Non-traditional statistical process control for commercial irradiation

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Abstract

Commercial irradiation typically involves applying electron beam or gamma radiation to a product with a view to sterilizing the product and killing any bacteria present. This is extremely important in the medical device industry where packaged products or pallets require irradiation between a minimum and maximum dose. As packaged product provides a level of shielding it is difficult to monitor such processes to ensuring that all products on the pallet received a dose greater than the minimum and yet less than the maximum. This difficulty was solved for both the gamma ray and electron beam radiation facilities by the use of non-traditional Statistical Process Control (SPC) techniques. By combining standardized charts and group charts, a single control chart could accommodate both minimum and maximum doses while effectively monitoring the entire process. In addition, guidance tables were developed the allowed operations to determine a window of suitable dosages that would simultaneously satisfy the irradiation requirements of different groups of products.
Keywords: Statistical Process Control, irradiation, standardized charts.

Introduction

The initial step in planning an irradiation process for a new product involves performing a dose mapping exercise. The aim of this is to characterise the process variability for the product and to determine and identify the locations where the minimum and maximum doses, D_{min} and D_{max} exist. This exercise results in the determination of a Dose Uniformity Ratio (DUR) that relates dosage received at any location to the applied radiation dose. In fact it is possible that the location where the minimum dose is found cannot be used for routine dosimetry measurements, as it will involve unacceptable unpacking or de-palletising of shippable product. A measure of process variability referred to as p is determined from the dose mapping exercise that that includes calibration uncertainty, dose mapping uncertainty and dosimeter reproducibility.

Methods

The level of quality (p) is specified for the process and a target level of radiation dose called D_{mean}. This value of D_{mean} incorporates the influence of the dose uniformity ratio and allows an operation widow of acceptable values of D_{mean}.

Typically p will be 0.001 indicating that 99.9% of all doses will be within the specified sterilization dosage range. The use of an operating window allows the planning and incorporation of numerous products inside the sterilization chamber without having to devote the test to an individual product type. Having selected appropriate values of D_{mean} for each product or group of products it is now possible to monitor the process using dosimeters. If the process is under statistical control, the measured doses at the minimum dose location will be centred on D_{mean} and will exhibit a spread consistent with the variability expected from the relevant components of uncertainty σ_p. For each product, or group of products, the dose at the monitoring location(s) D_{mon} (corresponding to D_{mean} as calculated from the dose mapping) is determined. The plot point on the control chart D_{plot} is then calculated using: $D_{plot} = (D_{meas} - D_{mon})/\sigma_p$ where D_{meas} is the measured dosage at the monitoring location(s).

Results

Guidance tables were developed that assisted in the determination of the D_{mean} operating process window for various values of σ_p. Standardised group charts allowed the monitoring of all products and multiple simultaneous dosimeter measurements on the same SPC chart. The standardised control limits were set at $\pm 3.5\sigma_p$ to avoid unnecessary false alarms in the process. Both the minimum and maximum measured doses were plotted on the same chart.

Discussion

This control charting method has proven very effective in the monitoring and control of commercial radiation facilities and has been accepted by the European panel on gamma and electron irradiation as the method of monitoring and controlling irradiation processes in these facilities. The use of the operating window for D_{mean} has meant that numerous products can be irradiated simultaneously with a common value of D_{mean} that meets the minimum and maximum specified doses of all the products.

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