder can be determined by a code which should be written on the solder container. An "R" code means the flux is non-activated rosin; "RMA" is a Mildly Activated flux; "RA" is Activated; "RSA" is Super-Activated having approximately twice the activity as RA; "OA" is organic-acid filled. There is also an "IA" inorganic-acid filled flux, but this flux should not be used in electronic applications as it is highly corrosive.

Fingerprints are sources of salt, grease and oils. In the presence of moisture, finger salts may dissolve into sodium and chloride ions which are highly mobile and may contribute to metallic migration, dendrites and current leakage or otherwise degrade circuit operation. Therefore, it is especially important that the cleaning process remove fingerprints in circuitry that is densely packed and operates in a high humidity environment. Finger salts are water soluble and can be removed with water or mixtures of the flourinated or chlorinated cleaning solutions and water, alcohol or acetone. The flourinated and chlorinated degreaser solutions are effective in removing grease and oils. The manufacturer should be using a cleaning process that will remove both polar and nonpolar contaminants. Gloves should be used for handling work when there is danger of fingerprints contributing to device failure.

Other common contaminants are non-soluble particles, sediment and dirt. Foreign particles can absorb atomspheric contaminants at different rates than the rest of the soiled article and may cause spot corrosion and electrical leakage. Of course the device may also become contaminated by materials used in the process.

The manufacturer of a medical device must know the types of contaminants that are likely to be introduced by the manufacturing process in order to develop an effective cleaning process. Questions in this area can reveal a lot regarding how well the manufacturer understands his manufacturing process and the controls necessary to produce a reliable product.

There are various means by which the manufacturer can monitor the effectiveness of the cleaning process. A "clean" production model of work can be tested by the extraction process to detect the level of ionic residue after the cleaning process. In this method the model is immersed in an ion free solution. The conductivity of the solution is then measured as it rises in direct proportion to the amount of ionic contamination introduced. Also, to check for salts, the model may be rinsed with distilled water and a silver nitrate solution added to the rinse. Turbidity will indicate the presence of chloride ions. Parts can be inspected under ultraviolet light for rosin residue. Fluorescence indicates rosin is present. Work may also be inspected under 20 to 30x magnification for particulate matter, sediment and dirt. (W. Fred Hooten 443-3276)

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