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COLLEGE OF PHYSICIANS & SURGEONS OF ALBERTA

Psychedelic-Assisted Psychotherapy (PAPT) Accreditation Standards

Version: Consultation Draft D2

Developing Committee: **Medical Facility Accreditation Committee**

Final Approval Authority: **Council of the CPSA**

Approval Date:

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Introduction

Role of College of Physicians & Surgeons of Alberta (CPSA)
The CPSA is mandated by legislation (*Health Professions Act*) to regulate the practice of medicine in Alberta and is responsible for licensing physicians, administering standards of practice and conduct, and resolving physician-related complaints. It also provides leadership and direction on issues of importance to the health care system such as access to services, quality improvement, patient safety and privacy. Authority to accredit specified medical services and facilities is one aspect of the mandate. The CPSA administers accreditation programs for those services that the CPSA Council determines deserve explicit standards and verification of compliance with those standards, to ensure the safety of those services to the public in the settings proposed.

Accreditation emphasizes continuous quality improvement and promotes optimum performance to ensure quality health services, and subsequently a high standard of patient care in the Province of Alberta. The CPSA's accreditation programs are overseen by a standing committee the Medical Facility Accreditation Committee (MFAC), with members appointed by the Council from diverse disciplines in clinical and diagnostic medicine. MFAC conducts a secondary review of practice standards developed by the accreditation advisory committees, hears argument on changes to accreditation standards and reviews all facility accreditation statuses.

CPSA Psychedelic-Assisted Psychotherapy Accreditation Program Model
Facilities are assessed initially when opened and subsequently on a four year rotation. An interim assessment is required as a result of significant change to scope/location of services, or may be required if unsatisfactory performance is reported/noted. The key features of the CPSA accreditation assessment model are as follows:

- Assessments are conducted:
  - on a 4 year rotation
- Assessments are conducted by assessment teams of practicing professionals:
  - Assessment Coordinators - CPSA consultants who ensure assessments are consistent, comprehensive, accurate and lacking assessor bias; serve as a key assessment resource and liaison to the Accreditation Committee
  - Assessors with subject matter expertise.
  - Facilities receive pre-assessment notification.
- Assessment teams are vetted for approval to ensure no direct conflict of interest.
- Assessment model encompasses both a desk audit of documentation and an on-site assessment.
- Facilities are required to submit a "Pre-assessment Data Verification Form" listing key facility pre-assessment information required for assessment and are also directed to upload required desk audit documentation utilizing a secure SharePoint site.

- The focus of the on-site assessment is on high risk, patient/staff/safety elements and those activities requiring direct observation/validation.
- Final accreditation reports are distributed to facilities/zone within 30 business days of the last day of the assessment via a secure SharePoint site.
- Responses to non-compliances are due within 90 days of final report; evidence of compliance may be requested for certain key findings for confirmation of compliance. Responses to serious safety citations may be requested within 30 days.
- Facilities and assessment team members receive evaluation/feedback surveys after each assessment to assist the CPSA in process improvement/enhancement.
- There is no mandatory mid-cycle assessment.
- Facilities are NOT required to submit on-going self-assessment/audit documents.

Standards Documents Overview

The Standards are the basis for accreditation decisions and are developed by the Medical Facility Accreditation Committee with final approval by the CPSA Council.

The Standards are evidence based and reference accepted best practices, Provincial and Canadian legislation, relevant International Organization for Standardization (ISO) standards, and other recognized provincial, national and international standards (e.g. CLSI, GOC, CSA, etc.). Each accreditation standard has accompanying reference citations.

All standards included in the documents are mandatory requirements for accreditation.

The Standards are process-based and incorporate a quality management system approach. The language, terms and organization of the documents are consistent with *ISO 15189, Medical Laboratories-Particular Requirements for Quality and Competence.*

A review of accreditation standards occurs on an ongoing basis, considering and incorporating stakeholder feedback. Comprehensive formal review occurs on an annual basis, with broad stakeholder review occurring every 4 years.

Document Format:

- CPSA standard number
- Patient or staff safety risk category (where applicable)
- Each standard has been reviewed to determine if it represents a direct and/or immediate patient or staff safety risk.
  - Those with either a patient safety (PS) or staff safety (SS) designation indicate that any non-compliance may have direct and/or immediate impact on safety.
  - PS/SS standards are 'shaded' for ease of detection
  - Assessors must ensure that ALL standards with either a PS or SS designation are directly assessed at the time of the on-site assessment.

Safety Risk Category		
PS	**Patient Safety**	non-compliance may have direct and/or immediate impact on patient safety
SS	**Staff Safety**	non-compliance may have direct and/or immediate impact on staff safety

- Specific reference(s) (e.g. CLSI, ISO)
- Interpretation guidance where relevant regarding the application of requirements
- Assessment of compliance questions (AOC) that provide specific guidance and practical direction for evaluation of compliance with the standard.
  - Although the AOC questions address the key evidence required to meet the intent of each standard, they **are not meant to be all encompassing.**
  - In addition to the AOC questions, there may be other evidence that demonstrates compliance with the standard. Individual assessors apply their own expertise in determining compliance with each standard.
  - Where standards state "all of the following", compliance with all elements is expected to achieve compliance with the standard.
  - Compliance with the standard may be assessed by review of documents and records, observation, interviews or a combination of these techniques.
  - Upon assessment of the objective evidence, failure to meet the intent and/or requirement of the standard will result in an assessment of non-compliance.
  - "In Progress" citations require submission of future evidence of compliance based on direction from the assessor and/or the Advisory Committee.
  - "Exceeds Requirement" citations are for those situations where a facility exceeds the intent of the standard and employs commendable practice. The intent of capturing these occurrences is to promote and focus on quality initiatives.

- Receipt of "FULL" accreditation status is contingent upon satisfactory resolution of all non-compliances (N and P).

Compliance Assessment Category:	
C	meets intent and requirements of standard
P	in progress (working towards meeting intent and requirements of standard; assessor notes evidence of progress towards full compliance)
E	exceeds requirements of standard
N	does not meet intent and/or requirements of standard
N/A	not applicable to scope of service

- Compliance Assessment Category checkboxes
- Observation field for recording of objective evidence (field is expandable in electronic document)

References

A detailed reference list is provided at the end of this document. Specific references can be accessed by clicking on individual link(s) included beside each standard. The references support the content and intent of each standard. It should be noted that all components of the cited references may not always be relevant and/or applicable. **Compliance is expected with CPSA Standards.**

Terms and Definitions

A listing of applicable terms and definitions is provided at the end of this document.

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The following standards are applicable to the provision of Psychedelic-Assisted Psychotherapy in CPSA accredited Facilities.

Psychedelic-assisted psychotherapy is defined as "Services to treat a psychiatric disorder with psychotherapy and one or more designated psychedelic drugs, whether or not the administration of the drug and the psychotherapy are provided on the same day or on different days" [1].

This definition applies to circumstances where the same service provides both the psychedelic drug and the psychotherapy session and also where the services are linked in a care plan or contract and are provided by different providers.

Patients being seen for these indications must be referred from their most responsible physician with formal, documented attestation of an assessment or evaluation by a psychiatric support program for pre and post treatment support. Self-referrals are not permitted.

Referral to the facility administering the psychedelic psychotherapy treatment must be made by a physician not affiliated with the facility.

Psychedelic drug treatment is limited to oral, sublingual, intranasal or intramuscular administration. These Standards do not address the provision of psychedelics for palliative care or treatment of psychiatric disorders outside of psychotherapy.

Physicians providing these treatments must be appropriately credentialed and compliant with the Practicing Outside of Conventional Medicine Standard and Part 3 of the Mental Health Services Protection Regulation (AR114/2021) and associated service standards[1].

CPSA has developed these standards to ensure the safety and quality of these services for Albertans and does not endorse the efficacy of the treatments.

References:
1. GOA[9]

#	Standard	Reference	Assessment of Compliance
PAPT.1.0 ORGANIZATION, MANAGEMENT & PERSONNEL			
PAPT.1.1 Organization, Management & Personnel			
PAPT.1.1.1	The Psychedelic-Assisted Psychotherapy (PAPT) facility, or the organization of which the facility is a part, is legally identifiable.	CSA[3] 26000 –6.2 ISO[1] 15189 – 4.1.1.2	Is there evidence of the articles of incorporation or partnership agreements that prove the PAPT identifiable? Is there evidence of professional liability coverage for all staff? C ☐ P ☐ E ☐ N ☐ N/A ☐ Observation:
PAPT.1.1.2	The (PAPT) facility defines, documents, and communicates the responsibilities, authorities and interrelationships within the organization.	CLSI[3] QMS01 – 3.1.2, 3.4 CSA[3] 26000 – 6.2 ISO[1] 15189 – 4.1.2.1.d, 4.1.2.5 ISO[2] 9001 – 5.3 ISQua[1] – 3.5 Guidance: An organizational chart may be used to define and document organizational roles and reporting hierarchy	Are the responsibilities, authorities and interrelationships within the facility organization: • defined? • documented? • communicated? Does this include, where appropriate: • medical director? • facility supervisor? • facility manager? • clinical / non-clinical staff? • 'quality manager'? • safety officer? Are persons appointed to undertake the duties of key management and clinical personnel in their absence (deputies)? C ☐ P ☐ E ☐ N ☐ N/A ☐ Observation:

#	Standard	Reference	Assessment of Compliance
PAPT.1.1.3	The PAPT facility has clearly identified the type and scope of services performed at the Facility.	APA[1] CLSI[3] QMS01 – 3.1.1.2 ISO[1] 15189 – 4.1.2.1.d, 4.1.2.5 ISO[2] 9001 – 4.1 ISQua[1] – 3.1	Is there evidence the facility has clearly identified the type and scope of the psychedelic-assisted psychotherapy services occurring? C ☐ P ☐ E ☐ N ☐ N/A ☐ Observation:
PAPT.1.1.4	Facility management ensures the availability of the resources needed to provide quality PAPT services.	CLSI[3] QMS01 – 3.1.4, 5.1 ISO[1] 15189 – 4.1.2.1.i ISQua[1] – 3.7	Are there adequate levels of all of the following: • staff? • supplies? • equipment? • physical space? C ☐ P ☐ E ☐ N ☐ N/A ☐ Observation:
PAPT.1.1.5	The facility develops and implements written operational policies, processes and procedures and ensures that all policies, processes and procedures are followed.	CLSI[3] QMS01 – 2.3, 3.7 GOA[7] ISO[1] 15189 – 4.1.2.3.b ISO[2] 9001 – 4.4.1, 8.1 ISQua[1] – 3.13, 6.4	Are there written operational policies, processes and procedures for all Psychedelic-Assisted Psychotherapy services? Is there evidence that the requirements of accreditation standards and applicable laws and regulations are incorporated into the policies, processes and procedures? Is there evidence of management review and oversight of compliance? Do personnel follow all policies, processes and procedures as written? C ☐ P ☐ E ☐ N ☐ N/A ☐

#	Standard	Reference	Assessment of Compliance
			Observation:
PAPT.1.1.6	The facility has a policy, process and procedure to ensure medical and clinical personnel are adequately trained, qualified and competent for the workload, range and complexity of the procedures performed in the facility.	CLSI[3] QMS01 – 3.1.4, 3.4 ISO[1] 15189 – 4.1.2.1.i, 5.1.2 ISO[2] 9001 – 5.1.1.e, 7.1.1, 7.1.2 ISQua[1] – 3.7, 3.8, 3.9 Guidance: Staffing may be considered insufficient if there is clear evidence from quality monitoring records, data derived from complaints or concerns, turnaround time, etc. Refer to Appendix A.2 for province specific directives	Is there a policy, process and procedure in place for recruitment of new medical and clinical personnel, including consultants as applicable, that includes verification of: • credentials? • education and training? • experience? • licensing? Are there adequate and appropriate medical and clinical personnel? Are PAPT personnel educated and qualified as appropriate for the workload, range and complexity of the procedures performed in the facility? Are all medical and clinical personnel registered in good standing with the appropriate regulatory authority? Does management ensure that staff are certified at required intervals for the following, as appropriate to their duties: • intravenous? • BCLS/CPR? Does the facility personnel include: • one qualified physician (psychiatrist) designated as director of the program who can provide evidence of an inter-professional program whose liaisons include physicians, nurses, psychologists, psychiatrists, counsellors, pharmacists, social workers and others as appropriate?

#	Standard	Reference	Assessment of Compliance
			• a clearly established and documented most responsible physician for each patient? • established and appropriate follow up patient care services? • clinical staff that are qualified and experienced in Psychedelic-Assisted Psychotherapy patient care management (e.g. mental health experience)? • administrative support staff? Do facility personnel have pre-arranged access/support to health professionals competent in managing severe symptoms (agitation, aggression, dissociation, psychotomimetic effects) of Psychedelic-Assisted Psychotherapy as required?
			C ☐ P ☐ E ☐ N ☐ N/A ☐
			Observation:
PAPT.1.1.7	Facility management has personnel policies and job descriptions that define qualifications and duties for all personnel.	CLSI[3] QMS01 -3.4.1 ISO[1] 15189 – 5.1.3, 5.1.9.a-d	Are there written personnel policies? Are there job descriptions for all positions that include: • educational and professional qualifications? • duties and responsibilities? Are job descriptions current and readily available?
			C ☐ P ☐ E ☐ N ☐ N/A ☐
			Observation:
PAPT.1.1.8	PAPT facility management maintains comprehensive and relevant personnel records that are readily available to	CLSI[3] QMS01 – 3.4.8 GOC[7] ISO[1] 15189 – 5.1.9	Are there personnel records that include all of the following where relevant: • educational qualifications? • evidence of medical director privileging/approval of physicians providing services?

#	Standard	Reference	Assessment of Compliance
	appropriately designated personnel.		• professional certification or license, if required? • required certification records (e.g. CPR, first aid)? • job description? • experience details? • training and orientation records? • assessment of initial and on-going competency? • records of continuing education? • documentation of untoward incident or accident reports? • immunization status? • performance evaluations? • registry of the signatures (physical and electronic), initials and computer identification codes? Are personnel records maintained in a confidential manner, including authorized access, consent to release and disposal?
			C ☐ P ☐ E ☐ N ☐ N/A ☐
			Observation:
PAPT.1.1.9	The PAPT is directed by a physician (a "Medical Director" or other title) who has the qualifications as required by the provincial accrediting organization, competence and delegated responsibility for the entire PAPT services provided and facility operations.	CPSA[11] ISO[1] 15189 – 4.1.1.4 Refer to the Appendix A.1 for province specific directives	Do the medical director's qualifications meet the requirements of the appropriate provincial regulatory body? Does the facility Medical Director have the qualifications appropriate for the work load, range and complexity of the services performed in the facility? Is the PAPT Medical Director registered in good standing with the appropriate regulatory authority?
			C ☐ P ☐ E ☐ N ☐ N/A ☐
			Observation:

#	Standard	Reference	Assessment of Compliance
PAPT.1.1.10	The medical director is responsible for the overall operation and administration of the PAPT facility to assure that quality patient services are provided. Where indicated in a standard, the medical director may formally delegate the responsibility to a qualified designate; however, the medical director retains ultimate responsibility for all medical director duties.	CPSA[11, 13] ISO[1] 15189 – 4.1.1.4, 4.14.2 ISO[2] 9001 – 5.1, 5.3	Is there evidence that the medical director has responsibility for all of the following functions within the Psychedelic-Assisted Psychotherapy facility: • ensuring the production of reliable and accurate reports by the facility? • providing effective direction and supervision of all personnel in the facility? • providing effective leadership of the PFL service, including budget planning and financial management, in accordance with organizational assignment of such responsibilities? • ensuring that methods employed and equipment used in the facility are selected and performed in accordance with currently accepted best practices? • providing direction for the production, development and review of service menus and appropriate use of services in accordance with best practices in medicine? • ensuring that effective and appropriate safety and emergency preparedness procedures are in place? • ensuring that an effective program of quality assurance and quality management is in place for all services? • ensuring that processes are in place to employ adequate numbers of sufficiently trained, qualified and competent personnel? • ensuring that services are performed only at the request of an authorized requestor? • ensuring compliance with the standards of the provincial accreditation body and other applicable laws and regulations? • ensuring access for the provincial accreditation body to the facility for the inspection of records, manuals and equipment, including the availability of personnel for interviews, and to any other data

#	Standard	Reference	Assessment of Compliance
			and information that may be required for the assessment of the operation and the quality of work produced by the facility? • notifying the provincial accreditation body in writing of impending changes of: ○ directorship? ○ location? ○ addition or deletion of services?
			C ☐ P ☐ E ☐ N ☐ N/A ☐
			Observation:
PAPT.1.1.11	If the Medical Director has delegated an activity or responsibility to a designate a policy, process and procedure that identifies the necessary qualifications of the designate and how the delegation is carried out is available.	CPSA[11, 13] ISO[1] 15189 – 4.1.1.4, 4.14.2 ISO[2] 9001 – 5.1, 5.3 Guidance: The director need not perform all functions personally. Administrative functions may be delegated to qualified managers and supervisors. Medical and clinical functions may be delegated to physicians and other qualified personnel as appropriate.	Is there evidence of: • a process for delegation of the applicable medical director duties? • a policy that specifies which responsibilities may be delegated? • formal written record of delegation of responsibilities to a named designate(s)?
			C ☐ P ☐ E ☐ N ☐ N/A ☐
			Observation:

#	Standard	Reference	Assessment of Compliance
PAPT.1.1.12	The PAPT facility has policies to ensure that personnel are free from conflicts of interest and involvement in any activity that may adversely affect the quality of work.	CP[1] CPSA[4] CSA[3] 26000 – 4.4 ISO[1] 15189 – 4.1.1.3	Does the PAPT facility have policies to ensure all of the following: • no involvement in activities that would diminish confidence in the facilities' competence, impartiality, judgment or operational integrity is avoided? • management and personnel are free from any undue commercial, financial or other pressures and influences that may adversely affect the quality of their work? • existing potential conflicts are openly and appropriately declared? C ☐ P ☐ E ☐ N ☐ N/A ☐ Observation:
PAPT.1.1.13	PAPT facility management ensures that confidentiality of patient information is maintained by all personnel in accordance with provincial and national regulations.	ISO[1] 15189 – 4.1.1.3 ISQua[1] – 4.12, 5.1	Are there processes in place to ensure the confidentiality of patient information? Is there evidence of compliance with the processes? C ☐ P ☐ E ☐ N ☐ N/A ☐ Observation:
PAPT.1.1.14	PAPT facility management ensures that personnel take part in regular continuing education and professional development or other professional liaison.	CLSI[3] QMS01 – 3.4.6 ISO[1] 15189 – 5.1.8 ISQua[1] – 3.11	Is continuing education promoted, supported and made available to personnel? Is there evidence of PAPT facility personnel participation in continuing education/professional development activities or other professional liaison? C ☐ P ☐ E ☐ N ☐ N/A ☐ Observation:

#	Standard	Reference	Assessment of Compliance
PAPT.1.1.15	PAPT facility management performs and documents performance evaluations at regular intervals as defined in facility policy.	CLSI[3] QMS01 – 3.4.5 ISO[1] 15189 – 5.1.7	Are performance evaluations done for each staff member in accordance with facility policy? C ☐ P ☐ E ☐ N ☐ N/A ☐
PAPT.1.1.16 **PS / SS**	The PAPT facility ensures adequate training of all staff.	CLSI[3] QMS01 – 3.4.2, 3.4.3, 3.4.4 CLSI[4] QMS03 ISO[1] 15189 – 4.1.2.1.h, 5.1.4, 5.1.5 ISO[2] 9001 – 7.1, 7.2 ISQua[1] – 3.8, 5.1 Guidance: This standard applies to all non-physician staff members.	For new personnel and personnel introduced to new or revised tasks, is there evidence: • of specified training and orientation records? • that staff members are knowledgeable about the contents of procedure manuals, relevant to the scope of their activities? Do personnel receive training on: • ethics and confidentiality of patient information? • the prevention and containment of the effect of adverse incidents? • patient centered care as appropriate? • patient equity, diversity, inclusion and cultural sensitivity? Does the facility perform a review of errors attributable to training and initiate corrective action where required? Is there periodic review of the training program for effectiveness? C ☐ P ☐ E ☐ N ☐ N/A ☐ Observation:
PAPT.1.1.17	The PAPT facility performs competency assessment of staff following training and periodically thereafter. Retraining and	CLSI[3] QMS01 – 3.4.4 CLSI[4] QMS03 ISO[1] 15189 – 4.1.2.1.h, 5.1.6	Is there evidence of assessment of competency of each person to perform assigned supervisory or clinical tasks according to established criteria? Is there evidence of:

#	Standard	Reference	Assessment of Compliance
	reassessment occur when the need is identified.	ISO[2] 9001 – 7.2 ISQua[1] – 3.10 Guidance: This standard applies to all non-physician staff members.	• competency assessment immediately following training for new staff and following introduction of tasks? • regular competency assessment for each staff member that encompasses all relevant phases and scopes of service? • periodic evaluations to assess competency? Does the competency assessment process use a **combination of the following approaches** under the same conditions as the general working environment, **as appropriate to the specific activity:** • direct observation of routine work processes and procedures, including all applicable safety practices? • direct observation of equipment maintenance and function checks? • monitoring the charting of clinical results? • review of work records? • assessment of problem-solving skills? Where an employee has demonstrated unacceptable competency assessment, is there evidence of corrective actions?
			C ☐ P ☐ E ☐ N ☐ N/A ☐
			Observation:
PAPT.1.1.18	There are appropriate policies and procedures to ensure that personnel treat human samples according to relevant legal requirements.	CLSI[3] QMS01 – 3.1.1 ISO[1] 15189 – 4.1.1.3.d	Is there a policy that includes the relevant legal requirements for the ethical and safe treatment of human samples? Is there evidence that personnel are adhering to the policies and procedures?
			C ☐ P ☐ E ☐ N ☐ N/A ☐

#	Standard	Reference	Assessment of Compliance
			Observation:
PAPT.1.1.19	PAPT facility management has an effective system for communicating with staff.	CLSI[3] QMS01 – 3.1, 3.1.7 ISO[1] 15189 – 4.1.2.6	Does facility management have an effective means of communicating with staff? Are records kept of items discussed in communications and meetings?
			C ☐ P ☐ E ☐ N ☐ N/A ☐
			Observation:
PAPT.1.1.20	The facility has a policy, process, and procedure for participation by the facility in research.	CPSA[3] ISO[1] 15189 – 4.1.1.3 ISQua[1] – 5.4	Is a policy and procedure in place if the facility participates in research activities that identifies: • the documentation to be required on site, e.g. copy of an approved protocol? • separation of patient records specific to the research? Is there evidence that research activities involving patients or information about patients have been approved by a local ethics board, e.g., the Health Research Ethics Board of Alberta (HREBA)?
			C ☐ P ☐ E ☐ N ☐ N/A ☐
			Observation:

#	Standard	Reference	Assessment of Compliance
PAPT.2.0 QUALITY MANAGEMENT SYSTEM (QMS)			
PAPT.2.1 QMS – General			
PAPT.2.1.1	There is an individual with delegated responsibility and authority for the QMS.	CLSI[3] QMS01 – 3.1.2.1 ISO[1] 15189 - – 4.1.2.7 ISO[2] 9001 – 5.3, 7.1.2 Guidance: This role can be fulfilled by a staff member who has other responsibilities in the facility.	Does the individual with delegated responsibility and authority for the QMS ensure the following: • that processes needed for the QMS are established, implemented and maintained? • reports to the level of facility management at which decisions are made on Psychedelic-Assisted Psychotherapy policy and resources? C ☐ P ☐ E ☐ N ☐ N/A ☐ Observation:
PAPT.2.2 QMS – Quality Policies, Processes and Procedures			
PAPT.2.2.1	The PAPT facility has detailed written quality policies, processes and procedures that describe the essential elements of the QMS and the structure of the documentation used in the QMS.	CLSI[3] QMS01 – 3.1.3.1 ISO[1] 15189 – 4.2.2.2 ISO[2] 9001 – 5.2.2., 7.5.1 Guidance: The quality policies, processes and procedures: • generally makes reference to supporting processes and procedures but	Are there detailed written quality policies, processes and procedures? Do the quality policies, processes and procedures include all of the following essential elements: • a description of the organization and management structure of the PAPT facility and its relation to any parent organization? • the quality policy? • description of the scope of the QMS? • roles and responsibilities of Psychedelic-Assisted Psychotherapy facility management for ensuring compliance with the QMS? • description of the structure and relationships of documentation used in the QMS?

#	Standard	Reference	Assessment of Compliance
		does not include them. • may reference policies of the parent organization but all policies must be accessible to facility personnel.	• documented policies established for the QMS and reference to the managerial and clinical activities that support them? Do all PAPT facility staff have access to the quality policies, processes and procedures and are they instructed on the use and application of the quality and reference documents? C ☐ P ☐ E ☐ N ☐ N/A ☐ Observation:
PAPT.2.3 QMS – Documents & Records			
PAPT.2.3.1	There is documented review and approval of all documents issued to PAPT personnel by the medical director or designate prior to issue and at regular intervals as defined by facility policy.	CLSI[3] QMS01 – 3.1.3.1 ISO[1] 15189 – 4.3.a,h ISO[2] 9001 – 7.5.2 ISQua[1] – 3.3	Is there evidence that PAPT facility documents have documented review and approval by the medical director or designate prior to issue and at regular intervals as defined by facility policy? Is there a formal process for document revision that ensures all changes are reviewed and approved before use? Does the revision process determine how changes to the document could affect needed changes in other documents? C ☐ P ☐ E ☐ N ☐ N/A ☐ Observation:
PAPT.2.3.2	PAPT facility management ensures that current authorized documents are readily available	CLSI[3] QMS01 – 3.8.1.1 ISO[1] 15189 - – 4.3.b,c,d,f ISO[2] 9001 – 7.5.3	Are current authorized documents readily available for active use at all relevant locations? Is there a formal process / contingency plan for the access to procedures when the on-line system is not available?

#	Standard	Reference	Assessment of Compliance
	for active use at relevant locations.	Guidance: The document control log may be a simple manual list, or an electronic system. It must include unique identification for all documents and the title of the document. Only authorized personnel can make changes to the document control log.	Does the facility maintain a document control log identifying the current valid versions and their distribution? C ☐ P ☐ E ☐ N ☐ N/A ☐ Observation:
PAPT.2.3.3	PAPT facility management establishes and implements appropriate document control procedures for discontinued, invalid and obsolete controlled documents.	CLSI[3] QMS01 – 3.8.1.5 ISO[1] 15189 – 4.3.i,j ISO[2] 9001 – 7.5.3	Is there evidence that discontinued, invalid and obsolete controlled documents are: • promptly removed from all points of use? • archived for later reference? • appropriately identified to prevent their inadvertent use? • retained for a period as defined by facility policy? C ☐ P ☐ E ☐ N ☐ N/A ☐ Observation:
PAPT.2.3.4	There is a procedure for the amendment of controlled documents by hand, pending the re-issue of documents.	CLSI[3] QMS01 – 3.8.1.3 ISO[1] 15189 – 4.3.e,f,g ISO[2] 9001 – 7.5.3	Is there a procedure for hand-written amendments to controlled documents that defines the authority for such amendments? Do following criteria: • made by designated individuals only? • clearly identified? • initialed and dated? • made with indelible ink?

#	Standard	Reference	Assessment of Compliance
			• made in a way that does not obscure the original information? Are revised documents formally reissued as soon as practical? amendments of controlled documents meet all of the
			C ☐ P ☐ E ☐ N ☐ N/A ☐
			Observation:
PAPT.2.3.5	There is a procedure that defines how changes to electronic documents are made and controlled.	CLSI[3] QMS01 – 3.8.1.3 ISO[1] 15189 – 4.2.2.1 ISO[2] 9001 – 7.5.3	Is there a procedure that defines how changes to electronic documents are made and controlled? When changes to electronic documents are made, is there evidence that: • the procedure is followed? • there is appropriate document control?
			C ☐ P ☐ E ☐ N ☐ N/A ☐
			Observation:
PAPT.2.3.6	All PAPT facility documents are uniquely identified.	CLSI[3] QMS01 – 3.8.1.1 ISO[1] 15189 – 4.3.b ISO[2] 9001 – 7.5.2	Are all PAPT facility documents identified including all of the following: • title? • unique identifier on each page? • edition and/or current revision date and/or revision number? • page number to total number of pages (where applicable)? • authority for issue?
			C ☐ P ☐ E ☐ N ☐ N/A ☐

#	Standard	Reference	Assessment of Compliance
			Observation:
PAPT.2.3.7	PAPT facility management establishes and implements policies and procedures for the control of quality and clinical records.	CLSI[3] QMS01 – 3.8.2 ISO[1] 15189 – 4.13 ISO[2] 9001 – 7.5 ISQua[1] – 4.12	For quality and clinical records, are there appropriate policies and procedures that include all of the following: • identification? • collection? • indexing? • access? • storage? • maintenance? • confidential disposal?
			C ☐ P ☐ E ☐ N ☐ N/A ☐
			Observation:
PAPT.2.3.8	PAPT facility management ensures that all records are legible and stored such that they are readily retrievable, secure and accessible only to authorized personnel.	CLSI[3] QMS01 – 3.8.2.1, 3.8.2.4, 3.8.2.5 CSA[1] Z8000 – 9.9.3.8.6 ISO[1] 15189 – 4.13 ISO[2] 9001 – 7.5.3 ISQua[1] – 4.10 Guidance: Records may be maintained on any appropriate media including video recording.	Are all records legible? Are all records readily retrievable? Is there a suitable environment for record storage that prevents damage, deterioration, loss or unauthorized access? Is there a process for the management and correction of facility records that meets the following criteria: • made by designated individuals only? • clearly identified? • initialed and dated? • made with indelible ink? • made in a way that does not obscure the original information?

#	Standard	Reference	Assessment of Compliance
			Are records maintained and stored in alignment with applicable national, provincial and local legislation and codes, e.g. the Health Information Act? C ☐ P ☐ E ☐ N ☐ N/A ☐ Observation:
PAPT.2.3.9	The PAPT facility retains all documents and records for a period of time as defined by facility policy.	CLSI[3] QMS01 – 3.8.2.6 ISO[1] 15189 – 4.13 ISO[2] 9001 – 7.5.3.2 ISQua[1] – 4.12	Are retention requirements: • defined in the facility policy? • defined by the nature of the examination or specifically for each record type? • based on best practice and/or statutory authority? • reflective of legal liability where applicable? Is there evidence of appropriate retention? C ☐ P ☐ E ☐ N ☐ N/A ☐ Observation:
PAPT.2.4 QMS – External Services & Supplies			
PAPT.2.4.1	The PAPT facility has policies and procedures for the selection and verification of purchased external equipment and supplies that affect the quality of its services.	CLSI[3] QMS01 – 3.5.1 CSA[2] Z314-18 – 8,15 GOC[1] GOC[3] ISO[1] 15189 - – 4.6, 5.3.1.1 ISO[2] 9001 – 8.4 Guidance: In facilities where another department in the organization has primary	Do the facility's policies, processes and procedures for purchased equipment, consumables and supplies include (but are not limited to) the following: • selection and approval of suppliers? • requirement that all equipment is approved according to applicable national, provincial and local legislation? • requirements for the products or services to be purchased? • review of supplier contracts to ensure that requirements are adequately defined, documented and understood? Is there a list of accepted and approved suppliers?

#	Standard	Reference	Assessment of Compliance
		responsibility for this role (e.g. Central Purchasing) there must be documentation outlining the responsibilities.	When purchasing a reusable medical device, does the facility confirm that the device is: • properly licensed in Canada for medical use? • procured from a distributor with an establishment license? • compliant with applicable national, provincial and local legislation and codes? Do decisions relating to the purchase of medical devices and equipment involve representatives from the departments that will procure, use, reprocess and maintain the devices, as appropriate to the complexity, manufacturer's specifications, risk class and intended use of the device? When purchasing a pharmaceutical agent for use in services, does the facility confirm that the pharmaceutical product is properly licensed in Canada (i.e., has a Drug Identification Number [DIN])?
			C ☐ P ☐ E ☐ N ☐ N/A ☐
			Observation:
PAPT.2.5 QMS – Stakeholder Consultation			
PAPT.2.5.1	The PAPT facility has established protocols for regular communication with users of the facility service.	CLSI[3] QMS01 – 3.2.2, 4.4 ISO[1] 15189 – 4.1.2.6, 4.7 ISO[2] 9001 – 8.2.1	Is there evidence of regular communication with the users of PAPT facility services on the following: • advising of choice of treatments and use of the services? • advising on individual clinical cases?

#	Standard	Reference	Assessment of Compliance
		ISQua[1] – 3.15, 5.8	• professional judgments of the interpretation of the results of treatments? • promoting the effective use of Psychedelic-Assisted Psychotherapy services? • consulting on specific scientific and logistic matters?
			C ☐ P ☐ E ☐ N ☐ N/A ☐
			Observation:
PAPT.2.5.2	The PAPT facility has a process for the solicitation of feedback from relevant stakeholders for the improvement of appropriate aspects of the facility service.	CLSI[3] QMS01 – 3.2.5 CLSI[5] QMS06 – 4.7.2 CSA[3] 26000 – 4.5, 5.3.3 ISO[1] 15189 – 4.8, 4.14.3, 4.14.4 ISO[2] 9001 – 8.2.1 ISQua[1] – 3.14 Guidance: Stakeholders may include: • internal staff • external – clinicians, patients, etc.	Does the PAPT facility solicit feedback from the users of their services in a systematic way (e.g. surveys)? For all stakeholder suggestions, is there evidence of: • evaluation? • implementation as appropriate? • provision of feedback to stakeholders where appropriate? Does the PAPT facility have a process for the confidential communication of quality and safety issues and concerns to executive management?
			C ☐ P ☐ E ☐ N ☐ N/A ☐
			Observation:
PAPT.2.6 QMS – Resolution of Complaints			
PAPT.2.6.1	The PAPT facility ensures investigation and resolution of complaints or other feedback received from all stakeholders.	CLSI[3] QMS01 – 3.2.6 ISO[1] 15189 – 4.8 ISO[2] 9001 – 8.2.1, 9.1.2	Is there a process for the timely resolution of complaints or other feedback received from stakeholders? Is there evidence of complaint investigations and corrective action?

#	Standard	Reference	Assessment of Compliance
		ISQua[1] – 5.14	C ☐ P ☐ E ☐ N ☐ N/A ☐ Observation:
PAPT.2.7 QMS – Deviation, Non-conformance & Adverse Event Management			
PAPT.2.7.1 **PS / SS**	The PAPT facility ensures the timely identification, documentation and control of non-conformances and adverse events.	CLSI[3] QMS01 – 3.10 CLSI[7] QMS11 CPSA[10] CPSI[1] ISO[1] 15189 – 4.9, 5.3.1.6, 5.3.2.6 ISO[2] 9001 – 8.7, 10.2 ISQua[1] – 4.5 Guidance: Non-conforming events occur in many different areas and can be identified from a variety of sources including: • clinician complaints • checking of consumable materials • staff comments • reporting and certificate checking • management reviews • internal and external audits	Are there policies, processes and procedures for the identification and control of non-conformances and adverse events (e.g., clerical errors, significant service errors, unusual outcomes and excessive delays)? Does the system provide for timely identification, classification and correction of non-conformances and adverse events? Does documentation include all of the following, where applicable: • personnel responsible for problem resolution? • actions to be taken? • consideration of the medical significance? • notification of the requesting clinician where appropriate? • halting the treatment where necessary? • immediate corrective/remedial action? • responsibility for authorization of treatment resumption? • documentation of the event and review by PAPT facility management to detect trends and initiate preventive action? Are adverse incidents and accidents that are attributed directly to specific equipment or consumables investigated and reported to the manufacturer and appropriate authorities as required?

#	Standard	Reference	Assessment of Compliance
			Is there a formal policy and process for disclosure of adverse events to appropriate stakeholders involved in adverse events? Is the formal policy and process for disclosure of adverse events in compliance with any applicable legislation and within any protection afforded by legislation? C ☐ P ☐ E ☐ N ☐ N/A ☐ Observation:
PAPT.2.7.2 PS	The facility has a policy and process for the management of Reportable Incidents.	GOA[8] – 17 Guidance: Refer to Appendix A.4 for details of the CPSA Reportable Incident requirements.	Is there a policy and procedure for the reporting of significant incidents that is in compliance with the CPSA Reportable Incidents reporting requirements? C ☐ P ☐ E ☐ N ☐ N/A ☐ Observation:
PAPT.2.8 QMS – Continuous Improvement			
PAPT.2.8.1	PAPT facility management implements quality indicators for the systematic monitoring and evaluation of standards of performance and quality improvement activities relevant to critical aspects of pre-service, service and post-service processes.	CLSI[3] QMS01 – 3.11.2.2, 3.12.1.1,3.12.1.2 CLSI[5] QMS06 – 5.1 CLSI[11] QMS12 ISO[1] 15189 -4.12, 4.14.7 ISO[2] 9001 -9, 10 ISQua[1] – 6.1, 6.2	Are quality indicators established that: • are measureable in a consistent manner? • are comparable to best practice benchmarks where feasible? • are relevant to the outcome of patient care and PAPT services? Is there evidence that quality indicator benchmarks are being achieved? Is patient acceptance/rejection data tracked and monitored?

#	Standard	Reference	Assessment of Compliance
			Where quality indicator benchmarks are not achieved, is there evidence of investigation and corrective action? Do treatment related quality indicators include: • evidence that the facility Medical Director reviews patient outcome data on a regular basis to ensure: ○ patient safety and satisfaction? ○ long term patient outcomes? ○ quality of life? ○ improvement in symptoms or functional status? ○ documentation on the use of best practices and measuring outcomes? ○ monitoring the quality of condition management (e.g. depression, anxiety) across the continuum of care? ○ long term condition management follow up for all patients?
			C ☐ P ☐ E ☐ N ☐ N/A ☐
			Observation:
PAPT.2.9 QMS – Audits			
PAPT.2.9.1	The PAPT facility conducts formal internal audits of critical system elements.	CLSI[3] QMS01 – 3.11.2 CLSI[5] QMS06 – 5.1 CSA[4] ISO[1] 15189 – 4.14.5 ISO[2] 9001 – 9.2 ISQua[1] – 6.1 Guidance:	Is there evidence of internal audits that demonstrate that the pre-service, service, post-service and supporting processes are being conducted in a manner that supports the needs and requirements of users? Is there evidence of the performance of internal audits as defined in the procedures?
			C ☐ P ☐ E ☐ N ☐ N/A ☐
			Observation:

#	Standard	Reference	Assessment of Compliance
		Critical system elements are components within a process or procedure that are necessary to ensure consistent and accurate outcomes or results.	

#	Standard	Reference	Assessment of Compliance
PAPT.3.0 PHYSICAL FACILITIES			
PAPT.3.0.1 **PS / SS**	The PAPT facility has adequate, functional and reliable space to ensure its workload is performed without compromising quality, patient care services, patient confidentiality or safety of all individuals in the facility.	CLSI[3] QMS01 – 3.3.1.1 CSA[1] Z8000 – 6.2.1.1, 6.2.1.6.2, 7.5.2.7, 7.7.1.7, 9.1.5 ISO[1] 15189 – 5.2.1, 5.2.2, 5.2.3, 5.2.4 ISO[2] 9001 – 7.1.3 Guidance: Facility space may be considered inadequate if there is clear evidence of a safety risk to facility personnel and/or patients or operational deficiencies indicated by quality monitoring records, data derived from complaints or concerns, error statistics, adverse events, IPC issues, etc.	Is there adequate, functional and reliable space available for all of the following, where applicable to the scope of PAPT service: • patient waiting areas? • patient screening rooms? • patient washroom(s)? • clinical areas? • clerical/administration areas? • equipment, record, supply and consumable storage? • soiled or 'dirty' holding area? • staff only areas? C ☐ P ☐ E ☐ N ☐ N/A ☐ Observation:
PAPT.3.0.2 **PS**	The PAPT facility has accommodations that provide an environment promoting safety, comfort, privacy and confidentiality for all patients, including those with disabilities.	CLSI[3] QMS01 – 3.3.1.1 CSA[1] Z8000 – 6.1.4.1, 6.1.9, 7.5.2.7, 9.9.2.1, 9.9.3.1, 9.9.3.8.1.1, 9.9.3.8.5, 9.9.3.8.10, Table 9.8 ISO[1] 15189 - 5.2.1 ISO[2] 9001 – 7.1.4	Does the PAPT facility provide appropriate accommodations for: • special needs required by the patient population of the service? • patients with disabilities and/or using mobility equipment (e.g., wheelchair accessibility)? • patient comfort (e.g., adequate seating, reasonable ambient temperature)? • patient privacy / confidentiality? • optimization of treatment conditions?

#	Standard	Reference	Assessment of Compliance
			• infection prevention and control, including adequate patient spatial separation? • video surveillance of treatment areas? Are patient's personal belongings protected from theft or loss by offering a secure area for their storage and restricting access to the area? Is there clear signage to direct clients to the Psychedelic-Assisted Psychotherapy facility?
			C ☐ P ☐ E ☐ N ☐ N/A ☐
			Observation:
PAPT.3.0.3 **PS / SS**	The PAPT facility is designed to ensure operational efficiency, optimization of comfort and minimization of injury risk and occupational exposure and compliance with applicable legislation, regulations, codes and standards.	CLSI[3] QMS01 – 3.3.1 CSA[1] Z8000 – 6.1.11, 6.1.13, 7.1.9, 7.5.2.7, 7.6.6, 9.9.3.1, 12.4, 12.5 GOA[6] ISO[1] 15189 – 5.2.1, 5.2.2 ISO[2] 9001 – 7.1.3	Does the PAPT facility design ensure: • operational efficiency? • optimization of patient and facility personnel comfort? • minimization of injury risk and occupational illness? • patient safety? • personnel safety? • infection prevention and control best practice? Is there evidence that building specifications and operational systems / utilities meet all applicable legislation, regulations, codes and standards? Are all of the following utilities adequate in numbers, location and function, as applicable: • number of electrical outlets / designated emergency power outlets? • dedicated sinks of suitable types? • water?
			C ☐ P ☐ E ☐ N ☐ N/A ☐

#	Standard	Reference	Assessment of Compliance
			Observation:
PAPT.3.0.4 **PS / SS**	The PAPT facility monitors, controls and records environmental conditions and safety systems in alignment with applicable national, provincial and local legislation and codes, to ensure optimal operation and patient and staff comfort and safety.	CLSI[3] QMS01 – 3.3.1.3 CSA[1] Z8000 – 6.1.13, 7.6.4.8, Table 8 ISO[1] 15189 – 5.2.2, 5.2.6 ISO[2] 9001 – 7.1.4	Is there evidence that the PAPT facility monitors environmental conditions as appropriate for the work load, range and complexity of the facility treatments: • temperature? • noise level? • sterility? • electrical supply? • vibration levels? Are the environmental conditions in alignment with applicable national, provincial and local legislation and codes?
			C ☐ P ☐ E ☐ N ☐ N/A ☐
			Observation:
PAPT.3.0.5	The PAPT facility has appropriate measures to control access to and use of areas affecting the quality of the treatments and/or the safety of patients and personnel.	CLSI[3] QMS01 – 3.3.1.2 CSA[1] Z8000 – 9.9.2.3 ISO[1] 15189 – 5.2.2	Are treatment rooms, patient health information, reports, information system, resources, supplies, consumables and medications all secured from unauthorized access? Do security measures include: • an assessment of the threat of theft and tampering? • access restricted to authorized facility personnel only? • locks for internal doors, where appropriate?
			C ☐ P ☐ E ☐ N ☐ N/A ☐
			Observation:

#	Standard	Reference	Assessment of Compliance
PAPT.3.0.6	The PAPT facility has adequate storage space and conditions to ensure the integrity and security of equipment, supplies, consumables and patient records.	CLSI[3] QMS01 – 3.3.1.1 ISO[1] 15189 - 5.2.3	Do the storage space and conditions ensure the continuing integrity of the following, as applicable: • patient medical records? • documents, files and manuals? • consumables? • supplies (sterile and non-sterile)? • linens? • medications and crash cart supplies? • personal protective equipment? • secure storage for controlled drugs and substances? • housekeeping supplies? Are supplies and consumables that are used in performing treatments stored in a manner to prevent cross-contamination? C ☐ P ☐ E ☐ N ☐ N/A ☐ Observation:
PAPT.3.0.7	The PAPT facility workspace is kept clean and well maintained.	CPSA[1] – G.5.2, G.6.4 CLSI[3] QMS01 – 3.3.1 ISO[1] 15189 – 5.2.6	Is the facility workspace: • clean? • free from unnecessary clutter? • well maintained? Is garbage and dirty linen removed regularly and as needed? C ☐ P ☐ E ☐ N ☐ N/A ☐ Observation:
PAPT.3.0.8	PAPT facility management ensures that any new construction or structural changes comply with	CLSI[3] QMS01 – 3.3.1 CSA[1] Z8000 – 4.5, 5.1.5, 5.3.6	For any new construction or structural changes, does PAPT facility management ensure: • compliance with national, provincial and local legislation, building regulations and building codes

#	Standard	Reference	Assessment of Compliance
	applicable national, provincial and local legislation, building codes and provincial infection prevention and control requirements.		containing specific architectural safety standards for medical facilities? • appropriate written notice to the users of the service prior to structural or engineering work? • consultation with infection prevention and control regulating bodies?
			C ☐ P ☐ E ☐ N ☐ N/A ☐
			Observation:

#	Standard	Reference	Assessment of Compliance
PAPT.4.0 EQUIPMENT, CONSUMABLES & SUPPLIES (ECS)			
PAPT.4.1 ECS – General			
PAPT.4.1.1	The PAPT facility has processes for management, on-going monitoring and use of equipment, instruments, consumables and supplies.	CLSI[3] QMS01 – 3.5.3.3, 3.5.4 CSA[1] Z8000 – 10.4.1.1 GOC[2] ISO[1] 15189 – 4.6, 5.3.1.1 Guidance: Critical supplies and services refer to supplies and services that are essential for patient treatment. Management of these supplies and services includes, but is not limited to, purchasing and inventory, business continuity and traceability.	Does the PAPT facility have processes for equipment, consumables and supplies that include management and use? Has the facility identified critical equipment, consumables and supplies, and defined the characteristics or functional requirements for each? Does the facility have a process for the management of vendor notifications of recalls, defects or issues with equipment, consumables and supplies that have the potential to affect the provision of facility services? Does the facility have a process for the management of medical alerts and safety notifications from Health Canada and provincial regulatory bodies? C ☐ P ☐ E ☐ N ☐ N/A ☐ Observation:
PAPT.4.1.2	PAPT facility management ensures that adequate, functional equipment and required consumables and supplies are readily available for the provision of services as determined appropriate for the work load, range and complexity of the treatments performed in the facility.	CLSI[3] QMS01 – 3.1.4 ISO[1] 15189 – 5.3.1.1 ISQua[1] – 4.10	Does the PAPT facility have processes in place to ensure the following resources are adequate and available for the provision of services: • equipment? • ancillary equipment? • supplies? • consumables? Does the PAPT facility replace equipment as required to ensure the quality of services as per manufacturer specifications and the equipment lifecycle?

#	Standard	Reference	Assessment of Compliance
			C ☐ P ☐ E ☐ N ☐ N/A ☐
			Observation:
PAPT.4.1.3	There are documented processes, procedures and defined criteria for the receipt, inspection, acceptance, and storage of equipment, consumables and supplies.	CLSI[3] QMS01 – 3.5.3.1, 3.5.3.2 CSA[1] Z8000 – 10.4 ISO[1] 15189 – 5.3.2.1, 5.3.2.2, 5.3.2.3	For equipment, consumables and supplies, are there procedures for: • inspection? • acceptance/rejection? • handling in compliance with manufacturers' specifications? • storage in compliance with manufacturers' and facility specifications? • verification of performance before use?
			C ☐ P ☐ E ☐ N ☐ N/A ☐
			Observation:
PAPT.4.2 ECS – Consumables and Supplies			
PAPT.4.2.1	There is an inventory control system for critical consumables and supplies to ensure traceability, maintenance of adequate supply and the use of in-date materials.	CLSI[3] QMS01 – 3.5.4 CSA[1] Z8000 – 10.4 ISO[1] 15189 – 5.3.2.4	Does the inventory control system: • ensure traceability and maintenance of adequate supply? • physically separate uninspected or unacceptable consumables and supplies from inspected and accepted consumables and supplies that are ready for use? • ensure that only in-date inventory is used? Is there evidence of discard of unused/outdated consumables and supplies? For consumables and supplies that are removed from their original packaging / container for later use, is there a mechanism in place to allow traceability of the individual

#	Standard	Reference	Assessment of Compliance
			items for lot number, expiry date and other relevant information? C ☐ P ☐ E ☐ N ☐ N/A ☐ Observation:
PAPT.4.2.2	There are comprehensive records for all critical consumables and supplies.	CLSI[3] QMS01 – 3.5.3, 3.5.4 ISO[1] 15189 – 5.3.2.7	Are there records for critical consumables and supplies used in the facility service provision that include all of the following where applicable: • identification? • manufacturer's name? • batch code or lot number? • manufacturer/supplier contact information? • date of receipt and date put into service/use? • expiry date? • manufacturer's specifications? • condition upon receipt? • confirmation of acceptability? Are records retained for a timeframe as defined in facility policy? Are records readily available to authorized staff? C ☐ P ☐ E ☐ N ☐ N/A ☐ Observation:
PAPT.4.3 ECS – Psychedelic Drugs			
PAPT.4.3.1	The facility has policies, processes and procedures for the management of controlled drugs.	GOC[8]	Is one qualified individual (e.g. an RN, LPN, or a physician) designated to have overall responsibility for ensuring that all controlled drugs are handled in a manner that permits full auditing of the drugs from acquisition through to patient administration?

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			Is there a log of controlled drugs received by the facility that includes:
			• the name and quantity of the drug?
			• the date received?
			• administration record detailing:
			  ○ patient name?
			  ○ drug name?
			  ○ amount removed from inventory?
			  ○ date used?
			  ○ name of the person who administered the drug?
			• an end-of-day balance of the inventory via physical count, verified by the signatures of two qualified staff members on each day that controlled drugs are used?
			
			Is an investigation conducted and documented as a result of any inventory discrepancy?
			
			Are all controlled drugs kept in a designated secure and locked storage cabinet?
			
			Do facility policies follow Health Canada's *Controlled Drugs and Substances Act*?

			C ☐ P ☐ E ☐ N ☐ N/A ☐
			Observation:
PAPT.4.3.2	The facility has policies and procedures for the preparation, safe handling, storage and use of bulk and in-house prepared / compounded psychedelic drugs.	ACP[1] GOC[9] NAPRA[1]	Are all psychedelic drugs stored according to Manufactures' instructions for use (MIFU)? Is storage secured to prevent diversion or theft? • is access limited to authorized personnel? • are accurate inventory records maintained and reconciled on a regular basis?

#	Standard	Reference	Assessment of Compliance
			Does the facility have a procedure for compounding that meets the recognized regulatory requirements and best practice? Are psychedelic drug dilutions compounded by a pharmacist, psychiatrist or individual trained in preparing medications using aseptic technique? Are the various vials containing the compounded dilutions • marked with labels that clearly identify the concentration and date of preparation? Are complete records of the compounding available that • ensure traceability to the bulk supply? Is there a procedure for the recall of compounded sterile preparations that includes: • identifying patients who received the product? • notifying patients or caregivers? • performing the required follow up?
			C ☐ P ☐ E ☐ N ☐ N/A ☐
			Observation:
PAPT.4.4 ECS – Equipment			
PAPT.4.4.1 **PS / SS**	The PAPT facility ensures that equipment is capable of achieving the required performance and is in compliance with the manufacturers' recommendations, upon installation, before use and following interruptions in use.	CLSI[3] QMS01 – 3.6.2 GOC[3] ISO[1] 15189 – 5.3.1.2, 5.3.1.4, 5.3.1.7 Guidance:	Are there processes for the installation and compliance verification/calibration of all facility equipment that comply with relevant legislative standards and the manufacturers' recommendations? Is there evidence of verification of equipment / acceptance testing: • prior to clinical use?

#	Standard	Reference	Assessment of Compliance
		The term "equipment" in all standards includes all equipment in the PAPT facility (primary and ancillary).	• as indicated by performance? • in compliance with the manufacturers' instructions? Does the documentation of equipment compliance verification / acceptance testing indicate all of the following: • acceptable limits? • status of compliance? • date performed? When equipment compliance testing results deviate from acceptable limits: • are there defined corrective action criteria? • is there evidence that corrective action has been complete in accordance with the criteria? When equipment located in a fixed location is moved, serviced or modified or undergoes major maintenance, are installation and operational qualifications retested for compliance prior to clinical use?
			C ☐ P ☐ E ☐ N ☐ N/A ☐
			Observation:
PAPT.4.4.2 **PS / SS**	The PAPT facility performs regular monitoring, quality control and performance evaluations to ensure the proper functioning of equipment.	CLSI[3] QMS01 – 3.6.4 ISO[1] 15189 – 5.3.1.4, 5.3.1.3, 5.3.1.7	Is there evidence that the following function checks are performed and monitored at defined frequencies by qualified personnel as appropriate: • equipment is clean and well maintained? • electronic, mechanical and operational checks are performed? • equipment is free from obstructions (e.g., free from clutter which may interfere with operation)? Is monitoring performed in compliance with the manufacturers' instructions, including the minimum frequency described by the manufacturer?

#	Standard	Reference	Assessment of Compliance
			Is equipment quality control performed at defined intervals, following manufacturer's instructions with verification system mechanical integrity and stability? Is the quality control and performance evaluation data reviewed at defined intervals with initiation any required follow-up?
			C ☐ P ☐ E ☐ N ☐ N/A ☐
			Observation:
PAPT.4.4.3	The PAPT facility performs and documents preventive maintenance on all equipment in compliance with relevant, standards and the manufacturers' recommendations.	CLSI[3] QMS01 – 3.6.4 ISO[1] 15189 – 5.3.1.5, 5.3.1.7	Is there evidence that preventive maintenance is performed: • in accordance with manufacturer's specifications? • at a defined frequency?
			C ☐ P ☐ E ☐ N ☐ N/A ☐
			Observation:
PAPT.4.4.4 PS	The PAPT facility ensures that uninterruptable power supply (UPS) is provided to critical equipment and networks that directly affect patient safety and quality treatments.	CSA[1] Z8000 – 7.9.1.8, 7.9.6.1, 9.9.3.1	Is there evidence of a risk assessment performed to identify critical equipment that requires UPS or other mechanisms? Where required, is there a UPS system that: • meets applicable regulations? • is tested at defined intervals as specified by the manufacturer? Are testing and any required servicing scheduled so as not to interrupt patient services?
			C ☐ P ☐ E ☐ N ☐ N/A ☐
			Observation:

#	Standard	Reference	Assessment of Compliance
PAPT.4.4.5	All PAPT equipment is uniquely labeled, marked or otherwise identified specific to the facility.	CLSI[3] QMS01 – 3.6.2.1 ISO[1]15189 – 5.3.1.2	Is all equipment uniquely labeled, marked or otherwise identified? C ☐ P ☐ E ☐ N ☐ N/A ☐ Observation:
PAPT.4.4.6	There is a record for each piece of PAPT equipment that is readily available for the lifespan of the equipment.	CLSI[3] QMS01 – 3.6.5, 3.6.6 ISO[1] 15189 – 5.3.1.7	Is there a record for each item of equipment that includes all of the following, where applicable: • equipment identification? • type and identification/serial number? • manufacturer's name? • manufacturer's contact information? • date of receipt and date put into service? • current location? • condition when received? • manufacturer's specifications? • acceptance testing? • calibrations? • quality control? • preventive maintenance scheduled and performed? • troubleshooting? • damage to, or malfunction, modification or repair? • service records? • decommission date and final disposition? • predicted replacement date? Are equipment records retained as defined by facility policy? Are records readily available to appropriate staff? C ☐ P ☐ E ☐ N ☐ N/A ☐ Observation:

#	Standard	Reference	Assessment of Compliance
PAPT.4.4.7	The PAPT facility has instruction manuals for the appropriate use and maintenance of each piece of equipment that are readily available to appropriate personnel.	CLSI[3] QMS01 – 3.6.2.6, 3.6.4 ISO[1] 15189 – 5.3.1.3 ISQua[1] – 4.9	Is there a manual for each piece of equipment that includes: • operating instructions? • maintenance? • minor troubleshooting and repair of equipment (where appropriate)? Are these instructions readily available to the operator? C ☐ P ☐ E ☐ N ☐ N/A ☐ Observation:
PAPT.4.4.8	The PAPT facility ensures equipment is operated by authorized facility personnel only and is protected from unauthorized adjustments or tampering.	CLSI[3] QMS01 – 3.6.2.6 ISO[1] 15189 – 5.3.1.3 ISQua[1] – 4.9	Are there mechanisms to ensure that equipment is operated by authorized personnel only? Has the PAPT facility implemented any measures deemed necessary to ensure that patient and staff safety is not affected by unauthorized equipment adjustments or tampering? C ☐ P ☐ E ☐ N ☐ N/A ☐ Observation:
PAPT.4.4.9 SS	The PAPT facility has procedures for the decontamination, cleaning, and disinfection of equipment in conjunction with manufacturers' specifications.	CLSI[3] QMS01 – 3.6.5 GOA[1] – 5 ISO[1] 15189 – 5.3.1.5	Are procedures available for the decontamination, cleaning and disinfection of each piece of equipment in each of the following situations: • in case of accidents or spills that result in contamination? • prior to being serviced? • prior to repair? Is there evidence of compliance with the decontamination / cleaning / disinfection procedures?

#	Standard	Reference	Assessment of Compliance
			Are appropriate personnel aware of the procedures? C ☐ P ☐ E ☐ N ☐ N/A ☐ Observation:
PAPT.4.4.10 SS	The PAPT facility appropriately manages defective equipment ensuring patient and operator safety.	CLSI[3] QMS01 – 3.6.4, 3.6.5 ISO[1] 15189 – 5.3.1.5	If the results of any monitoring or testing fall outside of the acceptable limits, is corrective action: • initiated and is the equipment visually flagged for non-use? • performed by a qualified expert, as appropriate? Does the corrective action include: • cessation of all patient treatment activity until the non-conformance is corrected? • immediate appropriate action and notification if there is risk of imminent danger to patients or staff? • assessment of any impact on previous treatments? • acceptance testing after the problem has been addressed? • documentation of all actions, including follow-up acceptance testing? C ☐ P ☐ E ☐ N ☐ N/A ☐ Observation:
PAPT.4.4.11	The PAPT facility disposes of equipment appropriately.	CLSI[3] QMS01 – 3.6.5 ISO[1] 15189 – 5.3.1.5	Are there processes for the disposal of equipment that include where applicable: • communication with the manufacturer/supplier of the equipment to determine if the equipment can be recycled or returned? • determination if any equipment components contain hazardous materials?

#	Standard	Reference	Assessment of Compliance
			• ensuring the equipment is in an inoperable state? For decommissioned equipment, is confidential information in the instruments memory backed up and removed?
			C ☐ P ☐ E ☐ N ☐ N/A ☐
			Observation:

#	Standard	Reference	Assessment of Compliance
PAPT.5.0 INFORMATION SYSTEMS (IS)			
	PAPT.5.1 IS – General		
PAPT.5.1.1	PAPT facility management establishes policies that protect patients from harm by ensuring a high level of data/information integrity for information systems (IS).	CLSI[3] QMS01 – 3.9 CSA[1] Z8000 – 7.4.1,12.6 ISO[1] 15189 – 5.10.1, 5.10.3 Guidance: These standards are not applicable to: • desk top calculators • small programmable clinical computers • purchased services and outsourcing • computers used solely for word processing, spreadsheets or similar single user functions	Are there established IS policies that address data / information integrity? Does the IS meet applicable national and provincial requirements? Is the management of facility data and information in compliance with national or international requirements regarding data protection? C ☐ P ☐ E ☐ N ☐ N/A ☐ Observation:
	PAPT.5.2 IS – Environment		
PAPT.5.2.1	Computer areas and equipment are clean, well maintained and in a location and environment that is secure and complies with vendor specifications.	CLSI[1] AUTO8 – 4 CLSI[3] QMS01 – 3.3.1.3, 3.9.3 ISO[1] 15189 – 5.2.2, 5.2.6	Are computer areas and equipment: • clean? • well maintained? • well-ventilated? • protected from unauthorized access? Does the computer installation comply with hardware and software vendor specifications? C ☐ P ☐ E ☐ N ☐ N/A ☐

#	Standard	Reference	Assessment of Compliance
			Observation:
PAPT.5.3 IS – Computer Procedures			
PAPT.5.3.1	The PAPT facility ensures that current, comprehensive IS procedures are readily available to all authorized computer users.	CLSI[3] QMS01 – 3.9 ISO[1] 15189 – 5.1.5, 5.10.3	Do the IS/computer procedures include: • clearly documented user operation, training and testing protocols? • local maintenance, vendor support and emergency contact information? Are the IS/computer procedures: • current and readily available for all authorized users? • appropriate to the level of use of the system? • written in a language that is understandable to typical users?
			C ☐ P ☐ E ☐ N ☐ N/A ☐
			Observation:
PAPT.5.3.2	PAPT facility management ensures that the IS procedures are reviewed and approved as defined by facility policy	ISO[1] 15189 – 4.3	Are the PAPT computer procedures reviewed and approved as defined in the facility policy?
			C ☐ P ☐ E ☐ N ☐ N/A ☐
			Observation:
PAPT.5.3.3	The PAPT facility has written procedures to protect the data and computer equipment in case of fire or hardware / software failure.	CLSI[3] QMS01 – 3.9 CLSI[12] GP36 – 6.5 ISO[1] 15189 – 5.10.3	Are there written procedures that specify the actions necessary to protect data and/or computer equipment in case of: • fire or other natural disaster (i.e., water)? • hardware/software failure?

#	Standard	Reference	Assessment of Compliance
			Do these procedures allow for the timely restoration of service, including data integrity check? C ☐ P ☐ E ☐ N ☐ N/A ☐ Observation:
PAPT.5.4 IS – Security			
PAPT.5.4.1	There are policies that define those authorized to access the IS in accordance with the requirements of their duties.	CLSI[2] AUTO13 – 14.1.1 CLSI[3] QMS01 – 3.9.3 ISO[1] 15189 – 5.10.2	Are there policies and/or procedures that define who may: • use the computer system? • access, enter or change patient data? • authorize release of treatment results or reports? • access statistical reporting? • alter computer programs? Are computer programs protected against unauthorized or casual alteration or destruction? Is there a defined procedure for adding and removing user access to the system or programs? Is each user assigned an access security level appropriate to their level of duty? Are passwords changed periodically? C ☐ P ☐ E ☐ N ☐ N/A ☐ Observation:
PAPT.5.4.2	There are policies and procedures in place to prevent unauthorized installation of software by users.	CLSI[3] QMS01 – 3.9.3 ISO[1] 15189 – 5.10.2	Are there policies and procedures in place to prevent unauthorized installation of software by users? C ☐ P ☐ E ☐ N ☐ N/A ☐ Observation:

#	Standard	Reference	Assessment of Compliance
PAPT.5.4.3	There are adequate security measures to ensure confidentiality of patient data.	CLSI[3] QMS01 – 3.9.2	Are there systems in place to ensure confidentiality of patient data at all times, including if information is held on in-house servers or sent over a public domain such as the internet or stored via web hosting services or in "the cloud"? C ☐ P ☐ E ☐ N ☐ N/A ☐ Observation:
PAPT.5.5 IS – Data Entry & Reports			
PAPT.5.5.1	Where applicable, there is a process to validate and monitor interface engines that allow data from one computerized database to be translated and automatically entered into another divergent system.	CLSI[2] AUTO13 – 14.2, 14.5 CLSI[9] QMS01 – 3.9.4	If the system uses an interface to populate data into another computer system, is a documented encoding and transmission scheme such as Health Level-7 (HL7) utilized? Are acceptable transmission limits established for data throughput by the interface engine, and is this parameter periodically monitored and recorded? Is there evidence of verification that patient information is accurately transmitted from the point of data entry to patient reports (both paper and electronic)? C ☐ P ☐ E ☐ N ☐ N/A ☐ Observation:
PAPT.5.5.2	There is a documented review and approval of the content and format of electronic reports in order to ensure that they effectively communicate	CLSI[9] QMS01 – 4.3.2 ISO[1] 15189 – 5.8.1	Are IS-generated patient reports reviewed for content and format and approved by the medical director or designate? C ☐ P ☐ E ☐ N ☐ N/A ☐ Observation:

#	Standard	Reference	Assessment of Compliance
	treatment results and meet the needs of stakeholders.		
PAPT.5.5.3	The reporting system accommodates comments on service conditions that might compromise the accuracy of reports.	CLSI[3] QMS01 – 4.3.2 ISO[1] 15189 – 5.8.2, 5.8.3	Does the reporting system allow comments related to service conditions to be entered by the staff member? C ☐ P ☐ E ☐ N ☐ N/A ☐ Observation:
PAPT.5.6 IS – Data Retrieval & Storage			
PAPT.5.6.1	Stored patient result data and archival information is retrievable within a time frame consistent with patient-care needs.	CLSI[3] QMS01 – 3.8.2.4, 3.8.2.5 ISO[1] 15189 – 4.13, 5.10.3	Is the transfer of patient data to acceptable recording media validated? Is the time frame defined for result data and archival information retrieval that is consistent with patient care needs? Is the facility able to retrieve data within the defined time frame? C ☐ P ☐ E ☐ N ☐ N/A ☐ Observation:
PAPT.5.6.2	There are comprehensive back-up processes to prevent loss of patient data in case of hardware or software failure.	CLSI[3] QMS01 – 3.9.3.5, 3.9.5 ISO[1] 15189 – 5.10.3	Do effective back up mechanisms exist in case of hardware or software failure? Is there an alternative system that ensures necessary continuous operations (e.g. power outage) in the event that computerized data and computer-assisted functions are unavailable? Is there evidence that:

#	Standard	Reference	Assessment of Compliance
			• the computer system is checked to ensure data integrity after back up and / or each restoration of data files? • errors detected during system back up are documented along with corrective action taken? • errors detected during system back up are reported to designated personnel?
			C ☐ P ☐ E ☐ N ☐ N/A ☐
			Observation:
PAPT.5.7 IS – Hardware & Software			
PAPT.5.7.1	The medical director or designate approves all changes in the computer system that may affect patient care.	ISO[1] 15189 – 5.10.2	Are all changes to the computer system that may affect patient care approved by the medical director/designate?
			C ☐ P ☐ E ☐ N ☐ N/A ☐
			Observation:
PAPT.5.7.2	All personnel with authorized access to the IS are appropriately trained on its use.	CLSI[3] QMS01 – 1.2.1, App. A CLSI[4] QMS03 CLSI[8] QMS16 – 2.3.3 ISO[1] 15189 – 5.1.5	Is there an IS training program? Is there evidence of appropriate staff training for new or modified systems / applications?
			C ☐ P ☐ E ☐ N ☐ N/A ☐
			Observation:
PAPT.5.7.3	All significant computer malfunctions are promptly reported to designated personnel.	CLSI[1] AUTO8 – 7.4 CLSI[3] QMS01 – 3.9.5	Is the evidence that all significant computer malfunctions are promptly reported to designated personnel?
			C ☐ P ☐ E ☐ N ☐ N/A ☐
			Observation:

#	Standard	Reference	Assessment of Compliance
PAPT.5.8 IS – System Maintenance			
PAPT.5.8.1	There are readily available procedures and complete records of all preventive maintenance for all computer hardware.	CLSI[2] AUTO13 – 14.2.1 CLSI[3] QMS01 – 3.6.4 ISO[1] 15189 – 5.10.3	Are there written procedures for preventive maintenance for all computer hardware (i.e., peripherals, printers, network and communication equipment)? Is there documentation of preventive maintenance? C ☐ P ☐ E ☐ N ☐ N/A ☐ Observation:
PAPT.5.8.2	Records of regular maintenance and any work done on the computer system are maintained.	CLSI[3] QMS01 – 3.6.6 ISO[1] 15189 – 5.10.3	Are there readily accessible records that: • document regular maintenance? • allow operators to trace work done on the computer system? C ☐ P ☐ E ☐ N ☐ N/A ☐ Observation:

#	Standard	Reference	Assessment of Compliance
PAPT.6.0 PRE-SERVICE POLICIES, PROCESSES & PROCEDURES			
PAPT.6.1 Pre-Service – Treatment Request			
PAPT.6.1.1	The PAPT facility makes readily available its list of treatments and relevant information, requirements and specifications to all users of the facility services.	CLSI[3] QMS01 – 3.2.4, 4.1.2.4 ISO[1] 15189 – 5.4.2 ISQua[1] – 5.8	Is all relevant information readily available to users of the PAPT facility services if requested? Does the information include all of the following where applicable to the scope of facility service: • organization and facility location? • hours of operation? • booking process? • a list of current services provided? • educational documents for patients regarding services provided? • information and instructions provided to patients and caregivers in relation to preparation for treatment? • patient pre-assessment procedures and required patient information? • post-service instructions, if required? • instructions for completing a consultation request form? • on-call or effective hand-off care arrangements? • facility policy on confidentiality? • facility complaint policy? Does the provided information reflect current facility practice? C ☐ P ☐ E ☐ N ☐ N/A ☐ Observation:

#	Standard	Reference	Assessment of Compliance
PAPT.6.1.2 PS	The treatment consultation request form (requisition) or referral documentation requests information sufficient to uniquely identify the patient and the requesting physician / healthcare provider, as well as providing pertinent clinical information necessary for performance of the requested PAPT service.	CLSI[3] QMS01 – 4.1.1 CPSA[9] ISO[1] 15189 – 4.7, 5.4.3	Does the consultation request form (paper or electronic requisition) or referral documentation request all of the following elements, if applicable: • patient's first and last name? • a second unique patient identifier (e.g., personal health number)? • date of birth? • gender? • legible full name and location/address of requesting physician/healthcare practitioner? • full name, location/address of "copy to" physician/ healthcare practitioner? • how long the referring physician has known the patient? • any special instructions? • pertinent clinical information including indications, history and provisional diagnosis? • prior related treatment history if known? • medications? • potential contraindications? • date and time of patient referral by requester if applicable? • clinical information where appropriate to the treatment requested? If information on the form is incomplete, is there a process for the PAPT facility to obtain the required information prior to conducting the treatment? Does the facility have access to the provincial medical data repository e.g. Netcare? Is there evidence that the facility maintains a written or electronic record of all requests?

#	Standard	Reference	Assessment of Compliance
			Are consultation request forms reviewed on a regular basis to ensure they reflect current service treatment information and criteria? C ☐ P ☐ E ☐ N ☐ N/A ☐ Observation:
PAPT.6.1.3	There are policies and procedures concerning verbal PAPT treatment requests.	ISO[1] 15189 – 5.4.3	Are there procedures for the handling of verbal PAPT treatment requests requiring: • that facility personnel receiving verbal orders read back the treatment request including patient demographics to verify accuracy? • confirmation by request form or electronic equivalent within a defined time as per facility policy? (Note: this may be required prior to commencement of treatment) • that the person receiving the request document the request, the working diagnosis, the name of the requesting practitioner and the date and time of the request, as well as their own identity? C ☐ P ☐ E ☐ N ☐ N/A ☐ Observation:
PAPT.6.2 Pre-Service – Patient Preparation, Screening & Consent			
PAPT.6.2.1 PS	There are policies, processes, procedures and criteria for review and acceptance / rejection of patients and/or requested PAPT treatment services.	ISQua[1] – 4.3, 5.1, 5.3, 5.10 5.11 For authorized requestors refer to Appendix A.3	Are requisitions are received from authorized requestors? Are there patient preparation and pre-screening protocols that are appropriate for the psychedelic drugs and range and complexity of the psychotherapy treatments offered in the facility?

#	Standard	Reference	Assessment of Compliance
			Are patient provided with verbal and written instructions for preparing for treatments, where necessary? Does the facility have a policy requiring patients to complete a comprehensive pre-screening form where applicable? Does the facility have policy, process and procedure that defines inclusion and exclusion criteria? Does the facility have defined absolute / relative rejection criteria and a process to address them? Is there evidence that patients are being pre-screened as required?
			C ☐ P ☐ E ☐ N ☐ N/A ☐
			Observation:
PAPT.6.2.2	A documented, comprehensive, initial assessment is completed for each patient.	ISQua[1] – 5.10, 5.11	Does the facility have a process, and procedure for the comprehensive initial assessment for each patient? Does the facility have a policy, process and procedure for the provision of virtual mental health assessments is applicable?
			C ☐ P ☐ E ☐ N ☐ N/A ☐
			Observation:
PAPT.6.2.3	Patients are provided information necessary to make informed consent decisions	AHS[1] CMPA[2] CPA[1]	Is there a documented process that ensures patients are always appropriately informed by the most appropriate health professional before applicable PAPT services that complies with established Standards of Practice?

#	Standard	Reference	Assessment of Compliance
	specific to the treatment services.	CPSA[2, 12] ISO[1] 15189 – 5.4.4.1 ISQua[1] – 5.3, 5.4 GOA[9]	If a patient refuses, do facility personnel document the patient refusal, the reason and notify the requesting physician/healthcare provider, or most responsible physician? Is there evidence that the informed consent policy is being followed in the PAPT facility? C ☐ P ☐ E ☐ N ☐ N/A ☐ Observation:
PAPT.6.2.4	The facility has a policy and process to ensure the cultural context and spiritual preferences of patients/service users are recognised and respected.	CMPA[1] CPA[1] CPA[2] ISQua[1] – 5.6	Is there a policy and process to: • provide access to spiritual care or advice that meets patients'/service users' needs where possible in consultation with treating physician? • provide, where culturally appropriate and possible, gender separate services? C ☐ P ☐ E ☐ N ☐ N/A ☐ Observation:
PAPT.6.2.5	Patients are informed of the possible adverse effects.	AHS[3] CMPA[2] CP[1]	Is there evidence that all patients are informed of the possible adverse effects of the selected therapy/psychedelic drug utilized in treatment? Are documented adverse effects based on a risk assessment that includes clinical experience with patient population, psychedelic drug in use and/or current literature? C ☐ P ☐ E ☐ N ☐ N/A ☐ Observation:

#	Standard	Reference	Assessment of Compliance
PAPT.6.3 Pre-Service – Patient Identification and Examination Confirmation			
PAPT.6.3.1 PS	PAPT services are traceable to an identified patient.	AHS[2] CLSI[3] QMS01 – 4.1.4 ISO[1] 15189 – 5.4.4.3 ISQua[1] – 4.6	Is there a process in place to ensure unique identification of patients? Is patient identity confirmed before performing any PAPT treatment using at least two unique patient identifiers? Is there a process for the identification of patients with communication challenges (e.g. language barriers, facial trauma, etc.)?
			C ☐ P ☐ E ☐ N ☐ N/A ☐
			Observation:

#	Standard	Reference	Assessment of Compliance
PAPT.7.0 SERVICE POLICIES, PROCESSES & PROCEDURES			
PAPT.7.1 Service – General			
PAPT.7.1.1	A unique tracked prescription is written for each individual patient for each individual treatment.	CPSA[1] GOA[1] Guidance: Individual treatment refers to a single treatment occurrence not a treatment course	Is there evidence that a unique tracked prescription or order is written for each individual patient? Is there evidence that prescription information is available in the Pharmaceutical Information Network (PIN) where applicable? Is the prescribing physician registered with the Tracked Prescription Program (TPP Alberta) where applicable? C ☐ P ☐ E ☐ N ☐ N/A ☐ Observation:
PAPT.7.1.2	A documented treatment management plan is available for each patient.	ISQua[1] – 5.11, 5.12	Is there evidence of a documented treatment management plan on each patient that includes all of the following as appropriate: • assessment findings? • baseline characteristics of condition? • physical, psychological, and socio-cultural factors shaping the condition? • etiology? • most effective pharmacological and non-pharmacological strategies? • management interventions? • current and future primary treatment plans? C ☐ P ☐ E ☐ N ☐ N/A ☐ Observation:

#	Standard	Reference	Assessment of Compliance
PAPT.7.1.3	The facility ensures adequate staffing during administration of all psychedelic drugs.	CPSA[11] ISQua[1] – 3.7 Refer to Appendix A.2 for staff requirements	During the treatment procedure does the staffing model ensure a qualified clinical staff member or physician administers the psychedelic drug? Does the facility have a policy, process and procedure for staffing reflective of their patient population, diagnoses and psychedelic drugs in use? Does the facility have a policy, process and procedure for patient monitoring reflective of their patient population, diagnoses and psychedelic drugs in use? Is the treating psychiatrist/physician available (in person or by telephone) until the patient is discharged? C ☐ P ☐ E ☐ N ☐ N/A ☐ Observation:
PAPT.7.1.4	The PAPT facility has treatment procedures and protocols that meet the needs of the users of the services and reflect currently accepted best practice.	ISO[1] 15189 – 5.5.1.1, 5.5.3 CPSA[5]	Are PAPT treatments procedures / protocols available that accurately describe all procedures currently performed in the facility? Are protocols for PAPT treatments comprehensive and written in a standardized, consistent format that reflects accepted practice? Do PAPT treatment procedures / protocols include all of the following, where appropriate: • document control identifiers (e.g. unique #, title etc.)? • purpose of the treatment? • treatment protocols? • personal protective equipment (PPE) usage and requirements?

#	Standard	Reference	Assessment of Compliance
			• latex sensitivity and/or allergy management? • treatment specifications and parameters? • patient preparation and education requirements? • patient management, including pre-screening, special requirements (pre/post service), medications, post- service or discharge instructions? • required equipment, supplies and consumables? • management of adverse events, medical emergencies and close-calls? • charting in patient health record?
			C ☐ P ☐ E ☐ N ☐ N/A ☐
			Observation:
PAPT.7.1.5	The facility has a policy, process and procedure for the video recording of all treatment sessions.	AP[1]	Does the policy and procedure for the video recording of treatment sessions include: • reason? • patient access if requested? • duration? • review period? • retention? Does the facility have a policy, process and procedure for the use of restraints (chemical or physical as applicable)?
			C ☐ P ☐ E ☐ N ☐ N/A ☐
			Observation:
PAPT.7.1.6	PAPT treatment protocols are readily accessible in the work	CLSI[3] QMS01 – 4.2.2 ISO[1] 15189 – 5.5.3	Are PAPT treatment protocols readily accessible in the work area for authorized staff to access and reference?

#	Standard	Reference	Assessment of Compliance
	areas as appropriate for the work load, range and complexity of the treatments performed in the facility.		Where electronic versions are used, does the PAPT facility maintain either paper copies or electronic copies that are accessible on alternate media (e.g., flash drive) in the event that the primary source documents are inaccessible (e.g., computer system or network downtime)? C ☐ P ☐ E ☐ N ☐ N/A ☐ Observation:
PAPT.7.1.7	Quick reference guides correspond to the PAPT facility policy, process and procedure manual and conform to the document control system.	CLSI[3] QMS01 – 3.8.1 ISO[1] 15189 – 5.5.3 Guidance: Quick references refer to any documentation that is an abbreviated version of the current manual and is available for facility	If abbreviated guides or instruction sheets for Psychedelic-Assisted Psychotherapy treatments and associated protocols are used, are they: • compliant with the current Psychedelic-Assisted Psychotherapy facility policy, process and procedure manual? • signed, dated and referenced to a procedure? • regularly reviewed to ensure that they are current and in compliance with the current manual? C ☐ P ☐ E ☐ N ☐ N/A ☐ Observation:
PAPT.7.1.8	The PAPT facility has change control protocols for treatment policies, processes and procedures.	CLSI[3] QMS01 – 3.7.4 CLSI[9] QMS18 – 2 ISO[1] 15189 – 5.5.3	Is there evidence of all of the following: • prior verification of substantive changes prior to clinical implementation? • review and approval of substantive changes to existing policies, processes and procedures by the PAPT facility Medical Director or qualified designate? • written communication to appropriate facility personnel of the changes? • that changes to PAPT treatments offered at the facility are communicated to users of the facility

#	Standard	Reference	Assessment of Compliance
			services in writing, prior to the introduction of the change? C ☐ P ☐ E ☐ N ☐ N/A ☐ Observation:
PAPT.7.2 Service – Patient Monitoring & Care			
PAPT.7.2.1	Patients are appropriately monitored and cared for during psychedelic drug treatments.	AHS[3] CPSA[11]	Do patients receiving psychedelic drug treatments: • have psychedelic drug dosing based clinical expertise and, where available, on recommended best practice guidelines? • receive only commercially packaged or pharmacy-prepared pre-mixed solutions (if administered by non-psychiatrist physicians)? • receive loading and/or subsequent doses as per the facility's procedure specific to each psychedelic drug administered? Is a double-check completed prior to initiating the drug administration which includes: • most current medication order including patient name, medication, dose, time, route, purpose/reason? • patient's relevant laboratory and/or diagnostic results? • medication strength/concentration? • dosing formula and calculations (e.g. mcg/kg/min, units/hr)? • weight, if applicable? • documentation of the independent double-checks? • comparison of independent double checks to determine accuracy or discrepancies (as appropriate)?

#	Standard	Reference	Assessment of Compliance

			If discrepancies are found during the double check:
			• is the process repeated?
			• is a second or third health care professional consulted if discrepancy still exists?
			• is the authorized prescriber consulted to verify medication orders?
			
			Does ongoing patient assessment, monitoring and documentation include:
			• respiration rate?
			• heart rate?
			• blood pressure?
			• sedation level?
			• mood scale as appropriate?
			• monitoring for adverse effects?
			
			Is there evidence that ongoing patient assessment and documentation completed includes (at a minimum):
			• Vital signs:
			  ○ pre treatment
			  ○ at midpoint?
			  ○ at completion?
			  ○ pre-discharge?
			  ○ monitoring for a defined period of time based on the specific psychedelic drug administered following treatment?
			
			Is ongoing patient assessment and documentation completed more frequently as indicated (e.g. high risk, unstable, elderly patients or those with significant comorbidities, medication dosage, dose increase, etc.?
			
			Does the patient remain in the treatment area for a defined period of time based on the specific psychedelic

#	Standard	Reference	Assessment of Compliance
			drug administered or until established discharge criteria is met after the psychedelic drug treatment is discontinued? Is the frequency of the treatment session determined by the treating physician on a case by case basis?
			C ☐ P ☐ E ☐ N ☐ N/A ☐
			Observation:
PAPT.7.2.2	Patients are appropriately monitored and cared for during psychotherapy.	AHS[3] CPSA[8, 11]	Does the facility have a policy, process and procedure for what psychotherapies will be offered based on patient assessment? Does the facility have a policy and process for virtual psychotherapy, if required, based on a documented assessment of the risks and benefits for a specific patient? Do patients receiving psychotherapy receive therapy based clinical expertise and where available on recommended best practice guidelines? • is the frequency of the psychotherapy sessions determined by the treating physician or qualified clinical staff on a case-by-case basis? Is ongoing patient assessment and documentation completed more frequently as indicated, e.g. high risk, unstable patients or those with significant comorbidities, medication dosage, dose increase, etc.?
			C ☐ P ☐ E ☐ N ☐ N/A ☐
			Observation:

#	Standard	Reference	Assessment of Compliance
PAPT.8.0 MEDICAL EMERGENCIES AND ADVERSE EVENTS			
PAPT.8.0.1 PS	The PAPT facility has policies, processes and procedures to manage medical emergencies and adverse events.	ISQua[1] – 4.5	Does the PAPT facility have medical emergency procedures and processes that include: • detection? • evaluation? • action? • treatment? • documentation? • reporting? • appropriate personnel training in first aid and cardiopulmonary support (initial and regularly thereafter)? • designation of personnel responsible for the treatment of medical emergencies and adverse events? Does the facility have a procedure for initiating immediate help such as requesting additional facility staff and qualified emergency responders when a medical emergency arises? Are emergency contact numbers (e.g., code call number, 911) posted in highly visible areas? Are personnel aware of emergency contact procedures in case of a medical emergency and/or adverse event? Is there documentation of medical emergencies and adverse patient outcomes including: • treatments / interventions? • reporting as required by local, national and provincial legislation? • review for corrective / preventive action and opportunities for improvement?

#	Standard	Reference	Assessment of Compliance
			Does the facility prepare for medical emergencies and/or adverse events by holding or participating in simulated emergency drills or scenarios? C ☐ P ☐ E ☐ N ☐ N/A ☐ Observation:
PAPT.8.0.2 **PS / SS**	Periodic emergency drills ensure that the PAPT facility is physically prepared and staff are ready to act in the event of an emergency.	ISQua[1] – 3.8, 4.11	Is emergency preparedness ensured by having: • all personnel receive emergency readiness training? • patient appropriate critical event guides/protocols available? • training during orientation, with medication or equipment changes, with changes in roles/responsibilities, change in emergency policies, processes or procedures as applicable? • periodic mock emergency drills? • minimally every six months? Is the emergency drill training and attendance documented? Is a drill report identifying possible additional training needs or practice changes with corrective action details created? C ☐ P ☐ E ☐ N ☐ N/A ☐ Observation:
PAPT.8.0.3 **PS**	The PAPT emergency medical cart supports the early treatment of medical emergencies.	ACLS[1]	Does the emergency medical cart include all of the required medication, equipment and ancillary supplies as required for the patient population and services provided at the facility? Is all equipment stocked and organized according to function and priority?

#	Standard	Reference	Assessment of Compliance

			Is the emergency kit:
			• portable?
			• immediately available and located in a common patient area?
			• checked before the start of first patient of the day?
			• fully stocked and in working order?
			• duty of checking rotated amongst staff?
			• medications and equipment within labeled expired dates, accessible and organized including (at a minimum):
			  ○ anaphylaxis intervention e.g. EpiPen
			  ○ benzodiazepines e.g. Ativan
			  ○ oxygen source
			  ○ airway equipment
			  ○ AED
			• defibrillation pads on the AED or defibrillator checked for expiration date?
			• battery charge on the monitor/and or AED checked?
			• are checks documented?

			C ☐ P ☐ E ☐ N ☐ N/A ☐
			Observation:

#	Standard	Reference	Assessment of Compliance
PAPT.9.0 QUALITY ASSURANCE OF PAPT TREATMENTS			
PAPT.9.0.1	The PAPT facility has internal quality assurance systems that verify the quality and successful performance of the ordered treatment.	CLSI[3] QMS01 – 3.7.3, 4.2.2 ISO[1] 15189 – 5.6.2.1	Does the facility have internal quality assurance systems that verify the quality and successful performance of the ordered treatment? C ☐ P ☐ E ☐ N ☐ N/A ☐ Observation:
PAPT.9.0.2	The PAPT participates in a peer review system for all facility physicians and clinical personnel.	CMA[1]	Does the facility participate in peer programs, appropriate to the scope and complexity of service, e.g. rounds, case reviews, and critical incident debriefing? Does this program assist in assessing the overall system to help the PAPT facility manage treatment success and other quality improvements? C ☐ P ☐ E ☐ N ☐ N/A ☐ Observation:
PAPT.9.0.3	The PAPT facility encourages physicians to participate in quality practices to help ensure optimal consultation performance of treatments.	CMA[1]	Does the PAPT facility participate in peer education programs, appropriate to the scope of services provided? Are the PAPT physicians actively engaged in continuing education? Are there criteria and processes in place to assess the initial training/competency and on-going competency of PAPT physicians? C ☐ P ☐ E ☐ N ☐ N/A ☐ Observation:

#	Standard	Reference	Assessment of Compliance
PAPT.10.0 PSYCHEDELIC-ASSISTED PSYCHOTHERAPY POST-SERVICE POLICIES, PROCESSES & PROCEDURES			
PAPT.10.1 Psychedelic-Assisted Psychotherapy Post-Service – Patient Management			
PAPT.10.1.1 PS	The PAPT facility has processes for the provision of post-treatment patient care.	ISQua[1] – 5.13	Are there post-treatment processes for all phases of treatment: • administration of the psychedelic drug? • provision of psychotherapy? Do the processes address: • management of adverse patient reactions? • management of patients after treatment including any special requirements for post-treatment recovery? • post-treatment instructions for patients, and or care-givers? • determining whether any further treatments of the patient are required?
			C ☐ P ☐ E ☐ N ☐ N/A ☐
			Observation:
PAPT.10.1.2	Follow up assessments are conducted on all patients.	ISQua[1] – 5.12	Is there evidence that all patients receive periodic, documented follow up assessments appropriate to the patient and following the care plan?
			C ☐ P ☐ E ☐ N ☐ N/A ☐
			Observation:
PAPT.10.1.3	Patients are appropriately discharged from the facility.	ISQua[1] – 5.13	Does the facility has policies, processes and procedures in place that define discharge criteria for each phase of the service: • administration of the psychedelic drug?

#	Standard	Reference	Assessment of Compliance
			• provision of psychotherapy? Is there evidence that patients (and/or their guardian/responsible adult) discharged from the facility have: • met established discharge criteria? • been instructed in the aftercare? • been provided with verbal and written discharge instructions that include all of the following: ○ when to resume taking medications taken before the treatment? ○ not to take additional psychedelic drugs or alcohol? ○ not to drive, operate dangerous machinery, or take part in strenuous activity for the rest of the day? ○ follow-up care, telephone contact numbers for the most responsible physician? ○ written materials applicable to the type of treatment? Does the most responsible physician remain on the premises until the patient meets predetermined discharge criteria?
			C ☐ P ☐ E ☐ N ☐ N/A ☐
			Observation:
PAPT.10.2 Psychedelic-Assisted Psychotherapy Post-Service – Reporting of Results			
PAPT.10.2.1	The facility maintains comprehensive patient medical records.	ISQua[1] – 4.12 CPSA[5] CPSA[6]	Does each patient record include: • full name, address, phone number, personal health number? • age and gender?

#	Standard	Reference	Assessment of Compliance

			• patient's emergency contact information?
			• history of the present condition and diagnosis?
			• height and weight?
			• initial patient assessment?
			• diagnostic test results (e.g. laboratory results, urine screen)?
			• informed consent to PAPT treatment?
			• most responsible physician referral/attestation?
			• mental health assessment including (as appropriate):
			  ○ baseline depression scores (e.g., Montgomery-Asberg Depression Rating Scale (MADRS), The Implicit Association Test (IAT), Hamilton)?
			  ○ PTSD checklist?
			  ○ psychiatrist referral and/or follow up?
			• written treatment order?
			• patient history including allergies and previous adverse reactions to psychedelic drugs?
			• all medications consumed in the 24 hours prior to the treatment including:
			  ○ prescribed?
			  ○ over the counter (e.g., vitamin, herbal, homeopathic)?
			  ○ recreational drugs or substances, e.g. alcohol, cannabis?
			  ○ stimulants, e.g. caffeine, energy drinks
			• benzodiazepines, sedatives or hypnotics consumed in the 72h preceding the treatment session?
			• any changes in perceived health status?
			Are any abnormalities or changes reported to the most responsible physician?
			C ☐ P ☐ E ☐ N ☐ N/A ☐

#	Standard	Reference	Assessment of Compliance
			Observation:
PAPT.10.2.2	The PAPT facility has processes for the production of reports.	CLSI[3] QMS01 – 4.3 ISO[1] 15189 – 5.8 CPSA[6]	Are there processes that define all of the following, where applicable: • when an interim or preliminary report is required? • the entering of interpretive comments? • dictation? • patient record storage? • protocols when a result cannot be reported for a requested service? • policies for the use and disclosure of personal information to patients and other stakeholders that align with applicable national, provincial, and local legislation? • turnaround time for reports? • method of delivery of final reports?
			C ☐ P ☐ E ☐ N ☐ N/A ☐
			Observation:
PAPT.10.2.3	There is a standardized patient PAPT report, format and criteria that include all relevant demographics, patient information, PAPT treatment findings and facility information.	CLSI[3] QMS01 – 4.3.2 ISO[1] 15189 – 5.8.2, 5.8.3 ISQua[1] – 4.10	Do patient reports include all of the following, where applicable: • patient's first and last name? • facility location and contact information? • a second unique patient identifier (e.g., personal health number)? • patient's age? • patient's gender? • clinical history? • dose of the psychedelic drug? • treatment performed? • indications for treatment?

#	Standard	Reference	Assessment of Compliance
			• unique identifier of the authorized requester and the requester's location? • date of treatment (s)? • time of treatment, if relevant? • description of treatment? • deviations from the facility protocol (if applicable)? • findings of the treatment? • comparative data, including prior treatment findings where appropriate? • any significant patient reaction? • conclusion with an interpretive commentary on the information described? • recommended follow up and/or additional treatments, when appropriate? • identification of the person authorizing the release of the report? • indication of amended results, if applicable? • date and time of release of report, which if not on the report, is readily accessible when required?
			C ☐ P ☐ E ☐ N ☐ N/A ☐
			Observation:
PAPT.10.2.4	PAPT reports are legible, accurate, and delivered to the authorized personnel within a designated timeframe.	CLSI[3] QMS01 – 4.3.2 ISO[1] 15189 – 5.8.1, 5.9.1 ISQua[1] – 4.12	Is there evidence that reports meet all of the following criteria: • reported in a timely fashion? • accurate? • legible? • reported to authorized personnel?

#	Standard	Reference	Assessment of Compliance
		Guidance: The facility defines the appropriate number, type and frequency of report audits.	Are patient treatment results available in the provincial medical data repository e.g. Netcare or its successor? Is there a procedure to trace late or lost reports including referred out treatments? In the event of a computer system failure, is there a contingency plan to ensure treatments with significant findings are reported in a prompt and effective format? C ☐ P ☐ E ☐ N ☐ N/A ☐ Observation:
PAPT.10.2.5	The confidentiality of PAPT facility reports and patient health information is assured and in compliance with applicable national, provincial, and local legislation and regulations.	CLSI[3] QMS01 – 3.8.2.4, 3.9.2 CPSA[6] ISO[1] 15189 – 4.1.1.3, 5.10.1 ISQua[1] – 4.12, 5.1	Are there processes to ensure the confidentiality of patient information in compliance with national, provincial and local legislation and regulations? Are there policies to ensure that internal and external storage and transfer of data maintains patient confidentiality and security? C ☐ P ☐ E ☐ N ☐ N/A ☐ Observation:
PAPT.10.2.6	The PAPT facility establishes and monitors turnaround times for reports in consultation with the users of the facility services.	CLSI[3] QMS01 – 4.3.2.1 ISO[1] 15189 – 4.14.7	Are turnaround times (TAT) established for PAPT reports? Are turnaround times monitored from the time of presentation of the patient to the facility to the time of the report issue by the facility? Are identified problems with turnaround times adequately monitored and addressed? C ☐ P ☐ E ☐ N ☐ N/A ☐

#	Standard	Reference	Assessment of Compliance
			Observation:
PAPT.10.2.7 PS	There are PAPT report generation, review and release procedures.	CLSI[3] QMS01 – 4.3 ISO[1] 15189 – 5.9.1	Are there procedures for: • proof-reading of the final report to avoid typographical errors, accidentally deleted words and confusing or conflicting statements? • authentication of the final report by the reporting/dictating physician? Do these criteria include reports generated when senior supervisory specialists are not on site (e.g. residents reporting)? Are there procedures for: • the release of PAPT reports including those authorized to release and receive reports? • the release of PAPT reports directly to patients and third parties?
			C ☐ P ☐ E ☐ N ☐ N/A ☐
			Observation:
PAPT.10.2.8 PS	The PAPT facility has processes for report alteration.	CLSI[3] QMS01 – 4.3.2.2 ISO[1] 15189 – 5.9.3 Guidance: Report alteration refers to changes to reports made <u>after</u> the narrative report and interpretation are completed, signed and	Do alterations to PAPT records or reports indicate the date, time, and person who made the changes? Is the original reporting physician made aware of the revisions, as well as other critical users? Are alterations made in such a way that the original entry is visible? In the case of a computer record, is the original entry identified and retained?

#	Standard	Reference	Assessment of Compliance
		released to the referring healthcare professional.	Is the original report part of the permanent patient record? When there are multiple, sequential corrections of a single report, are all corrections referenced in sequential order on subsequent reports? Is there a documented system to ensure that all revised reports for previously reported incorrect (erroneous) patient reports are identified as revised, corrected or amended on all forms of patient reports (paper, video displays, etc.)? Are PAPT reports that have been available for clinical decision-making retained in subsequent cumulative reports and clearly identified as having been revised? If the reporting system cannot capture amendments, changes or alterations, is an audit log in place? When alterations are made to electronic reports: • are there processes for appropriate editing procedures? • do the reports clearly indicate the alteration? • are the original records retained?
			C ☐ P ☐ E ☐ N ☐ N/A ☐
			Observation:

#	Standard	Reference	Assessment of Compliance
PAPT.10.2.9	PAPT reports and records are maintained in a manner that facilitates prompt retrieval for the time periods defined by the facility and in compliance with relevant regulations and/or standards.	CLSI[3] QMS01 – 3.8.2.4, 3.8.2.5, 3.8.2.6 ISO[1] 15189 – 4.13 ISQua[1] – 4.12	Is there a policy for the retention of PAPT reports and records that is in compliance with relevant regulations and/or standards? Are reports and records easily retrievable for the defined time period? C ☐ P ☐ E ☐ N ☐ N/A ☐ Observation:

#	Standard	Reference	Assessment of Compliance
PAPT.11.0 SAFETY			
PAPT.11.1 Safety – Physical Facility			
PAPT.11.1.1 SS	The PAPT facility design allows for safe working conditions.	CLSI[3] QMS01 – 3.3.1.1 CSA[1] Z8000 – 4.2, 7.6.4, 7.7, 10.6.1 ISO[4] 15190-20 – 4.2 ISQua[1] – 4.7 WHO[2] – 3.3	Is there sufficient unobstructed space for safe working conditions? Is there adequate space around equipment to allow for free movement of staff and emergency equipment on both sides of patient stretcher/chair? Are passageways unobstructed? Are all exits clear of obstructions? Is storage space safely separated from Psychedelic-Assisted Psychotherapy facility working space? Is there appropriate security for facility personnel working off-hours (e.g., Working Alone policy)? C ☐ P ☐ E ☐ N ☐ N/A ☐ Observation:
PAPT.11.1.2 SS	The drug administration area has adequate space and equipment.	CSA[1] Z8000 – 7.6.1.3	Does the treatment area have adequate patient stations equipped with: • pulse oximetry? • blood pressure monitor? • immediate access to an emergency medical kit? • standardized protocols or checklists? • medications? Does the facility have a policy, process and procedure for the use of restraints (chemical or physical as applicable)? C ☐ P ☐ E ☐ N ☐ N/A ☐

#	Standard	Reference	Assessment of Compliance
			Observation:
PAPT.11.1.3 PS / SS	There are appropriate, dedicated hand hygiene stations within patient care and treatment areas.	CPSA[1] – G.2.1, G2.2 CSA[1] Z8000 – 7.5.12, 9.9.3.4.1 ISO[4] 15190-20 – 4.2 PHO[1] – 2.1.1 PHO[2] – p.21 WHO[2] – 3.3	Are there dedicated and clearly designated hand washing sinks or hand hygiene stations within patient care and treatment areas? Do the sinks have unimpeded drainage (i.e., no stoppers in the basin)? If faucets are hand-operated, is there a process that requires that paper towel or similar material be used to turn them on/off? If not, is there alcohol-based hand rub (ABHR) (60-90%) immediately available?
			C ☐ P ☐ E ☐ N ☐ N/A ☐
			Observation:
PAPT.11.1.4 SS	There is appropriate natural or artificial lighting that is optimal for safe working conditions.	CLSI[3] QMS01 – 3.3.1.1 CSA[1] Z8000 – 7.8.4, 9.9.3.3 ISO[1] 15189 – 5.2.2 ISO[2] 9001 – 7.1.4 ISO[4] 15190-20 – 4.2 WHO[2] – 3.3	Is the level of lighting optimal for safe working conditions? Are portable emergency lights provided where back-up emergency lighting is not available in clinical and / or patient areas? Is there evidence that battery-operated emergency lights are inspected to be in operating order on a regular basis?
			C ☐ P ☐ E ☐ N ☐ N/A ☐
			Observation:
PAPT.11.1.5		CLSI[3] QMS01 – 3.3.1.3	Is the ambient temperature and humidity controlled as far as possible to be comfortable for personnel and patients?

#	Standard	Reference	Assessment of Compliance
	The ambient temperature and humidity is controlled as far as possible to be comfortable for personnel and patients.	GOA[2] ISO[1] 15189 – 5.2.6 ISO[2] 9001 – 7.1.4 ISO[4] 15190-20 – 9.6	C ☐ P ☐ E ☐ N ☐ N/A ☐ Observation:
PAPT.11.1.6	The PAPT facility ensures that facility activities, workspace and equipment are designed to reduce the risks of ergonomic distress disorders and accidents.	CSA[1] Z8000 – 7.6.1.3 ISO[4] 15190-20 – 12	Are PAPT facility activities, workspace and equipment designed to reduce the risks of ergonomic distress disorders and accidents? C ☐ P ☐ E ☐ N ☐ N/A ☐ Observation:
PAPT.11.1.7 PS / SS	The PAPT facility has procedures and physical controls for emergency evacuation of the facility.	CSA[1] Z8000 – 6.1.9.3 ISO[4] 15190-20 – 11.2	Is there a readily available procedure for emergency evacuation of the facility? Do all personnel completely understand the evacuation procedure? Are emergency exits easily visible and distinguished from normal exits? Are evacuation routes posted and easily understood? Are muster points identified in the procedure and on the posted evacuation routes? C ☐ P ☐ E ☐ N ☐ N/A ☐ Observation:
PAPT.11.2 Safety – Safety Program			
PAPT.11.2.1	The PAPT facility has designated personnel who are responsible for	CLSI[3] QMS01 – 3.3.2 ISO[3] – 5.3, 9	Is there evidence that there is a designated staff member responsible for the development, maintenance and monitoring of an effective facility safety program?

#	Standard	Reference	Assessment of Compliance
	the development, maintenance, monitoring and compliance of an effective safety program.	ISO[4] 15190-20 – 5.1, 5.5 WHO[2] – 7.3	Is this designated individual authorized to: • stop unsafe activities? • review all incidents? • make recommendations to prevent recurrence of an incident? C ☐ P ☐ E ☐ N ☐ N/A ☐ Observation:
PAPT.11.2.2	There is a physical inspection of all facility work areas to ensure appropriate and effective safety measures, at least annually or as required by provincial regulations.	GOA[4] – B:2.1.3.7 ISO[4] 15190-20 – 5.7 ISQua[1] – 4.10	Is there evidence of a physical inspection of the facility at the required intervals that includes all of the following: • readiness and function of fire emergency apparatus, alarms and evacuation procedures? • containment and control for the storage of flammable and combustible, infective, materials? • decontamination and disposal procedures? • environmental parameters? • electrical requirements and hazards? • availability and use of personal protective equipment? C ☐ P ☐ E ☐ N ☐ N/A ☐ Observation:
PAPT.11.2.3	All PAPT facility safety records are retained for a period as defined in facility policy and in compliance with applicable regulations and/or standards.	ISO[1] 15189 - 4.13 ISO[2] 9001 – 4.4.2, 7.5.3.2 ISO[4] 15190-20 – 5.8	Are retention periods for all safety records defined in facility policy and in compliance with applicable regulations and/or standards? Is there evidence of appropriate record retention? C ☐ P ☐ E ☐ N ☐ N/A ☐ Observation:

#	Standard	Reference	Assessment of Compliance
PAPT.11.3 Safety – Training			
PAPT.11.3.1 **PS / SS**	There is a comprehensive safety training program for all PAPT facility personnel.	CLSI[3] QMS01 – 3.3.2.8 GOA[4] – B:2.8.1 GOC[6] – Part 6 ISO[3] – 5.2, 7.2, 7.3 ISO[4] 15190-20 - – 5.9 ISQua[1] – 4.5 WHO[2] – 3.2	Does the safety training program include all of the following where applicable to the scope of PAPT service: • an introduction for new employees? • periodic retraining for experienced employees? • a requirement for facility personnel to read the appropriate safety manual before beginning to work? • documentation that facility personnel have received appropriate training and have read and understood the safety manual (s)? • a system for evaluating each employee's understanding of the information given to them? • training for all facility-associated personnel, including transport and cleaning staff? • emphasis on safe work practices? • training in emergency procedures? • incident and accident management and reporting? • fire prevention and preparedness? • initial WHMIS training as applicable to the chemicals used in the facility? • biological hazards and infection prevention? Is the training program job or task specific and tailored according to the employee's job description? C ☐ P ☐ E ☐ N ☐ N/A ☐ Observation:
PAPT.11.4 Safety – Incidents, Injury, Accidents & Occupational Illnesses			
PAPT.11.4.1		ISO[3] 45001 – 10.2	Is there a process to identify, document and investigate occupational health and safety incidents that includes:

#	Standard	Reference	Assessment of Compliance
PS / SS	The PAPT facility has processes for the management and reporting of safety and occupational health incidents.	ISO[4] 15190-20 – 19 ISQua[1] – 4.5 WHO[2] – 3.8, 3.9	• maintaining the confidentiality of individuals? • promoting a safe work place environment by facilitating a "blameless" reporting culture? • reporting to the appropriate regulatory and health authorities if applicable (e.g. WCB, administration)?
			C ☐ P ☐ E ☐ N ☐ N/A ☐
			Observation:
PAPT.11.5 Safety – Personnel Responsibilities			
PAPT.11.5.1	The PAPT facility has appropriate immunization policies and procedures for all staff.	CLSI[3] QMS01 – 3.3.2.1 CSA[2] Z314-18 – 6.3, 6.7.1.1 GOC[4] – A.III.B.3 GOA[1] – 5 ISO[4] 15190-20 – 5.4.2 PHO[1] – 5.1 WHO[2] – 4.1	Has the PAPT facility conducted an infection-risk assessment to determine the needs of the facility immunization program? Has PAPT facility management developed a defined personnel immunization process based on potential exposure? Are all facility personnel strongly encouraged to have immunizations to prevent infections to which the person may be exposed?
			C ☐ P ☐ E ☐ N ☐ N/A ☐
			Observation:
PAPT.11.5.2 SS	The PAPT facility has policies and procedures that require safe personal practices in administrative and clinical work areas.	ISO[4] 15190-20- 14.1, 14.2, 14.3, 14.4, 14.5 WHO[2] – 3.1.1	Are all of the following prohibited in clinical work areas: • eating and drinking? • smoking? • vaping? • application of cosmetics? • handling of contact lenses?

#	Standard	Reference	Assessment of Compliance
			• rings, earrings, wristwatches, bracelets, necklaces and other jewelry, or unsecured loose clothing (e.g., ties), if there is any danger of them being caught in equipment or contaminated by infectious substances or chemicals? • long hair that is not secured back and off the shoulders? • storage of personal property, clothing and cosmetics in areas where they may become contaminated? • decorations that may present contamination and / or fire hazards? • use of personal electronic devices (e.g. cell phones) unless required to deliver the standard of care? Are food and drink only allowed in areas designated for their preparation and consumption? Are refrigerators appropriately labeled and used for their indicated use only? Is there evidence of compliance with personal work practice requirements?
			C ☐ P ☐ E ☐ N ☐ N/A ☐
			Observation:
PAPT.11.5.3 SS	Appropriate footwear is worn to ensure facility personnel safety.	GOA[3] – Part 18 ISO[4] 15190-20 – 15.6 WHO[2] – 3.6.2	Is footwear suitable for the duties being performed and designed to minimize the risk of injury?
			C ☐ P ☐ E ☐ N ☐ N/A ☐
			Observation:

#	Standard	Reference	Assessment of Compliance
PAPT.11.6 Safety – Personal Protection			
PAPT.11.6.1 SS	The PAPT facility has a comprehensive first aid program appropriate for the work load, range and complexity of the treatments performed.	CSA[2] Z314-18 – 6.7.1.1 GOA[3] – Part 11 ISO[4] 15190-20 – 5.9.4, 10.2 ISQua[1] – 4.5, 4.8 WHO[2] – 3.3, 3.8, 5.9 Guidance: Availability of first aid personnel can be accomplished by access to appropriately trained personnel on staff (e.g., MD).	Does the first aid program include all of the following: • facility personnel training? • materials and procedures to mitigate adverse effects and incidents occurring to people within the facility potentially infectious materials? • guidelines for the treatment? • where required, immediate emergency medical attention consistent with the hazards likely to be experienced within the facility? • procedures for the follow-up of any incident of exposure (e.g. blood-borne pathogens, needle stick injuries, etc.)? • incident reporting as required by facility policy? Is first aid training provided for designated facility personnel upon hire, regularly and as required thereafter? C ☐ P ☐ E ☐ N ☐ N/A ☐ Observation:
PAPT.11.6.2 PS / SS	The PAPT facility has appropriately trained personnel and first-aid/emergency equipment available.	GOA[3] – Part 11 ISO[4] 15190-20 – 5.9.4, 10.2 WHO[2] – 3.3, 3.8	Are appropriately trained personnel readily available when required? Are all of the following readily available, where appropriate: • first-aid box? • first aid equipment? • protective clothing and safety equipment for the person rendering first-aid? • provision for summoning medical assistance and prompt transfer to a hospital when required?

#	Standard	Reference	Assessment of Compliance
			Are facility personnel aware of location and criteria for use for all first aid equipment and supplies? C ☐ P ☐ E ☐ N ☐ N/A ☐ Observation:
PAPT.11.7 Safety – Hazardous Materials			
PAPT.11.7.1 SS	The PAPT facility has processes and procedures for the handling of hazardous chemicals utilized in the facility.	CLSI[3] QMS01 – 3.3.2.2 CSA[1] Z8000 – 7.6.3 GOA[3] – Part 4, Part 29 ISO[4] 15190-20 – 8 PHO[1-] 3.1.2.2, 4, 5.5.1, 6.2.2 WHO[2] – 3.3	Are there processes in place for handling of hazardous materials including: • approved safety precautions? • safe work practices? • personal protective equipment? • protocols for incidents? Are WHMIS regulations followed, including: • current and accessible Safety Data Sheets (SDSs)? • WHMIS labelling of chemicals? • storage and disposal of WHMIS controlled materials handled in accordance with applicable regulations? • annual review of the WHMIS training/education program to ensure that it reflects current regulations and requirements relative to the scope of chemical utilized in the facility? • appropriate WHMIS training for staff? Is there a mechanism for annual review of chemicals available in the facility? Are hazardous liquids handled using safety equipment or devices that have been deemed appropriate for the materials and the task? Does the storage of flammables meet all of the following criteria:

#	Standard	Reference	Assessment of Compliance
			• in containers that comply with WHMIS specifications? • below eye level? • not stored under sinks where contamination by moisture may occur?
			C ☐ P ☐ E ☐ N ☐ N/A ☐
			Observation:
PAPT.11.7.2 SS	The PAPT facility has policies, processes and procedures for the mitigation of biohazards.	CSA[1] – Z8000 – 7.6.2 ISO[4] 15190-20 – 7.1.1 WHO[2] – 2.4	Are standard blood and body fluid precautions used for handling and disposal of material of biological origin?
			C ☐ P ☐ E ☐ N ☐ N/A ☐
			Observation:
PAPT.11.7.3 SS	PAPT facility work practices reduce the risk of injury during the handling of medical sharps, sharp instruments and needles.	CPSA[1] _- G.4.1 CSA[1] Z8000 -7.6.2.2 CSA[2] Z314-18 – 6.7.1.1, 11.2.3 GOA[3] – Part 35 GOA[1] – 2, 5 GOC[4] – A.III.B.3 ISO[4] 15190-20 – 7.1.1, 14.8 ISQua[1] – 4.8 PHO[1]_- 4, 5.3, 7.2.1, 7.2.2	Are PAPT facility personnel trained in safe handling and use of sharp instruments, needles and medical sharps? Are medical sharps safety-engineered (e.g. one-handed re-capping system)? Are contaminated needles and other sharps discarded in designated containers immediately after use? Do the sharps containers have all of the following characteristics: • single-use (not emptied and reused)? • puncture resistant? • have a fill line to which the container can be safely filled? • closable during normal handling and disposal? • tamper proof? • leak-proof on the sides and bottom?

#	Standard	Reference	Assessment of Compliance
			• clearly labeled or color-coded? Is there evidence that sharps containers are not filled beyond the visible fill line? Are sharps containers securely stored until final disposal in accordance with appropriate local, regional or national guidelines?
			C ☐ P ☐ E ☐ N ☐ N/A ☐
			Observation:
PAPT.11.7.4 PS/SS	Equipment and supplies utilized during the treatment process are safely and appropriately stored, handled, transported, and disposed of.	CSA[1] Z8000 – 7.6.2.2, 10.7.2.2 ISQua[1] – 4.8 Guidance: Equipment and supplies may include medication vials, syringes, etc.	Is there evidence that all equipment, supplies and any excess or unused aliquots of psychedelic drugs utilized during the treatment process are handled and disposed of in a manner that: • is safe? • prevents tampering or theft? • is in compliance with national, provincial, and local regulations and codes?
			C ☐ P ☐ E ☐ N ☐ N/A ☐
			Observation:
PAPT.11.8 Safety – Fire			
PAPT.11.8.1 PS / SS	The PAPT facility has policies and procedures regarding fire safety that complement local fire regulations and codes.	CLSI[3] QMS01 – 3.3.2.5 GOA[4] ISO[4] 15190-20 – 5.6, 11	Are there policies and procedures for fire safety that are specific for the PAPT facility? Is there evidence that the PAPT facility has ensured compliance with the institution policies and local fire department regulations and codes?

#	Standard	Reference	Assessment of Compliance
			Are fire drills conducted: • for all facility areas? • for each shift? • at defined intervals, but at least annually? Is there evidence that all facility personnel have participated in a scheduled fire drill or alternate training has taken place? Are the results from fire drills used to improve fire safety and evacuation plans if necessary? Are there functioning automatic smoke or heat detectors and alarm systems as required by fire regulations and codes? Are alarm systems regularly tested to ensure their function and to familiarize all facility personnel with their operation?
			C ☐ P ☐ E ☐ N ☐ N/A ☐
			Observation:
PAPT.11.8.2 **PS / SS**	Fire emergency procedures and exit routes are clearly posted for timely execution ensuring a rapid exit in the event of a fire or other type of emergency.	GOA[3] – Part 7, Part 8 GOA[4] – B:2.8 ISO[4] 15190-20 – 11.2	Are primary and secondary (where applicable) exit routes designated? Are evacuation routes appropriately identified for timely evacuation and are evacuation signage posted in highly visible areas? Do facility personnel know the location of refuge or safe holding areas, evacuation devices (if required), fire-rated doors and accessible exit routes? Are any doors along the exit route locked or secured in a way that impedes emergency exit?

#	Standard	Reference	Assessment of Compliance
			Are evacuation routes / corridors clear and unobstructed at all times? Does the PAPT facility have a process to practice emergency procedures on a regular basis, or as needed if there is a change in procedure?
			C ☐ P ☐ E ☐ N ☐ N/A ☐
			Observation:
PAPT.11.8.3 **PS / SS**	PAPT facility management ensures that fire safety training is given to all facility personnel.	CLSI[3] QMS01 – 3.3.2.5 CLSI[13] GP17 – 7.4 GOA[4] – B:2.8 ISO[4] 15190-20 – 11.1.5.1	Are all PAPT facility personnel instructed in all of the following: • recognition and evaluation of fire hazards? • planning to reduce the risk of fire? • all actions to take when fires occur? • their responsibility to ensure people's safety by orderly evacuation rather than attempts to extinguish fires? Is the fire safety program reviewed by personnel upon hire and on an annual basis? Is there evidence that facility personnel know all of the following: • how to sound an alarm? • how to recognize the sound of the alarm from their respective work areas? • the proper use of extinguishers? • the proper use of fire blankets, if present in the facility?
			C ☐ P ☐ E ☐ N ☐ N/A ☐
			Observation:

#	Standard	Reference	Assessment of Compliance
PAPT.11.8.4 PS / SS	The PAPT facility has appropriate equipment to extinguish containable fires and to assist in the evacuation of all individuals from the vicinity of a major fire.	GOA[4] – B:2.1.5 ISO[4] 15190-20 – 11.1.6	Are there sufficient numbers of portable fire extinguishers (PFEs)? Is the selection and location of PFEs appropriate for the types of fire possible within the facility (i.e., Class A, B, and C)? Is there evidence that PFEs are: • properly installed and maintained? • routinely inspected in accordance with local fire regulations? C ☐ P ☐ E ☐ N ☐ N/A ☐ Observation:
PAPT.11.9 Safety – Waste Disposal			
PAPT.11.9.1 PS / SS	There are waste disposal processes that comply with national, provincial and local regulations and safety codes.	CPSA[1] - G.5.4 GOC[4] – A.III.B.3 GOC[6] ISO[1] 15189 – 5.2.3 ISO[4] 15190-20 – 17 PHO[1]_– 7.2, 7.3 WHO[2] – 3.5 Guidance: Facility waste, rubbish and routine paper waste	Does the process for contaminated waste disposal: • comply with national, provincial and local regulations and safety codes? • minimize the hazards in handling, collecting, transporting, treating and disposing of waste? • minimize harmful effects to the environment? • support accident prevention? Does the PAPT facility use biological waste containers for the discard of all biological material? Is there a procedure for the discarding and safe disposal of every chemical product used in the facility, including: • disposal in compliance with the SDS?

#	Standard	Reference	Assessment of Compliance
		that is known to be contamination free can be handled and processed as nonhazardous waste.	• sufficient details of the local regulatory process to enable full compliance? Do disposal containers meet all of the following criteria: • specifically designed, intended and marked for disposal of hazardous waste? • not filled beyond their designed capacity? • removed on a regular basis so that waste is not allowed to accumulate? • held in a designated secure place prior to decontamination or final disposal? Is biomedical waste segregated and securely stored until final disposal? Is final disposal of biomedical waste in accordance with municipal by-laws (e.g. approved biomedical waste company)? Are splash proof containers used for discard of liquid waste in the facility? Is hazardous waste handled only by appropriately trained facility personnel using appropriate personal protective equipment? Are general waste receptacles emptied at acceptable frequencies? Is general waste disposed of in a manner that is practical, efficient, and in accordance with municipal by-laws?
			C ☐ P ☐ E ☐ N ☐ N/A ☐
			Observation:

#	Standard	Reference	Assessment of Compliance
PAPT.12.0 INFECTION PREVENTION & CONTROL (IPC)			
PAPT.12.1 IPC – General			
PAPT.12.1.1 PS / SS	The PAPT facility has policies and procedures along with administrative controls applicable to infection prevention and control.	CPSA[1] CSA[1] Z8000 – 7.5, 7.6.1 GOA[1] GOC[4] – A.III ISQua[1] – 4.7 PHO[1] PHO[2] PHO[3]	Are there policies and procedures applicable to infection prevention and control that: • meet all applicable national, provincial and local legislation and codes? • address the use of personal protective equipment? • are based upon an organizational risk assessment for infection prevention and control, as applicable to the scope and complexity of services provided in the facility? Are all individuals educated in the appropriate policies and procedures, where applicable? Do facility personnel receive documented infection prevention & control training: • during orientation? • at defined on-going intervals (minimum annually)? • as a result of special circumstances (e.g., outbreaks, new equipment or updated information)? Are systems in place to monitor the infection control practices in the facility, including monitoring of staff compliance? C ☐ P ☐ E ☐ N ☐ N/A ☐ Observation:

#	Standard	Reference	Assessment of Compliance
PAPT.12.1.2 **PS / SS**	The PAPT facility is physically designed to minimize bio-burden and particulate contamination.	CPSA[1] – G.5.1 CSA[1] Z8000 – 7.2.1.2, 7.2.2, 7.3, 7.5.9.1, 9.9.2.3, 9.9.3.4.4 CSA[2] Z314-18 – 6.7.1.1 GOA[1] – 5 GOC[4] – A.III.B.2 PHO[1] – I.2 WHO[2] – 3.3	Is the PAPT facility designed such that: • functional work areas are separated by walls or partitions? • there is physical separation of the decontamination/dirty areas from the clean areas? Are all work surfaces: • able to withstand frequent cleaning with hospital-grade detergents, cleaners and disinfectants? • non-supportable of microbial growth? • non-porous and smooth? • cut and impact resistant? • seamless? C ☐ P ☐ E ☐ N ☐ N/A ☐ Observation:
PT.12.1.3 **PS / SS**	The PAPT facility takes appropriate measures to control potential exposure from an infected source.	CPSA[1] – 3.1, 6.1.2, 6.4,9.1.1 GOA[1] – 5 GOC[4] – A.III Guidance: Barrier paper/sheets alone are not an effective barrier to microorganisms/ contamination.	Are there policies and procedures in place to manage individuals who present with a known infectious disease that are consistent with the local health authorities? If individuals present with an infectious disease, are there additional precautions in place that are based on the mode of transmission, including: • airborne? • droplet? • contact? Does the PAPT facility have an outbreak policy?

#	Standard	Reference	Assessment of Compliance
			Are source control measures employed, including: • appropriate spatial separation of patients and visitors in clinical and waiting areas? • respiratory hygiene signage, patient education and provision of materials? • hand hygiene? • aerosol reduction strategies? Is the treatment bed/chair cleaned and disinfected between each patient? Where a barrier sheet/paper is utilized: • is the treatment bed/chair cleaned and disinfected between each patient? • is the barrier sheet/paper changed between each patient?
			C ☐ P ☐ E ☐ N ☐ N/A ☐
			Observation:
PAPT.12.1.4 SS	There are policies and procedures for the proper use of personal protective equipment (PPE).	CLSI[3] QMS01 –3.3.2.1 CPSA[1] – G.3.2, G.3.3 CSA[2] Z314-18 – 6.7.2, 6.7.4, Annex D GOA[1] – 3, 5, 7, App.2 GOC[4] – A.III.A.3, A.III.C.2 ISQua[1] – 4.8 ISO[4] 15190-20 – 15 PHO[1] PHO[2]	Is there evidence that all PAPT facility personnel are appropriately trained on the proper: • selection and use of PPE? • donning and doffing of PPE? Is there evidence a risk assessment related to the use of PPE has been completed? Is appropriate PPE available and provided to individuals when and where required, including: • gowns? • disposable plastic aprons and/or fluid-resistant gowns? • gloves (sterile, non-sterile and latex free)?

#	Standard	Reference	Assessment of Compliance
		WHO[2] – 3.6, 4.6.5	• protective eyewear (e.g., goggles/safety glasses/face shields)? • masks? • hair coverings? Is PPE: • appropriate to the level of risk? • considerate of user safety and comfort? • stored in designated areas? • changed at appropriate intervals to ensure cleanliness / infection prevention? • changed between patients? • changed immediately when contaminated with hazardous materials? • if reusable, designated to specific personnel and appropriately cleaned and disinfected between use? • if disposable, appropriately discarded after use? • removed before leaving the facility? • used when handling contaminated medical devices? Is contaminated protective clothing: • placed and transported in appropriately identified bags / containers that prevent leakage? • appropriately cleaned to ensure chemical and biological decontamination? Are approved glasses or goggles, face shields, masks or other protective eye and face protection used: • if there is a splash hazard? • when handling hazardous materials? • when performing aerosol-generating procedures? • for patient interactions involving activities likely to generate coughing, splashes or sprays of blood, body fluids, secretions or excretions?

#	Standard	Reference	Assessment of Compliance
			Are all of the following glove usage protocols in place where applicable: • changed between patient contacts? • inspected for integrity leakage before using? • worn to completely cover the hands and wrists and, where appropriate, overlap the gown or coat sleeve? • replaced if torn, damaged, or if internal contamination is suspected? • removed and properly disposed of when the task is completed or interrupted? • removed before handling non-contaminated items/resources (e.g., reference materials, telephones, keyboards, etc.)? Is comfort, fit, flexibility, grip, abrasion resistance, puncture resistance and tear resistance assessed prior to selection of gloves? Are un-powdered gloves and/or alternative materials / supplies provided for: • workers who suffer from allergies and other reactions? • use when working with latex sensitive patients? Are respiratory protection devices (e.g., masks, personal respirators) provided where applicable to the scope of service to prevent the inhalation of air contaminated with airborne vectors, harmful dusts, gases, fumes, and vapors? Does the respiratory protection program specify: where the use of respiratory protection devices is required

#	Standard	Reference	Assessment of Compliance
			• fit-testing is utilized to provide personnel with the required protection? • protective measures for personnel who are unable to form a tight facial seal when wearing a respirator? • personnel perform a fit / seal check each time they put on a respirator? Is there evidence of individual-fit testing for facility personnel using respiratory protection devices? Is there evidence of facility personnel training and instructions on the indications for and proper use of respiratory protection devices? Is there evidence of workplace monitoring, medical evaluation, and supervision to ensure the respiratory protection devices are being used correctly and judiciously?
			C ☐ P ☐ E ☐ N ☐ N/A ☐
			Observation:
PAPT.12.1.5 PS / SS	The PAPT facility ensures hand hygiene policies and procedures are implemented for the protection of all individuals who enter the facility.	CPSA[1] – G.2.0 CSA[1] Z8000 – 7.5.12 CSA[2] Z314-18 – 6.6.2, 6.7.1.2, 6.7.2.1.6 GOA[1] – 5, 7	Is hand hygiene performed: • before gloves are donned and after gloves are removed? • before and after contact with a patient or their environment? • after contact with blood, body fluids or contaminated surfaces? • after removing PPE? • before leaving the facility? • before eating or smoking? • after personal body functions?

#	Standard	Reference	Assessment of Compliance
		GOC[4] – A.III.C.2 ISQua[1] – 4.6, 4.7 PHO[2] – p.9 PHO[3] WHO[1]	Is hand hygiene performed according to recommended procedures such as: • soap and water used according to recommended procedures? • using alcohol-based hand rub used according to recommended procedures? Is hand hygiene performed with an antiseptic agent: • when there is visible soiling? • before performing invasive procedures? • before contact with immune-compromised patients? • before contact with patients with extensive skin damage? • before and after direct contact with patients who have antimicrobial-resistant infections? Do alcohol-based hand-cleansing products contain 60-90% alcohol? Is the use of antimicrobial soap discouraged for routine hand hygiene use? Is there a policy regarding artificial fingernails and nail polish for personnel directly involved with patient contact or equipment cleaning? Are all facility personnel educated and trained on the hand hygiene policies, processes and procedures?
			C ☐ P ☐ E ☐ N ☐ N/A ☐
			Observation:

#	Standard	Reference	Assessment of Compliance
PAPT.12.2 IPC – Equipment/Device Cleaning			
PAPT.12.2.1 PS	The PAPT facility ensures that sterility of all sterile equipment and supplies is maintained.	CPSA[1] – G.5.6 CSA[1] Z8000 – 9.9.3.4.4 CSA[2] Z314-18 – 10.2.5, 14.1.3, 16.8.8, 17 GOA[5] – 8, 9	Are sterile items handled and transported: • in compliance with manufacturers' specifications? • separately from soiled / contaminated items? Is sterility maintained until point-of-use? If contamination of a commercial product sold as sterile is suspected: • are items from suspected lots quarantined? • are lots numbers recorded? • is prompt notification provided to: • infection control? • Health Canada? • provincial health authorities? • manufacturer? Is there an appropriate dedicated storage area for sterile equipment / supplies that protects from: • moisture? • dirt, dust or vermin? • damage to packages? C ☐ P ☐ E ☐ N ☐ N/A ☐ Observation:
PAPT.12.3 IPC – Housekeeping			
PAPT.12.3.1 PS / SS	There is an environmental cleaning program that includes assurance that all environmental surfaces, non-critical patient care items, all equipment and work	CPSA[1] – G.5.2, G.6.3 CSA[1] Z8000 -10.2 CSA[2] Z314-18 – 6.7.1.2, 10.5	Does the environmental cleaning program specify: • responsibility and accountability for routine cleaning and disinfection of patient care equipment and environment? • detailed procedures, including required frequency and documentation?

#	Standard	Reference	Assessment of Compliance
	areas are appropriately cleaned and disinfected at defined regular intervals, or as required.	GOA[1] – 5 GOC[4] – A.III.B.3 PHO[1] PHO[2] – p.18	• provision of services and supervision by facility personnel trained in effective methods of cleaning and the importance of their work? • monitoring of adherence to procedures? • assessment of the cleanliness of the facility at defined frequencies? • processes to address any identified issues with the cleanliness of the facility? Is routine cleaning of environmental surfaces, noncritical patient care items, work areas and equipment sufficient to keep surfaces clean and dust free? Are work surfaces decontaminated: • at least daily and when visibly soiled? • whenever spills or other contamination has occurred? • using low or intermediate level disinfectant? Can all PAPT facility electronic equipment (e.g., keypad, mouse, monitoring screens, CPU stack, telephones,) be easily cleaned and disinfected? Is wet mopping used? Are mop heads changed after each use? Are cleaning and disinfecting agents mixed and used according to manufacturers' recommendations? Are tools used for cleaning and disinfecting cleaned and dried between uses?
			C ☐ P ☐ E ☐ N ☐ N/A ☐
			Observation:

#	Standard	Reference	Assessment of Compliance
PAPT.12.3.2	PAPT facility housekeeping personnel are trained in the use of routine practices and additional precautions when performing environmental cleaning.	CSA[2] Z314.18 – 6.7.1.2 GOC[4] – A.III.B.3 PHO[1] – 4	Is there evidence that all housekeeping personnel are trained in the use of routine practices and additional precautions when performing environmental cleaning including: • hand hygiene? • use of PPE where indicated? • standardized cleaning protocols? C ☐ P ☐ E ☐ N ☐ N/A ☐ Observation:
PAPT.12.3.3	The PAPT facility stores cleaning supplies in appropriately secured areas.	CSA[1] Z8000 – 7.6.3 PHO[1] – 5.5.1, 6.2	Are cleaning supplies stored in appropriately secured areas? Are storage areas cleaned at a defined frequency? C ☐ P ☐ E ☐ N ☐ N/A ☐ Observation:
PAPT.12.3.4	The PAPT facility ensures laundering of linen / washable goods is done according to IPC best practices and manufacturers' specifications.	CPSA[1] - G.6.4 GOC[4] – A.III.B.3 GOC[5] – p.34-36 PHO[1] – 7.1	Are linens laundered according to specifications of the manufacturers of the laundry machinery, laundry chemicals and textiles? Is soiled linen placed in containers and handled as little as possible? If laundry chutes are used, are they designed, maintained and used in a manner to minimize dispersion of aerosols from contaminated laundry? Is appropriate PPE worn when sorting dirty linen, or when appropriate?

#	Standard	Reference	Assessment of Compliance
			Is clean linen covered, stored and transported in a manner to prevent contamination?
			C ☐ P ☐ E ☐ N ☐ N/A ☐
			Observation:

TERMS AND DEFINITIONS	
Accreditation	The public recognition of quality achievement by a healthcare organization as demonstrated through an independent external peer comparison of the organization's performance against current "best practices"
Adverse event	An unanticipated event involving risk to patients or staff that has the potential to ultimately result in harm
Aerosol	Respirable particles dispersed in a dust, gas, smoke, vapor, or fog that can be retained in the lungs
Audit	A systematic evaluation to determine whether actual activities comply with planned activities, are implemented effectively, and achieve objectives. Types of audits/assessments include external, internal, peer review, and self
Calibration	The process of testing and adjustment of an instrument, kit, or test system to provide a known relationship between the measurement response and the value of the substance measured by the test procedure
Competence	An individual's demonstrated ability to apply knowledge and skills needed to perform their job tasks and responsibilities
Continuous Improvement	Recurring activity to increase the ability to fulfill requirements and increase the effectiveness and efficiency of activities and processes
Corrective action	Actions taken to address the root cause(s) of an existing non-conformance or other undesirable situation in order to reduce or eliminate recurrence
Deviation	A departure from policies, processes, procedures, applicable regulations, standards, or specifications
Device	Any reagent, reagent product, kit, instrument, apparatus, equipment or related product, whether used alone or in combination, intended by the manufacturer to be distributed for use in vitro for the examination of human samples
Document	Information and its supporting medium; this may be paper-based or electronic
Examination	Set of operations having the object of determining the value or characteristics of a property; test, analytic or measurement procedure
Examination procedure	Set of operations, described specifically, used in the performance of treatments according to a given method
Facility	The individual psychotherapy location / service
Hazardous waste	Any waste that is potentially flammable, combustible, ignitable, corrosive, toxic, reactive, or injurious to people or the environment

Health Level-7 (HL7)	Refers to a set of international standards for transfer of clinical and administrative data between software applications used by various healthcare providers
Maintenance	Those activities that prolong the life of an instrument or minimize breakdowns or mechanical malfunctions. Examples include cleaning, changing parts, fluids, tubing, lubrication, electronic checks, etc.
Nonconformance	Failure to fulfill a requirement, as defined by defined by stakeholders, practice standards, regulatory agencies, or law
Organization	Overarching healthcare structure (e.g. hospital, large operational group of multiple facilities) or entity (Provincial Health System body)
Personal protective equipment (PPE)	Material, including clothing, used to prevent contamination of a person by chemical or biological matter
PHAC	Public Health Agency of Canada
Plan	Written account of intended future course of action aimed at achieving specific goal(s) or objective(s) within a specific timeframe and explains in detail what needs to be done, when, how, and by whom
Policy	A documented statement of overall intentions and directions defined by those in the organization and endorsed by management
Post-examination	Policies, processes and procedures following the examination including systematic review, formatting and interpretation, authorization for release, reporting and transmission of the results and storage of the samples and records of the laboratory treatments
Pre-examination	Policies, processes and procedures starting from the request for examination and including the examination request, preparation of the patient and ending when the examination procedure begins
Preventive action	Action to eliminate the cause of a potential nonconformity or any other undesirable potential situation.
Procedure	Specified way to carry out an activity of a process; a set of instructions that describe the stepwise actions taken to complete activities identified in processes
Process	Set of interrelated or interacting activities that transform inputs into outputs
Program	Group of interrelated activities managed in a way to obtain results that are not achievable if they are attempted individually; e.g.: safety program, quality control program, training program
Psychedelic-assisted psychotherapy	Services to treat a psychiatric disorder with psychotherapy and one or more designated psychedelic drugs, whether or not the administration of the drug and the psychotherapy are provided on the same day or on different days.

Psychedelic drug	A substance of combination of substances that is or contains any one of the following, whether synthesized or naturally occurring, and includes racemic mixtures, enantiomers and any mixtures of enantiomers, or any compound that, through metabolism in the recipient , yields metabolites that are drugs with equivalent functional effects including and any salt thereof: • 3,4 methlyenedioxymethamphetamine (MDMA) and any salt thereof • Ketamine (2-(2-chlorophenyl)-2-(methylamino) cyclohexanone), including in racemic or specific enantiomer form (R,S-ketamine, S-ketamine (Esketamine) and R-ketamine (Arketamine) and any salt thereof • Lysergic acid diethylamide (LSD) (N, N-diethyllysergamide) and any salt thereof • Mescaline (3,4,5-trimethoxybenzeneethamine) and any salt thereof • N,N-Dimethyltryptamine (DMT) (3-[(2-dimethylamino) ethyl]indole and any salt thereof • 5 methoxy DMT and any salt thereof • Psilocin (3-[2-(dimethylamino)ethyl]-4–hydroxyindole) and any salt thereof • Psilocybin (3-[2-(dimethylamino)ethyl]-4-phosphoryloxyindole) and any salt thereof
Protocol	A detailed plan of a scientific or laboratory procedure; a detailed written set of instructions.
Quality assurance	Part of quality management focused on providing confidence that quality requirements will be fulfilled; quality assurance is also described as a planned and systematic set of quality activities.
Quality Control	Part of quality management focused on fulfilling quality requirements; the set of mechanisms, processes, and procedures designed to monitor the measuring system to ensure the results are reliable for the intended clinical use; this includes the operational techniques and activities that are used to fulfill requirements for quality; in clinical laboratory testing, QC includes the procedures intended to monitor the performance of a test procedure to ensure reliable results.
Quality Improvement	Part of quality management focused on increasing the ability to fulfill quality requirements; quality improvement is also described as the continuous process of seeking opportunities for system improvement based on the planned processes of monitoring, interpretation, implementation of required action for change, and re-monitoring.
Quality Indicators	Observations, statistics, or data defined by the organization or service that typify the performance of a given work process and provide evidence that the organization or service is meeting its quality intentions.
Quality Management System (QMS)	A set of interrelated or interacting elements that organizations use to direct and control how quality policies are implemented and quality objectives are achieved. A process based QMS is a network of many interrelated and interconnected processes (elements).

Quality policy	Overall intentions and direction of an organization related to quality as formally expressed by executive management.
Record	Data and information captured in writing or electronically that provide objective evidence of activities performed, observations made, or results achieved.
Risk	Combination of the probability of occurrence of harm and the severity of that harm.
Risk assessment	Overall process comprising a risk analysis and a risk evaluation.
Traceability	The ability to follow the history of a product or service from source to final distribution or disposition using existing process records.
Treatment Resistant Psychiatric Disorder	Treatment Resistant Psychiatric Disorder- Treatment that has not responded to at least two treatments during the index episode.
Spaulding's Classification	The three categories are critical, semi-critical, or noncritical. The system also established three levels of germicidal activity for disinfection (high, intermediate, and low).
Users	Referring clinical health professionals and patients
Validate	Confirmation, through the provision of objective evidence, that the requirements for the specific intended use or application have been fulfilled. Validation is performed by the manufacturer or by the laboratory, for those processes that have been developed solely by the laboratory or for those processes that have been modified from that published by the original manufacturer or process developer.
Verify	Confirmation, through the provision of objective evidence, that specified requirements have been fulfilled. Verification is the act of determining whether products and services conform to specific requirements. It is a means by which previously established performance specifications from validations performed by the manufacturer, other developers, or this laboratory are challenged by following the laboratory's defined process to confirm acceptable repeatable performance.
WHMIS	The Workplace Hazardous Materials Information System (WHMIS) is Canada's national hazard communication standard. The key elements of the system are hazard classification, cautionary labelling of containers, the provision of safety data sheets (SDSs) and worker education and training programs.

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APPENDIX A - REQUIREMENTS FOR ALBERTA PSYCHEDELIC-ASSISTED PSYCHOTHERAPY FACILITIES

A.1 Medical Director Requirements: (Standard Reference: PAPT.1.1.9)

The Medical Director must review and sign the College of Physicians & Surgeons of Alberta (CPSA) *Medical Director Roles and Responsibilities Acknowledgement* document:

- Prior to a 4 year assessment
- When there is a change to Medical Director
- Prior to opening a new facility

Medical Directors in the role are fully accountable in accordance with the signed attestation form(s) until such time as the CPSA receives formal notification / signed Attestation Form from a new medical director acceptable to the CPSA.

Medical Directors must be appropriately credentialed and compliant with the CPSA Standard of Practice regarding Practicing Outside of Conventional Medicine and Part 3 of the Mental Health Services Protection Regulation (AR114/2021) and associated service standards and;

- be an fellow of the Royal College of Physicians and Surgeons of Canada (RCPSC) in Psychiatry or;
- recognized as a specialist in Psychiatry by the CPSA registration department.

A.2 Clinical Personnel Requirements for Psychedelic-Assisted Psychotherapy (Standard Reference PAPT.1.1.6)

Facility Medical Directors are responsible for determining and maintaining the appropriate staff mix required with consideration to the number, complexity and type of treatment services offered. At a minimum personnel must:

- be a registered in good standing with their regulatory body and;
- have prior experience caring for patients with mental health disorders

Clinical personnel performing the administration of psychedelic drugs and the monitoring, treatment and care required must be a physician or another individual approved by the medical director and may also include (but are not limited to):

(i) Advance Care Paramedics,
(ii) Registered Nurses,
(iii) Registered Psychiatric Nurses, and
(iv) Licensed Practical Nurses.

Clinical personnel providing psychotherapy to a patient as part of psychedelic assisted psychotherapy must be individuals approved by the medical director and:

(a) be authorized to perform the restricted activity of psychosocial intervention under section 2(1)(p) of Schedule 7.1 to the Government Organization Act and be a regulated member of one of the following colleges under the *Health Professions Act*:
(i) Alberta College of Occupational Therapists;
(ii) College of Physicians and Surgeons of Alberta;

(iii) College of Alberta Psychologists;
(iv) College of Registered Nurses of Alberta;
(v) College of Registered Psychiatric Nurses of Alberta;
(vi) Alberta College of Social Workers,

(b) if not a psychiatrist or clinical psychologist,
(i) have a clinically related master's or doctoral degree,
or
(ii) have, in the assessment of the medical director, a minimum of 5 years' experience in treating post-traumatic stress disorder, mood disorders or related disorders with evidence-based psychotherapy,
and

(c) have the training and experience respecting psychedelic assisted psychotherapy or psychological counselling required by the medical director

A.3 Authorized Requestors: (Standard Reference : PAPT.6.2.1)

Registered physicians may refer directly to the facility.

A.4 CPSA Reportable Incidents requirements: (Standard Reference : PAPT 2.7.2)

Reportable incidents, as defined below, are also known as "significant mishaps" in the Health Care Protection Regulations of Alberta.

Notification Responsibilities:

• Medical Examiner

In the event of a death within the facility, the Medical Examiner will be notified prior to moving the body or removal of any lines or tubes from the body.

• Registrar- College of Physicians and Surgeons of Alberta

The Medical Director of a designated PAPT facility will ensure that full particulars of a significant mishap of which the director has knowledge are reported to the College of Physicians and Surgeons of Alberta (CPSA) Registrar/Accreditation Department not later than 24 hours (within one working day) after the discovery of any significant mishap/reportable incident including:

- Deaths within the facility or within 10 days of the treatment
- Transfers from the facility to a hospital regardless of whether or not the patient was admitted, e.g. treated in the ER and released

- Unexpected admission to hospital within 10 days of administration of a psychedelic drug in the context of psychotherapy
- Deterioration in the patient condition following the administration of a psychedelic drug in the context of psychotherapy
- Clusters of any infections among patients treated in the facility

Note: When notified of an unexpected admission of a patient to hospital within 10 days of the treatment in the facility, the Registrar may determine that written notification is not required when the reason given for admission to hospital is not related to the services provided in the facility.

• Within two weeks of notification, the following will be submitted to the College of Physicians & Surgeons of Alberta (CPSA):

- Completed reportable incident form signed by the Medical Director and the physician most involved in the case
- Copy of the facility clinical record

The Registrar will review the circumstances with the Medical Director and may consult with other practitioners to determine the risk of harm to patients. If necessary, the Registrar may suspend the accreditation of any facility on a suspicion of continuing risk. An investigation of the facility will then be initiated as soon as is reasonably possible.

Name:	
Title:	
Facility/Organization:	
Phone #:	
Email:	
Date:	

Name of Standards Document:	
Standard # or Standard Section #:	
State suggested revision:	
Specify rationale for revision:	
Indicate appropriate reference to substantiate request: (attach pertinent documentation)	

For submission e-mail to: papt@cpsa.ab.ca