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The "Comment Detail" field should describe the issue you feel should be addressed, and a justification for the proposed change.

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Example: How to complete the comment form:

*Sect./ Subsect.[1]	*Sect. ID	Para./Table /Fig./Comm ./Note	*Page No.	*Comment Type[2]	*Comment Detail	*Proposed Change
Clause	2.3	Table 1	16	Editorial	"diagram" incorrectly spelt	Correct spelling error
Appendix	C15.6		62	Technical	AS 5100.7 incorrectly referenced	Reference should be AS 5100.2

[1] Options include: Clause, Title, Table of Contents, Preface, Foreword, Introduction, Appendix, Bibliography or Index.
[2] Options include: Editorial, General or Technical.

*Section[1]	*Section Identifier	Paragraph/ table/ figure/ commentary/ note	*Comment Type[2]	*Page No	*Comment Detail	*Proposed Change
Preface	Preface			2-3	The Society of Hospital Pharmacists (SHPA) acknowledges that the Standard is not specifically written for the use of cytotoxic drug safety cabinets (CDSCs) to compound cytotoxic medicines. We also acknowledge that the Standards document the **minimum** requirements, rather than best possible requirements; therefore in general the Standard reflects the use of CDSC for other uses where the protection of the operator is less important than the compounding of cytotoxic medicines. However, we believe that it is the major use of CDSCs, therefore the Standards should include specific reference to issues that relate to the compounding cytotoxic medicines either in the body of the text or as an appendix.	Inclusion of an appendix that lists requirements / additional considerations specific to the use of CDSCs and surrounding environments when they are intended to be used for the compounding of cytotoxic medicines (referred to as Appendix E in this submission). The second last sentence in the first paragraph on page 3 should be rewritten to explain that the Standards document the minimum requirements for the use of CDSCs for any purpose and that there are additional minimum requirements when the CDSC is intended to be used for the compounding of cytotoxic medicines (Appendix E).
Preface		3rd paragraph	Technical	2	"The objective of this document … and the surrounding environment." We would like to highlight that a combination of factors impact on the protection of personnel and the surrounding environment.	The objective of this document is to provide a Standard for cytotoxic drug safety cabinets (CDSCs), their location and clean room enclosure and the surrounding environment which together offer protection to the operational …
Preface		5th paragraph	General	2	The paragraph states "There is no doubt that some cytotoxic materials do volatize, however, the level of risk that they can later condense on surfaces outside the cabinet, such as the room or exhaust ducting, cannot be determined" However, an Australian study has shown surface contamination within	The committee should reconsider the wording of this paragraph to: ▪ document the level of risk posed by cytotoxic materials condensing on surfaces outside of the cabinet ▪ remove the suggestion that the

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					clean room preparation areas in facilities with CDSCs and preparation areas that operate under the existing Australian standards. The authors recommended additional cytotoxic handling procedures. See: Siderov J, Kirsa S, McLauchlan R. Surface Contamination of Cytotoxic Chemotherapy Preparation Areas in Australian Hospital Pharmacy Departments. J Pharm Pract Res 2009; 39 (2): 117-21 Available at: http://jppr.shpa.org.au/lib/pdf/2009_06/2009_06_Siderov_RE.pdf	use of a carbon filter on the exhaust mitigates against all the risks listed and make it clear that they are designed to address the quality of air exhausted from the area.
Foreword			Editorial	5	SHPA would prefer the use of the term 'medicine' instead of drug where appropriate e.g. cytotoxic medicine	Replace 'cytotoxic drug' with cytotoxic medicine'
Foreword		1st paragraph	Editorial	5	The use of the word 'widespread' is unnecessary, the frequency of the use of cytotoxic drugs does not affect the inherent risks of their preparation, manipulation and compounding.	Remove the word 'widespread'
Foreword		3rd paragraph, point (b)	Technical	5	It is unclear what the term 'drug products' includes. We believe the intent is that it includes all raw materials, medicine products and final product prepared (including delivery devices).	Reword (b) so that it includes all materials required to compound a final product.
Foreword		4th paragraph	Technical	5	Given that these Standards reflect the use of CDSC for other uses where the protection of the operator is less important than the compounding of cytotoxic medicines and do not comment on the use of closed-drug transfer devices to reduce exposure to operators, the statement that these Standards provide a risk level that is as low as is reasonably achievable is misleading. A joint position statement from the Oncology Nursing Society (ONS), the American Society of Clinical Oncology (ASCO) and the Haematology/Oncology Pharmacy Association (HOPA) (https://www.ons.org/advocacy-policy/positions/practice/hazardous-drugs), and the International Society of Oncology Pharmacy Practitioners (ISOPP) Standards (http://www.oncosystems.com.tr/dosyalar/_ISOPP_Standards_of_Practice_-_Safe_Handling_of_Cytotoxics.pdf) both promote the use of closed-system transfer devices as **supplementary** engineering controls to reduce exposure of cytotoxic drugs to operators.	Include the use of closed-system transfer devices as supplementary engineering controls and decontamination procedures for the external surface of materials entering the CDSC and clean room which must also be addressed irrespective of the cabinet / environment to reduce exposure of cytotoxic drugs to operators in Appendix E.

*Section[1]	*Section Identifier	Paragraph/ table/ figure/ commentary/ note	*Comment Type[2]	*Page No	*Comment Detail	*Proposed Change
Foreword		5th paragraph	Technical	5	The final paragraph gives the reader the impression that cytotoxic drug safety cabinets (CSDC) are superior to Class II biological safety cabinets, however published data contradicts this. See: Siderov J, Kirsa S, McLauchlan R. Surface Contamination of Cytotoxic Chemotherapy Preparation Areas in Australian Hospital Pharmacy Departments. J Pharm Pract Res 2009; 39 (2): 117-21 Available at: http://jppr.shpa.org.au/lib/pdf/2009_06/2009_06_Siderov_RE.pdf	Do not imply that CSDCs remove all risk associated with the manipulation of cytotoxic medicines.
Scope	1	Notes 1	Technical	6	The notes state that the "use of a CDSC with a carbon filter on its exhaust … is the most effective method" to provide protection against gases and vapours that may be produced during compounding procedures.	It should be clear that this statement relates to protecting the surrounding environment rather than the operator.
Scope	1	Notes 1	Technical	6	The Standard is silent on the risks associated with the manipulation of solid materials which produce solid particle contamination (e.g. the crushing of a tablets to compound a medicine product).	Include comment on the increased requirements if manipulating solid materials that produce solid particle contamination. Include comment on the need to consider the use of an isolator if the manipulation of solid materials which produce solid particle contamination is routine in Appendix E.
Definitions	3		Technical	6-7	The Pharmacy Board of Australia has a series of definitions that should be used for the terms compounding and dispensing. There are also other definitions that may be applicable. See PBA Guidelines on compounding available from http://www.pharmacyboard.gov.au/Codes-Guidelines.aspx **"Batch** means a quantity of a product that is uniform in composition, method of manufacture and probability of chemical or microbial contamination, and is made in one cycle of manufacture and, in the case of a product that is sterilised or freeze dried, sterilised or freeze dried in one cycle. **Batch preparation** is the creation of a batch of multiple units of issue of	We believe that these definitions should be used for consistency between PBA, TGA and the Standards.

*Section[1]	*Section Identifier	Paragraph/ table/ figure/ commentary/ note	*Comment Type[2]	*Page No	*Comment Detail	*Proposed Change
					a product. **Compounding** means for the purpose of these guidelines, the extemporaneous preparation and supply of a single 'unit of issue' of a therapeutic product intended for supply for a specific patient in response to an identified need. The practice of compounding is classified in these guidelines as either simple or complex compounding. Unless otherwise stated, the guidance provided in these guidelines applies to both simple and complex compounding. Compounding/manufacturing may also be defined in state and territory legislation. **Simple compounding** means the preparation and supply of a single 'unit of issue' of a therapeutic product intended for supply for a specific patient in response to an identified need. It routinely involves the compounding of products from formulations published in reputable references such as the *Australian Pharmaceutical Formulary and Handbook* (excluding the preparation of sterile products from these formulations, which is considered complex compounding), or using other formulations for which information confirming quality, stability, safety, efficacy and rationality is available. **Complex compounding** means the preparation and supply of a single 'unit of issue' of a therapeutic product that is intended for supply for a specific patient and that requires or involves special competencies, equipment, processes or facilities. Examples are sterile preparations and preparations containing ingredients that pose an occupational health and safety hazard (such as cytotoxics or hormones), micro-dose single-unit dosage forms containing less than 25mg (or up to 25 per cent by weight or volume) of active ingredient, and sustained-release or other modified-release preparations. **Dispensing** is the preparation, packaging, labelling, record keeping and transfer of a prescription drug to a patient, their agent, or another person who is responsible for the administration of the medicine to that patient (see Guideline 1 *The dispensing process* in the Board's *Guidelines for dispensing of medicines*)."	
Clause	4		Technical	8-12	This clause is dedicated to the physical containment relating to the physical structure of the CDSC, the immediate and surrounding	Include the use personal protective equipment, supplementary engineering

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					environment. A joint position statement from ONS, ASCO and HOPA (https://www.ons.org/advocacy-policy/positions/practice/hazardous-drugs), and the ISOPP Standards (http://www.oncosystems.com.tr/dosyalar/_ISOPP_Standards_of_Practice_-_Safe_Handling_of_Cytotoxics.pdf) both promote the use of closed-system transfer devices as supplementary engineering controls to reduce exposure of cytotoxic drugs to operators.	controls and closed-system transfer devices etc. as additional requirements to reduce exposure of cytotoxic drugs to operators in Appendix E. Make reference to these and Appendix E at the commencement of Section 4.
Clause	4.2	Notes	Editorial	8	We understand that most 'regional health guidelines for handling cytotoxic drugs' refer to the reader to Australian Standard – so the reader is in a loop as both document refer / defer to the other. Reference should also be made to the *Australasian Health Facility Guidelines Part B - Health Facility Briefing and Planning 560 - PHARMACY UNIT* http://healthfacilityguidelines.com.au/AusHFG_Documents/Guidelines/%5bB-0560%5d%20Pharmacy%20Unit.pdf	Change to 'Regional guidelines, the Australasian Health Facility Guidelines and Standards for handling cytotoxic medicines should also be consulted' and refer to Appendix E.
Clause	4.3.2	Point 4.3.2	Technical	8	The term 'safety glass' should not be used.	Change to viewing window that is transparent and resistant to cleaning materials
Clause	4.3.3.	Point 4.3.3	Technical	10	From the perspective of the operator compounding cytotoxic medicines the most important requirements is the air curtain velocity and having a mechanism to alert the operator if this safety carrier has failed. Failure may be due to mechanical failure or over-crowding in the cabinet.	Include requirements for air curtain velocity and continuous monitoring alert for operator in Appendix E.
Clause	4.3.5	Point (a)	Technical	11	SHPA's *Standards of Practice for the Safe Handling of Cytotoxic Drugs in Pharmacy Departments* recommends that no more than two hours be spent working at the cytotoxic cabinet without a break. See http://www.shpa.org.au/lib/pdf/practice_standards/ps_cyto_handling.pdf	Include reference to maximum shift duration or reference to SHPA Standards of Practice which includes reference to other human factors such as the need for an equipment and operator log in Appendix E.

*Section[1]	*Section Identifier	Paragraph/ table/ figure/ commentary/ note	*Comment Type[2]	*Page No	*Comment Detail	*Proposed Change
Clause	4.4.1	4.4.1	Technical	12	SHPA believes that every CDSC / clean room should have a real-time Environmental Management System that ensures that the CDSC and clean room is working in accordance with the Building Management System developed for that site. This would enable operators to know that the CDSC and immediate environment is safe for use.	Include requirements for continuous real-time Environmental Management System with an alert with respect to room requirements for operator (including particulate matter, temperature, humidity, air pressure) in Appendix E.
Clause	5.4.2	5.4.2	Editorial	15	Reference to alarm systems should include the need for 'real time' Environmental Management System that ensures that the CDSC and clean room is working in accordance with the Building Management System developed for that site.	Include requirements for continuous real-time Environmental Management System with an alert with respect to room requirements for operator (including particulate matter, temperature, humidity, air pressure) in Appendix E.
Clause	6.1	6.1	Technical	16	The current wording that requires testing after relocation could be read as requiring testing every time a cabinet that has a gas-lift to move the cabinet up or down to adjust for the height of the operator. We believe that where testing upon installation confirms critical performance when the CDSC is in all possible height configurations and that there is real-time monitoring through and Environmental Management System that there is no need for additional testing when the CDSC is adjusted for the height of the operator.	Appendix E should include that adjustable height CDSC can meet the Standards when testing upon installation confirms critical performance when the CDSC is in all possible height configurations and that there is real-time monitoring through and Environmental Management System.
Clause	7.4.1	7.4.1	Technical	20	SHPA remains concerned that the Standards are not specific enough to ensure that exhaust from the CDSC and room are handled separate to the facilities other exhaust / air handling systems and do not feed into other air handling systems within the building.	Make language more explicit.
Clause	7.5.1		Technical	21	We believe that the air in any anteroom / changing room must also be not less than Grade B as operators entering and leaving the cleanroom permits an influx of anteroom air into the cleanroom. If the air is of a lower grade the air in the cleanroom would not meet specifications until several air changes have occurred. This requirement is critical to the compounding of medicines as the Pharmacy Board of Australia is in the process of describing Guidelines that dictate the expiry dates of compounded medicines linked to the facilities.	Include the statement that air in any anteroom / changing room must also be not less than Grade B in Appendix E.

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Table	Table 3	all	Technical	23	This table includes classification Grades A to D, however these grades are not referred to in the body of the standards.	Include reference of grade classification for the various applicable areas within Clauses 6 and 7 and cross-reference with Table 3.
Section	8		Technical	24	The CDSC and clean room will be contaminated if contaminated materials are brought from the preparation area into the CDSC and clean room (e.g. vials covered with dust or powder, packaged gloves with paper particulate matter)	The Standard should refer to appropriate cleaning of materials that enter the CDSC / clean room from a preparation area (e.g. trolleys, materials for manufacture including medicine products) and the need for personal protective equipment when cleaning materials.
Clause	8.1	(b)	Technical	24	This sentence could include positioning of robotic devices used by the operator to support the compounding of medicines and the need to ensure the work zone is adequate and safe for the operator.	Link to continuous real-time Environmental Management System with an alert with respect to room requirements for operator in Appendix E
Clause	8.3.1	8.3.1	Technical	24	SHPA suggests that waste materials and unrequired equipment / materials should be removed daily.	Include in paragraph.
Clause	8.4.1	1st paragraph	Technical	26	It is unclear what is meant by 'intermittent use of the cabinets should be avoided' however in practice cabinets would not be used 24 hours seven days a week. The standards should define what 'intermittent use' is.	Define 'intermittent use' or reword the sentence. Refer to requirements for continuous real-time Environmental Management System with an alert with respect to room requirements for operator in Appendix E.
Appendix B	B2	(b)	Technical	28	The appendix refers to a 'workmat', this is not mentioned in the body of standards. If the Committee advocates the use of work-mats, the standards should reflect this and provide the evidence for this work practice.	Include the use of work-mats in the standards if the Committee believes it is required as part of standard compounding processes.
Appendix B	B3	list	Technical	29	SHPA's *Standards of Practice for the Safe Handling of Cytotoxic Drugs in Pharmacy Departments* recommends the contents of a spill kit, some of the items are not included in the proposed list e.g. instructions for	Revisit contents of proposed skill kit and provide references.

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					cleaning a cytotoxic spill. See http://www.shpa.org.au/lib/pdf/practice_standards/ps_cyto_handling.pdf	