Appendix 1. Standards Content Analysis Table

Topic ('X' mark indicates topic is covered)	ASHP Guidelines on Compounding Sterile Preparations	NCCP oncology medication safety review	HPAI National Guidelines for Aseptic Compounding in Irish Hospital Pharmacy Practice	HSE Guideline on the Safe Handling of Cytotoxic Drugs 2022	REGULATION (EU) No 536/2014 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 16 April 2014 on clinical trials on medicinal products for human use.	Royal Pharmaceutical Society Quality Assurance of Aseptic Preparation Services: Standards	WHO good manufacturing practices for sterile pharmaceutical products	EudraLex - Volume 4 - Good Manufacturing Practice (GMP) guidelines & Annex 1 Revision: Manufacture of Sterile Medicinal Products	Resolution CM/Res(2016)2 on good reconstitution practices in health care establishments for medicinal products for parenteral use
Country	USA	Ireland	Ireland	Ireland	EU	UK	International	Sweden	EU
Regulatory framework of guidelines	X			X	X	X		X	X
Inspections									
Details of internal audit process	X		X	X	X	X			X
Details of internal audit schedule	~		~		X	X			X
Details of external audit process					X	X			
Details of external audit schedule				~		X			
Monitoring requirements	X		X	X	X	X	X	X	X
Personnel									
PPE	X		X	X		X	X	X	X
Qualifications	X		X	X		X		X	X
Training	X		X	X		X	X	X	X
Health monitoring				X					
Premises and equipment									
Clean rooms	X		X			X	X	X	
Design	X		X			X	X	X	
Waste management	X		X	X		X	X	X	
Policies and procedures									
SOPs	X		X	X	X	X		X	
Logs	X		X	X	X	X	X	X	X
Aseptic preparation									

Topic ('X' mark indicates topic is covered)	ASHP Guidelines on Compounding Sterile Preparations	NCCP oncology medication safety review	HPAI National Guidelines for Aseptic Compounding in Irish Hospital Pharmacy Practice	HSE Guideline on the Safe Handling of Cytotoxic Drugs 2022	REGULATION (EU) No 536/2014 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 16 April 2014 on clinical trials on medicinal products for human use.	Royal Pharmaceutical Society Quality Assurance of Aseptic Preparation Services: Standards	WHO good manufacturing practices for sterile pharmaceutical products	EudraLex - Volume 4 - Good Manufacturing Practice (GMP) guidelines & Annex 1 Revision: Manufacture of Sterile Medicinal Products	Resolution CM/Res(2016)2 on good reconstitution practices in health care establishments for medicinal products for parenteral use
Dating methods	X		X			X			
Storage/transport	X		X	X		X		X	X
Procedures for preparation	X		X			X	X	X	X
Procedures for compounding	x		x			X			X
Quality assurance system									
Contents	X		X	X		X		X	
Results and plans	X		X	X		X		X	
Quality assurance of products	X		X	X		X	X	X	
Risk management									
Risk management plan						x		X	X
Risk assessment	X		x	X		X	X	X	X
Action plan						X		x	X

Topic ('X' mark indicates topic is covered)	Resolution CM/Res(2016)1 on quality and safety assurance requirements for medicinal products prepared in pharmacies for the special needs of patients	USP General Chapter <797>	USP General Chapter <800>	Institute for Safe Medicinal Practices Guidelines for Safe Preparation of Compounded Sterile Preparations	PIC/S GUIDE TO GOOD PRACTICES FOR THE PREPARATION OF MEDICINAL PRODUCTS IN HEALTHCARE ESTABLISHMENTS & ANNEX 1 GUIDELINES ON THE STANDARDS REQUIRED FOR THE STERILE PREPARATION OF MEDICINAL PRODUCTS	PIC/S Guide to Good Manufacturing Practice for Medicinal Products Part 1 and 2	QuapoS 6-Quality Standard for the Oncology Pharmacy Service'	National Association of Pharmacy Regulatory Authorities MODEL STANDARDS FOR PHARMACY COMPOUNDING OF HAZARDOUS STERILE PREPARATIONS
Country	EU	USA	USA	USA/ International	International	International	International	Canada
Regulatory framework of guidelines	X	X	X					x
Inspections								
Details of internal audit process		~	~		X	X		~
Details of internal audit schedule					X	X		~
Details of external audit process	~				~			
Details of external audit schedule								
Monitoring requirements		X	X		X	X	X	X
Personnel								
PPE		X	X		X	X	X	X
Qualifications			X		X	X	X	X
Training		X	X	~	X	X	X	X
Health monitoring			x		X			
Premises and equipment								
Clean rooms		X	X		X	X	X	X
Design		X	X		X	X	X	X
Waste management		X	X	X	X	X	X	X
Policies and procedures								
SOPs		X	X	X	X	X	X	X
Logs		X	X	X	X	X	X	X
Aseptic preparation								
Dating methods		X					X	X
Storage/transport		X	X	X	X	X	X	X
Procedures for preparation		X	X	X	X	X	X	X

Topic ('X' mark indicates topic is covered)	Resolution CM/Res(2016)1 on quality and safety assurance requirements for medicinal products prepared in pharmacies for the special needs of patients	USP General Chapter <797>	USP General Chapter <800>	Institute for Safe Medicinal Practices Guidelines for Safe Preparation of Compounded Sterile Preparations	PIC/S GUIDE TO GOOD PRACTICES FOR THE PREPARATION OF MEDICINAL PRODUCTS IN HEALTHCARE ESTABLISHMENTS & ANNEX 1 GUIDELINES ON THE STANDARDS REQUIRED FOR THE STERILE PREPARATION OF MEDICINAL PRODUCTS	PIC/S Guide to Good Manufacturing Practice for Medicinal Products Part 1 and 2	QuapoS 6-Quality Standard for the Oncology Pharmacy Service'	National Association of Pharmacy Regulatory Authorities MODEL STANDARDS FOR PHARMACY COMPOUNDING OF HAZARDOUS STERILE PREPARATIONS
Procedures for compounding	~	~	X	X	X		X	X
Quality assurance system								
Contents		X		X	X	X	X	X
Results and plans		X		X	X	X	X	X
Quality assurance of products		X		X	X	X	X	X
Risk management								
Risk management plan	X	X					X	X
Risk assessment		X			X	X	X	X
Action plan		X						X

Topic ('X' mark indicates topic is covered)	National Association of Pharmacy Regulatory Authorities MODEL STANDARDS FOR PHARMACY COMPOUNDING OF NON-HAZARDOUS STERILE PREPARATIONS	American Society of Clinical oncology Standards for Safe Handling of Hazardous Drugs (Endorse existing standards and add further recommendations)	MHRA Guidance for Specials Manufacturers	Läkemedelsverkets föreskrifter (LVFS 2010:4) om tillverkning av extemporeläkemedel1	ISOPP safe handling of cytotoxics	GMP-Z & Annex 1 Manufacture of sterile products	National Institute for Occupational Safety and Health Preventing Occupational Exposures to Antineoplastic and Other Hazardous Drugs in Health Care Settings
Country	Canada	USA	UK	Sweden	International	Netherlands	USA
Regulatory framework of guidelines	X	X	X		X	X	x
Inspections							
Details of internal audit process	~			X	X	X	
Details of internal audit schedule	~			~	X	X	
Details of external audit process			X				
Details of external audit schedule			X				
Monitoring requirements	X		X	X	X	X	X
Personnel							
PPE	X	X	X	X	X	X	X
Qualifications	X		X	X	X	X	
Training	X		X	X	X	X	
Health monitoring		x			X		X
Premises and equipment							
Clean rooms	X		X	X	X	X	
Design	X		X	X	X	X	
Waste management	X	X	X	X	X	X	X
Policies and procedures							
SOPs	X		X	X	X	X	X
Logs	X		X	X	X	X	X
Aseptic preparation							
Dating methods	X						
Storage/transport	X		X	X	X	X	X
Procedures for preparation	X		X	X		X	X

Topic ('X' mark indicates topic is covered)	National Association of Pharmacy Regulatory Authorities MODEL STANDARDS FOR PHARMACY COMPOUNDING OF NON-HAZARDOUS STERILE PREPARATIONS	American Society of Clinical oncology Standards for Safe Handling of Hazardous Drugs (Endorse existing standards and add further recommendations)	MHRA Guidance for Specials Manufacturers	Läkemedelsverkets föreskrifter (LVFS 2010:4) om tillverkning av extemporeläkemedel1	ISOPP safe handling of cytotoxics	GMP-Z & Annex 1 Manufacture of sterile products	National Institute for Occupational Safety and Health Preventing Occupational Exposures to Antineoplastic and Other Hazardous Drugs in Health Care Settings
Procedures for compounding	X			X	X	X	X
Quality assurance system							
Contents	X		X	X		X	
Results and plans	X		X	X	x	X	
Quality assurance of products	X		X	X	X	X	
Risk management							
Risk management plan	X				X	X	
Risk assessment	X		x	X	X	X	X
Action plan	X				X	X	

Topic ('X' mark indicates topic is covered)	Directive 2004/37/EC - carcinogens, mutagens or reprotoxic substances at work	ADKA guideline: Aseptic production and Testing of ready-to-use parenterals	Ordinance on the application of good manufacturing practice in the manufacture of medicinal products and active ingredients and on the application of good professional practice in the manufacture of products of human origin (AMHWV)	TGA Good manufacturing practice for medicinal products	Pharmacy Board of Australia-Guidelines on Compounding Medicines	SHPA Guidelines for Medicines prepared in Hospital Pharmacy Departments 2010	SHPA Standards of Practice for the Safe Handling of Cytotoxic Drugs in Pharmacy Departments
Country	EU	Germany	Germany	Australia	Australia	Australia	Australia
Regulatory framework of guidelines	X	X	X		X		
Inspections							
Details of internal audit process			X	X	X	X	X
Details of internal audit schedule			X	X	X	X	~
Details of external audit process				~		~	
Details of external audit schedule							
Monitoring requirements		X	X	X		X	X
Personnel							
PPE	X	X	X	X	X	X	X
Qualifications	X	X		X	X	X	X
Training	X	X	X	X	X	X	X
Health monitoring	X						X
Premises and equipment							
Clean rooms		X	X	X	X	X	X
Design		X	X	X	X	X	
Waste management		X	X	X	X	X	X
Policies and procedures							
SOPs		X	X	X	X	X	X
Logs	X	X	X	X	X	X	X
Aseptic preparation							
Dating methods							
Storage/transport		X	X	X	X	X	X
Procedures for preparation		X	X	X	X	X	X
Procedures for compounding		X			X		

Topic ('X' mark indicates topic is covered)	Directive 2004/37/EC - carcinogens, mutagens or reprotoxic substances at work	ADKA guideline: Aseptic production and Testing of ready-to-use parenterals	Ordinance on the application of good manufacturing practice in the manufacture of medicinal products and active ingredients and on the application of good professional practice in the manufacture of products of human origin (AMHWV)	TGA Good manufacturing practice for medicinal products	Pharmacy Board of Australia-Guidelines on Compounding Medicines	SHPA Guidelines for Medicines prepared in Hospital Pharmacy Departments 2010	SHPA Standards of Practice for the Safe Handling of Cytotoxic Drugs in Pharmacy Departments
Quality assurance system							
Contents			X	X	X	X	
Results and plans			X	X	X	X	X
Quality assurance of products		X	X	X	X	X	X
Risk management							
Risk management plan	X				X		
Risk assessment	X		X	X	X	X	x
Action plan	X				X		