



NOTE: Original TJC e-mail abridged, and grammar and spelling errors corrected.

24 April 2015

Thank you for your inquiry. Below you will find the response to your original submitted question(s).

The following question was submitted:

The question has arisen in imaging CT regarding the "imaging bulk pack" (Isovue) that is being used as a contrast medication drawn up aseptically with the bulk pack remaining in the room and separate syringes being utilized on multiple patients. This product has FDA approval for packaging, but again the concern in multiple patient use from a single source. The bulk pack remains in the room during various patients and exams.

The Joint Commission response:

Isovue Imaging Bulk Package is a specific combination multi-patient, multi-dose compliant contrast medium. It is approved by the FDA for point of care use in CT. A bulk contrast package is not considered to be a multi-dose vial (MDV) as there is no preservative in the container therefore it has a short time that it can actually be used. MDV guidelines do not apply.

I hope you will find this information helpful. If you have additional questions, please visit our website and complete the online question submission form. Please indicate if you are accredited by The Joint Commission when completing the form.

Please understand that full compliance with the intent of the standards may only be assessed during an onsite survey.

Updates to The Joint Commission accreditation and certification requirements are published in the Perspectives Newsletter and via our weekly on-line newsletter. Your organization's Accreditation Coordinator has access to the Perspectives Newsletters...

Thank you,

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