

# Description of the ISO 9001/2000 certification process in the parenteral nutrition area

M. T. Miana Mena, S. Fontanals Martínez, Y. López Púa<sup>1</sup>, E. López Suñé, C. Codina Jané, J. Ribas Sala

*Pharmacy Service. <sup>1</sup>Quality Control Unit - Evaluation, Support and Prevention Unit.  
Hospital Clínic i Provincial. Barcelona, Spain*

## Resumen

**Objetivo:** Garantizar la calidad y seguridad e incrementar la satisfacción del usuario ha llevado a organizaciones del ámbito sanitario a integrar un sistema de gestión de calidad en su estructura. Este trabajo describe el proceso de implantación de la norma UNE-EN-ISO-9001/2000 en el área de nutrición parenteral.

**Método:** Un grupo multidisciplinar definió el alcance de la norma, centrándose en transcripción, acondicionamiento, dispensación y control microbiológico.

**Resultados:** Se elaboró un procedimiento detallando secuencialmente los circuitos y actividades asociadas, el personal responsable y las pautas de actuación a seguir. Se establecieron indicadores de calidad y de actividad.

**Conclusiones:** Este proceso ha permitido establecer un sistema normalizado cuyos procesos están perfectamente descritos y documentados, logrando la trazabilidad y supervisión de las fases. Al no disponer de histórico de los datos actualmente obtenidos, no es posible establecer una comparación directa; por tanto, deberá analizarse su evolución en un futuro.

**Palabras clave:** Servicio de farmacia. Nutrición parenteral. Certificación. Norma ISO-9001/2000. Indicadores de calidad.

---

*Miana Mena MT, Fontanals Martínez S, López Púa Y, López Suñé E, Codina Jané C, Ribas Sala J. Description of the ISO 9001/2000 certification process in the parenteral nutrition area. Farm Hosp 2007; 31: 370-374.*

Received: 19-03-2007  
Accepted: 31-10-2007

Correspondence: María Teresa Miana Mena. Servicio de Farmacia. Hospital Clínic i Provincial. C/ Villarroel, 170. Escalera 8. Sótano. 08036 Barcelona, Spain. e-mail: mtmiana@clinic.ub.es

## Summary

**Objective:** In order to guarantee quality and safety and to increase user satisfaction, healthcare organisations have integrated quality management systems into their structures. This study describes the process for introducing the UNE-EN-ISO-9001/2000 standard in the parenteral nutrition area.

**Method:** A multidisciplinary group established the scope of the standard, focusing on transcription, preparation, dispensation and microbiological control.

**Results:** A detailed procedure describing the sequences of circuits and associated activities, the responsible staff and the action guidelines to be followed was established. Quality and activity markers were also established.

**Conclusions:** This process has enabled a standard system to be implemented, with its operation perfectly described and documented, allowing its stages to be traceable and supervised. As there is no record of the data obtained beforehand, no direct comparison can be made; its evolution must therefore be analysed in the future.

**Key words:** Hospital pharmacy service. Parenteral nutrition. Certification. ISO-9001/2000. Markers.

---

## INTRODUCTION

An increasing number of healthcare organisations, among which pharmacy services<sup>1-3</sup> (PS) are included, are deciding to implement a *quality management system* (QMS) in order to show their ability to provide services and/or prepare products.

The ISO standard (International Organization for Standardization) is intended to manage/ensure the quality of systems, in contrast to other models that may be more

focused on the concept of total<sup>4</sup> quality such as the EFQM (European Foundation for Quality Management).

Within this context, the PS considered a QMS according to the international quality model UNE-EN ISO 9001:2000, to improve circuits and the quality of the final products. This model promotes process management<sup>5</sup> and requires a clear identification and definition of the services to be provided according to the customers' needs and the processes developed.

It was decided to apply this QMS in the following areas: Purchase, storage, dispensation and distribution of drugs, sample management and assessment of clinical trials protocols, drug evaluation and information, preparation and repackaging, pharmaceutical care and teaching.

As an integral part of the drugs repackaging and preparation block, the adult parenteral nutrition (PN) preparation area was included.

The rough number of adult PN carried out annually in the hospital is 9,000 preparations. Both the composition and the subsequent follow up of total (TPN) or peripheral (PPN) parenteral nutrition are the responsibility of pharmacists or endocrinologists.

The PN is requested by the doctor through an electronic interconsultation. Following this, the pharmacist or the endocrinologist accesses the medical history via the computer system to consult reports, analysis, tests, etc.

The treatment, vital signs and diet are checked in the hospital ward. The composition of the PN is based on this data.

All TPN notified 24 hours in advance are ordered from an external company, which supplies it the following day. Otherwise, they are prepared by the PS.

The purpose of this work is to describe the process of integrating the UNE-EN ISO 9001:2000 standard into the PN area.

## METHOD

In the year 2003 the process of introducing the QMS according to the UNE-EN-ISO-9001/2000 standard began. The areas into which the standard would be integrated were defined and a plan was drawn up regarding how the process would be organised.

ISO 9001 standard requires documentation of the QMS<sup>6</sup>, so a quality and procedures manual giving details of the QMS and describing the staff's relationships and responsibilities was developed.

The aspects of the PN on which this process focused were: Data collecting and transcribing, standardising the preparation process (order in which the components are to be added<sup>7</sup>, packaging, labelling), dispensation and microbiological control.

For the purposes of this project, a working group was made up of a pharmacist and the area technicians, PS and hospital UASP (*Unitat d'avaluació, Suport i Prevenció*) quality managers, and external consulting company *Con-*

*sultors Politècnics Associats* (CPA) which managed and supervised the project.

Staff received specific training, by means of talks on quality management, the implementation process, the follow up and the certification by a QMS.

The proposals for changes in the processes or documents approved arising from daily observation of the circuits and/or the internal post-certification audits are *improvement plans* (IP). After they have been approved, a deadline is set for introducing the changes suggested. At the end of this time period, the centre's audit team checks these changes have been introduced.

## RESULTS

A procedure that is made up of processes was described; these processes were then subdivided into the activities developed in the PN area, as well as the work instructions or associated action guidelines.

All the activities were expressed in the documentary system by means of two *process mapping*: *Validation and follow up of PN* (Fig. 1) and *preparation of the PN*.

These set out the activities in each process, allowing them to be followed up and reproduced. The decisions, activities and staff responsible are set out in these flow diagrams in a sequential, well organised way.

The timing of the introduction process coincided partially with the setting up of the Spanish Royal Decree 175/2001, which involved the physical restructuring of pharmacotechnology and intravenous preparation sections. Consequently, instructions on clothing, hygiene and cleanliness were published jointly.

Table I shows the aspects subjected to the most changes in daily practice in the PN area.

On the other hand, objective and easily-obtained parameters were established in order to document, quantify and evaluate the processes, so-called markers<sup>8-11</sup>; which are assessed monthly by the PS quality manager. There are two different types of marker: Quality markers and activity markers.

Once the markers have been defined, their "quality standards"<sup>10,11</sup>, threshold values are set by the pharmacist in charge, to guarantee the quality of the product and for the purposes of comparing the values obtained in each period assessed (Table II).

It was decided, due to organisational and time constraints, to set the limit that would allow the desired quality of the work to be guaranteed at 25 PN preparations per day.

After obtaining all the quality system documentation and before the external audit was performed by the external certification company, internal audits were performed by the consulting company (CPA). The aim was to assess the viability of the certification process, determine the compliance with what was established and make the appropriate changes.

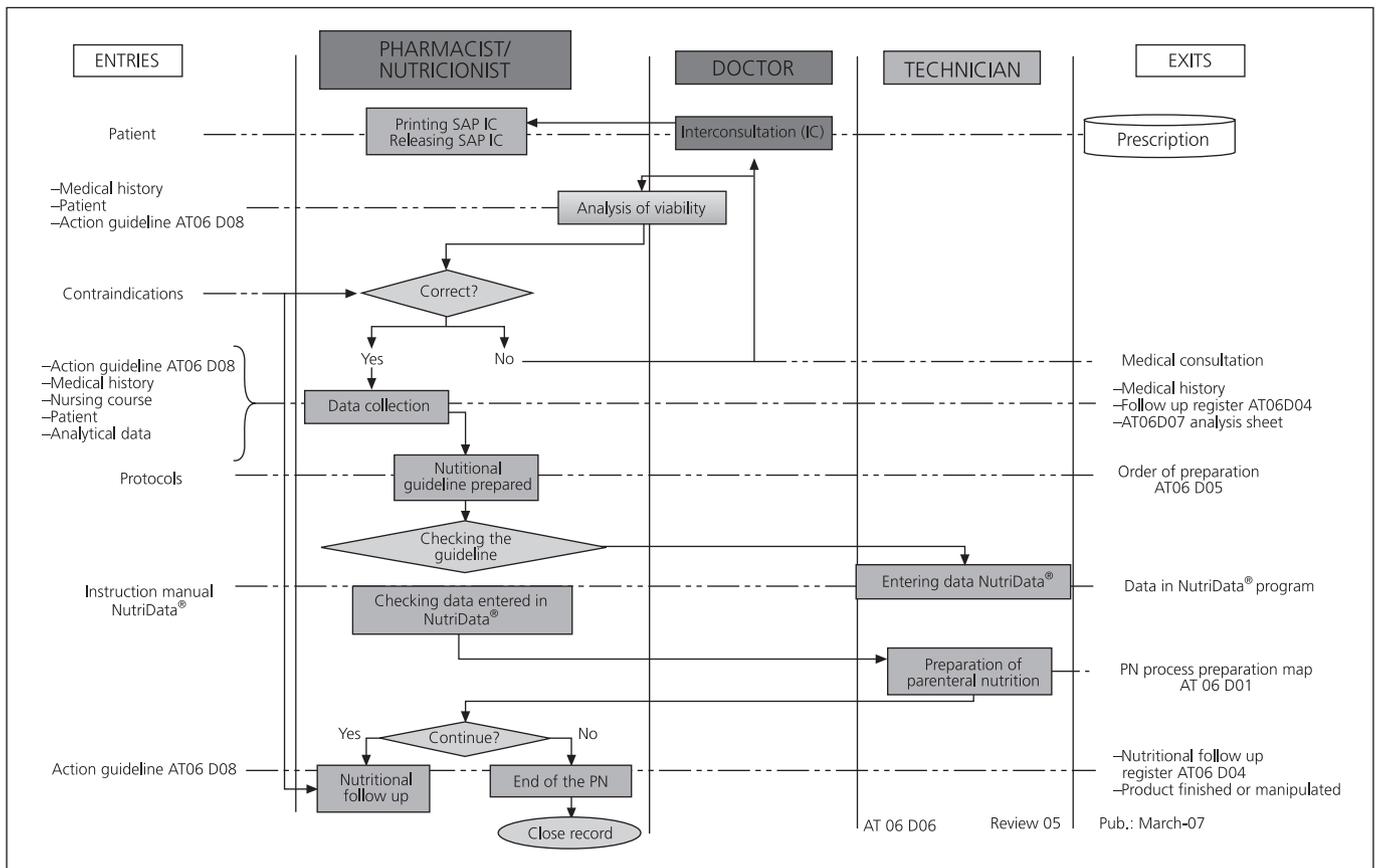


Fig. 1. Map of the validation and follow-up process of the parenteral nutrition.

**Table I.** Changes that have involved the certification to an ISO standard

Activity	Before ISO	After ISO	Consequences
Request for PN	Via telephone Verbal request in ward Prescription on treatment sheet Interconsultation	Interconsultation	Centralise request Avoid errors from PN request not been notified Register the request for PN in the patient's medical history
Transcription of nutritional guidelines to NutriData®	Pharmacist	Technician	The opportunity to spend more time following up patients Decrease in the accumulation of work during certain time periods Double check the composition written on the record
Checking the transcription	-	Review by the pharmacist	Detecting errors in registered data before preparation
Supply of PN by external company	-	The order is checked	Detecting incidences (too many or too few) regarding the number of PN supplied Registering who is doing the control
Staff involved in handling the PN	-	Register (signature) of the technician	Corroborates that each PN has been prepared, labelled and located correctly
The pharmacist checks the active PN	-	A daily list of the PN is made	Double check that all the PN have been prepared and the of those brought in
Creation of a document containing the guidelines for internal operation	-	This information is available in written format	Standardisation of the working system in the PN area Speeds up training of new staff

PN: Parenteral nutrition.

The PS underwent a certification audit during October 2005, performed by the company APPLUS+. Certification was obtained for the entire scope defined, which included the PN area, and it has now successfully passed its first follow-up audit.

The proposed IP in the post-certification period have emphasised diverse aspects such as: To advocate the use of logs containing the signature of staff members involved in each process, to create an action plan in case of obtaining a positive microbiological culture, to add a

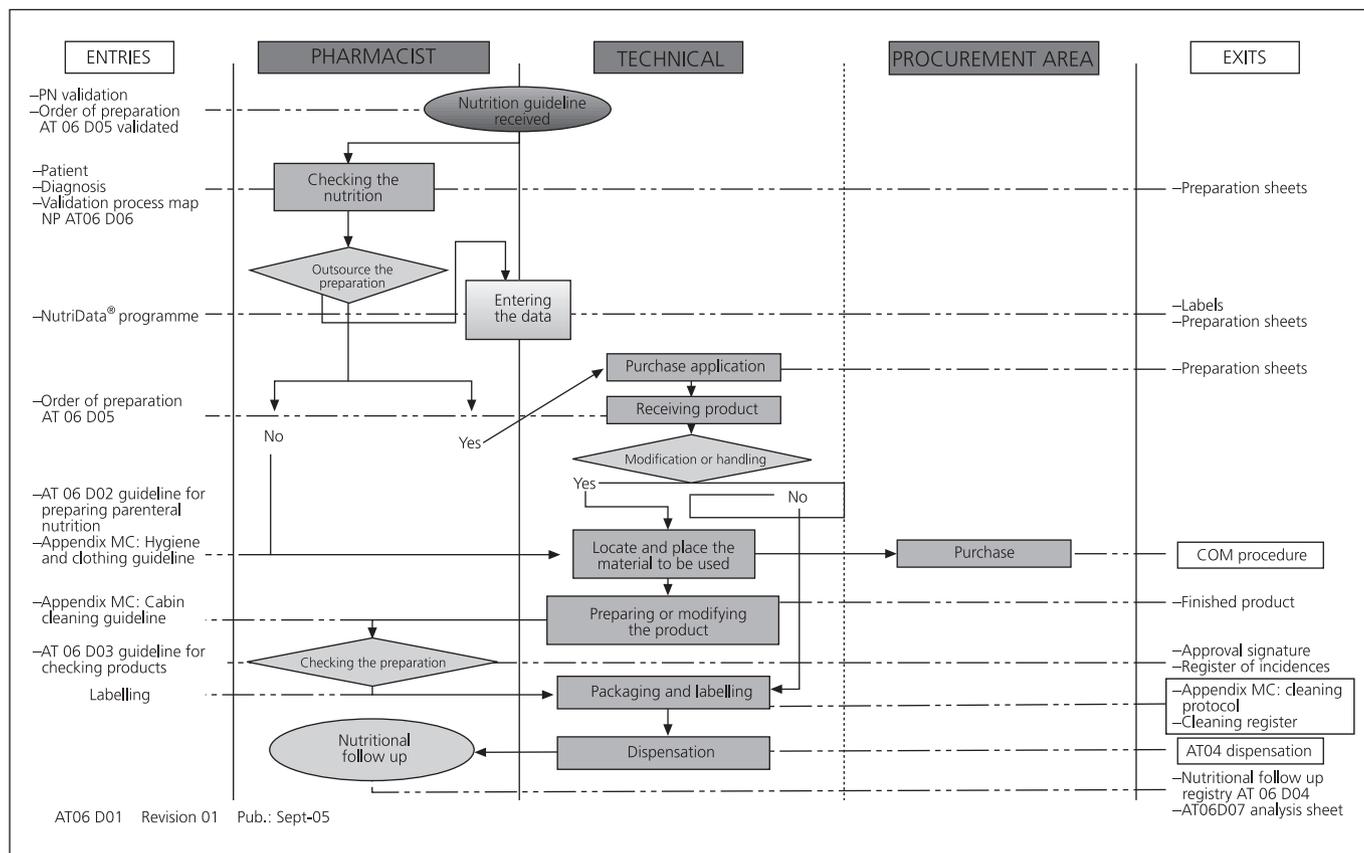


Fig. 2. Map of the process of preparing parenteral nutrition.

Table II. Standards set for each marker

(Monthly) marker	Standard established
<b>Quality markers</b>	
(contaminated PN/total No of TPN) x 100	< 0.5%
Preparation incidences <sup>a</sup>	< 5
(Preparation errors <sup>b</sup> /No of PN prepared) x 100	< 1%
(No of catheter-related bacteraemias TPN/No days catheterised with TPN) x 1,000 <sup>c</sup>	< 5/1,000
<b>Activity marker</b>	
No of days with more than 25 PN prepared	0
No of PN prepared/month	< 750

PN: parenteral nutrition; TPN: Total parenteral nutrition; PS: Pharmacy service; <sup>a</sup>Transcription, validation or labelling discrepancy in the PN detected before the product leaves the PS; <sup>b</sup>Transcription discrepancy, validation, labelling and dispensing the PN detected once the product has left the PS; <sup>c</sup>Information provided by the Bacteraemias Study Group by a clinical follow up of positive blood cultures, in collaboration with the PS.

$$\frac{\text{No of bacteraemias related to TPN catheters}}{\text{Total No of catheterised days with TPN}} \times 1,000$$

new activity marker and modify labelling of the PN. To date, these IP have been satisfactorily approved, and the documentation has been modified as established.

## DISCUSSION

Firstly, we would point out that that the UNE-EN-ISO-9001/2000 standard does not replace the law in force, but is a working framework for creating an optimum management system<sup>1</sup>.

With the introduction of this standard, there has been no essential change in working methods, rather a standardised system has been established, the most important processes of which are perfectly described and documented. Consequently, “everything accomplished must be written and everything written must be accomplished”<sup>2</sup>, facilitating the traceability of the process and optimising the supervision of all the stages involved.

The activity carried out, is quantified and the level of quality offered is ascertained by means of a monthly evaluation of the markers and by comparison with the standards. When higher values than those set as standards are obtained (from time to time or over time) this warns of the risk of not complying with the target quality requirements, and could justify the need for using more resources.

On the other hand, double-checking the different points in the process shown in table I facilitates the control of the product and decreases the possibility of error

in the fitting-out and dispensation. However, not having a log of incidences and errors before the introduction of the system, limits this work, because no direct comparison can be made and the changes cannot be quantified. In future works, we will compare the data from different periods after the certification is obtained and the adaptation of the protocols, indications of PN, pharmaceutical interventions, will be introduced.

The bases supporting the introduction of a QMS are the same as in any organisation<sup>5,11-13</sup>, although the decision to adapt procedures, markers and standards meeting their needs lies within each area. This, together with the fact that very few works on PN and certification have been published, and that it is a relatively new field, makes it difficult to compare centres.

One essential aspect in the introduction of a QMS is the commitment of the members of the company and the management of this task, which must become integrated

into the culture of the organisation and considered part of their daily work<sup>3</sup>. Participation and experience lead to new ideas that improve the processes<sup>6</sup>.

In short, the application of the ISO standards should be understood not as an action that takes place from time to time or as fixed criteria for action, but as a dynamic process that promotes the continuous improvement of the QMS.

## ACKNOWLEDGEMENTS

All the staff of the Pharmacy Service at Hospital Clínic i Provincial de Barcelona for their efforts and willingness to improve.

To Dr Jordi Massó for taking the initiative of this process and for his valuable contribution to the development of nutritional support at the Hospital Clínic i Provincial de Barcelona.

## References

1. Martínez Fernández-Llamazares C, Barrueco Fernández N, Jiménez Manzorro A, Lobato Matilla E, Caro González L, Sanjurjo Sáez M. Implementation of a quality plan (ISO 9001) in a hospital pharmacy service. *EJHP Practice* 2005; 2: 25-8.
2. Llodrá Ortolá V, Morey Riera MA, Perelló Roselló X, Vaquer Sunyer X. Acreditación de un Servicio de Farmacia según la norma ISO 9002. Experiencia en la Fundación Hospital Manacor. *Farm Hosp* 2001; 25: 229-39.
3. Traverso ML, Salamano MC, Pérez B, Botta CA, Sopranzetti V, Colautti M. Aplicación de un programa de Acreditación en Servicios de Farmacia hospitalarios en Argentina. *Farm Hosp* 2002; 26: 356-65.
4. Martínez García C, Roig Martínez M, Capdevila Prim C. Introducció a la Gestió de la Qualitat a la farmàcia: la norma ISO 9001:2000 i el model EFQM. *Circ Farm* 2006; 64: 98.
5. López-Revuelta K, Lorenzo S, Gruss E, Garrido MV, Moreno JA. Aplicación de la gestión por procesos en nefrología. Gestión del proceso hemodiálisis. *Nefrología* 2002; 22: 329-39.
6. Bonal J, Domínguez-Gil A, Gamundi MC, Napal V, editores. Gestión de la Calidad. Farmacia Hospitalaria. 3ª edición. 2002.
7. Mirtallo J, Canada T, Jonson D, Kumpf V. Safe practices for parenteral nutrition. *JPEN* 2004; 28: S39-70.
8. Font Noguera I, Cercós Lletí AC, Llopis Salvia P. Quality improvement in parenteral nutrition care. *Clin Nutr* 2001; 20: 83-91.
9. Llop JM, Badia MB, Tubau M. Selección de indicadores para una política de control de calidad a partir del seguimiento clínico. *Nutr Hosp* 1993; 8: 43-52.
10. Gottschlich M, editor. Quality performance improvement indicators and standards. USA: The Science and Practice of Nutrition Support; 2001.
11. Arenas MD, Álvarez U de F, Egea JJ, Gil MT, Amoedo ML, Millán I, et al. Impacto del seguimiento de indicadores de calidad de hemodiálisis. *Nefrología* 2004; 24: 261-75.
12. Geraedts HPA, Montenarie R, Van Rijk PP. The benefits of total quality management. *Comp Med Imag Graph* 2001; 25: 217-20.
13. Villalba R, Eisman D, Fornes G, Mesa A, De Torres P, Ariza MJ, et al. Implementation of a quality plan (ISO 9002) in a regional tissue bank. *Cell Tissue Bank* 2001; 2: 45-9.