Study on Applicability of 10 CFR Part 21 to APR1400 DC Project

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1. Introduction

It is well known that nuclear quality is assured by the helps of several in-depth quality assurance requirements when it is compared to the other industrial sectors. The tools such as NCR (non conformance report), CAR (corrective action request) and CAP (corrective action program) are widely used for that purpose based upon the rule of 10 CFR Part 50 Appendix B [1] and the ASME Code NQA-1 [2] requirements. These are the tools for a utility, as a purchaser taking over related basic components and services, to ensure strong quality assurance. During the conduct of the project for the acquisition of the standard design certification for APR1400 nuclear power plants from the U. S. NRC (APR1400 DC Project), a new CAP procedure that is appropriate to conduct this unique project was developed. However, it was also recommended to comply with the requirements under 10 CFR Part 21 [3] which enhances nuclear safety quality assurances. Consequently, a new QA procedure is developed in order to deal with the 10 CFR Part 21 issues and this is integrated to the CAP procedure

In this paper, the current corrective action program for the APR1400 DC project is introduced and the result of the study on the applicability of 10 CFR Part 21 to the project is indicated. In addition, further improving aspects to be considered are identified.

2. Modified Current CAP Procedure

KHNP already has the well-established standard operating procedure of CAP. However, as it is mainly focusing upon the operation of nuclear power plants, it is not so appropriate to apply directly to APR 1400 DC project which deals with design and certification phases rather than operation of a nuclear power plant. A customized procedure was developed by modifying and improving the existing standard operation procedure. The sequential procedural activities need to be taken are drawn in the flow chart as shown in Fig. 1 and These activities are categorized into six steps as follows:

2.1 Step 1: Condition Report Initiation

Any member of the Project Team may identify a condition adverse to quality and then he or she initiates a condition report (CR) through e-CAP system.

2.2 Step 2: Immediate Corrective Action (Optional)

The purpose of this step is to take immediate actions in the case that the identified condition is significantly adverse to quality and to require immediate actions. The person who found it out should contact the responsible manager or directly to PM. The responsible manager or the PM designates a responsible person to carry out the immediate corrective action (CA).

2.3 Step 3: Condition Report Review and Assignment

The validity of CR is firstly reviewed. If the CR is determined to be a duplicate already in e-CAP system or not clearly described, it is canceled or returned to the initiator. If not, the condition review group classifies the significance level of the CR and check up the reportability in accordance with 10 CFR Part 21. If the condition is considered to be potentially reportable, it should be evaluated and processed according to the quality assurance procedure for controlling of 10 CFR Part 21 reporting. If not, the necessity of causal evaluation (CE) is reviewed by an assigned CE responsible person (RP).

2.4 Step 4: CE Conducting and CA Planning.

The causal evaluation responsible person performs the causal evaluation, which is subject to approval by CARB (Corrective Action Review Board) or QA verifier and the corrective action responsible person makes a plan for implementing the corrective action.

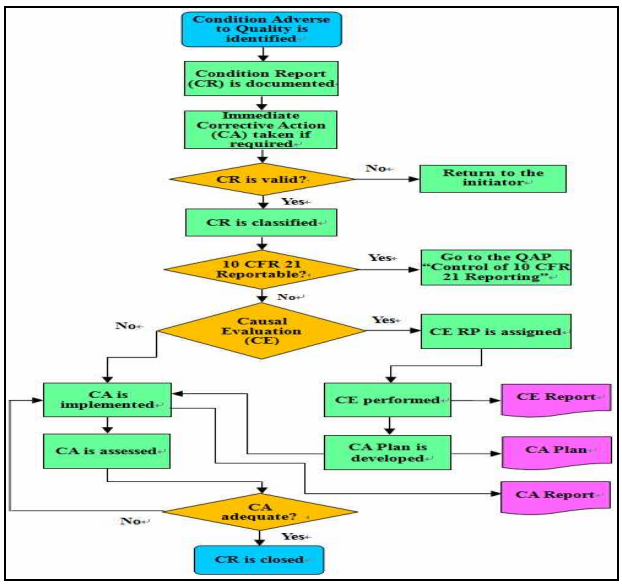

Fig. 1 CAP Flowchart for APR1400 DC Project

2.5 Step 5: CA Implementation and Assessment.

The CA is implemented by the CA responsible person and the CA is assessed and evaluated by the QA Verifier. If CA due date extension is necessary, the CA RP should prepare a CA extension request which is approved by the CARB.

2.6 Step 6: CA Closure

After checking that every required process for a CR is done, the CAP Coordinator closes the CR and the closing of the CR is informed to the CR initiator.

3. Considerations for Further Improvement

3.1 Applicability of 10 CFR Part 21

As the basis for the establishment of the Nuclear Regulatory Commission, which began operations on January 19, 1975, the Energy Reorganization Act of 1974 (ERA) had provided the ground rule for 10 CFR Part 21 in its section 206, "Noncompliance" and this seems to be comparable to the newly legislated provision of 15.3 "Reporting of Noncompliance" within the domestic Nuclear Safety Law of Korea.

10 CFR Part 21 establishes procedures and requirements for implementation of section 206 of the ERA and is composed of five parts; general provisions, notification, procurement document, inspections and records, and enforcement. It defines the related basic concepts such as basic component, significant safety hazard, defect, deviation, etc., and it indicates posting requirements, notification methods and procedure, including the provision concerning civil penalty, and etc.

Major key points to successfully comply with the regulation in the aspect of design certification are considered as follows:

1) All kinds of conditions adverse to safety are influenced by this regulation.
2) Only defects and failure-to-comply determined to be related or creating significant safety hazards need to be notified to the NRC.
3) Director/Responsible Officer or a person designated have the responsibility of notification.
4) For timely corrections, the timelines for each activity (shown in Fig. 2) should be met.

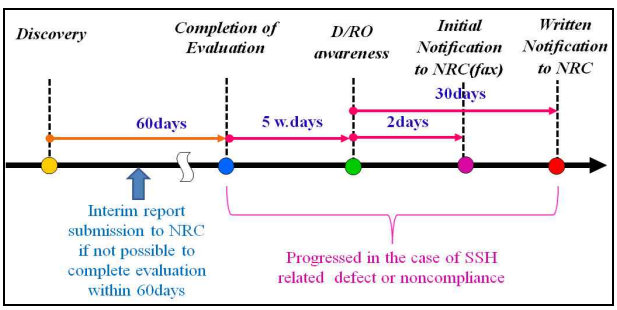

Fig. 2 Time frame for Notification to the NRC

3.2 Further Considerations and Prospects

For the successful implementation of the 10 CFR Part 21 requirements in the ARP1400 DC project, further tuning within the related procedures needs to be performed as follows:

1) Adding specific criteria on the determination of the reportability in accordance with 10 CFR Part 21 in the CAP procedure
2) Progressing two activities of CR classification and 10 CFR Part 21 reportabiliy review in parallel
3) Considering the concept of 'regulatory life', which means the time frame from docketing to termination or expiration of the standard design certification or the last license, directly or indirectly, referencing the SDC [4].

On the other hand, the NRC has schedules to propose the rulemaking of a Regulatory Guide for 10 CFR Part 21 in 2014 and to complete the final rule in 2015. Moreover, the guide is anticipated to be more extended and enhanced by dealing with CFSI (counterfeit, fraudulent, and suspect items) issues [5]. Therefore, the corresponding procedures for the APR1400 DC project will be further evolved following such the gradual improvements of the U. S. regulations.

4. Conclusions

As a frontier project to obtain the standard design certification for APR 1400 model from the U. S. NRC, a modified CAP procedure is developed and enhanced to deal with safety concerning issues in accordance with 10 CFR Part 21. In addition, the newly established QA procedure to directly control the reportability on 10 CFR Part 21 is interfaced into the existing CAP procedure. Through the further improvements identified in the above part, the nuclear safety and the quality assurance aspects of the APR1400 DC project is anticipated to be more firmly strengthened.

REFERENCES

[1] 10 CFR Part 50, Appendix B, "Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants"
[2] ASME Code & Standard, NQA-1-2008, "Quality Assurance Requirements for Nuclear Facility Applications"
[3] 10 CFR Part 21, "Reporting of Defects and Non-compliance"
[4] NRC Proposed Generic Communications, NRC-2010-0122, "Applicability of 10 CFR Part 21 Requirements To Applicants for Standard Design Certifications, 2010.
[5] NRC, ML12248A200, "Draft Regulatory Basis to Clarify the Requirements of 10 CFR Part 21", May, 2013