

Radiation Chemical Process Indicators

Radiation Chemical Process Indicators (CPIs) are manufactured to meet performance specifications described in ANSI/AAMI/ISO 11140-1






“Sterilization of health care products - Chemical indicators - Part 1: General Requirements,” for Class 1 Process Indicators. The color transitions are dose dependent (see chart to the right). Radiation CPIs are not intended for use as dosimeters, but rather as throughput process indicators used to monitor exposure to radiation processes. Radiation CPIs are intended for use in gamma or e-beam radiation sterilization processes.

Radiation CPIs are labeled with 24 months of shelf life and room temperature storage ($23 \pm 7^\circ \text{C}$). The shelf life is based on the date the indicating ink is applied to the substrate. Product may have a shelf life of less than 24 months at the time of purchase. Moderate heat (up to 35°C) will not adversely affect indicators performance. Labeled storage conditions should be observed at all times to maintain optimum sensitivity. Avoid contact or storage of indicators near fluorescent lighting and direct sunlight which are forms of radiation.

Exposed indicators are stable and remain the signal color when stored under labeled conditions. Each roll is individually packaged with a certificate of conformance to ensure the products’ quality and consistency.

Radiation CPIs are non-odorous and non-hazardous to use. The printed labels are safe to dispose in general waste receptacles. No MSDS required per CFR.1910.1200.

Process Indicator Configurations

Code	Product Type	Dose Level	Number of Indicators / Roll	Example
CPI-R01	Plain 1/2" (12.7 mm) circles	$\geq 10 \text{ kGy}$	5,000	
CPI-R02	Meto® gun indicators for hand-held labeling systems	$\geq 10 \text{ kGy}$	1,000	
CPI-R03	Imprinted 1/2" (12.7 mm) circles. Text reads: “Red is Exposed.”	$\geq 10 \text{ kGy}$	5,000	
CPI-F01	Low dose. Plain 1/2" (12.7mm circles)	$\geq 3 \text{ kGy}$	5,000	
CPI-R06	Meto® gun indicators for hand-held labeling systems	$> 10 \text{ kGy}$	1,000	

Product Color Change Performance¹ Radiation Chemical Process Indicators

Product CPI-R01

Unexposed		1 kGy ³	
UV Light ² 20 Minutes		10 kGy	

Product CPI-F01

Unexposed		1 kGy ³	
UV Light ² 20 Minutes		10 kGy	

¹ Samples are representative of performance according to ISO 11140-1 for Class 1 Process Indicators.

² The ultraviolet radiation that is designed to show the indicator does not change color when exposed to short periods of non-ionizing radiation such as sunlight.

³ No change or a change that is markedly different from the visible change to red or violet is expected after exposure to a dose level of 1 kGy.