2004 National Patient Safety Goals FAQs

Questions about the applicability of the National Patient Safety Goals (NPSGs) and associated requirements:

Will these goals apply to organizations other than acute care hospitals? I see that some of the seven goals could be implemented in our setting, however some could not.
The NPSGs apply to all accredited organizations and to those seeking accreditation. Each requirement should be considered with respect to its relevance to the services the organization provides. For example, if the organization doesn’t do any surgical or other invasive procedures, the requirements relating to wrong-site surgery would not be relevant. For 2004, some of the terms used in the NPSGs have been modified to conform to the conventions of the settings of care and patient populations of the specific accreditation programs. Also, during the early part of 2004, new program-specific goals and requirements will be identified for implementation in 2005. Please visit the individual accreditation program web pages for more details about the program-specific safety goals. [Revised 1/1/04]

If some of the requirements are not relevant to the services we provide, will we then need to submit alternate efforts to make a list of 13?
No. If only eight of the requirements are relevant to the services you provide, then you only need to attend to those eight. Certainly, if you want to do more, we would encourage that, but we won't require it or survey it.

What is the evidence base for these goals and requirements?
Like most of what we do in medicine, these requirements are not based in solid, well-designed, statistically valid, controlled, double-blinded scientific research. One only has to look at the AHRQ/Stanford Evidence Report #43: Making Health Care Safer to realize that there is very little such evidence available. In the absence of good scientific evidence, we have to ask ourselves, is it better for our patients if we practice medicine based on expert consensus or on individual practitioner preference? JCAHO’s position favors the former and that is the approach we have used in developing the NPSGs. The "expert consensus" comes from the Sentinel Event Alert Advisory Group and other "expert" recommendations in the literature. There are also supporting data from our Sentinel Event Database, which includes more than 2,400 sentinel events and their root cause analyses.

To what extent is an accredited organization accountable for implementation of the NPSGs by “outside” individuals or other organizations that provide services to the accredited organization and its patients?
In these situations where the accredited organization cannot directly influence the actions of the “outside” individual, service, or organization, the accredited organization must, at a minimum, inform that entity about the relevant requirements of the NPSGs and encourage their compliance with those requirements. For example, this “inform and encourage” approach is applicable to accredited health care networks with respect to their unaccredited components or to accredited freestanding pharmacies with respect to prescribing practitioners who are not employed by the pharmacy. It is not applicable to members of a hospital’s medical staff when providing care to the hospital’s patients. In this situation, the hospital is accountable for compliance with the NPSG requirements by the members of its medical staff and other independent practitioners granted privileges to provide care to patients in the organization. [New 1/1/04]
What are the expectations for an accredited health care network with respect to the NPSGs?
Health care networks typically provide patient care services through their component provider organizations and practitioner sites. If a component of a network is accredited, then it will be expected to comply with all of the relevant NPSG requirements as part of its own accreditation requirements. For unaccredited components of the network, the network itself is required to inform those unaccredited components about the relevant requirements of the NPSGs and encourage their compliance with those requirements. [New 1/1/04]

Questions about implementing the requirements:

Do we have to be compliant with all seven patient safety goals and their associated requirements or do we have the option of picking two patient safety goals to work with in the ensuing year?"
You must be in compliance with all of the requirements associated with the seven NPSGs (there are 13 requirements for 2004). The only exception would be if a requirement is not relevant to the services provided by your organization.

As of January 1, 2004, are health care organizations expected to have all of the requirements implemented or are we allowed to stage them over the course of the calendar year?
The expectation is that each accredited organization will have implemented all of the requirements (there are 13 of them) associated with the seven NPSGs that are relevant to the services the organization provides. For requirements that were part of the 2003 NPSGs (goals 1 through 6), at least 12 months of compliance will be expected for organizations surveyed after January 1, 2004. For requirements that are new for 2004, compliance from January 1 forward is expected. [Revised 1/1/04]

What if we want to address a particular NPSG requirement using a different approach than is specified by JCAHO?
An organization may substitute an approach that is different from a published NPSG requirement if that alternative approach is submitted to JCAHO and is accepted by JCAHO based on review and advice from the Sentinel Event Alert Advisory Group. Details of the process and the form for submitting a request for review of an alternative approach are available on the JCAHO website at <www.jcaho.org>.

What measurement requirements are associated with the NPSGs?
In general, there are no prescribed requirements for measurement/data collection relating to the NPSGs; the requirement is only to be in compliance with the goals and their specific requirements. For some of these, a surveyor might ask how you know that you are in compliance on an ongoing basis throughout the organization. This might involve some sort of surveillance or monitoring, but JCAHO doesn’t specify how to do that. Keep in mind that if compliance with a particular goal requires a significant new design or redesign, then certain measurement requirements are established by applicable Leadership and Performance Improvement standards. Also, the Leadership standards require the leaders to set priorities for improving the safety and quality of care, and the Performance Improvement standards require data collection for activities related to those priorities. It is expected that the requirements of the NPSGs will be at least considered as high-priority activities to be monitored. If not, the organization should be prepared to explain why other activities were assigned higher priorities.
Questions about how the goals and requirements will be surveyed:

In what type of surveys will compliance with the NPSGs be evaluated?
The NPSGs are surveyed in all regularly scheduled and unannounced surveys.

What will surveyors be looking for? Do we need to be able to show an action plan with an evaluation of the goal, steps to achieve, completion date, post-implementation monitoring, and plan for holding the gain?
Surveyors will look for evidence of consistent implementation of the requirements, but you don’t need to do any special documentation for JCAHO that you wouldn't be doing for yourselves in implementing these requirements. The surveyors will look at whatever documentation you have that is relevant and will interview the organization's leaders and direct caregivers to determine whether the requirements have been implemented and how consistently they are being done. It's the actual performance we are interested in, not the paperwork. The topic of post-implementation monitoring may come up in conversations with organization leaders who may be asked, "How do you know if this is being consistently done on a day-to-day basis?" (See Q&A on “measurement requirements” in preceding section.)

Is it sufficient to have these goals in place when we are surveyed or will surveyors be looking for a “track record” of compliance?
Regardless of when a survey is conducted during the year, scoring will be based on an expectation of continuous compliance. For requirements that were part of the 2003 NPSGs (goals 1 through 6), at least 12 months of compliance will be expected for organizations surveyed after January 1, 2004. For requirements that are new for 2004, compliance from January 1 forward is expected. A significantly shortened track record will result in a Requirement for Improvement. [Revised 1/1/04]

Questions about the scoring, follow-up, and disclosure of non-compliance with the NPSGs:

Will these goals and requirements be scored against the standards? Which ones?
In 2004, the specific requirements associated with each of the first three goals are also found in the 2004 standards. These requirements will be scored at their respective standards. For each of the remaining four goals, noncompliance with one or both of its requirements will be scored at the Accreditation Participation Requirement (APR) associated with the goal. [Revised 1/1/04]

How do we clear a Requirement for Improvement associated with the NPSGs? 
Assignment of a Requirement for Improvement for noncompliance with an NPSG requirement must be addressed in the Evidence for Standards Compliance (ESC) report as for any standards-based compliance issues identified on survey. This ESC must provide evidence of actions taken by the organization to come into compliance with all NPSG requirements found not in compliance at the time of survey, and the plans—including appropriate measures—for ensuring sustained compliance. [Revised 1/1/04]

What if compliance is not demonstrated in the ESC report?
Failure to demonstrate full compliance will result in a change in status to Provisional Accreditation. [Revised 1/1/04]

What information about organizations’ compliance with the NPSGs will JCAHO make available to the public, and when?
Compliance with the NPSGs will be included in organization-specific Quality Reports beginning around mid-year 2004. Aggregate data on NPSG compliance during 2003 is posted on this website. [Revised 1/1/04]

Questions about the other recommendations published in Sentinel Event Alert:

Some time ago, JCAHO suspended the survey and scoring of organizations’ compliance with Sentinel Event Alerts. Are there plans to reinstate the scoring of the Sentinel Event Alert recommendations when an organization does not implement the recommendations? No. The only Sentinel Event Alert “recommendations” that will be scored are those that are identified as requirements of the NPSGs. All other SEA recommendations will be published and available for consultation by surveyors and consideration by the health care organizations, but they will not be scored (unless they are also requirements of the standards).

Will organizations still need to document that they are reviewing each issue of Sentinel Event Alert and implementing the recommendations? No. We expect organizations to review the Alerts and implement the recommendations that are relevant to the services they provide, but we will not be surveying and scoring their responses to the Alerts in general, only those requirements that are associated with the NPSGs.

I understand that the Sentinel Event Alert Advisory Group identified a pool of recommendations that were valid and should be considered by health care organizations for implementation, even if they were not among the requirements associated with the NPSGs. What about all the other recommendations published in Sentinel Event Alert that were not selected for this “pool?” To be selected for the “pool,” a recommendation had to meet all of the Advisory Group’s selection criteria, including being evidence-based or expert consensus-based, practical for implementation in all organizations providing relevant services, cost-effective, having potential for significant improvement in the safety of individuals receiving care, and being sufficiently well defined to be actionable. A recommendation was not included in the "pool" if it did not meet all of the Advisory Group's selection criteria. Even those recommendations that are not in the pool are valid recommendations that should be considered for implementation on a selective basis by health care organizations.

Will the NPSGs replace the Sentinel Event Alerts? No. The goals and associated requirements are derived from the Alerts but we will continue to publish new Alerts periodically.

Questions about goal #1 (Patient identification):

What is the intent of the requirement for using “two identifiers”? The intent here is two-fold: first, to reliably identify the individual as the person for whom the service or treatment is intended; second, to match the service or treatment to that individual. Therefore, the two patient-specific identifiers must be directly associated with the individual and the same two identifiers must be directly associated with the medication, blood products, or specimen tube (such as on an attached label).
What do you mean by "two patient identifiers"? For those patients with armbands, we're thinking patient name and ID number compared to the order/MAR would be the two identifiers. Also, most of our patients could be asked their names as a third identifier. Yes, that is acceptable. The two identifiers may be in the same location, such as a wristband. It is the person-specific information that is the "identifier," not the medium on which that information resides. Acceptable identifiers may be the individual's name, an assigned identification number, telephone number, or other person-specific identifier. Bar coding that includes two or more person-specific identifiers (not room number) will comply with this requirement.

Is JCAHO now requiring the use of armbands for identification?
No. While the use of identification bands is common in the acute care environment, this is not routine in other settings of care or for certain patient populations, and it is not a JCAHO requirement. Other methods of identification may be used as appropriate to the care setting and individuals served. [New 1/1/04]

Is it necessary to ask the patient to state his/her name and other identifier each time a medication or blood product is administered or a blood sample is drawn?
No. The requirements for identifying the patient do not specify that the patient has to be asked to state his/her name or other identifiers. The two-identifier requirement assumes a process at the time of admission whereby the patient identifiers are reliably obtained. After that, if the identifiers are "attached" to the patient (such as on an armband), they can be used to identify the patient and match to the medication/blood/sample tube without necessarily asking the patient to recite back the identifiers. [New 1/1/04]

A lot of our outpatients—those who come for a lab draw and other simple procedures, our home health patients and our ambulatory care patients—do not have an armband. Would asking them their name and comparing it to any paperwork we have constitute two identifiers?
No. In the requirement for using two identifiers, the term "identifier" refers to the ways the care recipient can be identified rather than the source of the information. So, comparing the individual's stated name with the name on the requisition would be one identifier. Examples of a second identifier for a care recipient without an armband might be date of birth, social security number, address, or phone number.

Do the same two identifiers have to be used throughout the organization?
No. Different identifiers may be used in different settings as long as their use is consistent with the intent of this requirement as stated above. However, the identifiers should be consistent within each setting, not just whatever the individual practitioner or staff person wishes to use.

How would you identify an injured ER patient who was unresponsive and could not communicate with others?
Such patients are usually assigned a temporary “name” (e.g., John Doe) and an E.D. number or medical record number. These identifiers could then be used to identify the patient and match against specimen labels, medications ordered for the patient, or blood product labels.

What about the home care situation? Do we need to keep checking two identifiers each time we give a medication?
The goal is to ensure accurate identification of care recipients. In the home care setting, this is much easier and less prone to error than in other settings. Certainly, at the first encounter, the requirement for two identifiers is appropriate in a literal sense. Thereafter, and in any situation of continuing one-on-one care where the nurse "knows" the individual, one of the identifiers can be direct facial recognition. In the home, the correct address (an acceptable identifier when used in conjunction with another person-specific identifier) is also confirmed.

We are a behavioral health care facility. The individuals in our care do not always wear wristbands. What other methods are acceptable for the “two identifiers”? A common approach in these situations is to include the individual’s photograph in the clinical record for purposes of visual identification by staff. For residential care settings that may serve only a few individuals, such as a group home, or settings in which the individual may stay for an extended period of time, where there is stability of the staff and client populations, and the individuals receiving care are well-known to the staff providing that care, we would accept that visual recognition and focus the survey of this requirement on the use of two identifiers for high risk interventions—perhaps for certain high-risk medications, like methadone—to ensure “matching” of the treatment to the individual. In other words, is the medication adequately identified (with two identifiers) for the specific individual who is to receive it? For high-risk interventions or in settings with less stable staffing and short length of stay, we would expect the "two identifier" requirement to be followed. In the future, biometric identification techniques may play a role.

Note: Effective July 1, 2004, the “time out” requirement in the NPSGs will be replaced by similar provisions in the Universal Protocol for Preventing Wrong Site, Wrong Procedure, Wrong Person Surgery™. Since the “time out” requirement is also in the 2004 standards, it will continue to be scored there. However, the expectations for compliance will be those associated with the Universal Protocol. Please refer to the FAQs for the Universal Protocol for additional details.

When should the “time out” occur?
The “time out,” or immediate preoperative pause, must occur in the location where the procedure is to be done (for example, when the patient is on the operating table). Given this restriction, the “time out” may precede induction of anesthesia or may occur after the patient is anesthetized (participation by the patient is not expected) but just before starting the procedure. [New 1/1/04]

If site marking is not required for a particular procedure, is the “time out” still required? Yes. Even if site marking is not required by goal 4b or by organization policy, the requirements for a preoperative verification process and a “time out” still apply. [New 1/1/04]

Who should participate in the “time out” process? The “time out” should involve the entire surgical team. At a minimum, this includes active participation by the surgeon, anesthesia provider, and circulating nurse. Participation by the other members of the team, as appropriate to their involvement in the procedure, is also encouraged. In particular, there should be no barrier to anyone speaking up if there is concern about a possible error. To include some members of the team but not others sends the wrong message. [New 1/1/04]

In requirement 1b, what does the term “active communication” mean? The objective is to engage all members of the surgical team in the positive identification of the patient, the intended procedure, and the site of the procedure. "Active" communication, in this
context, means an affirmation, orally or by some action, that the patient, procedure, and site are correct. It is not expected that the patient will participate in this final verification process (since at this point, the patient will usually be sedated or under anesthesia).

What if there is only one person involved in doing the procedure, such as for some bedside procedures? Is a time out still expected? Should someone else be brought in to do the time out?

Even when there is only one person doing the procedure, a brief pause to confirm the correct patient, procedure, and site is appropriate. It is not necessary to engage others in this verification process if they would not otherwise be involved in the procedure. [New 1/1/04]

Questions about goal #2 (Communication):

Has the “prohibited abbreviations” requirement under goal #2 changed? If so, how?

The long term objective of this requirement continues to be 100 percent compliance, in all forms of clinical documentation, with a reasonably comprehensive list of prohibited “dangerous” abbreviations, acronyms and symbols. However, recognizing that this type of change will take time, the survey and scoring of this requirement has been modified, effective immediately, for surveys conducted through the end of 2004, as follows:

If, on survey, the organization has not yet achieved 100 percent compliance as evidenced by open and closed medical record review, a score of “In compliance” will be recorded if the following conditions are met:

- Use of any item on the list is “sporadic” (less than 10 percent of the instances of the intended term are abbreviated or symbolized); AND
- Whenever any prohibited item has been used in an order, there is written evidence of confirmation of the intended meaning before the order is carried out; AND
- The organization has implemented a plan for continued improvement to achieve 100 percent compliance by the end of 2004. [Revised 11/3/03]

Is there a minimum number of items that must be on this list? Will JCAHO specify what should be on the list?

A "minimum list" of dangerous abbreviations, acronyms, and symbols has been approved by JCAHO. Beginning January 1, 2004, the following items must be included on each accredited organization’s “Do not use” list:

<table>
<thead>
<tr>
<th>Set</th>
<th>Item</th>
<th>Abbreviation</th>
<th>Potential Problem</th>
<th>Preferred Term</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>1</td>
<td>U (for unit)</td>
<td>Mistaken as zero, four or cc</td>
<td>Write “unit”</td>
</tr>
<tr>
<td>2</td>
<td>2</td>
<td>IU (for International unit)</td>
<td>Mistaken as IV (intravenous) or 10 (ten)</td>
<td>Write “International unit”</td>
</tr>
<tr>
<td>3</td>
<td>3</td>
<td>Q.D., Q.O.D. (Latin abbreviation for once daily and every other day)</td>
<td>Mistaken for each other. The period after the Q can be mistaken for an “I” and the “O” can be mistaken for “I”.</td>
<td>Write “daily” and “every other day”</td>
</tr>
<tr>
<td>4</td>
<td>5</td>
<td>Trailing Zero (X.0 mg) [Note: Prohibited only for medication-related notations]; Lack of Leading Zero (.X mg)</td>
<td>Decimal point is missed</td>
<td>Never write a zero by itself after a decimal point (X mg), and always use a zero before a decimal point (0.X mg).</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>---</td>
<td>---</td>
<td>---</td>
<td>---</td>
<td></td>
</tr>
<tr>
<td>5.</td>
<td>7.</td>
<td>MS</td>
<td>Confused for one another. Can mean morphine sulfate or magnesium sulfate.</td>
<td></td>
</tr>
<tr>
<td>8.</td>
<td>MSO₄</td>
<td></td>
<td>Write “morphine sulfate” or “magnesium sulfate”</td>
<td></td>
</tr>
<tr>
<td>9.</td>
<td>MgSO₄</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Effective April 1, 2004 (if your organization does not already have additional “do not use” items in place), each organization must identify and apply at least another three “do not use” abbreviations, acronyms, or symbols of its own choosing. [Revised 11/3/03]

**Is it true that use of a “trailing zero” is allowed for laboratory values and equipment sizes?**
Yes. The “trailing zero” is still prohibited for all medication orders and other medication-related documentation. However, in reporting laboratory values and in certain other numeric notations, the precision of the numeric value is indicated by the digits after the decimal point, even when that trailing digit is a zero. For example, a serum potassium level might be reported as 4.0 mEq/Liter, not 4 mEq/Liter. Similarly, sizes for endotracheal tubes and other clinical equipment are often specified numerically with one place after the decimal point. This is acceptable, even when the number after the decimal point is a zero. [New 1/1/04]

**Where can I get a list of abbreviations, symbols, and acronyms that should never be used?**
In addition to the “minimum required list” provided above, the following items should also be considered when expanding the “Do not use” list to include the additional three or more items referenced in the preceding FAQ:

<table>
<thead>
<tr>
<th>µg (for microgram)</th>
<th>Mistaken for mg (milligrams) resulting in ten-fold dosing overdose</th>
<th>Write “mcg”</th>
</tr>
</thead>
<tbody>
<tr>
<td>H.S. (for half-strength or Latin abbreviation for bedtime)</td>
<td>Mistaken for either half-strength or hour of sleep (at bedtime). q.H.S. mistaken for every hour. All can result in a dosing error.</td>
<td>Write out “Half-Strength” or “At bedtime”</td>
</tr>
<tr>
<td>T.I.W. (for three times a week)</td>
<td>Mistaken for three times a day or twice weekly resulting in an overdose</td>
<td>Write “3 times weekly” or “Three times weekly”</td>
</tr>
<tr>
<td>S.C. or S.Q. (for subcutaneous)</td>
<td>Mistaken as SL for sublingual, or “5 every”</td>
<td>Write “Sub-Q”, “subQ”, or “subcutaneously”</td>
</tr>
<tr>
<td>D/C (for discharge)</td>
<td>Interpreted as discontinue whatever medications follow (typically discharge meds)</td>
<td>Write “discharge”</td>
</tr>
<tr>
<td>c.c. (for cubic centimeter)</td>
<td>Mistaken for U (units) when poorly written.</td>
<td>Write “ml” for milliliters</td>
</tr>
<tr>
<td>A.S., A.D., A.U. (Latin abbreviation for left, right, or both ears)</td>
<td>Mistaken for OS, OD, and OU, respectively)</td>
<td>Write: “Left ear,” “Right ear” or “Both ears”</td>
</tr>
</tbody>
</table>
Also, the Institute for Safe Medication Practices (ISMP) has published a list of dangerous abbreviations relating to medication use that it recommends should be explicitly prohibited. This list is available on its website: www.ismp.org. [Revised 11/3/03]

Many of the listed abbreviations can be used in upper or lower case, with or without periods after the letters. If “Q.D.” is on our “do not use” list, can “QD” or “qd” be used? An abbreviation on the “do not use” list should not be used in any of its forms—upper or lower case; with or without periods. [New 11/3/03]

Confirming the intent of an order containing a prohibited notation may delay the patient’s treatment. What do we do if this places the patient at additional risk? The safety of the patient always comes first. If, in the judgment of the people providing care to the patient (e.g., the registered nurse and pharmacist), the order is clear and complete and the delay to obtain confirmation from the prescriber prior to execution of the order would place the patient at greater risk, then the order should be carried out and the confirmation obtained as soon as possible thereafter. [New 7/30/03]

Do these requirements apply to all types of documentation? As a long-term objective, ambiguous and otherwise dangerous forms of notation should be eliminated from all heath care documentation. However, through the end of 2004, the survey and scoring of this requirement will be limited to all handwritten, patient-specific documentation, not just orders. Recognizing that it will take time to deal with inventories of preprinted forms and software that contain the prohibited items, implementation of the “list” for print and electronic media will be encouraged, but not required, i.e., not scored, in surveys conducted through the end of 2004. Thereafter, compliance in all documentation media will be expected and scored. [New 7/30/03]

Does the requirement for standardizing abbreviations, acronyms, and symbols apply only to medication orders? No. This applies to all clinical documentation, including all types of orders, progress notes, consultation reports, and operative reports.

How will compliance with goal 2b be assessed by surveyors? Goal 2b is surveyed by identifying the various terms that are represented by the prohibited abbreviations, acronyms and symbols. Then, in reviewing patient care records, the denominator is the number of times these terms are used—either in their complete, acceptable form or in their abbreviated, unacceptable form. The numerator is the number of times they are abbreviated. If the abbreviated forms are >10 percent of the total, goal 2b will be scored as noncompliant. [New 11/3/03]

In addition to a list of abbreviations, acronyms and symbols not to use, isn’t there also a requirement for an "Approved Abbreviations List?" Actually, no. The last time the standards explicitly required a list of approved abbreviations was in 1991. The current requirement in the standards is the following:

> Standardizing terminology, definitions, vocabulary, and nomenclature facilitates comparison of data and information within and among organizations. Abbreviations, acronyms, and symbols are also standardized. (IM.3)

This has been generally (and historically) interpreted as meaning there should be a list of approved abbreviations, acronyms and symbols. However, if we acknowledge that the principle reason for the standardization is to protect patients from the effects of miscommunication, then
the most effective means of achieving this intent may not be a comprehensive "approved list." That's why the NPSGs focus on the (shorter) list of abbreviations, acronyms, and symbols not to use, reasoning that it will be easier to change behavior with respect to a short list than a long one. Having said that, if you wish to develop an “approved abbreviations” list, or reference Stedman's or SNOMED or some other medical terminology resource, that is quite acceptable under the standards, but it is not required. [New 11/3/03]

Whenever a nurse takes a telephone or verbal order in our hospital, he or she must repeat it back to the physician to confirm that it was understood correctly. Is this acceptable?
No. Simply repeating back the order is not sufficient. Whenever possible, the receiver of the order should write down the complete order or enter it into a computer, then read it back, and receive confirmation from the individual who gave the order.

Does the "read-back" requirement apply only to medication orders?
No. This applies to all verbal or telephone orders, not just those for medications. Also, beginning in 2004, the “read-back” requirement will apply to “critical test results” reported verbally or by telephone. [Revised 7/30/03]

What is meant by the term “critical test results?” Who decides?
This is defined by the individual health care organization and will typically include “stat” tests, “panic value” reports, and other diagnostic test results that require urgent response. For most organizations, this will include all test results reported verbally or by telephone. If a subset of “critical test results” is not defined by the organization, surveyors will consider all verbal or telephone reports of diagnostic tests to be “critical.” [Revised 10/27/03]

Is the term “critical test results” limited to laboratory tests?
No. The term “critical test results” applies to all diagnostic tests including imaging studies, electrocardiograms, laboratory tests and other diagnostic tests and studies. [New 10/27/03]

Does this “read-back” requirement also apply to physicians, such as when an attending gives a verbal or telephone order to a resident or when a nurse calls a test result to a physician?
Yes, it applies to all caregivers, including physicians. As it applies to communicating critical test results, JCAHO will not survey the actual performance of this read-back activity in physicians’ offices, nor do we expect the organization to directly evaluate this in physicians’ offices. However, the organization should establish with its medical staff an expectation for “read-back” whenever receiving critical test results verbally, including over the telephone. Organization staff should request a “read-back” whenever communicating critical test results verbally, including over the telephone. [Revised 10/27/03]

In an emergency situation such as a code in the ER, if the physician calls out the medication order and the RN repeats it back before administering the drug, and the code recorder is documenting the name of the drug, dose, time, route, and rate, is this acceptable?
Yes. In certain situations such as a code or in the OR, it may not be feasible to do a formal "read-back." In such cases, "repeat-back" is acceptable.

Requirement 2a states: "Implement a process for taking verbal or telephone orders that require a verification "read back" of the complete order by the person receiving the order."
How do you demonstrate that this occurs?
JCAHO has not established any documentation requirements for this goal. When we survey your compliance with the goals, we will ask how you track performance against the goal, i.e., how do
you know that the process is being done consistently? Whatever your method is, which may or may not include some form of documentation, we will evaluate your performance based on your approach for tracking compliance.

**In our home care service, physicians or their agents frequently leave orders on nurse voice mail. Is this acceptable given the NPSG requirement for read back?**

No. Voice mail orders are not acceptable within the context of the NPSGs. Also, most state laws require nurses and pharmacists to obtain the order directly from the prescriber or his/her agent. When not received directly, the nurse or pharmacist must call the prescriber back to get the order directly, including a “read-back.” [New 7/30/03]

**In home care, there are times when the parent or other family member is the patient's primary caregiver. This leads to the family member receiving verbal or telephone orders from physicians when there is no nurse in the home at the time, then communicating the orders to the nurse when she arrives. Is this acceptable?**

Patients or their family members are not considered physicians’ agents, nor are they qualified by law and regulation in most (if not all) states to receive orders for care. If, in a particular locality, this is legally permissible, then a “read-back” of any verbal or telephone order should be carried out, and the family member would have to be trained to do this. [New 7/30/03]

**Questions about goal #3 (High-alert medications):**

**What are “high-alert” medications?**

High-alert medications are drugs that bear a heightened risk of causing significant patient harm when they are used in error. Although mistakes may or may not be more common with these drugs, the consequences of an error with these medications are clearly more devastating to patients. A list of potential high-alert medications developed by the Institute for Safe Medication Practices (ISMP) is available at [http://www.ismp.org](http://www.ismp.org). [New 1/1/04]

**Hasn’t the potassium chloride problem been solved?**

Concentrated potassium chloride is not the only culprit. All concentrated electrolyte preparations should be closely controlled, including removal from general care units to avoid inadvertent use in undiluted form.

**In cardiac surgery, concentrated potassium is needed to arrest the heart and to counter large doses of insulin. What are your recommendations for availability of concentrated potassium to perfusionists (OR staff) for heart surgery?**

When clinically indicated, such as in this example, it may be permissible to have the undiluted concentrated electrolyte available in the patient care area. In general, these clinical situations are considered “alternative approaches” to goal 3a and must be submitted to JCAHO for review. However, the **Sentinel Event Alert** Advisory Group has reviewed, and JCAHO has determined, that storage of limited amounts of undiluted concentrated potassium chloride in the cardiac surgery area of the operating room is acceptable if the following precautions are taken:

- The concentrate must be segregated from all other drugs stored in the area.
- A par level of the drug must be established so that the amount maintained on the unit does not exceed the amount necessary to meet patient care needs over a limited time period (for example, one day).
A system for checking and restocking to par level by the pharmacy must be implemented.
Prominent warning labels must be applied to the drug container.
Access to the drug must be strictly limited to specially qualified staff. [Revised 1/1/04]

What about other clinical situations where concentrated electrolytes might be needed for emergency care, such as hypertonic saline on the dialysis unit?
Storage of hypertonic saline on a dialysis unit for treatment of hypotension or severe cramping related to the dialysis process is another situation that has been found acceptable if the precautions listed above are in place. As other clinical indications for on-unit storage of concentrated electrolytes are identified, they will be posted on the JCAHO website under “Samples of Alternative Approaches to the Requirements.” For these, it is not necessary to submit a “Request for Review of an Alternative Approach to a 2004 NPSG Requirement.” However, for other clinical situations in which an organization wishes to stock concentrated electrolytes on a patient care unit, a Request for Review must be submitted. [New 1/1/04]

Some of our patient care units have automated drug dispensing machines. Is it acceptable to store and dispense concentrated electrolytes using these machines?
No. The requirement makes no reference to automated dispensing machines, which carry their own set of “failure modes.” Many of the same risks inherent in storing these dangerous drugs in medication closets outside the pharmacy also exist with automated dispensing units.

The requirement mentions concentrated potassium chloride, potassium phosphate, and sodium chloride > 0.9%. What about magnesium sulfate, calcium chloride and calcium gluconate?
It is up to the individual organization to determine which concentrated electrolytes—beyond those stated in the requirement—pose a threat to patient safety and should be removed.

What about concentrated electrolytes (e.g., KCl) in emergency drug trays or on crash carts?
The risk of mistaking a vial of concentrated KCl for some other drug may be even higher during an emergency when these emergency drug sources are used. Therefore, such medication should be in ready-to-use form (i.e., already diluted) or, if needed in undiluted form, should have special protections against misuse.

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. 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. [Revised 1/1/04]
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—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.

Our pediatric and neonatal units use the “Rule of 6” to calculate patient-specific drug concentrations so that we can use standardized rates of infusion. Is this acceptable?

No. This approach has been extensively reviewed and JCAHO has concluded that the Rule of 6 and other dosing methodologies that result in individualized (i.e., non-standardized) concentrations are not in compliance with the requirement of goal 3b. [New 3/1/04]

What is the background and rationale for deciding that the Rule of 6 is not acceptable?

While originally developed for use with pressor agents in code situations, its use has extended beyond that. The Rule of 6 allows nurses to quickly approximate a pediatric dose by using a factor of six to adjust the concentration of the drug while keeping the rate constant. This is directly opposed to NPSG requirement #3b. In reviewing this issue specifically, we have found that there is significant evidence that the use of standardized concentrations in pediatrics (in place of the Rule of 6) is not only possible, but results in fewer errors.

Dosing of infusions can occur by one of two means: 1) keep the rate of infusion standardized but vary the concentration, or 2) keep the concentration of the drug standardized but vary the rate of infusion. Nationally, hospitals do it both ways, but are generally consistent in the approach that they use. There is evidence in the literature that limiting and standardizing concentrations (as opposed to the Rule of 6 approach, which uses patient-specific concentrations) is safer and less error-prone. The theoretical basis for error reduction is as follows. Two risk points in IV administration can occur - one at the calculation step (either calculating the proper concentration or the proper rate), and another at the drug preparation/compounding step. Both methods can result in potential errors at the calculation step. However, by standardizing the concentration, one reduces the potential for error at the drug preparation/compounding step. There is clear evidence that pharmacy prepared IV's are more accurate, and many are available premixed from the manufacturer, further minimizing the risk. Another important consideration is that the Rule of 6 is an approximation and can, itself, lead to dosing errors. The Institute for Safe Medication Practices (ISMP) collects data on medication errors nationally in conjunction with United States Pharmacopeia (USP) for the Food and Drug Administration (FDA). They have a significant number of reports of errors due to the use of the Rule of 6.

Also, from an infection control standpoint, the risk of contamination during preparation/compounding is reduced as well. Finally, if all hospitals use the same method, it will reduce errors relating to orientation, training and competence of new and temporary staff. A recent survey of critical care clinicians in children hospitals conducted by the University of Iowa demonstrated that nine of 27 institutions have abandoned the Rule of 6 to use standardized concentrations of drugs, even in neonates. Nine of nine respondents at centers employing standard concentrations exclusively have found the system to be effective. Three of these nine centers specifically noted that they have reviewed the safety impact and have found no change or have seen improvements in safety (based on informal methods [2], or through rigorous research-
based assessment [1]). Staff education and ongoing experience were cited as factors that contributed to rapid acceptance of these changes. In some cases, former supporters of Rule of 6 stated that the change to standardized concentrations has been a positive development for their staff and for patient safety. Researchers from the Albany Medical Center have research data showing a significant reduction in errors when switching from the Rule of 6 to the use of standardized concentrations. Their research, including a sample rate table (for dopamine concentration of 1 mg/mL), will be included in a manuscript in an upcoming issue of the *Journal of Pediatric Pharmacology and Therapeutics*. [New 3/1/04]

This is all new information to us and we have been using the Rule of 6 for many years. To immediately switch to a different approach could introduce new risks. Will there be an opportunity for a more controlled transition?

Yes. To provide for a safe transition to a methodology that uses a limited number of standardized concentrations of drugs, a transition period will be available for those organizations that have been using the Rule of 6 or similar dosing methods that use non-standardized concentrations. For the remainder of 2004, JCAHO surveyors will accept as evidence of compliance with this requirement, a transition plan with demonstrated progress toward full implementation of the plan by January 1, 2005. Discussions with the American Society of Health System Pharmacists (ASHP), the American Academy of Pediatrics (AAP), the National Association of Children’s Hospitals and Related Institutions (NACHRI), specialists in pediatric and neonatal intensive care, and others, will continue in an effort to achieve consensus on the safest approaches and strategies for implementation. Additional information and advice will be provided in updates to these FAQs and in other JCAHO publications. [New 1/1/04]

**Questions about goal #4 (Wrong-site surgery):**

**How do these requirements relate to the Universal Protocol for Preventing Wrong Site, Wrong Procedure, Wrong Person Surgery™?**

These NPSG requirements will remain in effect until June 30, 2004. Effective July 1, 2004, compliance with the *Universal Protocol* will be required of all JCAHO accredited organizations, to the extent that these requirements are relevant to the services provided by the organization. At that time, survey of compliance with these separate requirements of the NPSGs that relate to wrong site surgery will be discontinued. For further information about the *Universal Protocol*, please refer to the *FAQs for the Universal Protocol* on this JCAHO website. [New 1/1/04]

**What procedures fall under this goal?**

This goal and its requirements, as well as requirement 1b under goal #1, apply to all operative and other invasive procedures that expose patients to more than minimal risk, including procedures done in settings other than the operating room such as a special procedures unit, endoscopy unit, or interventional radiology suite. Certain routine “minor” procedures such as venipuncture, peripheral IV line placement, insertion of NG tube, or Foley catheter insertion are not within the scope of this goal. However, most other procedures that involve puncture or incision of the skin, or insertion of an instrument or foreign material into the body, including, but not limited to, percutaneous aspirations, biopsies, cardiac and vascular catheterizations, and endoscopies are within the scope of this Protocol. [Revised 1/1/04]
Does the site need to be marked for all procedures or is it just for right/left procedures?

Marking the site is required for procedures involving right/left distinction, multiple structures (such as fingers and toes), or levels (as in spinal procedures). Site marking is not required (nor is it prohibited) for other procedures. These may include mid-line sternotomy, Cesarean section, laparotomy and laparoscopy, cardiac catheterization and other interventional procedures for which the site of insertion is not predetermined. For those procedures in which marking the site is not required, the other requirements for preventing wrong site, wrong patient, wrong procedure surgery still apply (requirements 1b and 4a). [Revised 1/1/04]

In the FAQs for the 2003 NPSGs, there was a site-marking exemption for procedures done through a natural body orifice. Does that still apply? What if the incision/insertion site is midline but the organ to be operated on is right or left?

Our original advice concerning "orifices" was that site marking was not required for procedures done through or immediately adjacent to "natural body orifices." This was intended to include mid-line orifices such as mouth, anus, urethra. However, many procedures done through a mid-line orifice are intended to treat an organ that is "right" or "left" and therefore subject to a lateralization error. Similarly, many “open” or endoscopic procedures are done through a mid-line incision or insertion site but are intended to treat an organ that is “right” or “left.” Based on the above and the requirement for marking all cases involving lateralization, organizations must establish procedures for marking the skin at or near the proposed incision/insertion site to indicate the correct side of the proposed procedure, even when the proposed incision/insertion site is in the mid-line or through a natural body orifice. This mark, as for other site marks, must be positioned to be visible after the patient is prepped and draped unless it is technically or anatomically impossible or impractical to do so. In such technically difficult cases, an alternative method for visually identifying the correct side should be used (e.g., a temporary unique wristband or other similar device). [New 1/1/04]

What about dental procedures? I understand there have been several cases of extraction of the wrong teeth.

The American Dental Association (ADA) has been very supportive of efforts to eliminate wrong site surgery, including wrong dental extractions. However, the ADA acknowledges that there does not appear to be a practical or reliable method to actually mark the teeth that are intended for extraction. Therefore, dental procedures will be considered exempt from the site marking requirement (as are other procedures done through or immediately adjacent to a natural body orifice). In lieu of directly marking the teeth, the ADA recommends—and JCAHO concurs with—the following:

- Review the dental record including the medical history, laboratory findings, appropriate charts and dental radiographs. Indicate the tooth number(s) or mark the teeth site or surgical site on the diagram or radiograph to be included as part of the patient record.
- Ensure that radiographs are properly oriented and visually confirm that the correct teeth or tissues have been charted.
- Conduct a “time out” to verify patient, tooth and procedure with assistant present at the time of the extraction (two person rule).

Does the site have to be marked if there is an obvious wound or lesion?

In general, site marking is not required if there is an obvious wound or lesion that is the site of the intended procedure. However, if there are multiple wounds or lesions and only some of them are
to be treated, and the decision and direction for which ones are to be treated is determined at some time prior to the procedure itself, then the sites to be treated should be marked as soon as possible after the decision is made. [New 1/1/04]

**Is marking of the site necessary for bedside procedures such as chest tube insertion?**

Some of these “bedside” procedures do carry significant risk with respect to the consequences of a "wrong site" or "wrong patient" procedure. Our position on this situation takes into consideration the timing and continuity of contact between the patient and the practitioner performing the procedure. For cases that would otherwise require site marking (see above), if the practitioner performing the procedure remains with the patient continuously from the time the decision is made to do the procedure and consent is obtained from the patient up to the time of the procedure itself, then site marking is not required. However, if the person performing the procedure leaves the presence of the patient for any amount of time during that interval, then the site should be marked (before leaving the patient).

**Some of these cases may be done as emergency procedures. What then?**

As always, the overarching goal is patient safety, so none of these precautions should interfere with the timely care of the patient in an emergency situation. In most of these cases, when invasive procedures are performed under emergency or urgent conditions, the practitioner performing the procedure will be in continuous attendance of the patient from the point of decision to do the procedure. Under those circumstances, marking the site would not be necessary, although the "time-out" to verify the correct patient, procedure, and site would still be appropriate (unless it was such an emergency that even the time out would add more risk than benefit). In a more elective situation, marking the site is expected for “right/left,” multiple structure, multiple level procedures that carry significant risk if performed on the wrong patient or at the wrong site.

**Who should mark the site and when?**

The site marking should be done prior to moving the patient into the room where the procedure will be done. The requirement is that the site marking be done "with the involvement of the patient." For this to be done in a meaningful way, it should happen before the patient is significantly sedated. Note that the goal does not specify who should mark the site -- that is left to the organization to decide. However, the *Universal Protocol*, which goes into effect July 1, 2004, does have more specific expectations about who should mark the site (see *FAQs for the Universal Protocol*). It is certainly reasonable, and good advice, that the surgeon, or at least a member of the operating team, should do the marking. While we require that the patient be involved in the process, it is not expected, or even recommended, that the patient do the marking. [Revised 1/1/04]

**What if the patient cannot participate in the marking process?**

In cases of non-speaking, comatose, or incompetent patients or children, the "patient involvement" in the site marking process should be handled in the same way that you handle the informed consent process. Whoever has authority to provide informed consent for the patient to undergo the procedure would, as appropriate, participate in the site marking process. [New 1/1/04]

**What if the patient refuses site marking?**
The patient always has the right to refuse. This situation should be handled the same way as for any other refusal by a patient of offered care, treatment or services. The organization's responsibility is to provide the patient with information to understand why site marking is appropriate and desirable, and the implications of refusing the site marking. Then the patient can make an informed decision. The Protocol does not require that the procedure be cancelled because the patient refuses site marking. Organization policy should describe the related procedural and documentation requirements. [New 1/1/04]

**How should the site be marked (an X, the word yes, the surgeon’s initials)?**

The goal does not specify the type of mark—that is left to the organization to decide—but whatever the decision, the process should be consistent throughout the organization. Use of “X” is discouraged since this may be ambiguous: Does “X” mean operate here or do not operate here? A line indicating the intended site of incision, the surgeon’s initials, or the word “yes” are all acceptable ways to mark the site.

**For “right/left” cases, is it acceptable to mark the opposite site with a “NO” rather than marking the intended operative site?**

No, that is not acceptable. The goal requires marking the intended site of the procedure. Marking only the non-operative site is unacceptable. Several cases of wrong-patient surgery have occurred in organizations that have a policy for marking only the non-operative site. Many experts advise that marking the non-operative site should not be done even in addition to marking the intended site. Note that marking the non-operative site is explicitly prohibited by the Protocol unless necessary for some other aspect of care (such as to warn against using a particular extremity for venous access because of a prior surgical procedure). [Revised 1/1/04]

**What is the recommended procedure for marking spinal surgery cases?**

For spinal surgery, we advise a two-stage marking process. First, the general level of the procedure (cervical, thoracic or lumbar) must be marked preoperatively. If the approach involves anterior versus posterior, or right versus left, then the mark must indicate this. Then, intraoperatively, the exact interspace(s) to be operated on should be precisely marked using the standard intraoperative radiographic marking technique. The requirement for the preoperative marking is based on reported cases in which a patient intended for a cervical procedure had a lumbar procedure started, and vice versa. [New 1/1/04]

**Our surgeons are concerned about an increased risk of wound infection from marking the surgical site. Is this a valid concern?**

There is no evidence in the literature that suggests an increased risk of infection from this process. The surgical site should be prepared in the usual manner. Special surgical marking pens that will not be washed off by the surgical prep are available.

**Isn’t this preoperative check list thing just another onerous JCAHO documentation requirement?**

The requirement is for a “preoperative verification process.” The checklist is an example of one approach—the most common one. The intent of the requirement is to ensure that all of the relevant documents are available prior to the start of the procedure and that they have been reviewed and are consistent with each other and with staff’s understanding of the intended patient, procedure and site. It is the process that is important, not just the documentation.
What are the “relevant imaging studies” referenced in the requirement for a preoperative verification process?
This is left to each organization to decide for itself. The intent was that any studies that have been done to help define the location or gross characteristics of the pathology, especially the side or level, should be included. [New 1/1/04]

Questions about goal #5 (Infusion pumps):

Does this safety goal also apply to syringe pumps, ambulatory pumps or enteral pumps?
It applies to ambulatory pumps, but not to syringe pumps or enteral pumps. [Revised, 5/30/03]

Do ambulatory pumps used for applications other than patient controlled analgesia (PCA) fall within the scope of goal #5? If so, what issues should be considered?
Many ambulatory pumps (for example, certain models of CADD brand pumps) can be used for applications other than PCA. Such applications include, but are not limited to, chemotherapy, antibiotic, and total parenteral nutrition (TPN) infusion. Although a PCA medication reservoir should be secured within the pump, reservoirs for other applications are frequently external containers and are hung above the pumps. Because the latter configuration creates a greater opportunity for inadvertent free-flow, JCAHO has determined that goal #5 applies to all ambulatory pumps. [New 5/30/03]

Some pumps with their administration sets do not have “built in” free-flow protection. Instead, the manufacturers provide “add-on” antisiphon valves to achieve free-flow protection. Are these acceptable?
Beginning January 1, 2004, add-on devices to achieve free-flow protection are no longer acceptable for compliance with this requirement. For systems that do not have built-in free-flow protection, some pump manufacturers include an anti-siphon valve in the package with its administration set, along with instructions for use of this add-on device. These add-on devices were permitted in 2003 as an interim measure pending availability of administration sets with intrinsic free-flow protection. JCAHO has determined that the majority of pump manufacturers are now providing intrinsic free-flow protection. Any continued use of add-on devices for this purpose must be submitted to JCAHO in a “Request for Review of an Alternative Approach to a 2004 NPSG Requirement.” Purchase and implementation of new equipment without intrinsic free-flow protection is not in compliance with this goal. [New 1/1/04]

Regarding free-flow "protection," all our devices immediately shut off when the door is open and the set is removed without closing any tubing clamps. However a patient or family member might easily figure out how to undo the free-flow protection mechanism. This would allow for the medication to infuse so we have no guarantee regarding free flow but we have "protection." Would these devices meet the intent of this requirement?
As you describe them, your infusion pumps are in compliance with the requirement. Most safety features can be overridden if there is sufficient determination to do so. The intent of the requirement is to achieve protection against the more common misadventures involving these pumps.

I’ve heard the term “set-based free-flow protection.” What does this mean?
The “protection” is actually an attribute of the administration set used with the pump rather than with the pump itself. It is important to always use the administration set that is specified for use
with the infusion pump. The term “set-based free-flow protection” refers to a design in which the protection is built in (intrinsic) to the administration set.

**How can I determine whether our general-purpose infusion pumps have free-flow protection?**

To test for free flow protection, turn the power off with the infusion set primed and loaded in the device. With all tubing clamps open and the fluid container as high above the device as the tubing will allow, verify that no fluid flows out of the set as it hangs straight down from the device. Then remove the set from the device (tubing clamps still open) and again verify that no fluid flows out of the set. (Source: ECRI’s *Health Devices Inspection and Preventive Maintenance System*.) [Revised 5/30/03]

**Do we have to test all of our infusion pumps to verify that they have free-flow protection?**

No. The test for free-flow protection described above is for use only when there is a reasonable question about whether the particular pump/infusion set has adequate free-flow protection. Configurations that have been tested by ECRI and rated as “Free-flow protected” or “Free-flow protected with dependencies” do not need to be tested on-site as long as they are being used in a manner consistent with manufacturers’ instructions and with the “dependencies” specified by ECRI. [New 5/30/03]

**Where can I get more information about specific infusion pumps?**

JCAHO recognizes ECRI as an authoritative source of information about the safety considerations relating to infusion pumps. As such, information published by ECRI indicating the adequacy of free-flow protection for specific pump/administration set configurations will be acceptable as evidence of compliance with goal #5 of the 2004 NPSGs, pending verification by on-site survey of the appropriate use of such configurations by the specific health care organization in the provision of health care services. In other words, if ECRI says a particular infusion system is capable of providing adequate free-flow protection, JCAHO will still survey the way in which that equipment is being used.

**What about PCA pumps—can you say more about free-flow protection with these devices?**

According to ECRI, most PCA pumps fall under the “Free-flow Protected with Dependencies” category, which means that the free flow protection of PCA pumps is dependent on the use of tubing sets with an integral positive pressure (anti-siphon) valve. These are usually purchased independent of the pump itself, so the key issue for assessment should be to determine whether the set is protected rather than whether the model of pump is acceptable. Although these sets may allow small amounts of solution to flow under conditions of maximum head height, PCA reservoirs are normally secured to the pump (not hanging above it) so head height during use is typically much less than that for general-purpose infusion pumps. [Revised 5/30/03]

**What about patients being treated in a hyperbaric chamber? Is free-flow protection required there?**

Yes. This requirement also applies to patient undergoing hyperbaric therapy. Infusion pumps capable of providing free-flow protection in this environment are available. [New 1/1/04]
Questions about goal #6 (Alarm systems):

What does “clinical alarm systems” include? Is it just the ventilator alarms that were discussed in Sentinel Event Alert #25 on ventilator-related events?

Actually, this goal is much broader. While it originated with our Sentinel Event Alert on ventilator-related events, our Advisory Group saw it as relevant to the full spectrum of alarm systems that are triggered by physical or physiologic monitoring of the individual, by variations in measured parameters of medical equipment directly applied to the individual, or self-actuated by the individual. In other words, any alarm that is intended to protect the individual receiving care or alert the staff that the individual is at increased risk and needs immediate assistance would be within the scope of this goal. Examples might include cardiac monitor alarms, apnea alarms, elopement/abduction alarms, infusion pump alarms, alarms associated with measuring gas pressure or concentration going directly to or coming from an individual on mechanical ventilation, or emergency assistance alarms such as “panic buttons” in care recipient bathrooms.

How does the requirement for preventive maintenance and testing of all clinical alarms fit into the “equipment management program” required by JCAHO standards?

All clinical alarms (as defined above for the NPSGs) must be identified in some type of inventory. They may be included on the inventories of existing equipment management programs (either medical equipment management, utilities management or any of the other inventories the organization has established for security, safety, life safety, etc.) If these alarms are included in medical equipment or utilities management programs, JCAHO standards permit organizations to use different maintenance strategies as appropriate (for example, predictive maintenance, interval-based inspections, corrective maintenance, metered maintenance, and so forth) to maintain them. The method and intervals for inspecting, testing, and maintaining clinical alarms should be based on criteria such as manufacturers' recommendations, risk levels, common and accepted industry practice, and current organization experience. See the related equipment management standard in the applicable accreditation manual(s) for additional information. Also, organizations should consider reviewing their current preventive maintenance and inspection protocols in their equipment management programs (starting with their most critical equipment and systems) to ensure that alarms are appropriately addressed. Finally, when reviewing reports of "problems, failures, and user errors," any patterns of failures of alarm annunciators on a model-specific or device-specific basis should be evaluated. Negative trends may serve to help identify maintenance, use, or training issues. [Revised 5/30/03]

What is the extent of the alarm system testing that is required by this goal?

The "testing" referred to in goal #6 is for more than just the alarm equipment itself; it is intended to mean an "end-to-end" or "user" test. Whether the failure is due to a technical failure of the alarm equipment, a failure to turn the alarm on or adjust it properly, inappropriate volume or communication medium, or whatever, the testing should be designed to detect a system that will not serve its intended purpose: to alert caregivers to a care recipient at immediate risk. Our sentinel event data suggest that, while not common, such failures do occur and have contributed to a significant number of sentinel events.

Are there any specific guidelines (expected decibel level) for “sufficiently audible” as mentioned in requirement 6b?

We have no specific recommendations for decibel levels nor are there any standards that we are aware of. This must be addressed in the actual setting where the alarm system functions. Further, it should be handled more as a user test (can the staff hear the alarm in the locations and under the
environmental conditions that would normally exist in the course of health care activities) than as a technical adjustment.

We have alarms that are “silent” but alert staff with a flashing light at the nursing station. **Is this acceptable given the “sufficiently audible” requirement?**

Yes, this is acceptable. The purpose of the alarm system is to alert staff when the patient needs attention. Most commonly, this is accomplished by using an audible alarm. However, other signaling methods (visual, pager or other alarm enhancement systems) are acceptable as long as they reliably alert staff to the patient’s need for attention. [New 1/01/04]

**Does this goal require the use of alarms under any particular clinical situations or specify when alarms may or may not be disabled?**

This goal applies to alarm systems that are patient-specific and are used for the purpose of alerting staff to a patient emergency. For alarm systems that meet these criteria, organization policy may specify when the alarm may be disabled. JCAHO doesn't say which alarms should be used or when they can be disabled. However, these judgments should be based on organization policy, not on individual caregiver preference. [New 5/30/03]

**Will health care organizations have to show documentation (e.g. flow sheet, for example) that clinical alarms are checked (on nursing units etc.) and how frequently?**

The requirement is that the alarms are activated, set properly and are sufficiently audible to achieve the objective of alerting staff when the patient needs immediate attention. There is no specific requirement for documentation. Therefore, how you determine whether the requirements of the goal are consistently met, and how you document that determination, are entirely up to you. Our surveyors will ask how you monitor compliance and will work with whatever methods and documentation you use. They may also evaluate compliance by direct observation of the alarm systems. [New 5/30/03]

**Is it acceptable to have nurse notification via a normal telephone line (one that also receives incoming calls, no other means to differentiate if the telemetry monitor tech is calling) for remote telemetry monitoring. The alarms sound in the remote monitoring stations but not on the unit where the patient resides.**

The goal does not specify the mechanism by which the direct caregivers are alerted to a patient’s need for immediate attention, but this system would seem to have several potential failure modes. It would have to be demonstrated through appropriate testing that using a telephone to alert the nurse on the unit will reliably accomplish this goal. [New 5/30/03]

**What, specifically, will surveyors be looking for in relation to alarms?**

Surveyors will look at your policies and procedures for the set-up of alarms (especially with respect to appropriate settings of high and low limits on physiologic monitoring alarm systems), then will check the alarms to see that they are set appropriately. They will also talk with staff about problems they have with hearing the alarms, distinguishing among the different alarms, ability to respond quickly to an alarm, "nuisance" alarms, etc. The bottom line is, if a patient’s condition warrants immediate attention, and there is an alarm system in place that is intended to alert staff to this change in condition, does the system work? Will an appropriate staff member be alerted to the situation so that he/she can respond? [New 5/30/03]

**Questions about goal #7 (Healthcare-associated infection):**
Where can I find the current Center for Disease Control and Prevention (CDC) hand hygiene guidelines? The full report is available at http://www.cdc.gov/handhygiene/. The report is extremely detailed and well documented. The specific recommendations referred to in goal #7 are on pages 31 through 34 of the report.

Does JCAHO require implementation of all the recommendations in the CDC hand hygiene guidelines? Each of the CDC hand hygiene guidelines is categorized on the basis of the strength of evidence supporting the recommendation. All “category I” recommendations (including categories IA, IB, and IC) must be implemented. Category II recommendations should be considered for implementation but are not required for accreditation purposes.

What do these categories mean? Category IA recommendations are strongly supported by well-designed experimental, clinical, or epidemiological studies; category IB recommendations are supported by certain experimental, clinical, or epidemiological studies and a strong theoretical rationale; category IC recommendations are required by regulation; category II recommendations are supported by suggestive clinical or epidemiological studies or a theoretical rationale. The CDC also includes among its recommendations several “unresolved issues” for which it makes “no recommendation.”

They say that health care personnel should not wear artificial nails and should keep natural nails less than one quarter of an inch long if they care for patients at high risk of acquiring infections (e.g. patients in intensive care units or in transplant units). Will JCAHO actually be requiring this? Both of these recommendations are included in the CDC guidelines. The "artificial nails" recommendation is a category IA recommendation, so will be required for those individuals providing direct care to high-risk patients. However, the "1/4-inch nail tips" recommendation is category II, so should be considered for implementation but will not be required.

Do we have to use alcohol-based hand cleaners? Accredited organizations are required to provide health care workers with a readily accessible alcohol-based hand rub product (CDC recommendations 8 C&D). However, use of an alcohol-based hand rub cleaner by any individual health care worker is not required. The Guidelines describe when this type of cleaner may be used instead of soap and water. If you choose not to use it, then soap and water should be used instead. [Revised 1/1/04]

Isn’t the alcohol-based hand sanitizing gel flammable? Should we be concerned about a fire hazard? The typical alcohol gel and foam dispensers used in the healthcare setting are of such limited size and volume that their contribution to the hazard of acceleration of fire development or fire spread in most situations is small. In a recent survey of 800 facilities reporting a cumulative 1,430 years of hand-rub use, no fires attributable to or involving a hand-rub dispenser were reported. However, the 2000 edition of the National Fire Protection Association (NFPA) 101 Life Safety Code® prohibits the installation of alcohol-based hand sanitizing gel dispensers in egress corridors. JCAHO recommends that organizations install these dispensers just inside each
patient’s room (and whichever other rooms the organization deems necessary), or just outside the room if this is not an “egress corridor.” Studies have shown significantly better compliance when the dispensers are located just outside the room (when permissible) rather than just inside. Do not install them in egress corridors, above heat/ignition sources, electrical outlets, or light switches. Note that local or state fire code requirements may differ from the national codes, therefore, you should determine and follow the requirements for your particular locale.

Where can I get more information about the fire safety issues?
A number of organizations including the National Association of State Fire Marshals (NASFM), the American Society of Healthcare Engineering (ASHE), and the Association for Professionals in Infection Control and Epidemiology (APIC) have published interim guidance documents for the placement of dispensers and control of bulk storage of alcohol-based hand cleaners. These are subject to revision as more data become available.

How will this “hand hygiene” requirement be surveyed and scored?
Compliance with goal 7a will be surveyed through interviews with caregiver staff and direct observation. Caregivers should know what is expected of them with regard to hand hygiene and should practice it consistently. It is expected that noncompliance will be quite low, so that any pattern of noncompliance, i.e., more than a sporadic miss, will be scored as noncompliance.

Regarding the “manage as sentinel events” requirement, how do we know which cases should have a root cause analysis?
The intent of this requirement is to manage any unanticipated death or major permanent loss of function as a sentinel event, even if the patient acquires a nosocomial infection, not simply because the patient has acquired an infection. This is really a reminder of an existing requirement, not a new requirement. The decision to designate and review an occurrence as a "sentinel event" should be based on the outcome of the case (unanticipated death or major permanent loss of function), not on any presumptive cause.

If this is not a new requirement, why make it a NPSG?
Even though the requirement for root cause analysis in response to an unanticipated death or major permanent loss of function is not new, many cases that meet this definition have not been considered sentinel events—apparently because infection was associated with the outcome. In other words, there has been an assumption that the presence of infection excludes a case from consideration as a sentinel event. This is not, and never has been, an intended exclusion. As a result, there are very few cases of infection-associated sentinel events in the Sentinel Event Database (in relation to other types of sentinel events and to the number of infection-associated cases reported to be occurring annually). JCAHO believes that managing these cases as sentinel events will provide additional information, not so much about the infection itself, but about managing patients at risk for infection and who have acquired an infection. In this manner, the new goal, while not necessarily a new requirement, will contribute to reducing the risk of patient harm from health care-associated infection.

Many patients who die with nosocomial infections are very sick and may have multiple other problems. How do we determine whether the patient’s death was “unanticipated?”
This determination is based on the condition of the patient at the time of admission to the organization. A death or major permanent loss of function should be considered a sentinel event if the outcome was not the result of the natural course of the patient's illness or underlying condition(s) that existed at the time of admission. For example, an otherwise healthy patient who is admitted for an elective procedure, develops a wound infection, becomes septic, and dies
should be considered a sentinel event. However, cases in which the patient is immunocompromised or elderly with multiple co-morbidities are more difficult to classify. The knowledge that a certain percentage of patients with a given condition will die does not mean that the death of any one of these patients is "anticipated." If, at the time of admission, the patient’s condition is such that he or she has a high likelihood of not surviving the episode of care (e.g., the hospitalization), then that patient’s death would not be considered a sentinel event. Otherwise, it should be managed as a sentinel event, that is, a root cause analysis should be conducted.

**How should I go about doing a root cause analysis on an infection?**

Just as the identification of an occurrence as a sentinel event is not dependent on whether the patient did or did not have an infection, the root cause analysis we are looking for is not just an analysis of the infection (if there was one), but of the event itself, i.e., why did the patient die or suffer major permanent loss of function. It is anticipated that this analysis will identify system and process factors that through appropriate redesign can reduce the risk of serious adverse patient outcomes even as the risk of nosocomial infection remains high.

**I am an infection control practitioner (ICP) and my day is already full with the usual surveillance, analysis and prevention activities. How can I do all these root cause analyses and still have time for my regular important work?**

There is no expectation that the burden of conducting the analysis will be placed on the infection control practitioner, although if there were an associated infection, the ICP's participation on the root cause analysis team could be very beneficial.

**Won't this require a significant increase in our surveillance activities?**

No, there is no expectation for increased or otherwise modified surveillance activities.

**Where is the evidence that root cause analysis will help reduce the risk of health care-acquired infections?**

The efficacy of root cause analysis to identify system failures and thus direct improvement has been convincingly demonstrated over the past several decades in most high-risk fields and, more recently, in health care for the broad array of serious adverse events that occur. While it is true that the effectiveness of root cause analysis specifically for reducing harm from nosocomial infections has not been proven, that may be only because it hasn't been given an adequate chance with this specific type of event. Nor has the traditional rate-based approach, by itself, been sufficient. Perhaps a combined approach might move us further along.