Radiation Safety Audit

K.P.I. K. Kadadunna*[a] and Noriah Mod Ali[b]

[a]Division of Radiation Protection, Atomic Energy Authority,
60/460, Base Line Road, Orugodawatta, SRI LANKA.
[b]Secondary Standard Dosimetry Laboratory (SSDL),
Malaysian Nuclear Agency (Nuclear Malaysia)
Bangi, 43000 KAJANG, Selangor, MALAYSIA

Abstract. Audit has been seen as one of the effective methods to ensure harmonization in radiation protection. A radiation safety audit is a formal safety performance examination of existing or future work activities by an independent team. Regular audit will assist the management in its mission to maintain the facilities environment that is inherently safe for its employees. The audits review the adequacy of facilities for the type of use, training, and competency of workers, supervision by authorized users, availability of survey instruments, security of radioactive materials, minimization of personnel exposure to radiation, safety equipment, and the required record keeping. All approved areas of use are included in these periodic audits. Any deficiency found in the audit shall be corrected as soon as possible after they are reported. Radiation safety audit is a proactive approach to improve radiation safety practices and identify and prevent any potential radiation accident. It is an excellent tool to identify potential problem to radiation users and to assure that safety measures to eliminate or reduce the problems are fully considered. Radiation safety audit will help to develop safety culture of the facility. It is intended to be the cornerstone of a safety program designed to aid the facility, staff and management in maintaining a safe environment in which activities are carried out. The initiative of this work is to evaluate the need of having a proper audit as one of the mechanism to manage the safety using ionizing radiation. This study is focused on the need of having a proper radiation safety audit to identify deviations and deficiencies of radiation protection programmes. It will be based on studies conducted on several institutes/radiation facilities in Malaysia in 2006. Steps will then be formulated towards strengthening radiation safety through proper audit. This will result in a better working situation and confidence in the radiation protection community.

KEYWORDS: Radiation Safety, Audit, Safety Culture

1. Introduction

Considering the present world has many applications of radiation, it is essential for those in radiation protection field to establish the programmes procedures and rules to protect workers and public from unnecessary exposures from radiation. Radiation Protection is defined as the science and practice of limiting harm to human beings from radiation in every activity in daily lives. Throughout history finding a way to protect individuals from radiation exposures has brought about a great deal of research to find ways to keep individuals safe.

The radiation safety measures accompanying the use of nuclear technologies are more extensive than the protection associated with most other technologies. As a result, a relatively good safety record has been achieved over the three decades of commercial nuclear power and the even longer period for medical, industrial research and agricultural uses of ionizing radiation. Thus the quest for radiation safety excellence necessarily involves the establishment of an all pervasive safety consciousness among the host of individuals whose work bears either directly or indirectly on the safety of radiation practices and sources. This safety consciousness derives from a common level of understanding of the principles and criteria for radiation safety and of the reasons for these safety practices and the consequences of their violations [1]. Thus, the primary objective of radiation protection is to ensure that any operation involving or associated with ionizing radiation is so conducted that the health and safety

* Presenting author, E-mail: prageethkadadunna@yahoo.com

of individuals inside and outside the establishment are protected. Maintaining and improving safety culture requires continuous evaluation. There are a variety of methods for assessing. Safety culture and each method have its own relative strengths and weaknesses. International experience in accessing safety culture is a valuable source of information particularly when it demonstrates how the challenge is met in developing a positive safety culture in different national and organizational environments. Before selecting and implementing a solution to a safety culture problem, it is important to consider the circumstances in which an organization finds itself, and its capability to implement the proposed solution.

Safety audit will help identify the non-compliance of safety culture as well as the deviation of management, individual and policy level commitment, the audit and review of radiation protection program and activities should be preceded [2]. As a result, safety culture of the facility can be improved. Personnel attitudes and habits are generally intangible but the deviations of personnel attitudes and habits through the safety culture also can be tangible through safety audit. Therefore, the safety culture components should be developed through the radiation safety audit.

This study is focused on the need of having a proper radiation safety audit to identify deviations and deficiencies of radiation protection programmes. It is based on studies conducted during visits to several institutes/radiation facilities in Malaysia in 2006. Steps will then be formulated towards strengthening the radiation safety through proper audit. This will result in a better working situation and confidence in the radiation protection community.

2. Radiation Safety Audit

The effectiveness of the safety culture can be improved if radiation safety audit is performed on the system. Radiation safety audits are an in-house means of ensuring radiation safety compliance at all times. It is a systematic and independent examination to determine whether radiation safety activities and related result comply with planned arrangement and whether these arrangements are implemented. Audits are typically performed to evaluate compliance with local and international regulations and considered as a key to monitor and promote radiation-wide safety. Through self-audit, the performance of the radiation safety system can be monitored to check its effectiveness and to achieve stakeholders' satisfaction. The data and findings from the audit can be used as a basis for decision within the organization through adequate analysis. It is useful to describe improvement or deterioration in the system and may give chance for early action to prevent any non-conformity in the system.

The systematic application of the principles and the appropriate strategies to ensure the safe management of technologies involving radiation can be further improved through implementing self-assessment or audit on the system. In summary the main aims of audit are to:

(a) Maintain facilities and equipment in a safe operating condition
(b) Provide a safe working envinronment for all employees and assess the level of emergency readiness.
(c) Ensure that all procedures and activities are conducted in a safe and prudent manner.
(d) Ensure adherence to the content of the safety manual.

2.1 Method of Audit

Audit is defined as a systematic, independent and documented process for obtaining audit evidence and evaluating it objectively to determine the extent to which audit criteria are fulfilled. Audit involves three main processes.

(a) Audit evidence: Records statements of fact other information relevant to the audit criteria and which are verifiable. It is based on samples of the information available, since an audit is conducted during a finite period of time and with finite resources. However, the use of sampling is appropriate to the confidence placed in the audit conclusions.
(b) Audit criteria: Set policies, procedures, or requirement used as reference.

(c) Audit findings: Results of the evaluation of the collected audit evidence against audit criteria. Audit findings can indicate either conformity or non-conformity with audit criteria or opportunities for improvement.

A proper safety audit will help to identify the deviations of radiation a protection program and to take necessary action to fulfil the regulatory requirements. Opportunities for improvement raised during the audit can be carefully considered and used to improve the implementation of the existing systems in each and every radiation facility, whenever appropriate. Evidences of audit are obtained from interview with the staff, observations and reviewing the documents.

Interview allows for a greater flexibility in questioning, with the possibility for follow-up questions, making it easier to get to the deeper meanings and to clarify ambiguities in meaning. A difficulty with interviews is that they are not directly comparable with one another. They are also relatively time consuming, usually based on only a limited sample. This can make it difficult to generalize results for the whole organization. Observation is often a useful complement to interviews with an advantage that the observer can watch the culture as it enacts itself, thus it is possible for the observer to confirm results obtained from interviews and/or questionnaires. Observation can also provide new information on cultural phenomena, but they cannot be quantified and used for statistical purposes. There are other limitations. It may be difficult for the observer to interpret cultural phenomena in the right way. There is also the risk of over-generalization from too few observations. Review of documentation available within the radiation industry generally possesses an extensive hierarchy of documentation. Frequency of document is reviewed will reflect the organization's attention to maintaining up-to-date information, and this in turn can reflect the priority that is given to safety.

2.2 Audit Process

An overview of an audit process and activities carried out is a shown and summarized in **Table 1**. Steps involved include:

(a) Pre-audit: Selection of audit team, preparation of audit plan and checklist.
(b) Audit performance: To collect objective evidence.
(c) Post-Audit: Verifying corrcetive action and final reporting.

An obvious task to start is to have a proper radiation safety plan and records. The easiest way to do this is to have a checklist, which is developed, based on the requirements derived from the Basic Safety Standard (BSS) for Protection against Ionising Radiation. The standard specify requirements for notification of the regulatory authority of the intention to undertake a practice, and for authorization, either by registration or by licensing. Another aspect that merit special mention is reporting of non-conformance, also known as non-compliance (NCR). The most common way of reporting NCR is by completing a specially prepared form. Anything found during the audit that is not satisfactory must be noted with details of remedial actions. Written audits are provided to the designated recipients, along with sugestión for mitigation of issues and steps for reporting the corrective action taken or plan for correction. Audits indicate the areas for improvement, which is a key to providing effectiveness in the radiation safety and its can be described as continuous and continual. This was followed by focusing on finding and fixing problems, indicating that the system is being used positively, and lastly, data análisis for further improvement of the radiation safety program.

3. Overview of Radiation Safety in Malaysia

The radiation protection program achieve a broader scope when the activities of using ionizing radiation increased throughout the country. In Malaysia, radiation industries are only small-sized organizations or teams of workers using radiation sources. In 2006, there are about 1,800 workplaces involved with ionizing radiation, with around 13,000 radiation workers from 3 categories of job activities, namely medical, industrial and non-destructive testing (NDT). Enforcement of the legal international requirements under the Malaysia Atomic Energy Act, Act 304, requires the establishment of programs to determine or estimate the radiation doses or exposures received by workers exposed to ionizing radiation resulting from the activities of the licensee or owner [3]. This requirement is in accordance to the Basic Safety Standard, where the occupational exposures of these workers ought to

be assessed based on individual monitoring or other appropriate information.

Table 1: Steps in the Radiation Safety Audit

Audit Phases	Program	Activities
Pre Audit	PREPARATION AND PLANNING	• Selection of the audit team • Identify audit scopes • Audit schedule and agenda • Notice to auditee • Document review • Audit check List
Actual Audit	AUDIT PERFORMANCE	• Opening meeting • Auditing • Reporting of non-conformance • Closing meeting • Recommendation
Post-Audit	FOLLOW-UP	• Verification of corrective action • Final

One important component of safety, particularly in the nuclear industry, is radiation safety for employees and local communities. Malaysian Nuclear Agency (Nuclear Malaysia), formerly known as Malaysian Institute for Nuclear Technology Research (MINT), and the Atomic Energy Licensing Board (AELB) strive to keep radiation doses as low as reasonably achievable (ALARA) for workers that use radiation sources in Malaysia. This means going beyond compliance with regulatory limits to further reduce exposure for employees and the public. There are also adequate arrangements on education, training and public information and resources for these, as well as appropriate means of informing the public, its representatives and the information media on health and safety concerns. Facilities and services for radiation protection and safety must be well established at the national level. These include laboratories for personal dosimetry and environmental monitoring, and calibration and intercomparison of radiation measuring equipment; they could also include central registries for radiation dose records and information on equipment reliability.

Regulatory limits are expressed in terms of effective dose and an annual dose limit are derived to limit the possibilities of risks induced by radiation. The monitoring of individual workers is carried out on monthly basis and dosimeter readings will serve to ensure compliance with legal dose limits and assure employers that radiation exposure in their premises are kept as low as reasonably achievable (ALARA). The information is useful in helping the regulating body, AELB, and the employer, to establishing whether the general conditions in the workplace are satisfactorily under control and reflects the effectiveness of radiation protection program in their premises.

Management of radiation protection through the Personal Dosimetry service in Malaysia dated back to the 1980's when the Secondary Standard Dosimetry Laboratory, SSDL-MINT was established and had acquired the status of national laboratory with the basic aim of improving accuracy in radiation dosimetry in the country [4, 5]. Ever since its establishment, the laboratory had maintained and utilized state of the art dosimetric equipment for the providing personal dosimetry service which is referred to as monitoring service for measuring occupational ionizing radiation exposure to radiation workers. The laboratory is also responsible for the calibration of radiation survey instrument and dosimeters, provides training and offers advice to users of ionizing radiation on up-to-date measurement procedures and techniques.

The efectiveness of a radiation program implemented is evidence in the workplace is based on the trend of occupational exposure. Collection, analysis and discussion on radiation dose statistics is one way in which the authority promotes the "as low as reasonably achievable" (ALARA) concept. The routine and systematic collection of data on individual and collective occupational doses categorized by work activity is a key tool to provide information on conditions in the workplace. This information is crucial to identify priority areas for dose reduction and to assess efforts undertaken to maintain ALARA doses. In all cases where single dose levels are high (> 20 mSv), or where accumulative doses approach or exceed the limit (50 $mSv.year^{-1}$), the AELB or Ministry of Health (Ministry of Health) will be informed. This will then be followed by an enquiry by the AELB or Ministry of Health (MOH) and advice on appropriate remedial action. The records on distribution doses achieved through radiation protection control are periodically reviewed. It is interesting to note that the percentage of exposed worker exceeding 50 mSv per year was less than 1% and this was maintained for over a 20-year period [4]. Industrial radiographers are among the most highly exposed group of workers as compared to others. The nature of their work, the strength of the sources and the energy of radiation used in radiography works contributes to the high exposure received. The reduction of dose received is evidence of the implementation of good radiation protection programme at the workplace. It indicated proper planning and implementation of radiation safety program to achieve ALARA doses in the country.

The low average doses received in the radiation industry in Malaysia may not be sustainable in the face of changes in work requirements. In specific work that involves high routine exposure, safety relies largely on procedures and human performance. Inadequate training and the limited availability of information on hazards and how to deal with them further compound these constraints. Constituents, therefore, need assistance in adopting and reviewing policies and programmes for the prevention of occupational accidents, major industrial accidents; promoting safety in the use of radiation sources, and designing and implementing measures to improve the working environment. Similar comments are also relevant to the use of gauge sources in general industry, and the wider issue of source security is becoming a significant international concern with lost sources becoming a hazard to working groups not normally exposed to radiation. Current management practice demands that organizations inculcate culture of safety to protect the workers, public and the environment from the hazards of radiation.

3.1 Status of Radiation Protection Program at the Irradiation facilities

A survey on the implementation of the radiation protection was carried out during visits to several irradiation facilities in Malaysia. The survey includes:

(a) Gamma irradiator with cobalt-60 source (up to 2 MCi).
(b) Electron beam facility with energy of up to 3 MeV.
(c) Nuclear Medicine Department, General Hospital.

Both gamma irradiator visited (i.e. comercial and semi-commercial) have implemented quality management system through the ISO 9001:2000 and European standard EN 552 certified and the electron beam facility was also certified to ISO 9001:2000 since 2003. The Nuclear Medicine Department, General Hospital has followed and implemented a good safety procedure as required by the MOH and also by regulation, which is adopted for the safety standards on the International Basic Safety Standards. **Table 2** lists the result of the survey on the gamma and electron beam irradiator, and it indicated that it complied with radiation safety practices except for the radiation safety audit and radiation emergency plan. The same factors werealso addressed for the radiation safety practice at the Nuclear Medicine Department (**Table 3**). From this finding, it showed that internal safety audit is the most common aspect ignored in all facilities. This does not indicate a healthy approach to a safety culture characteristic. With the capacity of the source strength use in irradiation facilities and widening scope of radioactive application this may lead to unwanted events relating to the radiation industry.

Table 2: Survey Report for Gamma and Electron Beam Facilities

Survey Criteria	Results/Remarks		
	I	II	III
Facilities and equipment	C	C	C
Safety operation Inter locks system.	C	C	C
Warning signs and labeling.	C	C	C
Training and instruction to workers.	C	C	C
Internal audits and review	N/C No planning for radiation safety audit	C	C
Safety operations (management)	C	C	C
Safety operations (technical)	C	C	C
Radiation sources	C	C	C
Receipt and transfer of radioactive materials	C	C	NA
Classification of areas and local rules	C	C	C
Area and individual monitoring	C	C	C
Transport of radioactive materials	C	C	NA
Verification of public protection	C	C	C
Accident history and emergency planning	C	N/C No proper emergency plan	C

Note:
[I]Gamma irradiator (Commercial) [II] Gamma irradiator (Semi-commercial) [III] Electron beam facility
C: Compliance N/C: Non Compliance , NA: Not applicable

Radiation Protection Officers (RPOs) are also challenged with developing a radiation safety culture in diverse organizations. This includes radiation safety audit processes and ongoing development of safety programs and training. Appropriate training of the workers at all levels is a fundamental building block in the attainment of a good radiation protection safety culture. Updating of training and refresher courses are also known to contribute to a good radiation safety culture. Of particular interest will be sharing the experiences of different types of radiation safety programs from small organization to larger consolidated facilities.

3.2 Promoting Radiation Safety Audit

The effectiveness of the safety program can be improved if radiation safety audit can be performed on the system. Through self-audit, the performance of the radiation safety system can be monitored to check its effectiveness and to achieve stakeholders satisfaction. The data and findings are useful to describe improvement or deterioration in the system and may give chance for early action to prevent any non-conformity in the system.

Rapid development in the assessing the radiation safety has created a new opportunity in training needs. Nuclear Malaysia has pioneered abd conducts training for radiation safety management audit in the past four years for the radiation industries [7]. The radiation safety management audit course is developed with modules describing the content of audit trainings and the performance of internal audit in organization dealing with nuclear technology. Through this course, the RPO will able to conduct self-audit in his or her premise. In realising the broader safety need, an Intergrated Radiation Safety Management System course has been initiated. It is aimed to highlighted the intergration of IAEA and AELB standards and requirement into the Occupational Safety and Health (OSHA) management. Through this integration, the audit is able to manage variety of hazards on the environment, safety and health and by promoting safe behaviour at all levels of workers. To improve

safety performance in an organization, those involved in radiation activities are required to undergo continuous professional education (CPE) to refresh and enhance their knowledge, and improve skills in radiation related areas

Table 3: Survey Report for Nuclear Medicine Department

Audit Criteria	Result
Verification of safety	C
Facility design and location	C
Personnel protection – safety control and equipment	C
Safety operations –(management)	C
Safety operations (technical)	NC No safety interlocks system in the PET-CT room. A person can enter the exposure room (for CT) during operation
Internal audit and reviews	NC No audit and review of radiation safety program internally but all important documentation are well maintained
Classification of areas	C
Local rules and supervision	C
Area and individual monitoring	C
Verification of public protection	C
Emergency preparedness	NC No review, revise and separate emergency plan from local rules.
Medical exposure	C
Training and instruction of workers	C
Transport of radioactive sources	C

Note: C: Compliance N/C: Non Compliance , NA: Not applicable

4. Conclusion

Radiation protection should be seen as an integral part of general healthy and safety regulation and management systems in the workplace. It is important to recall that the principle of ALARA, which is the cornerstone of radiation protection in the workplace, relates not only to engineering and physical protection measures, butit should also relate to aspects such as safety organization and management, safety culture and safety training, many of which are associated with a proper radiation safety audit.

Radiation safety audit is seen as a continuing process of improvement to which everyone can contribute. It can be done either internally or externally. External safety audit is more effective to comply with the regulations. Opportunities for improvement raised during the audit can be carefully considered and used to improve the implementation of the existing systems in each and every radiation facility in Malaysia, whenever appropriate. The effectiveness of a regulatory system in Malaysia can be improved further through implementation of efficient safety management system by having a strong safety culture in the organization.

REFERENCES

[1] ABEL, J. GONZALES, Timely Action Strengthening the Safety of Radiation Sources and the Security of Radioactive Materials, IAEA Bulletin 41/3/99, 1999.

[2] Safety Culture, Safety Series No 75, INSAG -4.

[3] LAW OF MALAYSIA ACT 304: Act of Atomic Energy Agency (1984).

[4] NORIAH MOD ALI, Trends in Occupational Exposure in Malaysia, 11th International Congress of the International Radiation Protection Association (IRPA), Madrid, Spain, 23-28 May 2004.

[5] NORIAH, M.A, Gaining Competitive Advantage in Personal Dosimetry through ISO 9001 Certification, Radiat. Prot. Dosimetry, Vol.125, No. 1-4, 2007

[6] NORIAH M.A., Promoting Safety Culture in Radiation Industry through Radiation Audit, Prceedings of an International Conference, Challenges Faced by Technical and Scientific Support Organizations in Enhancing Nuclear Safety, Aix-en- Provence, France, 23-27 April 2007.

[7] NORIAH MOD ALI, Challenges in Promoting Safety Culture, 4th International Symposium on Radiation Safety and Detection Technology, Seoul, Korea, 18-20 July 2007.