

A New Bulk Package for Filling Sterile Contrast Syringes in the CT Suite

A Pharmacy Bulk Package (PBP) is a container of sterile preparation for parenteral use that contains many single doses. The contents are intended for use in a pharmacy admixture program and are restricted to the preparation of admixtures for infusion through a sterile transfer device, for the filling of empty sterile syringes (USP's definition, 2015). PBP is intended to be prepared in a suitable work area, such as a pharmacy with a laminar flow hood. Contrast used in radiology is usually prepared through a PBP.

A new bulk package has recently been developed that allows filling of multiple sterile, single-use-only syringes with a syringe-based power injector system from one container in the computed tomography (CT) suite, using only an approved transfer set (**i.e. Bracco Injengineering Transfer Set**). Use of a laminar flow hood in the pharmacy is not required. Each individually filled syringe would be used for a single patient. **The FDA has approved this new contrast system for use outside the pharmacy in CT and has provided a new labeling package insert named "Imaging Bulk Package (IBP)".**

The Joint Commission has determined that the use of this new IBP is consistent with The Joint Commission's standards as long as certain conditions are met. The list below identifies these conditions and the associated Joint Commission hospital accreditation standards.

1. The IBP contrast system is used only in the CT suite and stored according to manufacturers' recommendations.
Relevant Standard: MM.03.01.01, EP 2.
2. The IBP contrast system is used according to the manufacturers' recommendations: i.e. The IBP is used in conjunction with a syringe-based power injection system or approved contrast management system for multiple patient use.
Relevant Standards: MM.03.01.01, EPs 2 & 7, MM.05.01.07, EP 2, MM.05.01.09, EPs 1, 2, 3 & 5 and IC.02.01.01, EP 1.
3. Staff are educated on the IBP contrast system for use in CT.
Relevant Standard: HR.01.05.03, EPs 1, 4, 5, 6, & 7
4. Staff are competent to use the IBP contrast system for use in CT.
Relevant Standard: HR.01.06.01, EPs 1, 2, 5, 6, & 15.

Surveyors will be focusing on these areas to determine if the organization is using the IBP safely in CT.

Additional sources for this topic are:

<http://www.ismp.org/Newsletters/acutecare/showarticle.aspx?id=89>

http://imaging.bracco.com/sites/braccoimaging.com/files/technica_sheet_pdf/PR-ISOVUE-IBP-Press-Release-11-19-14.pdf