Republic of Namibia

Namibia Institute of Pathology Ltd.

Collaboration Program with the Private Sector for Disseminating Japanese Technology for Laboratory Quality Management System in Namibia
Final Report
[Summary]

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Chapter 1 Summary

1 Background of the project

The mortality rate for infectious diseases, including HIV/AIDS, remains high in the Republic of Namibia. Furthermore, the number of patients of lifestyle-related diseases has begun increasing in recent years. The hematology testing is essential for diagnosis of these diseases and must be operated with reliability and rapidity. However the management of operating clinical laboratory has not been fully established in Namibia, facing insufficient medical human resource. The environment has not been formed for providing medical treatment efficiently while maintaining the test quality and, as a result, appropriate tests cannot be conducted for the patients.

Under such circumstances, the Namibia Institute of Pathology (NIP), which is the public clinical test service institute of Namibia, has set the objectives to establish the core functions of test quality control as domestic hubs: it is projected that the 11 main testing laboratories in Namibia will be certified for the international standard authentication ISO 15189, and all the laboratories will achieve a five-star evaluation by the SLIPTA (Stepwise Laboratory Improvement Process Towards Accreditation)[1] by 2020.

2 The technology projected to be spread in this project

A) Blood analyzer "XN-1000"
Brief description: The flagship model of Sysmex Corporation which has the largest global market share for hematology equipment.

B) Online maintenance system "Sysmex Network Communication Systems (hereafter, "SNCS")"
Brief description: A system that monitors the status of operation of equipment by remote online.

C) Local training "Sysmex Quality Guidance Manual (hereafter, "SQGM") Mentorship"
Brief description: A mentorship style training program using the manual for building quality control system of clinical testing laboratories in accordance with the international standard for, ISO 15189

3 Purposes/Target of this project

A) Purposes of the project
This project is implemented in the three major clinical testing laboratories[2] of NIP; NIP Windhoek, NIP Rundu, and NIP Oshakati.. The two –year training course packages up the blood analyzer "XN-1000," the online maintenance system "SNCS," and the local training program "SQGM Mentorship." The purposes of this project are to contribute to improvement

[1] The program for auditing developed by WHO AFRO, which is designed for measurement of the quality control status in the laboratories. Scores are applied in accordance with the scoring table based on the ISO, to laboratories, which are evaluated on a scale of one to five represented by the number of star marks.

[2] NIP has expressed its policy of placing priority on these three institutions in improvement of their quality control systems.

of clinical test environment as well as quality of medical treatment in Namibia, which will result in strengthening the presence of Sysmex and expanding its business.

B) Targets of the project

Establishment, development and improvement of the quality control system designed for the three relevant testing laboratories which targets at:

- NIP Windhoek: *Renewal* of the ISO 15189 authentication
- NIP Rundu, and NIP Oshakati: Acquisition of the five-star level in the SLIPTA program and *acquisition* of the ISO 15189 authentication (achievement of requirements).

4 Project Activities

A) Purpose of activities in Japan and outline of the activity

(The project does not include implementation of such an activity.)

B) Purpose of the local activity and its outline

- Purpose: Establishment of system for continuous quality control in the relevant clinical laboratories.
- Outline: The blood analyzer "XN-1000" and the maintenance system "SNCS" is installed to the relevant testing laboratories to pursue operational efficiency, The "SQGM Mentorship," which is designed for document control and organization framework system in conformity with the international standards ISO15189, will be provided by the regular visits of three times a year.

5 Results/Achievements of the project

The project has achieved the following results through six local activities.

Table 1 Results of the Activities of the Project

Local activities	**Results**
No. 1	・ The official commitment of cooperation from each stakeholder were obtained by holding the kickoff ceremony for the project. ・ The blood analyzers were introduced in the three relevant testing laboratories and their operation started. ・ As a result of the instruction in the maintenance technique, the clinical examination technicians' skills were raised to the level which allows them to do daily maintenance of equipment.
No. 2	・ The staff members in the workplaces of NIP Oshakati (such as clinical examination technicians) deepened their understanding of the Quality Manual of Testing Laboratories through the SQGM Mentorship. They succeeded in raising efficiency of their daily business of testing and, at the same time, obtaining the skills of basic document control and document preparation for the Procedure Manuals.
No. 3	・ Activity similar to what was done in No. 2 was carried out also at NIP Rundu.

No. 4	・ Discussion on QMS and training on SNCS were implemented for NIP Windhoek. They resulted in clearly defining what to carry out to improve the QMS, leading to completion of arrangements for responding to the renewal examination of ISO 15189. ・ A workshop on QMS was held for NIP Oshakati. Major causes of not improving the SLIPTA evaluation were analyzed, which clarified what actions to be taken to improve it ・ Sales promotion and explanatory meetings were held for the new Sysmex products of hematology (XN-1500 and XN-L series models) as well as SNCS. We were able to appeal those products to NIP and to the private laboratories located in Windhoek to build a network which would help future sales activities.
No. 5	・ The final discussion was held on the mentorship utilizing SQGM with members of NIP Oshakati and NIP Rundu. With the case of NIP Rundu, in which it succeeded to obtain ISO certification, as an example of good practice, it was confirmed that it might be spread to NIP Oshakati as well as other NIP testing laboratories, for which it was difficult to raise the SLIPTA evaluation. ・ A feedback survey was conducted covering managers of the three relevant testing laboratories. It was confirmed that the project and Sysmex products were highly valued. It was also confirmed that the SNCS function was highly valued at NIP Windhoek and NIP Rundu.
No. 6	・ Closing ceremony was held at the NIP headquarters, The output of the project was shared among related parties; the status of achieving KPIs at the three relevant testing laboratories, what issues they had to address; the effects which the entire program of the project would have. Furthermore, it was confirmed that they would continue cooperating with NIP even after completion of the project.

6 Business Possibility at the current step

Through the project, it was highly appreciated by local counterparts of the capacity building (human resource development) to achieve the international standard certification and the quality control activities through the SNCS and the SQGM Mentorship. We have therefore concluded that we would be able to expand business in the future by continuously improving the services and the support, as well as reinforcing the human resource development program.

7 Reasons of judging the Business Possibility

A) It has been confirmed that the project as well as Sysmex products and services are highly valued at the three relevant testing laboratories.

B) The online quality assurance function of the SNCS has contributed to improvement of the quality level of laboratories at the three relevant testing laboratories.

C) The SQGM Mentorship has improved the quality level of the testing laboratories at each facility of the three relevant testing laboratories, resulting in the renewal of ISO 15189 attestation at NIP Windhoek as well as new ISO 15189 certification at NIP Rundu.

D) Through the project, the Ministry of Health and Social Services in the Republic of Namibia has recognized the superiority of our products, services and support. They have been highly valued.

E) NIP has requested us to develop the SNCS business to other institutions as the online quality assurance control platform.

8 Remaining issues for business development as well as countermeasures and policy

A) To continue support for ISO authentication of NIP Oshakati in 2019.

B) For subsidiary and agency to continue making proposals to the institutions which may be bid objects or related governmental agencies, in an attempt to obtain the on –going Government's bidding projects.

9 Plans for future business development

A) We will introduce a platform for improving quality control of testing laboratories by packaging up our analyzers, SNCS and SQGM Mentorship, in order to expand the business to other institutions of Namibia (public and private) as well as other South African nations.

B) We expect to expand sales increase in not only the hematology field but also the blood coagulation testing field and the urinalysis field. We will appeal to medical institutions with the usefulness and clinical value of our products and the improvement of the quality control technology for testing laboratories.

C) We will grope for the possibility that we may be of help for the Ministry of Health and Social Services in its measures to counter the spread of malaria, by introducing the blood analyzers equipped with our malaria detecting technique in the regions in Namibia where malaria is spreading (northern part of the country, which are to be covered by NIP Rundu or Oshakati).

10 Possibility of collaborating with ODA projects

Table 2 Summary of the Possibility of Collaborating with ODA Projects

Project	Outline
Grant aid for grass-roots groups for securing human safety	To consider the possibility of introducing our products utilizing the scheme of the grant aid for grass-roots groups, in cooperation with local medical institutions and the Japanese Embassy in Namibia, in order to improving the access to medical care services. We also target the implementation of the SQGM Mentorship, which has been implemented during the current project, after introducing the equipment.
SDGs-type support	In relation with the blood analyzers equipped with our malaria detecting technique, we will grope for the possibility that we may contribute to the development of the Namibian program to counter malaria carried out by the Ministry of Health and Social Services.
Project of technical cooperation	To consider introducing SNCS, and SQGM Mentorship to the institutions as JICA project. We will grope for expansion of the ways of rendering services by, in addition to the dispatch of our experts to the NIP testing laboratory, making good use of the Sysmex Academy, our training facility located in South Africa.