



# Written submission questions

## Draft Requirements for Haemopoietic Cellular Therapy (seventh edition)

You are invited to provide feedback to the Commission on the draft Requirements for Haemopoietic Cellular Therapy (seventh edition).

### Introduction

The Australian Commission on Safety and Quality in Health Care (the Commission) is revising the [\*Requirements for procedures related to the collection, processing, storage and issue of human haemopoietic progenitor cells\*](#). The revised Standard will be renamed the *Requirements for Haemopoietic Cellular Therapy (seventh edition)* (HCT Standard).

The HCT Standard aims to:

- align with the International FACT-JACIE (IX) Standard
- reduce duplication with current relevant Australian standards
- include the evolving technology around Immune Effector Cells (IEC).

The Commission has consulted broadly with the pathology sector, professional bodies, jurisdictions, and government agencies to revise the standard.

You can provide feedback by addressing all or any of the following questions. Your input will help shape the standard.

Read the draft [HCT Standard here](#).

### Submission questions

1. Do the actions in the revised standard provide a safety and quality framework consistent with contemporary practice?
2. Are there safety and quality concerns not addressed in the draft standard?
3. Which actions require refinement to improve clarity?
4. Are there areas of duplication or redundancy that could be removed?
5. The revised standard mandates ISBT 128 labelling in alignment with FACT–JACIE. Please address:
  - support or concerns regarding mandating
  - training and cost implications
  - risks for smaller or single-activity services



- recommended transition arrangements.
6. Are there any foreseeable unintended regulatory, operational or financial impacts?
  7. Are there any other concerns with the draft standard?

Respondents are requested to reference the relevant section and page number when providing feedback.

## Have your say

Submit written responses via:

### Email

Attention: HCT - Submission

[pathology@safetyandquality.gov.au](mailto:pathology@safetyandquality.gov.au)

### For more information

Please visit: [safetyandquality.gov.au/national-standards/pathology-standards](https://safetyandquality.gov.au/national-standards/pathology-standards).

If you have any questions about this consultation, please email the Commission's pathology team at [pathology@safetyandquality.gov.au](mailto:pathology@safetyandquality.gov.au)

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