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Process Recovery Procedures: What to do in the Event of a Process Interruption.

You are a production supervisor, sitting in your office writing a summary report. Out the window, you can see an approaching thunderstorm, and it looks rather ominous. Minutes later, a bolt of lightning strikes close by, its loud 'crack' startling you. The lights go out for a few seconds but power is quickly restored. Although it was only a momentary interruption, you know that it is likely that all or most of the process equipment in the manufacturing area ceased operations. Two of your running processes involve Wurster coating – one uses an Eudragit latex that is temperature sensitive, the other an organic solvent based polymer that is not temperature sensitive.

What to do? The interruption alone will likely trigger a deviation requiring a QA investigation for each of the processes. Since the power was off for only a few seconds, it seems reasonable to just hit the 'start' button on the machines and continue where you left off, noting the interruption on the batch record or in-process data sheets. What are the likely consequences of this action?

It should be obvious by now that you need a plan for a process re-start. The restart procedures may be complicated by several factors: first, the type of process (a Wurster re-start may differ from simple fluid bed drying or a top spray granulation process); the temperature sensitive Eudragit latex may not be easy to re-fluidize. The solvent process may present issues with respect to explosivity. Finally, although the hypothetical situation described herein involves a short duration shut-down due to a lightning strike, suppose you have pump problems or a clogged nozzle port – what then?

It is reasonable to write a global Standard Operating Procedure (SOP) for short and longer duration process interruptions. For any type of fluidized bed, a generic version describing the steps to be performed by an operator to recover from an interruption should suffice. However, if the product incorporates a thermally sensitive coating material it is prudent to write a procedure that is product specific.

The lightning strike described in the opening paragraph would completely stop a fluid bed processor, including its fan. The first step in the recovery would be to restart the process in the same recipe step, but with the machine in the pre-conditioning mode (process air through the air handler only – not the machine tower). It is likely that the controls will have reset their outputs and that dew point and process air temperature control will require a period of time to re-stabilize. If the process is immediately restarted dew point and process air temperature will almost certainly be operating outside of their stated operating ranges, and this may also trigger a deviation. Although there may not be an impact on Critical Quality Attributes for the product, it is best that these Critical Process Parameters be in control prior to the restart.

Probably the most critical aspect of a re-start is subsequent spray nozzle performance. If the machine is equipped with atomizing air sensors, as soon as the spraying step is re-enabled, compare the reading with one taken before the interruption. If it is substantively lower, there is a chance that a nozzle has accumulated product in its air annulus blocking the flow of compressed air. This is especially critical in Wurster processing, and if this is the case, agglomeration will be immediate, potentially severe and putting the batch at risk.

Re-start procedures must consider the time of the interruption, its duration, product considerations, etc. Instructions must be sufficiently detailed to ensure an effective recovery without adverse consequences to the Critical Quality Attributes of the product.