

FAQs for The Joint Commission's 2007 National Patient Safety Goals (Updated 1/07)

Questions about goal #3 (Medication safety):

[3A] Note: Requirement 3A (concentrated electrolytes) is not a requirement of the 2006 NPSGs. However, it remains a requirement of Medication Management standard MM.2.20, EP #9.

[3B] Does the requirement for standardizing and limiting the number of drug concentrations available in the organization refer specifically to concentrated electrolytes, or is it intended to be a general statement concerning drug concentrations? What about oral medications?

While the principle behind this requirement can apply to any drug, standardization is not usually a concern with oral medications because they come from the manufacturer in standardized concentrations. Very few hospital pharmacies compound different strengths of oral products on a regular basis. This requirement applies primarily to drugs frequently compounded in the hospital—most commonly to parenteral infusion or IV solutions. For purposes of the survey process, this requirement applies to “high alert” medications, including but not limited to concentrated electrolytes, intravenous anticoagulants, insulin preparations, opiates, cardioactive drugs, pressors, and antihypertensives. However, the principle of standardization to improve the safety of care recipients is broadly applicable, so a broader implementation of this requirement should be considered. [2/06]

New—[3B] Does the requirement for standardized concentrations apply to intermittent infusions? Some intermittent infusions, such as abciximab and cancer chemotherapy drugs, are dosed on a milligram/kilogram basis and standardizing concentrations does not seem to make sense.

Standardizing concentrations of medications given by intermittent infusion when the drug is not dosed on a milligram/kilogram basis is possible, practical and, most importantly, safer than using customized concentrations. For example, one does not need to compound a 1.346mg dose of cefazolin. Having cefazolin available in a limited number of concentrations (e.g. 1 gm/50ml, 1.5gm/50ml, and 2gm/50ml) is quite feasible and therefore is required by the safety goal. However, for drugs like cancer chemotherapy agents which are dosed based on the patient's weight or body surface area, standardized concentrations of intermittently infused drugs is not practical, is wasteful, and may have a higher potential for harm, particularly when dealing with hazardous cytotoxic chemotherapeutic agents. Therefore, this NPSG requirement for having a limited number of standardized concentrations does not apply in these situations. Requirement 2B is meant to apply only to drugs administered by continuous infusion and those intermittent infusions which are not dosed by weight (mg/kg) or body surface area (mg/m²). [New, 1/07]

[3B] We are a pediatric hospital and need to have multiple concentrations of certain drugs because our patients come in different sizes. How can we comply with this goal?

When multiple concentrations of a drug are necessary (such as for infants or other special clinical uses), special precautions should be taken to avoid dosing errors. For example, the order should specify actual drug dose, not volume, and write out the dose calculation—including the specific data elements such as the person's weight, dose per unit weight, rate of administration—

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as part of the order. The reason for this is to provide sufficient information for the pharmacist reviewing the order and preparing the medication, and the nurse administering the medication to re-calculate the dose as a check. [9/05]

New—[3B] Is the Broselow-Luten color-coded system for pediatrics acceptable under NPSG 3B?

To properly answer this, we must first note that there are two different Broselow systems available. One is a color-coded Broselow “crash cart” system for pediatric resuscitation events—this system is familiar to many organizations. The other is the recently-released Broselow-Luten color-coded system for dosing pediatric medications (including infusions) whenever the doses need to be adjusted for height or weight.

The older versions of the tape in the Broselow pediatric crash cart system that were used to measure the child and identify the proper zone had dosing guidelines for the medications given by continuous intravenous infusion that varied the concentration of the drug for the color zone, while keeping the rate of infusion constant (1ml/min). This is not acceptable under NPSG 3B. Newer versions of the tape have corrected this. However, the basic concept of a color-coded system is valid and acceptable, since the main purpose of the tape has been for dosing the multiple medications listed that are given IV push and those indications remain valid along with selecting the proper resuscitation equipment. However, if the older version of the tape is still in use, the hospital will have to develop and use a different method for dosing of pediatric infusions. This may involve developing a new set of charts that vary the rate of infusion to match the color zone while keeping the concentration of the IV drug constant.

The newer Broselow-Luten color-coded system for dosing non-emergency, intermittent infusion medications can be used without violating NPSG 3B. Requirement 3B only applies to drugs given by continuous infusion. The new system does include a component allowing standard concentrations for emergency infusions. In addition it addresses dosing of drugs given by intermittent IV infusion (such as antibiotics), and thus Requirement 3B is not applicable. However, it should be noted that the new Broselow-Luten system provides for—but does not require—admixing of medications by nurses on the patient care unit. This is not supported by The Joint Commission, and is contrary to standard MM.4.20, EP #1. This element of performance requires that the pharmacy prepare all IV admixtures except in emergency situations or when not feasible (e.g., due to the stability of the drug). The system may, however, be of value in emergency situations or when the stability of the drug does not allow pharmacy preparation, thus requiring the nurse to admix the drug. It may also be useful at the pharmacy level as well to shorten turn around time and decrease potential errors, especially for institutions that infrequently administer medications to children. [New, 1/07]

[3B] We are a pediatric hospital and have been using the Rule-of-6 method for preparing intravenous infusions. We understand the need to transition to standardized concentrations but want to do it in a planned, safe manner. Can we use the Broselow Tape while we are in transition?

The requirement to standardize and limit the number of concentrations of drugs has been in place since 2003. However, for organizations that provide pediatric or neonatal services that are not already using standardized concentrations, a transitional period has been provided (see next

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FAQ). The transition must be completed by the end of 2008. During this transition to standardized concentrations, if the organization has been using the Rule of 6 and the Broselow Tape is part of its system, then it may continue to use it for that purpose during the transition as long as it has submitted and received approval of a Request for Review of an Alternative Approach to the NPSG and is complying with the criteria for transitioning from the Rule of 6 to standardized concentrations.

[Revised, 1/07]

[3B] What are the criteria for pediatric/neonatal services making the transition to standardized concentrations?

For organizations that provide pediatric or neonatal services that are not already using standardized concentrations, a transition to standardized drug concentrations must be completed no later than December 31, 2008. Participation in this transition process will be handled as an Alternative Approach to this safety goal. Requests for Review of this Alternative Approach will be considered on an organization-by-organization basis and will require ongoing evidence of progress toward full implementation of the use of standardized drug concentrations. The eligibility criteria for participation in the transition process are as follows:

- The exception request applies only to the neonatal or pediatric acute care services provided by the organization.
- Emergent and nonemergent admixtures are prepared only by pharmacy staff in a sterile environment.
- Calculations respecting the drug solutions are validated during the preparation.
- The labeling of solution concentrations and drug per milliliter are clear to all caregivers, and the solution concentration (amount of drug per unit volume of solution) is clearly indicated on the label.
- If the Rule of 6 is used in a pediatric setting, but standardized drug concentrations are used in other parts of the hospital, guidance aids are made available to caregivers who may not be familiar with one of these systems.
- If the organization has a neonatal intensive care unit, the pharmacy is open 24 hours a day to support the admixture service.
- Smart pumps are utilized. [A “smart pump” is a parenteral infusion pump equipped with IV medication error-prevention software that alerts operators or interrupts the infusion process when a pump setting is programmed outside of pre-configured limits. Smart pumps are designed to recognize prescription errors, dose misinterpretations, and keypad programming errors.] [2/06]

[3B] Does NPSG 3b require that parenteral nutrition (PN) solutions be standardized in their component concentrations, including electrolytes?

Technically, these products are drugs and thus this safety goal should apply. However, standardization of multi-component solutions like PN is much more complex than with single drug solutions, for which this requirement was originally intended. The Joint Commission is aware that standardized preparations of PN are available commercially, are used in some hospitals for many of their patients, and potentially can improve the safety of the PN system. Studies on their use are currently underway in major teaching institutions. However, other

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systems for the compounding and administration of PN may provide certain patients more clinically appropriate formulations with proper safeguards. Because of the complexity of the problem and the limited experience in this area, standardized PN formulations are not currently required under NPSG 3B.

The Joint Commission has entered into discussions with the American Society of Parenteral and Enteral Nutrition (A.S.P.E.N.) to explore the possibilities for standardization in this clinical area. We have agreed that the intent of NPSG requirement 3B is to reduce variation and that a standardized process for managing PN is essential to meet this intent. A standardized PN process may include standardized commercial formulations of PN, but most importantly includes standardized ordering formats, labeling, terminology, etc. A task force has been appointed to develop recommendations for a standardized process for PN. Organizations are encouraged to review the current literature on this topic and to evaluate the pros and cons of using standardized PN formulations when appropriate for patients requiring nutritional support. [Revised, 1/07]

New—[3B] In our organization, the emergency department (ED) uses Dilaudid frequently for pain management. The typical ED dose is 1 mg. Approximately 75% of the doses are of this amount. However, only Dilaudid 2 mg/ml is available in the ED automated dispensing device. This causes a significant amount of wasting of the unused narcotic. In order to comply with the standardization of drug concentrations available in the hospital, the pharmacy is reluctant to allow that unit to have a different concentration of the drug than what is available in other units (all other units have Dilaudid 2 mg/ml only). Are we required to standardize the concentration of the drug across the entire hospital, or just to minimize concentrations available in each unit?

The intent is to limit and standardize drug concentrations across the organization. Some of the errors we have seen resulted from incorrectly stocking automatic dispensing devices with the wrong concentration of a drug that was available in the organization's pharmacy in multiple concentrations even though only one concentration was normally used on any given unit. [New, 1/07]

[New—3C] Have the lists of look-alike/sound-alike (LASA) drug pairs that are posted on The Joint Commission website been updated?

Yes. These lists were updated in August 2006 to reflect changes in the availability, names, and packaging of certain drugs. Changes are identified in the lists. Under Requirement 3C, each organization must review its list of LASA drugs on an annual basis. If you have not done this since August 2006, your organization-specific LASA list might be out-of-date and should be reviewed and compared with the updated lists on the website to be sure that all items on your list continue to be cited as LASA risks. The lists are available at <http://www.jointcommission.org/PatientSafety/NationalPatientSafetyGoals/> under "2007 Resources." [New, 1/07]

[3C] Can we select different combinations or mix and match medication pairs on the list?

You must select the pairs as listed on Tables I, II, &/or III on The Joint Commission's website under National Patient Safety Goals. [2/06]

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[3C] If our organization does not store or dispense medications does NPSG 3C apply?

If your organization “uses” medications, NPSG 3C applies. The term “use” refers to any component of the medication management process: selection and procurement, storage, ordering and transcribing, preparing and dispensing, administration or monitoring. [2/06]

[3C] If our organization does not use medications from 10 of the pairs on the lists of look-alike/sound-alike (LASA) medications, do we still need to select 10 pairs?

Your organization should start with the lists provided by The Joint Commission to identify 10 pairs of look-alike and sound-alike medications that your organization uses. If you are unable to identify 10 pairs from those lists, you should select other pairs of dangerous or easily confused medications pertinent to your organization to bring the total number of drug pairs up to 10. Comprehensive lists of LASA drugs are available on the web sites of the Institute for Safe Medication Practices (<http://www.ismp.org>) and the U.S. Pharmacopoeia (<http://www.usp.org>). [2/06]

[3C] What if we just can't identify 10 pairs?

If, after searching all available resources concerning LASA drugs, you are still unable to identify 10 relevant pairs, you must submit a Request for Review of an Alternative Approach to a National Patient Safety Goal, describing the services you provide, the medications you use, and the resources you have used in your effort to identify relevant pairs of LASA drugs. [2/06]

[3C] If we only use 1 drug in a pair that is listed or we use none of the look-alike/sound-alike medications on The Joint Commission's lists, how would this goal apply?

If your organization only uses 1 drug of a pair that is on one of The Joint Commission's lists, you need to have on your list at least the pair in which that drug appears. If you do not use any of the LASA medications on The Joint Commission lists or on the more comprehensive ISMP or USP lists, then this goal would not apply to your organization. [2/06]

[3C] Are there specific actions that we must take to avoid confusion of LASA drugs?

The requirement is to “take action to prevent errors due to the interchange of these drugs.” The specific actions you take are up to you. Your choices should be based on an analysis of your medication systems, recognized best practices, and specific strategies and general recommendations provided in the literature. Several suggestions are provided with the lists of LASA drugs posted on The Joint Commission web site. Note that standard MM.2.20, EP #6 uses the term “segregated” in relation to drugs that can be easily confused. This term is used in its broadest sense and does not specifically require spatial separation.

Specific actions should be considered for each phase of the medication management process: procurement, storage, transcribing/ordering, dispensing and administration. Further, in addition to protecting against interchange of different drugs that look alike or sound alike, the actions must also address different strengths of the same medication (see next FAQ). In addition, consideration should be given to the following actions: Staff involved in handling LASA drugs should be periodically educated on potential LASA medications and packaging, as well as the hospital's strategies to reduce LASA errors; the organization should evaluate technologies such

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as bar coding and computerized prescriber order entry (CPOE) systems that might be used to minimize LASA errors.

[Revised, 1/07]

[New—3C] Do we need to treat different concentrations of the same medication as LASA drugs?

Yes. It is a safe practice to store different concentrations or dosages of a drug in a manner that will minimize the risk of accessing the wrong strength of the drug. This does fall under the requirements of this “LASA” safety goal. The intent of this NPSG requirement is to avoid confusing different drug preparations, including different strengths of the same drug. Note that NPSG requirement 3B is relevant here: the number of concentrations (or dosages) of any given drug should be limited.

[New, 1/07]

[3D] Does NPSG 3D apply only in the operating room?

NPSG 3D applies to any surgical or other procedural setting and includes pre-, intra-, and post-operative/procedural components. Consequently, it applies not only to the surgical suite but also to prep areas, pre-op holding, and PACU. It also applies to medications used by anesthesia providers. In fact, it applies to all procedural areas that use medications or solutions including, but not limited to, radiology and other imaging services, endoscopy units, dental services, and patient care units where “bedside” procedures are done. [2/06]

[New—3D] The 2007 Rationale statement for Goal 3D speaks to this risk reduction activity as addressing the risks of "medications in perioperative settings." In 2006, we understood that this requirement applied to all procedural settings. Has this changed?

No; we haven't changed the applicability—at least not intentionally. This is another example of discrepancies that arose during the reformatting of the NPSGs. The scope of this requirement has been, and will continue to be, all “perioperative and other procedural settings” as was explicitly stated in the 2006 version of this requirement. This and other discrepancies that have been identified in the initial release of the 2007 NPSGs will be corrected, posted on The Joint Commission website, and published in subsequent updates to the accreditation manuals. [New, 1/07]

[3D] Are there any exceptions to the labeling requirement?

If during the peri-operative or peri-procedural process, a solution or medication (either in the sterile field or out) is poured, drawn into a syringe, or otherwise used from its original container and immediately administered or disposed of in some fashion, labeling is not required.

However, if the medication or solution that has been removed from its original container will be used over the course of a procedure, for instance—prep solutions, normal saline used to rinse cardiac valves, local anesthetics, clotting agents, etc.—the receiving container must be labeled.

This is also relevant to anesthesia services. If the anesthesia provider prepares a medication for immediate use (e.g., draws up and immediately administers and/or disposes of the entire contents of the syringe without leaving the area or moving to another function prior to administration), labeling of the syringe or other container is not required. However, if the

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medication is prepared and slowly administered over the course of a procedure, if the medication is prepared by a staff member other than the administering provider, if the medication is prepared in bulk for the day's cases, or if the provider preparing the medication participates in another function prior to administration, the syringe or other container must be labeled. [2/06]

[New—3D] If a clinician draws up two medications into two separate syringes, then administers both medications, do the syringes need to be labeled?

Yes; they would need to be labeled. The only exception to the labeling requirement is when a medication or solution is prepared (drawn up or poured) and immediately administered. In this context, "immediately" means with no intervening other activity. Preparing two medications at the same time does not meet this definition; therefore each would have to be labeled. [New, 1/07]

[3D] When labeling medications and solutions in the context of NPSG 3D, what information must be on the label?

The labeling expectations for this safety goal are consistent with the requirements of standard MM.4.30, Elements of Performance 3 & 4, which state the label must include:

- Drug name, strength, amount (if not apparent from the container)
- Expiration date when not used within 24 hours (this would be rare for procedures)
- Expiration time if less than 24 hours (applies to only a few drugs)
- Date prepared and the diluent for all compounded IV admixtures

In most cases of medications and solutions in the procedural setting, only the drug name and strength (concentration) will be needed. [2/06]

[3D] We have discovered that pre-sterilized, pre-labeled syringes are now commercially available. Is this acceptable?

No; prelabeling medication and solution containers is not acceptable. The label should be prepared and applied at the time the medication or solution is prepared. Applying the label immediately before drawing up the medication is acceptable and may make the process of checking the label against the original container more efficient. We have also heard that some people are engraving basins for use only with sterile saline or other routine solutions. This practice carries some risk of pouring a solution into a basin that is pre-labeled for a different solution and is not considered acceptable. It is quite acceptable to purchase and use pre-filled, pre-labeled syringes such as on procedure trays.

[Revised, 1/07]

[New—3D] It has been our practice to pre-label syringes for anesthesia medications for the anesthesia cart in the trauma room as a means of reducing the time it takes to prepare needed medications when faced with an emergency situation. Isn't this a reasonable exception to the "no pre-labeling" rule?

The basis of our current position prohibiting the pre-labeling of empty syringes is the established medication management principle that labeling is part of the medication preparation process and should be done at the same time the medication is prepared (drawn up into the syringe). Of course, the safest approach is to use manufacturer-prepared pre-filled, pre-labeled syringes.

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Unfortunately, only a few products are available that way. Pharmacy-prepared pre-filled, pre-labeled syringes would also be a safe approach but may not be practical for anesthesia services.

The concern with point-of-care pre-labeled syringes is that a pre-labeled syringe could be inadvertently used to draw up a medication other than what is on the label. Keep in mind that when medications are drawn up and used immediately, such as in emergency situations, labeling is not required. With respect to the efficiency concerns, our expert advisors recommend having pre-printed adhesive labels for the more frequently used anesthesia medications available in the anesthesia prep area. These pre-printed adhesive labels can be applied to the syringes when the medications are drawn up and checked against the original container with virtually no additional time. They also avoid the variability and illegibility problems associated with hand-written labels. [New, 1/07]

[3D] When requirement 3D was first announced, the Implementation Expectations said the initials of the person preparing the medication or solution and the date of preparation needed to be on the label. Are those items still required?

No. These additional requirements were reviewed late in 2005 and were deleted based on expert opinion that these items did not add to the safety of the medication use process. [2/06]

[3D] The Implementation Expectations also require a two-person verification of the label. Is this still required?

Yes; if two or more people participate in the preparation and administration of the medication or solution, a two-person verification of the label's accuracy is required. However, if the same person prepares and administers a medication, or pours and uses a solution, a two-person verification is not required. In these one-person scenarios, if the medication or solution is not used immediately, it will still need to be labeled, but verification by a second person will not be required. [2/06]

New—[3D] We have a pharmacist assigned to the OR to assist in the preparation of medications and solutions. Do syringes prepared or mixed by the Operating Room Pharmacist require another individual to verify the labeling of the syringes?

Medications prepared and labeled by a pharmacist would not require a second person verification. One of the reasons for this NPSG requirement is that in procedural settings, the usual processes for preparing and dispensing medications often are not followed. Involving the pharmacists gets it back to the "usual processes" and their attendant safeguards. [New, 1/07]

[3D] Is it acceptable to "label" a syringe by taping the vial (from which the medication was drawn up) to the syringe?

No; this is not acceptable as a label. [2/06]

[3D] Labeling med cups and basins on the sterile field has been challenging for us. Labels don't stick; markers don't mark; we're getting mixed opinions about pre-labeled containers. What do you suggest?

We are aware of these problems and, while there are no perfect solutions, we can offer some advice. First, sterile labels are available and will adhere to most containers, including bulb

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syringes, if the surface is dry. In the case of bulb syringes, this means the label must be applied before submerging the syringe. AORN recommends placing the label at the furthest point from contact with the solution and not placing the properly labeled device into the larger container of solution. For example, for an "Asepto" syringe, place the label at the top collar of the unit and do not leave the syringe in the irrigation basin. Other options are to use sterile skin adhesive strips across the top width of the bulb of the syringe. [2/06]

[3D] What is the expectation for labeling contrast media that are loaded into power injectors?

The expectations are the same as for other medications. If the contrast is drawn up and administered immediately, it doesn't have to be labeled. If it is not administered immediately, then it must be labeled. It doesn't matter whether it is administered manually or by power injector. [2/06]

[New—3D] For requirement 3D, Implementation Expectation (IE) #7 says "All original containers from medications or solutions remain available for reference in the perioperative area until the conclusion of the procedure" and IE #8 says: "All labeled containers on the sterile field are discarded at the conclusion of the procedure." We are being asked to place the opened vials, ampules, intravenous solution bags, and syringes (some with attached, non-disposable needles) in a plastic bag on our anesthesia carts. The bag is then discarded at the conclusion of the procedure. This raises a number of safety issues: clutter that can hamper the safe administration of the anesthetic to the patient; the plastic bag can be punctured by broken glass ampules or needles; excess fluids (some bloody) can spill out to contaminate other equipment on the cart; and providers can be subject to needle sticks or cuts from broken glass. Can't we go back to our previous safe practice in which those items were immediately disposed of in an authorized "sharps" container?

The Joint Commission's requirements do not specify that the vials, etc. be placed in plastic bags; the requirement merely states that the opened items "remain available for reference." Nothing is said about what kind of container would be appropriate or where, during the procedure, it should be kept. We are interested in staff safety as well as patient safety—the two should go together. If you were previously disposing of these items in a sharps container or other safe disposal method that retains the items in the perioperative area and that will allow access to the items if the need should arise, then that will be sufficient to meet this requirement. The need to re-verify the drugs and concentrations that have been administered to the patient should arise very infrequently. However, when it is needed, it should be possible to do so. [New, 1/07]