

Special Reviews

The National Blood Centre ISO 9002 Certification*

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The quality system according to ISO 9002 has been implemented at the National Blood Centre (NBC) the Thai Red Cross Society since 1998. It was initiated by former director Prof. Chaivej Nuchprayoon and became one of the major policies of the present director Dr. Srivilai Tanprasert. The NBC ISO 9002 was certified by Management System Certification Institute (Thailand) on May 12, 2000. The scope of certification covers blood transfusion services in general, special services and production for the transfusion service as follows:-

1. Public relations / Donor recruitment / Donor registration & statistics/Administration
2. Blood collection
3. Blood processing / infectious marker screening/blood and blood product distribution
4. Blood component preparation/Plasma frac-

tionation

5. Hemapheresis for therapeutic purposes and donations
6. Autologous donation / Freezing of red blood cells and stem cells.
7. Red blood cells / platelet / white blood cells (HLA) / antigen / antibody detection/ crossmatching / DNA analysis for HLA / leuko - filtration / irradiation of blood components / detection of CD 34 marker and leukemia phenotyping
8. Blood bag production
9. Antiserum / standard cell production
10. Quality control of reagents and products

Initial training and follow-up

It was realized that besides the management, the cooperation and participation of all staff are vital and essential in setting up a quality system in any institute. The training needs and motivation regarding the quality system for the staff of National Blood Centre (NBC) were realized when the Blood Quality Program Training was held at NBC, Bangkok, Thailand in November 1998. The training program was under the direction of Ms Lucia M. Berte and Dr Ian F Young from Blood Department, International

*This issue is a report as a case Business study report to the Blood Department, International Federation of Red Cross and Red Crescent Societies, to share experience and knowledge which may be able to better assist the implementation the Quality Programme in other existing Red Cross Red Crescent Blood Service.

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Federation of Red Cross and Red Crescent Societies. The learning objectives were set out so that the participants should be able to list, describe and identify the main components of the Blood Quality Program. To create the documents needed e.g. management policies, quality processes and standard operating procedures and the design of a document control system for the blood facility were included. The training also emphasized the development of training guides, training design and documentation systems, as well as how to monitor, audit and evaluate the results of implementing a quality system. In addition, the training was focused on creating a plan and timeline for the facility's quality system implementation. Thirty staff, including Heads of sections and Assistants of the NBC, attended the IFRC Quality Training Program. Nine months later, a follow-up assessment of the progress was made on the quality system implementation that had been carried out during August 16-18, 1999 by Ms Lucia M. Burte. From her feedback sessions for all divisions we knew that we had made satisfactory progress, yet there were still many opportunities for further development in our quality system.

Financial requirements

The main financial requirements are for the calibration of the measuring and test equipment. Financial support is also required for the training process which has been carried out continuously for all levels of the staff. Additional financial requirements for a team of consultants and experts who assist in the work of the NBC should

be allowed for.

Personnel requirements

The personnel require updating in the quality process including other relevant subjects or technical training which enable them to work more efficiently and harmoniously.

Problems faced and solutions found

Consultancy and expertise

It was very fortunate for the NBC to have Mr Thatree Kaokitvirach as our ISO 9002 consultant which enabled us to go through the enormous documentation preparation that is required.

One of the most difficult tasks in most quality systems is control of inspection, measuring and testing equipment which includes control, calibration and maintenance inspection, measuring and testing equipment as well as software tests of products to the specified requirements. To cope with this problem, we created a working group consisting of the representatives from each division of NBC to cooperate and share their expertise and responsibility to cover all equipment used at NBC. We also sought outside cooperation and assistance from NGO's and governmental organizations especially for the training and various related services.

Needs arising during and after the exercise

The Director and the Management's support as well as the staff's participation and cooperation are needed at all times before, during and after the exercise of quality program. The campaign for quality system should be carried on internally in a pleasant atmosphere.

Time needed for the completion of the pro-

gram.

The quality process is considered an endless activity. However, to be certified for the ISO 9002 may take a period of 1-2 years depending on the size or activity of the organization including the good intentions of all personnel from the top to the bottom.

How to extend the Quality Program to the Regional level

As all of our blood and blood components including other products and services of NBC and Regional Blood Centres are issued to the hospitals, where the ISO quality system and/or hospital accreditation program are being launched currently, all raw materials and supplies for hospital and laboratory use must be obtained from the approved or certified sources. This situation has led us to extend the ISO 9002 model to all of our Regional Blood Centres by starting with those who express their intention to do so. The staff in charge of the Regional Blood Centres visit and learn the ISO implementation from the headquarters of the NBC. He or She will be appointed as Quality Management Representative (QMR) and will be trained and supervised by the QMR of the headquarters. The establishment of quality system according to the ISO 9002 model for at least 4 of 8 Regional Blood Centres should be accomplished in one year from now.

Interaction or partnerships formed with other Institutions before, during and after the exercise

As you may know, quality is costly even

though it is cost-effective in the long term. We are all facing economic constraints in this region of the world. It does not mean that we cannot do anything at all concerning the quality. We thus explored the possibility of cooperation on the calibration of equipment from the authorities both NGO's and governmental bodies such as Government Pharmaceutical Organization and National Institute of Metrology (Thailand), Ministry of Science, Technology and Environment.

Major steps in setting up the NBC's quality system.

The evidence of transmitting HIV in blood transfusion has tremendous impact on the quality system of the Blood Program worldwide. As we are fully responsible for the National Blood Program in Thailand we need to secure community confidence in our facility. There was a good concordance between our ISO consultant and what we learned from IFRC/RCS Blood Quality Program Training in Bangkok in 1998. Four major steps in setting up the NBC's quality system had been adopted as follows:-

1. Development and organization of quality system documentation for quality policy, quality process descriptions, system procedures, work instructions, forms and quality manual as well as document control. The quality policy of NBC is as follows :-

Quality policy

National Blood Centre (NBC) shall provide voluntary, non-remunerated blood donation, every effort shall be made to attain and maintain the highest standards of safety and efficacy.

NBC shall maintain its quality of total commitment to donor satisfaction and patient's need of blood and blood products through its continuous implementation and maintenance of the ISO 9002 quality system.

NBC shall provide for staff training program on health care and safety concerning the blood collection and blood product preparation, the management of waste and prevention of all materials, equipment and all working places from microbial contamination.

NBC shall provide training to ensure the personnel's understanding, implementation and maintenance of the quality policy at all times.

To achieve the quality policy, NBC shall promote

1.1 All personnel participation in quality system.

1.2 Provide the blood donors good service in order to recruit and collect sufficient and safe blood.

1.3 Issue the blood and blood products to the hospitals as well as other products as requested and on time.

1.4 Continuously improve the personnel knowledge and work skills to meet the quality and standards.

1.5 Continuously develop blood products and other products including improving the services.

1.6 Promote the appropriate use of blood and blood products as well as all products.

2. Process analysis and control by implementing process of total quality management to

obtain the qualified and effective processes for all activities of NBC including services and production. This should include flowcharting processes and analyze the existing quality system against the ISO 9002 model. Development of training programs and training in system procedures and work instructions for all levels of staff.

3. Implementation of the ISO 9002 model according to those quality documents. Exercise self - assessment and reporting through internal quality audit which is planned for at least 2 times per year and quality indicators to see how well a process or procedure is functioning. External assessment by the certified body once a year will provide great opportunity for improvement. All divisions are able to review, supplement and expand their system procedures, work instructions and forms periodically.

4. Process improvement is dynamically carried out through external and internal assessments as well as complaint and occurrence management, implementation of corrective and preventive actions including contract review, customer feedback and management review.

During a period of 2 years, a total of 166 system procedures and 499 work instructions including a number of new forms from 11 divisions had been created and accomplished to put into our current quality documentation. The QMR is responsible for the quality manual and system procedure document control while the work instructions are under the control of Division Head.

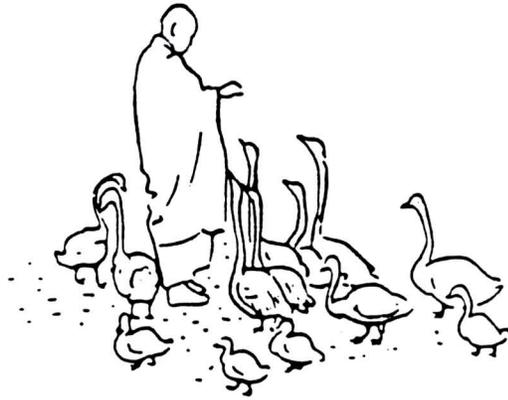
The benefits of ISO 9002 have been clearly

demonstrated. As a result all staff understand their own and others' role and responsibility without confusion, as well as reducing doing things in duplicate and unnecessarily which in turn reduce the cost of quality. In addition, all work and achievements of the staff have been documented.

Conclusion: The Quality of NBC has been established and maintained with the opportu-

nity of improvement through the application of the ISO 9002 model.

Finally we are willing to share our experience in setting up the quality system for other Red Cross and Red Crescent blood services especially those with limited resources, provided that they are able to prove their strong intention in setting up the quality system for their institutions.



การงาน

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— ปุณณิกานันท์ —