

Competency Assessment according to FACT-JACIE Standards

An introductory guide on implementing a competency assessment system for Transplant Program personnel



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ICMED approach

FACT-JACIE requirements for competency assessment

The regulatory framework

FACT-JACIE standards require each transplant program to implement a structured competency assessment system for personnel. This requirement applies to all professional figures involved in collection, processing, and administration of cells and tissues.

Competency assessment must be documented, periodic, and based on objective criteria. The system must ensure that each operator maintains the technical skills and knowledge necessary to perform their duties safely.

- Initial assessment before assignment of operational responsibilities
- Periodic reassessments according to defined frequencies
- Complete documentation of all assessments performed
- Training plans to address identified gaps

Specific standards and areas of application

FACT-JACIE 8th Edition standards define specific requirements for different areas of the transplant program. Section C (Clinical Program) requires documented clinical competencies for physicians and nurses. Sections D (Collection Facility) and E (Processing Facility) specify technical competencies for collection and laboratory operators.

Each operational area must identify core competencies required for specific roles. Assessment must cover theoretical knowledge, practical skills, and professional behaviors relevant to patient safety.

- Clinical area: patient management, toxicity, complications
- Collection area: apheresis procedures, donor management
- Processing area: cell manipulation techniques, quality control
- Cryopreservation area: freezing and thawing procedures

How to design an effective competency assessment system

Identifying core competencies

The first step is to identify specific competencies required for each role in the transplant program. This process requires involvement of clinical and technical experts to define essential knowledge, skills, and behaviors.

Competencies must be described clearly and measurably, using specific action verbs. For each competency, expected performance levels and objective assessment criteria must be defined to determine achievement of the required standard.

- Analysis of tasks and responsibilities for each role
- Definition of technical, cross-functional, and behavioral competencies
- Articulation in progressive levels of operational autonomy

An effective competency assessment system represents not only a regulatory requirement, but an opportunity for continuous professional growth. When well designed, the system provides personnel with constructive feedback, identifies areas for improvement and recognizes

Methods and tools for competency assessment

Assessment techniques

Competency assessment requires a multimodal approach combining different methodologies. Direct field observation allows evaluation of practical skills in real context. Knowledge tests verify theoretical understanding of fundamental concepts.

Simulations and clinical cases assess problem-solving and decision-making capabilities. Review of documentation produced by the operator provides evidence of work quality. Using standardized checklists is essential to ensure objectivity and reproducibility of assessments.

- Direct observation with structured checklists
- Written tests for theoretical knowledge assessment
- Practical simulations of critical procedures
- Documentation and records audit

Document management and traceability

An effective system requires structured document management. Each assessment must be recorded with date, assessor, method used, and outcome. Documentation must include individual development plans to manage identified gaps.

Traceability of competencies over time is essential to demonstrate maintenance of qualification. Dedicated databases or computerized systems facilitate monitoring of deadlines and planning of periodic reassessments, ensuring continuous compliance with FACT-JACIE standards.

- Individual files with complete assessment history
- Updated competency matrix for all personnel
- Alert system for deadlines and scheduled reassessments

ICMED support for competency assessment

Specialized consulting and digital tools

ICMED S.r.l. supports transplant programs in designing and implementing competency assessment systems compliant with FACT-JACIE standards. Thanks to experience gained in over 100 healthcare facilities, we provide personalized consulting to identify core competencies specific to each organizational context.

The IAAPP platform, ISO 27001:2024 certified, offers dedicated modules for competency document management, with automatic deadline tracking functionality and report generation for audits. The system integrates customizable assessment checklists and dynamic competency matrices for efficient and compliant management.

- Gap analysis and tailored system design
- Checklist templates and operating procedures
- Support in preparation for FACT-JACIE audits

ECM accredited training

As an AGENAS accredited ECM provider (ID 7158), ICMED delivers specialized courses on competency assessment for transplant programs. Our training paths cover regulatory aspects, assessment methodologies, and document management, with ECM credits for all healthcare professions.

Vincenzo Iaconianni, founder of ICMED with over 20 years of experience as a healthcare quality consultant, coordinates training programs ensuring content updated to the latest editions of international standards. We have trained over 500 professionals supporting their professional growth in the field of accreditation and quality.

- ECM courses on competency assessment and FACT-JACIE standards
- Practical sessions with case studies and exercises
- Downloadable educational materials and operational resources

LEARN MORE

Want to explore this topic further?

ICMED offers accredited ECM training, specialized consulting, and the IAAPP platform for complete quality system management.

Consulting

Accreditations, quality systems,
regulatory compliance

ECM Training

AGENAS accredited courses
(Provider ID 7158)

IAAPP

AI platform for quality
management — ISO/IEC 27001

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Magazine

Quarterly scientific
publication (ISSN 3103-1943)



Editore ICMED S.r.l.

ICMED Magazine — ISSN 3103-1943

ISO 9001 — Quality Management System

ISO/IEC 27001:2024 — Information Security

UNI/PdR 125:2022 — Gender Equality

ECM Provider AGENAS — ID 7158

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