National Recommendations for User-applied Labelling of Injectable Medicines, Fluids and Lines:

Frequently Asked Questions

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This paper is available on the Commission web site at www.safetyandquality.gov.au
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Introduction

The Australian Commission on Safety and Quality in Health Care (the Commission) is responsible for maintaining the National Recommendations for User-applied Labelling of Medicines, Fluids and Lines (the Labelling Recommendations) and for identifying and reducing national barriers to implementation.

These frequently asked questions (FAQs) are issues which have been raised often during implementation of the Labelling Recommendations and which were answered with reference to the Labelling Recommendations and the accompanying explanatory notes, implementation guide or with outcomes from the Labelling Recommendations pilot. Questions are grouped and each is provided with an answer. FAQs are updated regularly on the Commission web site at http://www.safetyandquality.gov.au/our-work/medication-safety/user-applied-labelling/labelling-recommendations-frequently-asked-questions/

Some issues raised during implementation cannot be answered by referring to the source documents, or the pilot, and must be referred to the Commission’s advisory groups for a response. These issues, and the responses to them, are recorded in the Labelling Recommendations Issues Register on the Commission web site at http://www.safetyandquality.gov.au/our-work/medication-safety/user-applied-labelling/issues-register/

Implementation of the Labelling Recommendations is an evolving process. The Commission invites facilities encountering implementation issues which cannot be answered by the Labelling Recommendations and implementation resources (including the FAQs and Labelling Recommendations Issues Register) to contact their jurisdictional contact in the first instance, and for health facilities with no jurisdictional contact, the Commission at mail@safetyandquality.gov.au
### Q1.1: Why are the Labelling Recommendations important?

A: Incomplete or inaccurate labelling of injectable medicines and fluids is a recognised risk in the safe administration of medicines. The Labelling Recommendations assist the user to identify medicines which can no longer be identified by their original packaging to promote safer use of medicines through standardisation and best practice.

### Q1.2: Is there a timeline for introducing the Labelling Recommendations?

The Labelling Recommendations have been endorsed by Ministers "for use in Australian hospitals" leaving the timing of implementation to individual jurisdictions and private hospitals. The Commission will report to Health Ministers in 2012 on the extent of implementation.

### Q1.3: How should the implementation of the Labelling Recommendations be audited?

Current incident management systems record incidents on a case by case basis and can reveal if errors in labelling were involved regardless of whether the incident led to harm, did not lead to harm or was detected prior to administration. Statistical rate analysis is not possible without recording the denominator (total number of drug administrations).

### Q1.4: Will additional resources be made available to support implementation?

No additional funding will be available for implementation. The cost of providing labels and storage must be taken from existing ward allocations. Existing QUM and best practice groups will meet the cost of education. The Commission will support these groups through the Labelling Recommendations Reference Group (LRRG).

### Q1.5: My hospital is producing a poster for each ward to assist with education. Do I need to acknowledge copyright?

A: Yes, the materials are free to use. However a statement acknowledging copyright in the *National Recommendations for User-applied Labelling of Injectable Medicines, Fluids and Lines* to the Australian Commission on Safety and Quality in Health Care is required.

### Q1.6: How do I cite the Labelling Recommendations?

2. Clinical application: General

Q2.1: Is it possible to make changes to the labels?
A: In theory, it is possible provided the minimum requirements of the Labelling Recommendations are met.
However, when introducing new information consider:
- Whether information can be recorded elsewhere;
- Increasing information content may reduce the clarity of minimum requirements; and
- Pilot testing did not identify any necessary additional information.
The use of non-standard labels has the following implications:
- They risk demonstrated safety benefits by not reflecting outcomes and feedback from national piloting;
- Additional label production costs through compromised economies of scale as label manufacturers incur additional set up and print costs;
- Implementation and education resources provided and maintained by the Commission would no longer be applicable;
- The labels in Word format posters for customisation by individual wards will no longer be valid; and
- Health professionals working across a number of hospitals will experience varied “national” labelling requirements.

Q2.2: Can the pink ‘miscellaneous’ label be used for any route if labels are out of stock?
A: No. A generic pink label headed ‘ROUTE’ in large bold type with a space adjacent for completion of route is included to enable safe labelling of all routes not specifically covered by the Labelling Recommendations. These miscellaneous pink labels are NOT to be used for routes with a dedicated label. Maintenance of adequate stock levels is critical to safe labelling.

Q2.3: During the implementation phase, what do I do if a patient is transferred into my clinical unit without the new labelling?
A: Leave current labelling in-situ for the remainder of the infusion. Do not transcribe onto a ‘new’ label. Use the labels directed by the Labelling Recommendations for the next infusion. Communicate with the referring area or ward.

Q2.4: How should extemporaneously prepared items for individual patient administration be labelled? These often come with lines attached; should these also be labelled?
A: No additional labelling is necessary for a medicine remaining in its original container. Items prepared for individual patients will already identify the patient identity and user and checked by signature prompts are usually included. Refer to page 6 of the Labelling Recommendations.
Lines attached to these original containers must comply with the Labelling Recommendations when the user makes a decision on the route of administration and will require a line label to identify route.

**Q2.5: How should cytotoxics be labelled?**

A: The Labelling Recommendations will apply to any medicine including cytotoxics. In practice, these are likely to remain in their original container prepared for individual patient use (see Q2.4). Presence of a cytotoxic is also highlighted by the purple cytotoxic label (Clinical Oncology Society of Australia (COSA) Guidelines). Inclusion of this label is in addition to the minimum requirements of the Labelling Recommendations.

**Q2.6: Do enteral medicines and fluids require labelling?**

A: Enteral medicines and fluids are outside the scope of the Labelling Recommendations. However, the same principles of the Labelling Recommendations apply and medicines and fluids given via the enteral route must be identified at all times. See Labelling Recommendations, page 13; Labelling non-injectable solutions.

- Non-injectable solutions must NEVER be given via the parenteral route
- Some of the principles in the Labelling Recommendations apply to the labelling of non-injectable medicines drawn up in syringes to be administered via non-injectable routes such as inhalation, oral and other enteral routes.
- ONLY syringes specifically designed for administration of medicines orally or via other enteral routes (e.g. nasogastric) should be used for these purposes. They should be clearly labelled with ‘For Oral Use Only’, ‘For Enteral Use Only’, etc.
- Syringes used for non-injectable solutions must NOT be compatible with parenteral entry portals.

**Q2.7: Should nebuliser solution drawn up in a syringe be labelled?**

A: Medicines for inhalation are outside the scope of the Labelling Recommendations. However, the same principles apply and medicines and fluids given via inhalation, including nebuliser solutions, must be identified at all times (see Q2.6 and Labelling Recommendations, page 13; Labelling non-injectable solutions).

Ideally, single use nebules emptied into a nebuliser bowl negate measurement via a syringe and will avoid the potential for administration via the wrong route. If it is necessary to measure the nebuliser solution in a syringe, that syringe must be clearly identified using principles outlined above.

**Q2.8: What is the difference between an epidural and regional block? And how should the Labelling Recommendations be applied?**

A: A regional anaesthetic block provides local anaesthesia to a discrete area of the body for the management of pain. Common regional anaesthetic blocks include extrapleural or para-vertebral blocks, intrapleural blocks, femoral nerve block, a catheter placed directly into the wound and an epidural block.

For an epidural regional block, the local anaesthetic is delivered directly into the epidural space via the thoracic, lumbar or caudal area.

The Labelling Recommendations provide a specific label for identification of containers and lines delivering an epidural block. For all other regional blocks, use the ‘For Regional Use Only’ container label and write the route of the anaesthetic block in the first line of the label prompted by the word ‘Type’ (see Figure 1).
Q2.9: Do pre-filled syringes require labelling?

A: Pre-filled syringes fall outside the scope of the *Labelling Recommendations*. Manufacturers of pre-filled syringes are governed by Therapeutic Goods Administration (TGA) guidelines for identification of these products.

Q2.10: Are AS/NZS4375:1996 and ISO 26825:2008 the same?

A: No. AS/NZS4375:1996 is an Australian and New Zealand Standard. ISO26825:2008 is an International Standard


ISO 26825:2008 draws heavily on, and supersedes, AS/NZ 4375:1996 with additional information regarding label quality and the differentiation of heparin and protamine from other medicines in the miscellaneous category labelled with black text on a white background.
3. Clinical Application: Containers

Q3.1 How many patient identifiers are required?
The National Safety & Quality Health Service Standards¹ (Standard 5: Patient Identification and Procedure Matching) states ‘At least three approved patient identifiers are used when providing care, therapy or services’. To comply with the standards, the container labels in the Labelling Recommendations were revised in November 2011 to include a third patient identifier, date of birth, described as DOB (see Figure 1). The revised container labels are available in print ready form on the Commission web site at http://www.safetyandquality.gov.au/our-work/accreditation/

Figure 1: Example container label for medicines delivered via the intravenous route

The revision applies to both sizes of container labels for all routes, intravenous, intrathecal, epidural, regional, subcutaneous, miscellaneous and the burette label. The revision is valid immediately, but will take effect as health services and manufacturers exhaust existing stock.

Q3.2: Our hospital labels contain "Drug & Quantity Added". Why do we need to include the calculation of concentration?
A: The Labelling Recommendations require the total amount of active ingredient/s, the total amount of fluid and the concentration to be identified and written as a calculation. The amount of medicine not expressed as a concentration has been recognised as a source of medicine administration error. Feedback from pilot sites, and from incident data, indicate that strength should be expressed as Amount (units), Volume (mL), and Concentration (units/mL) with the calculation recorded on the label to eliminate ambiguity.

Q3.3: What does “Units” mean?
A: The dose, volume and resulting concentration in units/mL is completed on the label. Units refers to the unit of measure e.g. microgram, milligram, gram, nanogram, micromole, or international unit.
Q3.4: There is no container label for intra-arterial infusions. If we infuse heparinised saline through an arterial line, how do we label the container?

A: It is essential to identify the intra-arterial line used as a monitoring line with the route line label. However, during development of the Labelling Recommendations there was no perceived demand for the container label. On balance it was felt introduction of the label might cause confusion over the purpose of the line.

However, if a container label to identify a container holding a medicine for delivery via the intra-arterial route is required use a label with prompts as for other route container labels, colour the label red (PMS 1787) and include the wording 'For Intra-ARTERIAL Use Only' at the top of the label (Figure 2). Suppliers will treat this as a special order as it is not described in the Labelling Recommendations.

Figure 2: Intra-arterial container label

Q3.5: How should the Labelling Recommendations be applied with the Vialmate device?

A: On addition of the additive from the Vialmate to the base fluid/diluent, the contents of the bag are no longer as described on the original container and must be identified. Immediately apply a bag label with details of patient, medicine, date and time and user IDs.

One of the most important messages from the pilot testing was to highlight the presence of an additive to bags using fully coloured labels. This will be accomplished with the bag label as well as identifying the medicine added via the Vialmate. In addition, the bag contents are recorded in the event the Vialmate becomes detached from the base fluid bag.

Q3.6: Can the volume of fluid be monitored when bag labels are applied to infusion bags?

A: Place the container label to identify an additive in an infusion by placing the label on the front of the bag to cover all information, except the name of the base fluid, the batch number and expiry. Also, place the label slightly to the left or right to ensure the graduations on at least one side of the bag are visible to monitor fluid delivery.

Q3.7 Do syringes in syringe drivers and pumps require labelling?

A: Yes. A container label with full details must be completed and adhered directly onto the syringe containing the medicine or fluid. Errors have been associated with labelling the driver or pump and leaving the syringe (primary container) unidentified.
4. Clinical application: Lines

Q4.1: Can pre-populated medicine labels be used to identify medicine content in a continuous infusion line?
A: All dedicated continuous infusion lines must be labelled with a label to identify route and a separate label to identify medicine. Individual clinical areas may choose to use pre-printed labels to identify the medicine for commonly used continuous infusions. However, the use of colour must comply with colour coding established in AS/NZS 4375 (colour code according to drug class). Some active ingredients (such as heparin, insulin and 0.9% sodium chloride) fall under the category 'miscellaneous' in AS/NZS 4375 and must be printed black on white to be consistent with the Labelling Recommendations. There is no established standard for colour coding medicine labels outside of those described in AS/NZS 4375.

Q4.2: Where are line labels placed when a multi-way port is in use?
A: Label the route of administration e.g. IV, after the port. Label the medicine prior to the multi-way tap.

Q4.3: Where are line labels placed on lines for paediatric patients?
A: Label the line near the container for patients who may tamper with the line label, including paediatric patients, (page 9, Labelling Recommendations).

Q4.4: Can the maintenance or intermittent drug administration line be labelled for medicine content?
A: For dedicated continuous infusions a medicine label is completed and attached to the line to identify the active ingredient (page 9, Labelling Recommendations). Infusion lines accommodating intermittent drug administration are often used for different active ingredients. Although these lines may be labelled to identify the active ingredient, medicine labels must be removed on completion of the infusion.

Q4.5: Are line labels washable?
A: Line labels tested during pilot testing withstood reasonable handling but were not water resistant. Any damaged labels require replacement to ensure the line may be identified at all times.

Q4.6: Do pulmonary artery (PA) catheters require labelling?
A: Labelling of the PA catheter is not necessary. It is important to differentiate between the central venous catheter and the pulmonary artery and a label is provided for the central venous catheter. It is generally well accepted that PA catheters are coloured yellow and overuse of an additional label is not expected to improve patient safety.

Q4.7: Do intracranial pressure monitoring lines require labelling?
A: Labelling of the intracranial pressure monitoring line is not necessary. The ICP line is used for monitoring purposes and not for administration. It is generally well accepted the ICP monitoring line is coloured green and overuse of an additional label is not expected to improve patient safety.

Q4.8: Do Intra-arterial lines used for monitoring require labelling?
A: Yes, intra-arterial monitoring lines which may be used occasionally to administer medicines and include an administration port must be identified with a red label 'For Intra-arterial Use Only'.
Q4.9 Do bladder irrigation lines require labelling?

A: Yes, if there is any possibility the bladder irrigation line could be confused with any other line. Use the pink ‘miscellaneous’ line label for this purpose and populate the ‘Route’ prompt with the wording ‘Bladder irrigation’.
5. Perioperative area

Q5.1: Anaesthetists in our hospital would like to continue using colour-coded medicine labels. Is this practice consistent with the Labelling Recommendations?

A: The Labelling Recommendations recognise the Australian and New Zealand anaesthetic standard (AS/NZ 4375:1996) and the International Standard ISO26825:2008 as they apply to for pre-printed labels for medicines in syringes used during anaesthesia colour-coded according to drug class.

Use ISO 26825:2008 (supersedes AS/NZS 4375:1996) labels to identify drugs in syringes used for the purposes of anaesthesia. Use the Labelling Recommendations for all other medicine containers and lines in the perioperative environment.


Q5.2 Can the abbreviated container labels be used in the preparation and recovery areas of the perioperative suite?

A: No. The abbreviated container labels are only for use on the perioperative sterile field. This is a closed practice environment and patient and user identification is recorded elsewhere. In the open practice environment outside of the operating room, including preparation and recovery areas, full identification provided by the Labelling Recommendations container labels apply. Refer to Labelling Recommendations Issues Register (IR10) [http://www.safetyandquality.gov.au/wp-content/uploads/2012/02/Labelling-Recommendations-Issues-Register-July-2012.pdf](http://www.safetyandquality.gov.au/wp-content/uploads/2012/02/Labelling-Recommendations-Issues-Register-July-2012.pdf)

Q5.3: Do contrast media require labelling?

A: Yes, contrast media are injectable fluids and should be identified if removed from their original packaging and placed in containers, including syringes. The minimum requirements of the Labelling Recommendations apply to contrast media. Use of the generic term 'contrast' in the closed practice environment of the operating room is appropriate; specifying the contrast material by brand or generic name(s) is unlikely to confer a benefit and may be misleading.

Labelling is not required where contrast is decanted directly into a high speed pump reserved solely for the purpose of contrast injection.

This issue is held and monitored in the Labelling Recommendations Issues Register (IR20).

Q5.4: Where can hospitals obtain sterilised labels consistent with the Labelling Recommendations for use on the sterile field?

A: Several label manufacturers supply labels described in the Labelling Recommendations. A proportion of these are able to supply labels packaged and sterilised for use on the perioperative sterile field. The provision of sterile packaged printed labels requires additional facilities. Please contact individual suppliers for more information. Also see Q7.2, Q7.3.

Q5.5: What method of sterilisation is preferred for paper labels?

Labels for pilot testing were printed, packaged and sterilised in 3 separate processes. This was chiefly due to the small quantities required. A single process of printing,
Packaging and sterilisation may be commercially viable for larger label quantities.

**Steam sterilisation** within local hospital facilities appropriate due to 3 areas of concern:
- Print dye may ‘gas’ during heat treatment
- Print dye may also be affected by steam
- Adherent properties of glue may be lost

**Ethylene oxide (EO)** has the following advantages:
- EO is highly unlikely to effect the condition of the labels
- Header bags will not become brittle and will remain sealed and peelable to open after sterilization

**Gamma irradiation** is an ideal method of sterilisation for paper products. For the small-scale pilot test operation this method was not viable due to:
- Packaging: Certain plastics will become brittle through gamma irradiation. Knowledge of the tolerance and acceptability of plastic packaging components following gamma irradiation is required.
- Radiation levels: The correct amount of gamma irradiation to achieve a sterile product requires calculation
- Testing: A test sterilisation of sample labels and packaging is necessary before proceeding with a full-scale operation.

**Q5.6: Pre-printed labels sets were used in the evaluation at Calvary Wakefield Hospital? Is each health facility required to use this set?**

**A:** No. This set was devised specifically for the perioperative health services at Calvary Wakefield Hospital. A single set of labels was established to cover all operations undertaken at the facility. Each operating theatre was issued with individually packaged sets of labels and a single set of labels was used for each procedure.

Health services may choose to produce label sets for the perioperative area in the same way. Alternatively, labels may be pre-printed and sterile packed individually or provided in labels sets to cover a particular procedure.

**Q5.7 Can the abbreviated container label be used instead of pre-printing any labels for the perioperative sterile field?**

**Yes.** However, the Calvary Wakefield Hospital evaluation demonstrated a preference for pre-printed labels which were easy to handle and select, reduced preparation time compared with populating an abbreviated label and negated the use of sterile marker pens.

The abbreviated container label provides a suitable alternative for medicine and fluid identification when no pre-printed alternative is available.

**Q5.8 Do the pre-printed and abbreviated container labels for the sterile perioperative area require to be ‘peel off’?**

A number of health services use reusable hollowware containers on the perioperative sterile field. For these to be cleaned and resterilised, the label is required to be removed in its entirety without leaving a residue. These health facilities will require labels to ‘peel off’ after use. An evaluation of label adherence to reusable hollowware containers has been conducted [http://www.safetyandquality.gov.au/wp-](http://www.safetyandquality.gov.au/wp-).
Q5.9: What are the practical considerations for labels used on the sterile field?

A: The lessons learned from the pilot testing and Calvary Wakefield trial of user-applied labels may assist when implementing the Labelling Recommendations on the perioperative sterile field.

- Route can change during a procedure and has been purposely omitted from the abbreviated container label.
- The abbreviated container label requires prompts for the medicine name and concentration. Amount and volume prompts are not required to be completed. On exhaustion of existing stocks of the abbreviated container label, the revised label with only medicine and concentration prompt may be ordered [http://www.safetyandquality.gov.au/our-work/medication-safety/user-applied-labelling/labels/](http://www.safetyandquality.gov.au/our-work/medication-safety/user-applied-labelling/labels/)
- Containers may be handled many times during a procedure. Label integrity must be retained even with repeated exposure to fluids. Individual manufacturers must be contacted for further information on the suitability of their products for use in the perioperative area.
- Labels must remain adhered to the container for the duration of the procedure. Test compatibility of sterile field labels with commonly used medicines. In the pilot test, papaverine released the test label from the container.
- After use, ensure labels can be removed entirely from any equipment to be cleaned and sterilised for reuse. Any residue on a stainless steel container will render it unfit for sterilisation.
- Do not pre-print disposable containers with medicine name. The use of preprinted containers has been associated with medication errors. There is a possibility the receptacle is selected for another medicine if it is the only container available.
- Keep label packaging small to minimise waste and facilitate handling.
- Ensure sterile pens are fit for purpose. Writing must remain clearly legible. Some surgical markers have a tendency to run.

Q5.10: The Labelling Recommendations state ‘All labelled containers on the sterile field must be discarded after the procedure (page 9, 4a). If we use containers that are intended for re-use after cleaning, do these have to be discarded completely?

A: The intention of the statement is to ensure all medicines removed from their original container and placed into a container and then labelled are discarded at the end of the procedure, regardless whether they were used or not. All single use syringes and disposable containers will be discarded completely. Any other labelled containers, which are potentially reusable, will be removed from the sterile field and handled and reissued according to local policy. Ensure labels are removed entirely from any equipment to be cleaned and sterilised for reuse. Any residue on a stainless steel container will render it unfit for sterilisation.
Q5.11: Should containers on the sterile field be labelled even if they do not contain injectable medicines?

A: Yes. All containers containing medicines or fluids should be labelled in the sterile field. See Labelling Recommendations, page 2 Minimum Requirements:

1. All medicines and fluids removed from the manufacturer's or hospital pharmacy's original packaging must be identifiable. Also refer to page 9, 4a): Labelling on the sterile field: all medicine containers, including jugs, basins and syringes, should be labelled according to the Labelling Recommendations; and page 13 'The Labelling Recommendations could be extended to include all solutions, chemicals and reagents used in perioperative units'.

Q5.12: What solvents may be used to remove adhesive residue from reusable hollowware containers?

A: The removal of residue is undertaken in the sterilising services unit or department. A number of solvents may be used to remove residue from reusable hollowware including alcohol swabs/solutions and eucalyptus oil. All these products are flammable and are required to be used sparingly with care. They are used in the cleaning area away from the patients in the perioperative area.

Eucalyptus is oil based and requires the appropriate temperature and detergent for removal of solvent residue.

Q5.13: Will the removal of pre-printed and generic abbreviated container labels from reusable hollowware be impractically labour intensive?

A: The time taken to remove adhesive residue is comparable to the time taken to remove blood products and preparation solutions such as povidone-iodine. Adhesive residue removal is an integral part of the cleaning process and should not disproportionately affect time and cost.
6. Special situations

Q6.1: Ambulatory patients: Do lines remaining ‘in situ’ on hospital discharge and in use by lay carers require labelling?

A: All medicine containers and lines should be identified for medicine (active ingredient) and route of administration. It is important these are identifiable by all health professionals responsible for patient care and labelling is to be applied. Where the patient identity is beyond doubt and the person administering the medicine is known, the abbreviated container label is provided as an alternative to the full bag/syringe labels.

Q6.2: Dialysis: Medicines are sometimes added to dialysis lines into the peritoneal cavity. How should this route be labelled?

A: Use the pink miscellaneous label where there is space provided to include the route - ‘intraperitoneal’. Bag/syringe and line labels are provided. Refer to page 5: ‘The Labelling Recommendations apply to injectable medicines defined as any sterile medicine intended for administration by bolus injection, perfusion or infusion by the following routes: Intravenous, intramuscular, intrathecal, intra-arterial, subcutaneous, intradermal, intraventricular, epidural, intravesicular, intravitreal, intrapleural and intraocular. Note: This list is not exhaustive. Other routes of injection should be considered in the context of the Labelling Recommendations, e.g. intraosseous and intraperitoneal’.

Q6.3: Are blood products included in Labelling Recommendations?

A: Blood components are not specifically referenced in the Labelling Recommendations. However, blood products are injectable fluids and should be identified if removed from their original container on patient administration. The minimum requirements of the Labelling Recommendations apply equally to blood products. For further information on administration of blood products, please refer to the Australian and New Zealand Society of Blood Transfusion Guidelines for the Administration of Blood Products (December 2011).


This issue is held in the Labelling Recommendations Issues Register (IR19).

Q6.4: Do the Labelling Recommendations extend to dental health and radiology?

A: Yes, any situation where injectable medicines and fluids require identification.

In addition to the peak professional bodies involved in the national consultation as described in the Labelling Recommendations (page 24), the Commission has contacted the following organisations with details of the Labelling Recommendations:

- Australian Dental Association Inc.
- The Royal Australian and New Zealand College of Radiologists
- Australian College of Operating Room Nurses (ACORN)
- Australian College of Critical Care Nurses Ltd. (ACCCN)
- Australian Nursing and Midwifery Council
- Royal Australian College of General Practitioners (RACGP)
• Cardiac Electrophysiology Institute of Australasia (CEPIA)
• Cardiac Society of Australia and New Zealand
• The Aged Care Standards & Accreditation Agency Ltd.
• Paramedics Australasia
• Australian Institute of Radiography
7. Label procurement

Q7.1: Does label quality differ between suppliers?
A: Label quality will depend on the paper stock used. The stock is not specified in the Labelling Recommendations but it is expected that labels will be printed on paper stock of sufficient quality to be durable and fit for purpose. In addition, the paper finish must be suitable to accept handwriting. Ensure the paper stock from an individual supplier is appropriate and obtain samples before placing an order. 

For the perioperative sterile field, label stock may need to be synthetic to ensure the label is fit for purpose. Exposure to fluids necessitates the quality of the label stock used on the sterile field must be suitable and the following requirements are met for the duration of the procedure:

- Label remains intact
- Label remains adhered to the container
- Writing remains legible

Please check the paper quality and order samples before placing an order.

Q7.2: Does glue strength vary?
A: Yes, glues come in different strengths. Essentially all labels with the exception of the burette and abbreviated container label for use on reusable containers must adhere and remain adhered to the container and line after application. There is no reason for these to be removed. Indeed, for containers they must remain in place for audit purposes.

The burette labels and abbreviated container labels for use on reusable containers need to be removed and should be ordered with glue designed for this purpose.

Q7.3: Can we continue to use container labels with patient name and ID but no prompt for date of birth (DOB)?
A: The third patient identifier, date of birth (DOB), has been introduced in line with the National Safety and Quality Health Service Standards that require at least three approved patient identifiers when care, therapy or other services are provided. The Labelling Recommendations container labels were revised November 2011 to include patient name (to be completed with given name and family name), ID (patient identifier, e.g. MRN, URN) and DOB (date of birth). Existing container label stock may continue to be used. However, on exhaustion of stock, manufacturers should switch to container labels with 3 patient identifiers using the EPS and PDF files available on the Commission web site http://www.safetyandquality.gov.au/our-work/medication-safety/user-applied-labelling/labels/

Posters intended for customisation by facilities for education purposes have also been updated to accommodate the third patient identifier http://www.safetyandquality.gov.au/our-work/medication-safety/user-applied-labelling/support-materials/

Remaining materials including the Labelling Recommendations, implementation guide, slide presentation and explanatory notes will be updated in due course.
8. Labels from external sources

Q8.1: Pharmaceutical manufacturers occasionally provide labels with their product. Are manufacturers being asked to comply with the Labelling Recommendations?

A: Yes, all label suppliers in Australia have been notified of the Labelling Recommendations. This includes manufacturers of labels supplied to pharmaceutical companies provided they source the labels in Australia.

Q8.2: Route identification labels are often included in sterile giving set packs. Do these need to comply with the Labelling Recommendations?

A: Yes, all label suppliers in Australia have been notified of the Labelling Recommendations. This will include manufacturers of labels used supplied to providers of customised giving set packs when the labels are sourced in Australia.

Last updated 9 August 2012