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

Issues Register

User-applied Labelling of Injectable Medicines, Fluids and Lines*

21 May 2013
Acknowledgment
Many individuals and organisations have freely given their time and expertise to support the development of this document. In particular, the Commission wishes to acknowledge State and Territory contacts that have coordinated implementation, and health services which have fed back implementation experiences and which have been the basis of this document. The involvement and willingness of all concerned to share their experience and expertise is greatly appreciated.

This paper is available on the Commission web site at www.safetyandquality.gov.au
# National Recommendations for User-applied Labelling of Injectable Medicines, Fluids and Lines:

## Issues Register

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1. 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 Injectable Medicines, Fluids and Lines (the Labelling Recommendations) and for identifying and reducing national barriers to implementation.

The Labelling Recommendations Issues Register records implementation issues that:

1. Cannot be resolved by reference to the Labelling Recommendations or related support materials
2. Have been referred to the Commission’s Labelling Recommendations Reference Group for consideration.

Labelling Recommendations issues referred to the Labelling Recommendations Reference Group are considered by the group and outcomes recorded. The outcomes potentially change the way that health services implement and use the Labelling Recommendations so it is important that the issues, and the outcomes, are publicly available. That is why the Labelling Recommendations Issues Register is available on the Commission web site at 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 Frequently Asked Questions (FAQs) and Labelling Recommendations Issues Register) to contact their jurisdictional contact in the first instance and, for health services with no jurisdictional representative, the Commission at mail@safetyandquality.gov.au

To assist health service organisations implementing or using the Labelling Recommendations, it is intended that a new version of the Labelling Recommendations will be made available in 2013 and which will combine the current version of the Labelling Recommendations with the Labelling Recommendations Issues Register outcomes and FAQs information where appropriate.

The ‘anaesthetic labelling standard’ (ISO 26825:2008) Anaesthetic and respiratory equipment - User-applied labels for syringes containing drugs used during anaesthesia

There are two types of user-applied labels used for injectable medicines in Australian hospitals. The International Standard ISO 26825:2008 User-applied labels for syringes containing drugs used during anaesthesia – colour design and performance (the ‘anaesthetic labelling standard’) standardises user-applied labelling of drugs in syringes used during anaesthesia. It describes labels pre-printed with medicine names and colour coded according to drug class. The other type is those described in the Labelling Recommendations. The Labelling Recommendations are intended for use alongside the ‘anaesthetic labelling standard’.

The Labelling Recommendations use a system of colour coding of injectable medicines labelling based on route of delivery. In addition, the Labelling Recommendations should be used to identify medicines on dedicated continuous infusion lines and containers in the perioperative sterile field and cardiac catheter laboratories. The written word is the primary identifier with colour as a secondary identifier. It is important that the use of colour to identify drug class in these settings should also be standardised.

Originally the Labelling Recommendations provided a single, black and white abbreviated container label for use on the perioperative sterile field designed to be completed during the procedure as appropriate. Health services found this label impractical. In addition a black and white medicine line label for continuous infusions was provided designed to be completed when the infusion was established. Health services implementing the Labelling Recommendations found this label difficult to manage especially compared to previously used pre-printed labels.

The Commission’s Labelling Recommendations Reference Group considered feedback from health services and agreed that colour coding according to drug class in the ‘anaesthetic labelling standard’ should be extended to continuous infusion line labels, labels for drugs in containers on the perioperative sterile field and labels for syringes in the cardiac catheter laboratory and radiography suites. Details of this decision are described in this document at Issues Register 21.

The ‘anaesthetic labelling standard’ will be referred to often in this document.
## 2. Issues summary

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<th>Date</th>
<th>Response</th>
<th>Reasoning/Action</th>
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<td><strong>I.R. 2</strong></td>
<td>Do the Labelling Recommendations extend to all health services?</td>
<td>No suggested change</td>
<td>All</td>
<td>05/2011</td>
<td>Yes</td>
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<td><strong>I.R. 3</strong></td>
<td>Do the Labelling Recommendations apply to ambulance services?</td>
<td>No suggested change</td>
<td>South Australia</td>
<td>01/2011</td>
<td>Yes</td>
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<td><strong>I.R. 4</strong></td>
<td>Do labels in custom procedure packs need to comply with the Labelling Recommendations?</td>
<td>No suggested change</td>
<td>Commission</td>
<td>04/2011</td>
<td>Yes</td>
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<td><strong>I.R. 5</strong></td>
<td>Is use of ‘units’ on container labels ambiguous?</td>
<td>Remove ‘units’ from container labels</td>
<td>Tasmania</td>
<td>05/2011</td>
<td>No</td>
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<td>Introduce a central venous container label.</td>
<td>NSW</td>
<td>03/2011</td>
<td>No</td>
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<td>I.R. 8</td>
<td>Can the labels be removed from containers used in perioperative areas?</td>
<td>Establish specifications for removable labels</td>
<td>All</td>
<td>Various</td>
<td>Yes</td>
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<td>I.R. 9</td>
<td>Are three patient identifiers required on container labels?</td>
<td>Add third patient identifier</td>
<td>Commission</td>
<td>09/2011</td>
<td>Yes</td>
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<td>I.R. 10</td>
<td>Should the ‘anaesthetic labelling standard’ be used to identify medicines in containers in open practice areas?</td>
<td>Use labels with medicine and concentration only in open practice areas such as emergency department and post anaesthetic recovery.</td>
<td>All</td>
<td>09/2011</td>
<td>No</td>
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<td>I.R. 11</td>
<td>Is a pre-printed label suitable for identification of medicines and fluids on the perioperative sterile field? If so, what are the specifications?</td>
<td>Pre-printed labels customised by each facility or specialty within a facility may be used as an alternative to the ‘abbreviated container label’.</td>
<td>All</td>
<td>07/2011</td>
<td>Yes</td>
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<td>I.R.12</td>
<td>Should syringes in syringe drivers and pumps carry abbreviated labelling?</td>
<td>Label lines attached to syringes in pumps and drivers with full details and include only medicine name on syringe.</td>
<td>South Australia</td>
<td>10/2011</td>
<td>No</td>
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<td>I.R.13</td>
<td>Does applying a syringe label affect the operation of a Niki T34 syringe driver?</td>
<td>No change suggested</td>
<td>Victoria</td>
<td>05/2011</td>
<td>No</td>
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<td>I.R.14</td>
<td>Can pre-printed container labels be used in cardiac catheter laboratories?</td>
<td>In the closed practice environment of the cardiac catheter laboratory, allow pre-printed labels with medicine and concentration only and colour coding consistent with ISO 26825:2008.</td>
<td>All</td>
<td>Various</td>
<td>Yes</td>
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<td>I.R.15</td>
<td>Line labels to identify the neural route are all coloured yellow with different borders. Do the labels require further differentiation?</td>
<td>There is further differentiation of epidural, intrathecal and regional routes with use of different colours.</td>
<td>Various</td>
<td>No</td>
<td>The differentiation of the neural routes in the Labelling Recommendations is appropriate. Perineural route identification will be monitored.</td>
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<td>I.R.16</td>
<td>Can the medicine name be pre-printed on the same line route label?</td>
<td>Create a line label with medicine name and route of administration.</td>
<td>Manufacturer</td>
<td>No</td>
<td>No rationale for combination. Apply separate ‘route’ line label and medicine label.</td>
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<td>I.R.17</td>
<td>Do all lines require route identification when multiple lines are in use?</td>
<td>Label each line for route and medicine when several dedicated continuous infusions are running.</td>
<td>LRRG</td>
<td>03/2012</td>
<td>No</td>
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<td>Is &quot;Line change due&quot; suitable for perineural route line labels?</td>
<td>Remove 'Line change due' prompt from perineural line labels</td>
<td>NSW</td>
<td>05/2012</td>
<td>No</td>
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<td>Should the Labelling Recommendations apply to blood components?</td>
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<td>South Australia</td>
<td>07/2012</td>
<td>Yes</td>
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<td>Should contrast media be labelled on the perioperative sterile field?</td>
<td>Contrast media are identified by the generic term &quot;contrast&quot; rather than the chemical name. Pre-printed &quot;contrast&quot; labels are colour-coded.</td>
<td>South Australia</td>
<td>07/2011</td>
<td>Yes</td>
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<td>I.R. 21</td>
<td>Can the 'anaesthetic labelling standard' colour coding be applied and extended beyond anaesthesia?</td>
<td>Extend colour coding beyond anaesthesia.</td>
<td>All</td>
<td>10/2012</td>
<td>Yes</td>
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<td>I.R. 22</td>
<td>Should the dialysis catheter be labelled for route and content?</td>
<td>A dialysis catheter label is proposed</td>
<td>All</td>
<td>10/2012</td>
<td>Yes</td>
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<td>I.R. 23</td>
<td>Should containers and lines for enteral medicines be labelled?</td>
<td>Enteral container and line labels are suggested.</td>
<td>All</td>
<td>11/12</td>
<td>Yes</td>
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3. Details of registered issues

**I.R. 1: Can medicine line labels be pre-printed? If so, can these labels be coloured and what is the specification guide?**

Labels are provided for identifying the route of, and the medicine used in, dedicated continuous infusion lines. The *Labelling Recommendations* provide a generic medicine label to be populated at time of use.

Pilot testing suggested that pre-printed labels for identifying the medicine in a dedicated continuous infusion are a suitable alternative to the generic medicine label. Subsequently the Commission engaged health facilities to evaluate pre-printed medicine labels for use on dedicated continuous infusion lines. The evaluation recommended that pre-printed labels for identifying the medicine in a dedicated continuous infusion line should be used where possible. Generic medicine labels, for completing at the time of use, may be used if a pre-printed alternative is unavailable.

The full evaluation report of pre-printed labels in four intensive care units is available in the *Evaluation of standardised medicine line labels for medicine in dedicated continuous infusions* (PDF 1.4MB).

Therefore, the nationally standard requirement for identifying medicines in dedicated continuous infusion lines is as follows:

a) Use a pre-printed medicine line label with the generic name of the medicine or fluid

b) In the absence of an established standard for colour coding medicine line labels, and where it is standard practice to apply colour, any colour should comply with ISO 26825:2008 *User-applied labels for syringes containing drugs used during anaesthesia* (the ‘anaesthetic labelling standard’) with the exception of (c) immediately below

c) High risk medicines that fall in the miscellaneous category should be printed red on white with the exception of heparin (see (k) below)

d) Other medicines in the ‘anaesthetic labelling standard’ miscellaneous category (such as 0.9% sodium chloride) should be printed black on white

e) Size of labels may be determined by the health facility

   *In the trial, line labels were produced in continuous strips (7mm wide)*

f) Formatting, including font size, may be determined by the health facility

   *In the trial, font size was 8mm allowing a 2mm border either side for printing diversion. The image width varied according to length of medicine name but did not exceed 70mm. The gap between images was 10 to 15 mm printed on continuous tape*

g) Labels must be produced using material that remains intact for the duration of use

   *In the trial, labels were printed on unplasticised PVC tape with tensile strength > 14.3kg/25mm.*

h) Labels must be produced with glue that ensures the label remains attached to the line for the duration of use.

   *In the trial, label peel adhesive was 600g/25mm (+/- 10%)*

i) It is recommended that the font used on the medicine line labels use *national Tall Man lettering* which can be found on the Commission web site at [www.safetyandquality.gov.au/our-work/medication-safety/national-tall-man-lettering/](http://www.safetyandquality.gov.au/our-work/medication-safety/national-tall-man-lettering/)

A set of examples for medicines regularly administered by dedicated continuous infusion is provided in the *Pre-printed medicine line label guide* (PDF 545kb).
Extending use of the ‘anaesthetic labelling standard’ to areas beyond anaesthesia (see Issues Register 21) suggests the following use of colour on continuous infusion medicine line labels as follows:

j) Antiplatelet agents/anticoagulants associated with teal green (PMS 3255)

k) Heparin and protamine to be coloured teal green (PMS 3255) in addition to differentiation of heparin and protamine with a solid black border for heparin and a black hatched border for protamine as specified in the ‘anaesthetic labelling standard’.

l) Medicines of opposite action, including antagonists, to be fully coloured in the centre behind the drug name and with a hatched coloured border. Therefore, labels for glyceryl trinitrate, nimodipine, sodium nitroprusside will be coloured violet (PMS 256) with a violet and white hatched border. Naloxone will be coloured blue (PMS 297) with a blue and white hatched border. (Trial labels had a white centre).

m) Isoprenaline is a sympathomimetic and chronotrope and should be labelled violet with a violet and white hatched border (PMS 256). Milrinone and levosimendan should also be labelled violet with a violet and white hatched border.

The application of colour to labels for the antiplatelet agents/anticoagulant drug class has yet to be evaluated on medicine line labels. The extension of colour to this drug class is ongoing in the cardiac catheter laboratory and in time will possibly extend to other areas where these medicines are used, including line labelling of continuous infusions.

Evaluation of the pre-printed labels for identification of medicines in dedicated continuous infusions is an evolving process which is reported through the Issues Register and re-evaluated as appropriate. The Commission will continue to work with users and the Labelling Recommendations Reference Group to monitor the safety and utility of the extension and the recommendations for identification of medicines in dedicated continuous infusion lines.

I.R. 2: Do the Labelling Recommendations extend to all health services?

Yes, the Labelling Recommendations apply to any situation where injectable medicines and fluids require identification.

I.R. 3: Do the Labelling Recommendations apply to ambulance services?

Results from pilot testing of the Labelling Recommendations in emergency departments, and other clinical areas likely to perform emergency resuscitation procedures, indicated that identification and safe administration of medicines is important in emergency situations. The Labelling Recommendations should be followed if staff are available in sufficient numbers to label syringes without compromising speed of drug delivery in an emergency.

This is reflected in the Labelling Recommendations as follows:

- Label medicines in an emergency. See pages 8 and 9: “Where injectable medicines are drawn up in a syringe for immediate emergency use (e.g. during resuscitation), standard operating procedures in emergency care should ensure that the principles in the Labelling Recommendations are followed to the extent possible. Pre-printed active ingredient (generic medicine) labels from ISO 26825:2008 should be considered.”

Note the following exemptions to labelling in all situations:

- When a single person draws up and immediately administers a medicine without the syringe leaving the hand
- Fluid bags for infusion where NO additional injectable medicines are added prior to administration e.g. IV fluids (e.g. 0.9% Sodium Chloride, 5% glucose), pre-mixed solutions (e.g. potassium, heparin infusion bags).

Use of pre-printed active ingredient (generic medicine) labels, consistent with the ‘anaesthetic standard’ may be suitable for ambulance services. However, these are not suitable if the patient identity needs to be recorded.
I.R. 4: Do custom procedure pack labels need to comply with the Labelling Recommendations?

Yes, suppliers of custom procedure packs should ensure labels that comply with the Labelling Recommendations are included in packs to identify route of administration and medicines used on the sterile field e.g. operating rooms and catheter labs.

The following suppliers have received correspondence relating to the Labelling Recommendations from the Commission:

- B. Braun Australia Pty Ltd
- Bard Australia Pty Ltd
- Covidien Pty Ltd
- ICU Medical Australia Pty Ltd
- Kimberley-Clark Health Care
- Mayo Healthcare Pty Ltd
- Medical Specialties Australia
- Medline
- Proact Medical Systems
- REM System Pty Ltd

If you represent a supplier of custom packs not listed above, and require further information on the Labelling Recommendations, please contact mail@safetyandquality.gov.au

In all clinical areas, medicines taken from their original container must be identified in the new container (syringe, bag etc.) with the following information:

- Patient name (given name and family name)
- Patient identifier e.g. URN, MRN
- Patient date of birth
- Active ingredient/s (medicine/s) added to the bag or syringe
- Amount of medicine/s added (including units)
- Volume of fluid (mL) - total in bag or syringe
- Concentration (units/mL)
- Diluent (for syringes)
- Date and time prepared
- Prepared by (signature)
- Checked by (signature)
- Route of administration (where not specified by wording and colour).

All Labelling Recommendations container labels provide space for this information and should be used.

However, they are not required on the label if the patient and user identifications are beyond doubt and recorded elsewhere such as in closed practice environments. In that situation, the abbreviated container label from the Labelling Recommendations or pre-printed labels are an appropriate choice (see Issues Register 11).

Any pre-printed labels based on the abbreviated container label should be coloured according to drug class in compliance with the ‘anaesthetic labelling standard’.

I.R. 5: Is use of ‘units’ on container labels ambiguous?

Feedback was received that use of the word ‘units’ for amount on container labels may be interpreted as ‘units as in insulin/ heparin’ rather than the amount of medicine. Note that the issue has not occurred in clinical practice.

Units are included to prompt the user to include units when writing the dose. Health services are advised to monitor the situation during implementation through incident audits.
I.R. 6: Should container labels be developed for specific intravenous routes e.g. peripheral venous, central venous and PICC?

Container labels for the intravenous (IV) route are to remain as described in the *Labelling Recommendations* and not tailored for specific IV routes, with the possible exception of the dialysis catheter (see Issues Register 22).

Results of the pilot testing informed this recommendation and which focused on two factors:

- Keeping the number of different type and size labels to a minimum facilitated the label selection process
- Bag labels with a predominantly white background and a small colour border are not sufficiently visible to draw attention to the presence of an additive.

Therefore, a single, fully coloured container label for intravenous bags with additives and syringes is included in the *Labelling Recommendations* for containers of medicines for either peripheral or central intravenous administration.

Differentiating peripheral from central intravenous administration is indicated by the line labels. A separate central venous line label is available.

It is acknowledged that clear differentiation between peripheral intravenous and central intravenous line labels with the same colour is required.

I.R. 7: Should the *Labelling Recommendations* include an intra-arterial container label?

Container labels for the intra-arterial route are now included in the *Labelling Recommendations*. The intra-arterial container label is used to identify syringes or bags containing medicines or fluids intended for intra-arterial administration. The label will be required occasionally and its procurement, availability and storage should be carefully considered.

*Fig 1: Intra-arterial container label*

An intra-arterial line label is available to identify the intra-arterial route and which is predominantly used for monitoring purposes only.

*Fig 2: Intra-arterial line label*

The intra-arterial line should be identified for route at all times.
I.R. 8: Can labels be removed from containers used in perioperative areas?

Stainless steel and other reusable containers are used in preference to disposable containers in a high proportion of Australian health services. The Labelling Recommendations specify that ‘peel off’ labels should be used as container labels on sterile field hollowware. Labels must be sufficiently adhesive as well as entirely removable from stainless steel and other reusable hollowware used in operating rooms. Insufficient adhesion means the labels are not fit for purpose. Any label residue renders containers unsuitable for reuse.


Labels from three suppliers were evaluated for adhesion to, and removal from, reusable plastic and stainless steel containers, and disposable plastic containers, after exposure to three fluids. Results indicated that labels adhered sufficiently while two of the three label sets could be removed either with or without application of alcohol wipes and/or eucalyptus oil.

Subsequent to this evaluation a trial undertaken at Calvary Wakefield Hospital (CWH) in South Australia tested the use of pre-printed labels in the perioperative sterile field. The labels were well accepted for the identification of medicines and fluids removed from their original container (see Issues Register 11). The April 2012 evaluation of label adherence to reusable hollowware containers was replicated to establish if the CWH labels are suitable for use on reusable containers. Sterile labels from 3 additional manufacturers were evaluated alongside the CWH label set and results are reported in www.safetyandquality.gov.au/wp-content/uploads/2012/02/Evaluation-of-label-adherence-to-hollowware-containers-used-in-the-operating-room-Report-2-Aug-2012.pdf

Outcomes of the above evaluations have been provided to label manufacturers that have made themselves known to the Commission. Identification of medicines in sterile field containers is mandatory so appropriately adhesive and completely removable ‘peel off’ labels assist health services conform to the national standard.

Note: Pre-labelling disposable containers with medicine name is a source of medication error and the user should apply appropriate labels at the time the container is filled.

I.R. 9: Are three patient identifiers required on container labels?

Standard 5 Patient Identification and Procedure Matching of the National Safety and Quality Health Service Standards states that ‘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 have been changed to include the patient’s date of birth as a third patient identifier (see Figure 3 below).

Figure 3: Revised container label with patient date of birth. The intravenous route container label is the example shown.

The revision applies immediately but may be implemented as existing label stocks are exhausted. The revised container labels are available in print ready form from the Commission web site at www.safetyandquality.gov.au/our-work/medication-safety/user-applied-labelling/labels/
I.R. 10: Should the ‘anaesthetic labelling standard’ or the Labelling Recommendations be used to identify medicines in containers in open practice areas?

Containers (bags and syringes) containing medicines removed from their original containers must be identified with full label inclusions, as per the container label in the Labelling Recommendations, in all open practice environments. An example of an open practice environment is the intensive care unit. The following elements are the minimum information requirement for labels:

- Patient name (first name and family name)
- Patient identifier, e.g. URN, MRN
- Patient date of birth
- Active ingredient/s (medicine/s) added to the bag or syringe
- Amount of medicine/s added (including units)
- Volume of fluid (mL) - total in bag or syringe
- Concentration (units/mL)
- Diluent (complete for syringes)
- Date and time prepared
- Prepared by (signature)
- Checked by (signature)
- Route of administration (where not specified by wording and colour).

The exception to this rule is the closed practice environment which is where the:

- Identity of the patient is beyond doubt
- Identities of the patient care team are recorded
- Medicine is administered completely within the closed practice environment.

Examples of closed practice environments include operating rooms, endoscopy rooms, cardiac catheterisation laboratories and radiology suites.

ISO 26825:2008 User-applied labels for syringes containing drugs used during anaesthesia (the ‘anaesthetic labelling standard’) describes medicine labels for syringes containing drugs used during anaesthesia. They are colour coded according to drug class and pre-printed with the medicine name and a prompt for concentration. The ‘anaesthetic labelling standard’ labels are intended to identify medicines drawn up and administered by the same practitioner. It has been agreed that the ‘anaesthetic labelling standard’ should be extended to identify medicine names and concentrations beyond anaesthesia in closed practice environments.

At the end of a procedure in a closed practice environment, all medicines prepared for use in the closed practice environment, including partially used or unused medicines, are to be discarded promptly.

Medicines prepared and labelled in the closed practice environment which will move with the patient to an open area must comply with the Labelling Recommendations. Examples include continued delivery of additives in fluid bags on patient transfer from the operating room to post-anaesthetic recovery unit (PACU) or syringes prepared to accompany the patient on transfer to the intensive care unit (ICU).

The emergency department is an open practice environment and labelling must comply with the Labelling Recommendations and which states “(w)here injectable medicines are drawn up in a syringe for immediate emergency use (e.g. during resuscitation), standard operating procedures in emergency care should ensure that the principles in the Labelling Recommendations are followed to the extent possible. Pre-printed active ingredient (generic medicine) labels from the ‘anaesthetic labelling standard’ should be considered.”
I.R. 11: Is a pre-printed label suitable for identification of medicines and fluids on the perioperative sterile field? If so, what is the specification guide?

The Labelling Recommendations provide an abbreviated container label to identify all medicines and fluids on the perioperative sterile field. Patient and user identifications are omitted as the perioperative sterile field is a closed practice environment and those details are recorded elsewhere.

Pilot testing found that pre-printed labels for use by scrub nurses and surgeons in the perioperative sterile field are a suitable alternative to the abbreviated container label for routine operations where the same medicines are used frequently. Benefits of re-printed labels include:

- No need for sterile marker
- Readily available
- Less time to select and apply

Calvary Wakefield Hospital, Adelaide evaluated pre-printed sterile labels in sheets on the perioperative sterile field. The sheets included labels for medicines and fluids most frequently used in routine procedures. The sheets were individually packaged and evaluated in terms of identification and label quality. The evaluation report concluded pre-printed labels are a suitable alternative to the abbreviated container label for identification of medicines and fluids on the perioperative sterile field. The report is available on the Commission web site at [www.safetyandquality.gov.au/wp-content/uploads/2012/02/Evaluation-of-pre-printed-labels-on-perioperative-sterile-field.pdf](http://www.safetyandquality.gov.au/wp-content/uploads/2012/02/Evaluation-of-pre-printed-labels-on-perioperative-sterile-field.pdf)

Perioperative sterile field use of the Labelling Recommendations is extended as follows:

a) Containers on the perioperative sterile field should be labelled with the name of the medicine or fluid.

b) Concentration should be included where this can be specified. Concentration may be written in line with the expression of concentration on the original container.

Note: For adrenaline administered as a single medicine, specify concentration. For adrenaline mixed with a local anaesthetic, concentration for both adrenaline and local anaesthetic may be omitted

c) The abbreviated container label may be used for medicines or fluids where a pre-printed label is not available.

d) The abbreviated container label requires prompts for the medicine name and concentration. Prompts for amount and volume are not required and may be printed as in Figure 4.

Figure 4: Abbreviated container label for user-applied identification in the closed practice environment e.g. the perioperative sterile field

| Medicine ........................................................... |
| Conc (units/mL) ............................................... |

e) Pre-printed labels should use full, generic medicine names in lower case letters with an initial upper case letter (consistent with the ‘anaesthetic labelling standard’).

f) Colour coding on pre-printed labels should follow colour coding in the ‘anaesthetic labelling standard’.

Labels for medicines in the ‘anaesthetic labelling standard’ miscellaneous category (such as insulin and 0.9% sodium chloride) should be printed black on white. The ‘anaesthetic labelling standard’ specifies differentiation of heparin and protamine with a solid black border for heparin and a black and white hatched border for protamine.
Where two medicines are combined in the original container, the user-applied label will include both medicines, such as local anaesthetic and vasopressor, and carry appropriate colour coding for both.

g) The size of the label may be determined by the perioperative facility while noting that larger labels (55mm x 20mm) used in the trial were acceptable for fluids such as water for irrigation, 0.9% sodium chloride and lactated ringers solution. Smaller labels (40mm x 10mm) were acceptable for other medicines and fluids such as heparin and chlorhexidine.

h) Font used for the medicine name should be plain (sans serif) and as large as possible. Font size may be determined by the perioperative facility while noting that the font size used in the trial was proportionate to label size. In the trial, 20 point was used for larger labels, 12 point for smaller labels and 11 point for the small labels with two medicine names, such as bupivacaine/adrenaline.

i) Labels must be produced using material that remains intact for the duration of the procedure.

j) Labels must be produced with adhesive that ensures the label remains attached to the syringe or container during the procedure.

k) Labels produced with adhesive that attaches throughout the procedure, but removes in its entirety at the end, will assist facilities using reusable containers in the perioperative area. The label set from the trial is undergoing evaluation for adhesion to reusable hollowware (See Issues Register 8).

Most operating rooms will be able to identify a short list of medicines used regularly. The exact composition of the customised pre-printed label sheet is best determined by the health facility or specialty within a facility.

I.R. 12: Should syringes in syringe drivers and pumps carry abbreviated labelling?

Containers (syringes) in syringe drivers and pumps should be identified with full label inclusions

- Patient name (first name and family name)
- Patient identifier (ID), e.g. URN, MRN
- Patient date of birth
- Active ingredient/s (medicine/s) added to the bag or syringe
- Amount of medicine/s added (including units)
- Volume of fluid (mL) - total in bag or syringe
- Concentration (units/mL)
- Diluent (complete for syringes)
- Date and time prepared
- Prepared by (signature)
- Checked by (signature)
- Route of administration (where not specified by wording and colour).

The small container label is often too large to allow syringe graduations to remain visible when using a syringe driver or pump. Facilities may consider changes to label placement provided the full, completed container label remains directly attached to the primary container, i.e. the syringe.

The following two suggestions from health facilities for fixing labels to syringes in syringe drivers and pumps may assist:
• A clear flag label (similar to the clear covers used to label ophthalmic preparations in pharmacy) may be used to attach a container label to a syringe in a syringe driver. This allows the label to be read while ensuring that graduations remain visible in some syringe drivers or pumps.

• Labels pre-printed with medicine name(s) may more easily identify medicines and combinations of medicines frequently administered through syringes in syringe drivers and pumps. The concentration should be completed on preparation and not be pre-printed.

I.R. 13: Does applying a syringe label affect the operation of a Niki T34 syringe driver?

Experience suggests that application of labels to syringes in Niki T34 syringe drivers does not interfere with the device accurately assessing syringe volume. Caesarea Medical Electronics (CME) advises the following:

‘The pump identifies syringes by their diameter. Most labels if applied carefully do not make a significant difference to the diameter and mostly the pump will still identify the syringe correctly. If the label is not flat and smooth the pump may initially guess the wrong syringe i.e. it will see a larger diameter.

At all times the user must check that the correct syringe is displayed before activating the pump. If the incorrect syringe is displayed initially the user must use the UP/DOWN button to select the correct syringe and then they can proceed.’

I.R. 14: Can pre-printed container labels be used in cardiac catheter laboratories?

Labels may be pre-printed with medicines names in cardiac catheterisation laboratories which are closed practice environments where the identity of the patient and patient care team are beyond doubt and recorded.

Pre-printed label sets may be produced for cardiac catheter laboratories as the same sets of medicines are used following set protocols for the same procedures.

The use of colour on medicine labels for containers (e.g. syringes) used in cardiac catheter laboratories should comply with ISO 26825:2008 User-applied labels for syringes containing drugs used during anaesthesia (‘anaesthetic labelling standard’). Labels for medicines in the miscellaneous category of the ‘anaesthetic labelling standard’ (such as 0.9% sodium chloride) should be printed black on white.

The following extensions to the ‘anaesthetic labelling standard’ (see Issues Register 21) are suggested in the cardiac catheter laboratory:

• Antiplatelet agents/anticoagulants associated with teal green (PMS 3255)
• Heparin and protamine to be coloured teal green (PMS 3255) in addition to differentiation of heparin and protamine with a solid black border for heparin and a black hatched border for protamine as specified in the ‘anaesthetic labelling standard’
• Heparinised saline associated with teal green border (PMS 3255)

Concentration may be omitted. The label is applied to a small syringe and the low light conditions of the cardiac catheter laboratory require the point size used for the medicine name to be as large as possible.

Label quality must be such that labels remain intact through sterilisation intact and retain integrity throughout the procedure.

Note that extension of the ‘anaesthetic labelling standard’ to labelling in cardiac catheter and radiology suites is an interim position and evaluation is ongoing. The Commission will continue to work with users and the Labelling Recommendations Reference Group to monitor the safety and utility of the extension, including thorough testing in this clinical area.
I.R. 15: Line labels to identify the neural route are all coloured yellow with different borders. Do the labels require further differentiation?

Labelling lines to identify the neural routes is a mandatory requirement of the Labelling Recommendations and the current differentiation of the neural routes by different borders remains supported.

Neural route identification will continue to be monitored.

I.R. 16: Can the medicine name be pre-printed on the same line route label?

Currently, there is no evidence to support improved safety through additional identification of medicine delivered through the neural route by including the medicine name on the route identification line label in addition to the medicine (active ingredient) label.

The route identification label remains separate to the medicine (active ingredient) line label. Combination of the two labels is not supported.

I.R. 17: Do all lines require route identification when multiple lines are in use?

It is critical to ensure that the medicines in each line can be promptly identified when a number of lines are in place in intensive care settings. Equally, identifying the route is important, particularly with intrathecal and intra-arterial routes. For intravenous infusion, and where multiple central lines converge into a common central line, the common line must be identified for route, but the individual lines do not require separate route labels. However the medicine in each individual lines will be identified.

I.R. 18: Is the ‘Line change due’ prompt suitable for neural route line labels?

The original neural (epidural, intrathecal and regional) line labels included the “Line change due” prompt and which is found on other line labels.

The length of time the neural catheter or line remains in place varies in clinical practice. At local and national levels, policy is open to change and a record of catheter insertion timing is more appropriate for the neural route identification labels. For the neural route, the percutaneous catheter and line are one sealed unit and any instruction is relevant to the whole device.

To avoid unnecessary and unsafe line change, reduce the risk of introducing infection and allow for assessment of the catheter by the user, it is agreed that “Line change due” be replaced by “Catheter inserted” combined with “Date” and “Time” prompts. Therefore, the neural line labels will be printed as shown in Figure 5.

Figure 5: Epidural, intrathecal and regional line labels.
I.R. 19: Should the Labelling Recommendations apply to blood components?

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 for patient administration. The minimum requirements of the Labelling Recommendations apply equally to blood products and the Commission will work with the Australian and New Zealand Society of Blood Transfusion and other relevant authorities to ensure identification for safe delivery.

I.R. 20: Should contrast media be labelled on the perioperative sterile field?

Contrast media are not specifically referenced in the Labelling Recommendations. However, contrast media are injectable fluids and should be identified if removed from their original container and placed in containers, including syringes.

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

Contrast media should be identified by the generic term ‘contrast’. Specifying the contrast material by brand or generic name(s) is unlikely to confer a benefit and may be misleading. The use of the generic term in the closed practice environment of the operating room and cardiac catheter laboratory is appropriate.

A brown (PMS 471) border is suggested to assist differentiation of the contrast, as shown in Figure 6.

Figure 6: Contrast media abbreviated container label

Contrast

The minimum requirements of the Labelling Recommendations apply to contrast media and the Commission is working with the Royal Australia and New Zealand College of Radiology to ensure identification for safe delivery.

IR 21: Can the ‘anaesthetic labelling standard’ colour coding be applied and extended beyond anaesthesia?

The international system for colour coding according to drug class in ISO 26825:2008 User-applied labels for syringes containing drugs used during anaesthesia (the ‘anaesthetic labelling standard’) is well recognised and should be implemented in all perioperative areas where anaesthetics are used. Classification of drug names should be determined by the primary therapeutic use of the drug and not its pharmacological class. For example, papaverine should be labelled as miscellaneous and not as an opioid.

The Labelling Recommendations should be used to identify medicines on dedicated continuous infusion lines and containers in the perioperative sterile field and cardiac catheter laboratories. The written word is the primary identifier with colour as a secondary identifier.

It is important that the use of colour to identify drug class in these settings should also be standardised and the Commission and ANZCA recommend applying the ‘anaesthetic labelling standard’ (see Table 1 below).
Table 1 - Background colours for user-applied labels for use on syringes containing drugs used during anaesthesia*

<table>
<thead>
<tr>
<th>Drug class</th>
<th>RGB colour</th>
<th>Examples of drugs</th>
</tr>
</thead>
<tbody>
<tr>
<td>Induction agents</td>
<td>Yellow</td>
<td>Thiopentone, methohexitone, propofol, ketamine</td>
</tr>
<tr>
<td>Benzodiazepines</td>
<td>Orange</td>
<td>Diazepam, midazolam</td>
</tr>
<tr>
<td>Benzodiazepine antagonists</td>
<td>Orange with white diagonal stripes</td>
<td>Flumazenil</td>
</tr>
<tr>
<td>Muscle relaxants</td>
<td>Fluorescent red or warm red</td>
<td>Suxamethonium, d-tubocurare, pancuronium, atracurium, vecuronium</td>
</tr>
<tr>
<td>Relaxant reversal agents</td>
<td>Fluorescent red or warm red with white diagonal stripes</td>
<td>Neostigmine, edrophonium, pyridostigmine</td>
</tr>
<tr>
<td>Opioids</td>
<td>Blue</td>
<td>Morphine, fentanyl, pethidine</td>
</tr>
<tr>
<td>Opioid antagonists</td>
<td>Blue with white diagonal stripes</td>
<td>Naloxone</td>
</tr>
<tr>
<td>Vasopressors</td>
<td>Violet</td>
<td>Adrenaline, ephedrine, phenylephrine, metaraminol</td>
</tr>
<tr>
<td>Hypotensive agents</td>
<td>Violet with white diagonal stripes</td>
<td>Nitroprusside, nitro-glycerine, phenolamine, hydralazine</td>
</tr>
<tr>
<td>Local anaesthetics</td>
<td>Grey</td>
<td>Procaine, lignocaine, bupivacaine, ropivacaine</td>
</tr>
<tr>
<td>Anticholinergic agents</td>
<td>Green</td>
<td>Atropine, glycopyrolate</td>
</tr>
<tr>
<td>Anti-emetics</td>
<td>Salmon</td>
<td>Droperidol, metoclopramide, tropisetron</td>
</tr>
<tr>
<td>Miscellaneous drugs</td>
<td>White</td>
<td>Oxytocin, heparin, protamine, potassium chloride, tetrhydroaminacrin, antibiotics</td>
</tr>
</tbody>
</table>

* Adapted from ISO268225: 2008 (the ‘anaesthetic labelling standard’)

The following extensions to the ‘anaesthetic labelling standard’ are suggested in the cardiac catheter laboratory (see Issues Register 14).

- antiplatelet agents/anticoagulants associated with teal green (PMS 3255)
- heparin and protamine to be coloured teal green (PMS 3255) in addition to differentiation of heparin and protamine with a solid black border for heparin and a black hatched border for protamine as specified in ISO26825:2008
- heparinised saline associated with teal green border (PMS 3255)

The extension of the ‘anaesthetic labelling standard’ to include a colour associated with antiplatelet/anticoagulant drug class is an interim position for labelling in cardiac catheter and radiology suites. The Commission will continue to work with users and the Labelling Recommendations Reference Group to establish the safety and utility of the extension. In time, the extension may be applied in other areas where colour coding is used (including dedicated continuous infusion lines and the perioperative sterile field).

Evaluation of pre-printed labels for identification of medicines is reported through the Issues Register and re-evaluated as appropriate. The Commission will continue to work with users and the Labelling Recommendations Reference Group to monitor the safety and utility of the extension and the recommendations for identification of medicines.

Extension of the ‘anaesthetic labelling standard’ beyond anaesthesia is suggested as follows:
Opposite action/Antagonist drugs

ISO 26825:2008 states 'For drugs of opposite action (including antagonists) at least the upper 20% of the height of the label shall be marked with diagonal stripes. The top of the drug name shall be separated from the diagonal stripes by at least 0.5 mm'.

Labels for a drug of opposite action should be printed fully coloured in the centre behind the drug name and with a coloured/white striped border. While evaluation is ongoing it is also acceptable to print the drug name black on white with a surrounding coloured/white striped border. This reflects the anaesthetic labelling standard (ISO26825:2008) which is open to interpretation for drugs of opposite action.

Papaverine

Colour is applied according to the primary indication of the drug. Papaverine is an opioid with a principal role as a vasodilator and should be violet with a striped-violet border.

Isoprenaline, levosimendan and milrinone

Isoprenaline is a sympathomimetic and chronotrope with vasodilatory action and should be labelled violet with a violet and white diagonal hatched border. Milrinone and levosimendan should also be labelled violet with a violet and white diagonal hatched border.

Beta-blocker

Beta-blockers, e.g. metoprolol, do not reverse adrenaline and have some antiarrhythmic properties. They are not strictly antagonists to vasopressors except for their effects on the myocardium. Beta-blockers should be printed on a plain black on white label.

I.R. 22: Should the dialysis catheter line be labelled for route and content?

Yes. Dialysis catheters should be labelled for route and used exclusively for dialysis (with the exception of emergencies). The label is coloured blue (PMS 2985) as the line is a central venous line. Dialysis catheters should also be labelled for content depending on the medicine in the catheter.

22.1 Medicines in the dialysis catheter

The dialysis catheter is generally 'heparin locked' to maintain patency. There is a potential risk associated with infusion of large doses of heparin resulting in over anticoagulation if the heparin is not removed from the 'lock' prior to dialysis. Alteplase may be used as an alternative to heparin to maintain patency. Any medicine in the dialysis catheter 'lock' must be removed prior to use. Other medicines that may be introduced into the dialysis catheter include antibiotics and urokinase.

Currently the practice is to label with a blue central venous line label to identify route and another label to identify medicine. However, a label has been specifically designed to identify the medicine 'locked' in the dialysis catheter (see Figure 7 below). The label is coloured blue (PMS 2985) as the line is a central venous line.

Figure 7: Example line label for medicine delivered via the dialysis catheter
The suggested label size is 60 mm x 50 mm; large enough to be legible and small enough for patient acceptability.

The label should be removed after removing the medicine from the lock. Therefore, the adhesive used on the label should be strong enough to adhere but not too strong that it cannot be removed as required.

The ‘dialysis catheter label’ is yet to be evaluated. Feedback on the use of this label will be reflected in the Labelling Recommendations Issues Register.

### 22.2 Medicines via the extracorporeal circuit

Other medicines, such as intravenous heparin, iron and antibiotics, are sometimes given via the extracorporeal circuit as an infusion and have the same minimum labelling requirements as in every other clinical setting.

### I.R. 23: Should containers and lines for enteral medicines be labelled?

The principles of the Labelling Recommendations apply to medicines and fluids via the enteral route. (See Labelling Recommendations page 13, Labelling non-injectable solutions.)

- Non-injectable solutions must NEVER be given through 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 through non-injectable routes such as inhalational, oral and other enteral routes.
- ONLY syringes specifically designed for administration of medicines orally or through other enteral routes (e.g. nasogastric) should be used for these purposes. They should be clearly labelled ‘For Oral Use Only’, ‘For Enteral Use Only’, etc.
- Syringes used for non-injectable solutions must NOT be compatible with parenteral entry portals.

Although the enteral medicines are beyond the scope of the Labelling Recommendations, the labels in Figures 8 and 9 are suggested examples for enteral medicines and fluids. Green (PMS 361) for enteral routes is consistent with Australian Standard 4940:2002 User-applied identification labels for use on fluid bags, syringes and drug administration lines and which preceded the Labelling Recommendations. The borders are hatched black and green in line with the Labelling Recommendations container and line labels. The central background is coloured 70% to improve legibility of printed and populated text.

**Figure 8: Example container label for medicines delivered via the enteral route**

**Figure 9: Example line label for medicines delivered via the enteral route**

These labels are a suggested and have yet to be evaluated. Feedback on user-applied labelling of the enteral route will be available on the Issues Register.