Quality Management System Program of in Vitro/in Vivo Test Facility of Boron Neutron Capture Therapy at Kartini Research Reactor

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Abstract. *Quality management system program of in Vitro / in Vivo Test Facility of Boron Neutron Capture Therapy at Kartini Research Reactor.* The quality management system program of in vitro / in vivo test facility of Boron Neutron Capture Therapy (BNCT) method as quality assurance requirement for utilization of radial piercing beamport of Kartini research have been done. Identification and management of technical specification and parameters measurement of the radial piercing beamport have been determined for preparing in vitro / in vivo test facility. The parameters are epithermal neutron flux is $9,8243\text{E}+05\text{ n cm}^{-2}\text{ s}^{-1}$ and thermal neutron flux is $3,0691\text{E}+06\text{ n cm}^{-2}\text{ s}^{-1}$, radiation shielding of paraffin, dimension and size of piercing radial and instrument and control system for automatic transfer of in vitro / in vivo samples have been documented. Management system of the documents for fulfill basic guidance to perform working job of in vitro / in vivo at the piercing radial beamport of Kartini Research Reactor in order purpose utilization of the reactor for safety worker of the radiation area, society and environment being safely

Keywords : *in vitro / in vivo test facility, neutron flux, radiation shielding.*

INTRODUCTION

The Kartini Research Reactor is one of the TRIGA (Training Research Isotope Production by General Atomic) type nuclear reactors which still operating for 100 kW power level. Since operated at the first time at April 1979, the research reactor has been used for research students of Universities, many training and education on nuclear programs such as operator and supervisor TRIGA reactor and , neutron activation analysis, research and developing on utilization related with nuclear utilization. To develop the utilization, the TRIGA reactor should be identify around technical specification, characterization and performance since the reactor is operating in power level whether in normal condition, transient condition or emergency condition.

As research reactor with low power 100 kW thermal, the Kartini Reactor has many experiment facilities for neutron activation analysis which located in Lazy Susan (LS),

Pneumatic Transfer System, 2 radial beamports, tangential beamport, thermal column and radial piercing beamport.

In Indonesia, researchers of neutron particle has been developing to study for application cancer therapy using neutron capture therapy (NTC) by using target nuclide of boron (^{10}B) and called Boron Neutron Capture Therapy (BNCT) method. Such as be known that the BNCT method many major as neutron physics with neutron source consist of nuclear research reactor, compact neutron generator (CNG) and cyclotron. Preliminary developing program of the BNCT is beginning to preparing test facility for in vitro / in vivo by using neutron source of radial piercing beamport of Kartini research Reactor. Known that the reactor has many neutron source facilities which can be used for neutron activation, furthermore there is one neutron activation facility which has potential for neutron activation of BNCT method i.e the neutron source radial piercing beamport. Because the radial piercing beamport has centrifugal

direction and pierce to biological shielding up to reactor core. By that design, the neutron flux from the reactor core will be highest than others. Related with potential utilization of the beamport, this facilities will be used for preparing in vitro/in vivo test facilities, it mean that many equipment and infrastructure as completion of in vitro/in vivo test facility should be carried out in once management system as working guidance policy of institution. Business process and mechanism of management system as guidance job description discuss about program or policy, how to carry out (performance) and supervision processing in order has quality product. By policy the management system should be completed document fulfil with organisation, task and responsibility, objective around many equipments and instruments, infrastructure, procedure, work instruction and data notification, audio and visual. Besides that the management system also fulfil with basic education of human resources, personal competency, on the job training skill and safety culture. Principally objective utilization need many objectives in purpose to fulfil radiation safety analysis for radiation worker, public and environment.

Scope

The management system is applicable to the establishment, implementation, assessment and continual improvement for radiation facilities; activities using sources of ionizing radiation; radiation protection activities; and any other practices or circumstances in which people may be exposed to radiation from naturally occurring or artificial sources;

Objective

Management system document is to define requirements for establishing, implementing, assessing and continually improving a management system that integrates safety,

health, environmental, security, quality and economic elements to ensure that safety is properly taken into account in all the activities of an organization. The main objective of the requirements for the management system is to ensure, by considering the implications of all actions not within separate management systems but with regard to safety as a whole, that safety is not compromised. Safety Requirements is applicable throughout the lifetime of facilities and for the entire duration of activities in normal, transient and emergency situations. This includes any subsequent period of institutional control that may be necessary.

METHODOLOGY

In Indonesia, preliminary study for neutron capture therapy by using BNCT method was developed by utilizing neutron source of Kartini research reactor using radial piercing beamport which has neutron flux higher than the others. with the development plan of the test facility in vitro / in vivo method of BNCT. Management process for preparing of the methodology should be put on the manuscript as follow.

Infrastruktur and Equipments.

Indonesia has TRIGA type for low power level 100 kW thermal which potentially for research and development related with utilization of nuclear energy concerning for in vitro / in vivo test facility on field BNCT method. Firstly research and developing preparation for in vitro / in vivo test facility using radial piercing beamport of Kartini research reactor as neutron source facility, where the beamport has neutron flux higher than others.

As neutron source because of fission product is happened in the reactor core than through out canal of radial piercing beamport. Nuclear reaction as fission product of neutron in reactor core could be figure out as follow.

Figure 1. Vertical Cross Section of Kartini Research Reactor

Fission reaction of uranium fuel produce neutron in reactor core at Figure 1.

Neutron particle through out from the reactor core to outside of radial piercing beamport with neutron flux value is $3,0691\text{E}+06 \text{ n/cm}^2 \text{ secon}$ for thermal neutron and $9,8243\text{E}+05 \text{ n/cm}^2 \text{ secon}$ for epithermal. Completed data of neutron flux on the long of radial piercing beamport as results by meassurement indicated at Table 1.

Table 1. Neutron fluks of radial piercing beamport of Kartini reactor.(1)

Distance from beamport (cm)	Fluks Neutron ($\emptyset$) ($\text{n cm}^{-2} \text{ s}^{-1}$)	
	Termal ($\text{n cm}^{-2} \text{ s}^{-1}$)	Epitermal ($\text{n cm}^{-2} \text{ s}^{-1}$)
0	1,3264E+09	1,3130E+09
25	4,1366E+08	3,3393E+08
50	4,0303E+08	3,9220E+08
75	1,0511E+08	8,3272E+07
100	2,0128E+07	1,4682E+07
120	8,3678E+06	3,3553E+06
140	8,3082E+06	1,5311E+06
160	3,0194E+06	3,1597E+06
180	5,9255E+06	4,5900E+05
200	5,2844E+06	4,7344E+05
220	3,6433E+06	1,2849E+06
240	4,4010E+06	5,2958E+05
260	3,0691E+06	9,8243E+05

Related with safety requirements aspect of

radiation protection considering with utilization for in vitro / in vivo test facility, in front of the hole radial piercing beamport should be covered with shielding material made of parafin block, such as indicated at Figure 2

Transfer system for sample of in vitro / in vivo target from the irradiation facility i.e. radial piercing beamport terminated outside far away around 3 meter, to fulfil safety requirements aspect of state regulatory.

Basic design of equipment for transfer system of sample in vitro / in vivo test facility also should be fulfil safety requirement aspect of radiation protection (Figure 4). So that terminal of sample should be far away from the target, and for the terminal put on 3 meter out side of radial piercing beamport as irradiation facility (FI) .

Management System Of Radiation Source In Vitro / In Vivo Test Facility.

The main purpose utilization nuclear technology is safety requirements for radiation worker, public domain and invironment. Safety requirements document defines the requirements for establishing, implementing, assessing and continually improving a management

Figure 2. Basic design of neutron kolimator placed in the radial piercing beamport

Figure 3. Radiation shielding of paraffin block for protection radiation.

Figure 4 a. Instrumentation and Control System

Figure 4b. Pneumatic transfer system

1. Silindrik pneumatik double action *rodless*
2. one direction control system
3. Control *on/off* solenoid
4. Source and control pressurized air.
5. Linear Potensiometer
6. Sensor Unit
7. Amplifier ang control unit.
8. Pressure meter.

system. A management system designed to fulfil these requirements integrates safety, health, environmental, security¹, quality² and economic³ elements. Safety is the fundamental principle upon which the management system is based. These requirements must be met to ensure the protection of people and the environment and they are governed by the objectives, concepts and principles of regulatory safety standard fundamentals documents [1].

Content of the document supports the achievement of the two general aims of the management system, that are :

- To improve the safety performance of the organization through the planning, control and supervision of safety related activities in normal, transient and emergency situations; and
- To foster and support a strong safety culture through the development and reinforcement of good safety attitudes and behaviour in individuals and teams so as to allow them to carry out their tasks safely.

Safety requirements document should be covers the security of facilities, nuclear material and sources of radiation only to the extent that security measures for physical protection are essential to safety and the failure of such measures has consequences for safety.

Content of the document management system is based on two key concepts:

- that work may be structured and interpreted as a set of interacting processes; and
- that all individuals involved contribute to achieving safety and quality objectives.

The requirements established in the document may be used by organizations in the following ways:

- As the basis for the management systems of organizations directly responsible for operating facilities and activities and providing services.
- As the basis for the regulation of these facilities and activities by the regulatory body;
- As the basis for the management systems of the relevant regulatory bodies [6];
- By the operator, to specify to a supplier, via contractual documentation, any specific requirements of the safety requirements document that must be included in the supplier's management system for the supply and delivery of products¹.

Management system should be completed with organization to support achievement of the job discription in the in vitro/in vivo test facility which has been fulfil in the document, such as Figure 6. follow.

Task and Responsibility

Each task in the field of cooperative organizations are :

Figure 6. Organization of in vitro in vivo test facility.

License Holder

Licence holder has task for establishing, implementing, assessing and continually improve the management system in accordance the organization purpose contribute to the achievement goals organization.

- To coordinate operation of system, structure and componen of in vitro / in vivo test facilities,
- Shift sceduling to operate the system, structure and componen of in vitro / in vivo test facilities

Manager

Senior management called manager means the person (or group of people) whowhich directs, controls and assesses an organization at the highest level.

Manager responsible and authorized to coordinate the development and implementation of management systems, as well as the assessment and continuous improvement, resolve any conflicts that may occur between the management requirements of the implementation of the management system; and report to the license holder's performance management system, including the effects on safety and safety culture, and any need for improving the product.

Maintenance Division

Task and responsibility of the Manintenance Division are :

- Planning, coordinating and implementing of mechanical treatment.
- mechanical treatment facilities.
- treatment of civil facilities and structures

Radiation Protection Divission.

Task and responsibility of the Radiation Protection Division are :

- Supervise to safety aspec of nuclear safety
- Supervise the implementation of protection and safety program
- Reviewing the effectiveness of the protection program and
- Protection and Radiation Safety program

Operation Division

Task and responsibiliti ot the Operation Division are :

Safety Division.

Task and responsibility of the Safety Division are :

- evaluation and promotion of nuclear safety
- coordinating safety engineering
- safety management committee
- safeguards

Services dan Administrasi

Task and responsibility of the Services dan Administrasi Division are :

- environment, administration, relations with the public
- computerized management system improvement
- documentation system
- personnel problems and employee
- financial and salaries
- distribution and supply inventory

RESULT & DISCUSSION

The Kartini research reactor is designed for low power and operated for 100 kW thermal aimed for education and training operator / supervisor of TRIGA reactor, Neutron Activation Analysis (NAA), laboratorium work, innovation research and experimentation final project for students of Universities in nuclear technology utilization and development. The reactor TRIGA type has advantages in terms of: simple, safe, and easy in maintenance, and flexible for innovation research purposes. Related with this discussion for innovation research, the Kartini reactor will be used for developing utilization preparing in vitro/in vivo test facility using radial piercing beamport. In order to fulfil safety requirements and suitable with regulation the program should be covered with management system as guidance for quality of product. Main policy the utilization for research innovation such as preparing for in

vitro / in vivo test facility at the radial piercing beamport of Kartini research reactor is safety requirement of radiation protection aspect which covered in the quality management system. So that management system contain the program for quality of product refers to the degree to which a product, process or service satisfies specified requirements and supervising. The term of management system reflects and includes the initial concept of 'quality control' (controlling the quality of products) and its evolution through quality assurance (the system to ensure the quality of products) and 'quality management' (the system to manage quality). The management system is a set of interrelated or interacting elements that establishes policies and objectives and which enables those objectives to be achieved in a safe, efficient and effective manner. Economic objectives should be included in the list of elements that have to be integrated, as it is recognized that economic decisions and actions may introduce or may mitigate potential risks.

Integrated management system requirements defined in this discussion cover topics that either relate directly to safety or are part of the managerial framework without which safety cannot be ensured and maintained. Thus topics such as management commitment, communications and other aspects are included from the perspective of seeking to enhance safety aspect as well as performance.

A graded approach based on the relative importance to nuclear safety aspect of each item, i.e realistic planning, service or process, supervising and assessing shall be implemented. The graded approach shall reflect a planned and recognized difference in the applications of specific quality management system requirements.

In general, the highest grade should require the most stringent application of the quality management system requirements.

The following are examples of topic areas where grading should be applied:

- Type and content of training
- Amount of detail and degree of review and approval of instructions
- Need for and detail of inspection plans,
- Degree of in-process reviews and controls,
- Requirements for material traceability
- Type of assessment,
- Records to be generated and retained.

CONCLUSION

Nuclear safety requirement aspect shall be the fundamental consideration in the identification of the items, fulfil with realistic planning, services and processes, supervising and assessing to which the quality management system programme applies to the Kartini research reactor for innovation of research and development of utilization in vitro / in vivo test facility of BNCT method.

Basically the Kartini research reactor can be utilized for research innovation and developing for preparing in vitro / in vivo test facility of BNCT method using radial piercing beamport, however should be covered with safety requirement management system and must be implemented consistently.

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