NUBIKI

NUCLEAR SAFETY
RESEARCH INSTITUTE

REGULATORY REQUIREMENTS AND RECOMMENDATIONS CONCERNING RISK MONITORS IN CERTAIN COUNTRIES

January 2013

NUBIKI NUCLEAR SAFETY RESEARCH INSTITUTE

Budapest, P.O.B. 49, H-1525 Hungary

REGULATORY REQUIREMENTS AND RECOMMENDATIONS CONCERNING RISK MONITORS IN CERTAIN COUNTRIES

Public Report

Rev. 0

Prepared by:

BAREITH Attila, bareith@nubiki.hu
JÁVOR Tamás, javor@nubiki.hu

January 2013

RISK ASSESSMENT DIVISION

Prepared by

NUBIKI Nuclear Safety Research Institute

Prepared in 1 copy

January 2013

CONTENTS

1. INTRODUCTION

The Hungarian Atomic Energy Authority (HAEA) has declared its strong commitment to introduce risk-informed regulation in its activities and to promote risk-informed safety management among all regulated parties. (Clause 8 of [1], [2])

In 2012 the HAEA ordered a study from NUBIKI to support regulatory oversight over risk monitoring to be possibly introduced at a licensee. The order included enumeration of risk monitor application areas, usability assessment of a certain licensee-purchased software to these applications, conditions (including PSA model requirements) necessary to operate a risk monitor. From the point of view of this report, the most important part of it was a survey of international practice in regulatory position on risk monitors. The aim of this study was to underpin formulation of national risk monitor regulatory requirements. From the beginning of the work, our research was voluntarily extended from requirements only to regulatory recommendations, too.

2. INTERNATIONAL SURVEY

2.1. Content

Our survey on international regulatory practice of risk monitor regulation was based on two main sources:

- direct regulatory or regulatory TSO contacts of NUBIKI,
- publicly issued foreign regulatory documents.

To some extent, other sources were used, such as:

- an extensive report of the OECD Nuclear Energy Agency (NEA) about risk monitor usage in member states [3],
- a chapter of a more general NEA report about PSA [4], dealing with PSA applications,
- knowledge obtained during recent and on-going similar tasks (mainly international risk-informed regulatory practice).

A questionnaire was developed for the foreign parties (either authority or TSO). The first question (#0) was if there are regulations or guides in force at all in that state concerning risk monitors. Answers to subsequent questions were required only if the answer to this question was Yes.

In the second part the content of these regulatory documents was inquired. The question groups were aimed at whether these national requirements (rules) or recommendations (guides)

- address the risk monitor PSA model (#1),
- declare numerical risk goals and processes to be followed in case of non-compliance with these (#2),
- deal with decisions based on risk monitor results (#3, #6-7),
- address the risk monitor computer software (#4),
- address the procedure of introducing a risk monitor at licensees (#5).

Our questionnaire is presented in Appendix 1.

The request was sent to 14 countries in May and June 2012, essentially to all which NUBIKI keeps regular contact with, or which are considered to be generally advanced in risk-informed applications. Each of the NPP operating states bordering Hungary were purposely included (even, if necessary, with the intermediation of HAEA). The addressees were:

- Canada
- Czech Republic
- Finland
- France
- Germany
- Lithuania
- Romania
- Slovakia

- Slovenia
- Spain
- Switzerland
- Ukraine
- United Kingdom
- United States of America

2.2. Results

By October 2012, 13 replies were received (and from one country the sole PSA application guide in force).

According to the respondents, in seven of the questioned countries there are no requirements or recommendations for risk monitors[1].

The remaining states that could fill the questionnaire in detail were:

- Czech Republic
- Romania
- Slovakia
- Spain
- UK
- USA

(The public report does not contain filled-in questionnaires.)

During the evaluation it became clear that our conclusions should not be supported solely by the answers of regulatory and TSO staff given in the forms, but also by the inquired (public) regulatory documents themselves. In some cases the respondents already cited and named these, others were subsequently consulted to name the documents referred to. These texts were also studied. Finally, such documents were used even from some of the countries having had given a No answer. (It significantly facilitated our work if these legal documents had already been – at least informally – translated into world languages and published on the website of the national authority. In some cases, only the original text is allowed or possible to be included as a reference in this report.)

From the replies and regulatory documents the following conclusions were drawn:

It can be generally stated that no authority applies general regulation or a guide specifically for risk monitors. The following cases are typical:

1. The same principles are valid for the risk monitor (its underlying PSA model, the decisions based on it etc.) as for the – regularly updated but static – PSA. (E.g. [5], [6], [7], [8])

[1] There were cases when this statement was not in full agreement with the information provided for the [3] or [4] NEA reports. However, as these replies were developed specifically for our survey and were more recent, they were always considered primary.

2. There are recommendations for PSA applications – or the regulatory verification of the applicability of these – which are the same for every application. (E.g. [9], [10], [11]) A risk monitor is one of the possible applications.
3. Licensees use a risk monitor for certain operational purposes and decisions (for example maintenance planning, establishing risk-informed limiting conditions of operation (LCO), but justification of compliance with more general goals also occur, such as maintaining risk as low as reasonably practicable). Requirements and recommendations address these areas, independent of the usage of either a risk monitor or a different tool by the licensee. (E.g. [12], [13], [14], [15], [16], [17])

Because of the aforementioned, the responding staff members often cited guides not directly addressing risk monitors. Especially typical is the acceptability of using a risk monitor for compliance with the required *monitoring of maintenance effectiveness* (USA, Spain, Switzerland). Also, because of the absence of specific risk monitor regulation, the respondents often could answer our questions not one by one, but rather grouped and more generally.

From certain country replies the following facts deserve consideration:

- Being the only one among those who gave responses, the authority of Romania requires the continuous monitoring of operational risk by regulation (Chapter VI, Art. 22. of [8]). However, in the Czech Republic the same is imposed on licensees as part of their operational license, and the intention of the authority is to maintain this clause in long term.
- In Slovakia, the risk monitor is one of the few PSA applications especially recommended by the authority. (Chapter 7.3.2. of [18])
- In the United States, the two main applications of risk monitors are
    - monitoring the effectiveness of maintenance ,
    - risk-informed review of LCO, even licensing of its amendment.

  For these two the NRC has issued two guides, too [14], [15]. (Meanwhile, any kind of method is acceptable for these applications, as mentioned.)
- *Limits* for risk values or their increments are applied in several countries. However, these, along with case 3 above, usually refer to certain applications (e.g. risk increment induced by some maintenance activities or system configurations), not to instantaneous or cumulative values indicated by the risk monitor without respect to their cause. (Spain, USA, Slovakia, Czech Republic, Canada)[2]
- In a number of responses it was indicated that the adequacy of the risk management or PSA application program of the licensees is to be ensured by the *regulatory inspection program* over them or the *regulatory approval of the internal licensee procedures* rather than the rules and guides inquired by us.
- Regarding the monitoring *software* and the *introduction* of a risk monitor there is hardly any official regulatory standpoint or guidance in any country, beyond that – just

[2] According to Chapter 12.1 of the [3] NEA report the same is true for Slovenia, from where we received a No answer. The data in that chapter stems from a 2002 autumn international survey, the details of which are not given in the report.

as with any other change to the licensing basis – properly justified decisions maintaining transparency and safety are expected from the licensee.[3]

- Licensees report risk profiles measured by their risk monitor to their regulator in three of the six states:
  - Czech Republic: annually
  - Romania: annually
  - Spain: monthly (of both instantaneous and cumulative risk).
- In the majority of the responding countries the regulations, recommendations or regulatory approved procedures were developed jointly by the authority and the licensee, in an iterative process of several steps.

The survey also revealed differences in nuclear legislation of different states. In some countries the nuclear authority is empowered to declare general obligations of the licensees. The most typical example is the USA (where the NRC itself performs research necessary in support of legislation, too). However, in Hungary, for example, only the government may issue decrees (the nuclear authority may only compel licensees in given particular processes). There are also countries in which regulatory guides express "strong" recommendations, i.e. the guides are not just a possible way of fulfilling certain requirements, but directions, deviations from which shall be justified (e.g. Switzerland, Finland).

[3] According to the answer from Slovakia, their licensees shall demonstrate equivalence of the results of the static PSA and the risk monitor, but no written source was referenced. Chapter 12.1 of the [3] report mentions Mexico, where the authority supervised this conversion process in detail.

ACKNOWLEDGMENTS

The authors thank all the partners who responded to the information request. Naturally, those of them faced the more difficult task who gave detailed answers about regulatory documents on risk monitors. We express our special thanks to those who answered some clarifying questions in a relatively short time frame during the evaluation of the answers.

REFERENCES

[1] *A Nukleáris Biztonsági Igazgatóság biztonsági politikája és működésének alapelvei* (*Safety Policy and Operating Principles of the Nuclear Safety Directorate*). Hungarian Atomic Energy Authority, Nuclear Safety Directorate, date unknown (in Hungarian only)
http://www.oah.hu/web/v2/portal.nsf/letoltes_hu/B126DBAA47EC214CC125710B0057E2AF/$file/nbibiztp.pdf, retrieved: 18/12/2012

[2] *Terms of Reference. Pilot project to enhance operational safety of the Paks NPP based on risk-informed decision making*. HAEA–Paks NPP Co., KSZD-EM, Version 1.0, Paks, 23 April 2010

[3] *Risk Monitors: The State of the Art in their Development and Use at Nuclear Power Plants.* Produced on behalf of IAEA and OECD NEA WGRisk. NEA/CSNI/R(2004)20, 2004
http://www.oecd-nea.org/html/nsd/docs/2004/csni-r2004-20.pdf, retrieved: 03/01/2013

[4] *Use and Development of Probabilistic Safety Assessment.* NEA/CSNI/R(2007)12, Nuclear Energy Agency Committee on the Safety of Nuclear Installations, WGRISK, 14 November 2007
http://www.oecd-nea.org/documents/2007/sin/csni-r2007-12.pdf, retrieved: 03/01/2013

[5] Instruction on *criteria and requirements on the performance of probabilistic safety assessments and their applications for nuclear power plants.* IS-25, Consejo de Seguridad Nuclear, 9 June 2010 (unofficial English translation of Spanish original)
http://www.csn.es/images/stories/publicaciones/unitarias/normativa/is-_25i.pdf, retrieved: 25/06/2012

[6] *Actualización y Mantenimiento de los Análisis Probabilistas de Seguridad* (*Updating and maintaining probabilistic safety assessment*). GSG-01.15, Consejo de Seguridad Nuclear, 17 March 2004 (in Spanish only)
http://www.csn.es/images/stories/publicaciones/unitarias/guias_seguridad/gsg1_15.pdf, retrieved: 25/06/2012

[7] *Probabilistic Safety Analysis* (Issue 03). Technical Assessment Guide T/AST/030, United Kingdom Health and Safety Executive, 19 February 2009
http://www.hse.gov.uk/nuclear/operational/tech_asst_guides/tast030.pdf, retrieved: 10/11/2012

[8] *Normă privind evaluările probabilistice de securitate nucleară pentru centralele nuclearoelectrice* (*Norm regarding probabilistic nuclear safety assessments for nuclear power plants*). Comisia Națională pentru Controlul Activităților Nucleare, 17 November 2006 (in Romanian only)
http://www.cncan.ro/assets/NSN/nsn-8.pdf, retrieved: 07/11/2012

[9] *An Approach for Determining the Technical Adequacy of Probabilistic Risk Assessment Results for Risk-Informed Activities.* Regulatory Guide 1.200 U.S. Nuclear Regulatory Commission, February 2004; last updated: Rev. 2, March 2009
http://pbadupws.nrc.gov/docs/ML0904/ML090410014.pdf, retrieved: 03/01/2013

[10] *Criterios básicos para la realización de aplicaciones de los Análisis Probabilistas de Seguridad* (*Basic criteria for the implementation of PSA applications*). GSG-01.14 (Rev. 1), Consejo de Seguridad Nuclear, 12 July 2007 (in Spanish only) http://www.csn.es/images/stories/publicaciones/unitarias/guias_seguridad/gsg_1_14_revision1.pdf, retrieved: 25/06/2012

[11] *Probabilistic safety analysis in safety management of nuclear power plants*. YVL 2.8, Säteilyturvakeskus, 28 May 2003 (unofficial English translation of Finnish original) http://www.edilex.fi/stuklex/en/lainsaadanto/saannosto/YVL2-8, retrieved: 13/11/2012

[12] Instruction on *the requirements for monitoring the effectiveness of maintenance at nuclear power plants*. IS-15, Consejo de Seguridad Nuclear, 31 October 2007 (unofficial English translation of Spanish original) http://www.csn.es/images/stories/publicaciones/unitarias/normativa/is-15i.pdf, retrieved: 25/06/2012

[13] *Medida de la eficacia del mantenimiento en centrales nucleares* (*Monitoring the effectiveness of maintenance in nuclear power plants*). GSG-01.18, Consejo de Seguridad Nuclear, 31 October 2007 (in Spanish only) http://www.csn.es/images/stories/publicaciones/guias_seguridad/gs1-18ok1.pdf, retrieved: 25/06/2012

[14] *Monitoring the Effectiveness of Maintenance at Nuclear Power Plants.* Regulatory Guide 1.160, U.S. Nuclear Regulatory Commission, June 1993; last update: Rev. 3, May 2012 http://pbadupws.nrc.gov/docs/ML1136/ML113610098.pdf, retrieved: 03/01/2013

[15] *An Approach for Plant-Specific, Risk-Informed Decisionmaking: Technical Specifications*. Regulatory Guide 1.177, U.S. Nuclear Regulatory Commission, August 1998; last update: Rev. 1, May 2011 http://pbadupws.nrc.gov/docs/ML1009/ML100910008.pdf, retrieved: 03/01/2013

[16] *A Risk-Informed Technical Specifications Initiative 4b: Risk-Managed Technical Specifications (RMTS) Guidelines*. NEI 06-09 (Rev. 0), Nuclear Energy Institute, November 2006 (approved by NRC on 17 May 2007) http://pbadupws.nrc.gov/docs/ML1228/ML12286A322.pdf, retrieved: 08/01/2013

[17] *Nuclear power plant pressure equipment. In-service inspection with non-destructive testing methods.* YVL 3.8, Säteilyturvakeskus, 22 September 2003 (unofficial English translation of Finnish original) http://www.edilex.fi/stuklex/en/lainsaadanto/saannosto/YVL3-8, retrieved: 13/11/2012

[18] *Požiadavky na vypracovávanie analýz a štúdií PSA* (*Requirements for elaboration of PSA assessments and studies*). BNS I.4.2/2006, Úrad Jadrového Dozoru, 2006 (in Slovak only) http://www.ujd.gov.sk/files/legislativa/Bezpecnostne_navody/BNS%20I.4.2-2006%20Poziadavky%20na%20studii%20PSA.pdf, retrieved: 13/11/2012

APPENDIX 1.

RISK MONITOR REGULATORY QUESTIONNAIRE

Questions to Nuclear Authorities concerning Risk Monitor requirements

Country:	**Szöveg beírásához kattintson ide.**
Person providing the answers:	**Szöveg beírásához kattintson ide.**

0. *Issuance of requirements or guides*

- Has the Authority defined any requirements on Risk Monitors?
  Szöveg beírásához kattintson ide.
- Has the Authority developed any Regulatory Guides concerning Risk Monitors?
  Szöveg beírásához kattintson ide.

If yes…

1. *Do the requirements/guidance address* ***the PSA model****?*

- Do they refer to PSA scope?
  - types of initiating events (internal events, internal and external hazards)
  - plant operational states (e. g. full power, low power and shutdown modes, etc.)
  - possible sources of radioactivity (e.g. reactor core, spent fuel pool)
  - consequence categories (or levels of PSA level)
  - Is seismic PSA to be integrated into Risk Monitors? If yes, are there any difficulties or limitations foreseen in handling seismic risk together with other risk contributors?

  Szöveg beírásához kattintson ide.
- Are there any requirements in place on PSA quality (e.g. a performed independent review) that are specific to Risk Monitors?
  Szöveg beírásához kattintson ide.
- Do they refer to its Risk Monitor characteristic features? (e.g. unavailabilities due to maintenance, extension of the model to handle components in each train in symmetric multi-train systems which were handled together in the PSA, etc.)
  Szöveg beírásához kattintson ide.
- Do they address the frequency and contents of the model's updates?
  Szöveg beírásához kattintson ide.

2. *Are there requirements/guidance for* ***numerical risk targets or criteria*** *(CDF, LERF, etc.)?*

- Are there requirements for any point-in-time risk values? What are the consequences of exceeding the limits?
  Szöveg beírásához kattintson ide.
- Are there requirements for any cumulative (integrated) risk values (e.g. CDP for a given timespan)? What are the consequences of exceeding the limits?
  Szöveg beírásához kattintson ide.
- Are there requirements/guidance for the measures (actions) to be taken when exceeding certain thresholds according to the Risk Monitor?

Szöveg beírásához kattintson ide.

- Are risk reports (either regular or occasional, mandatory or recommended) prepared for the Authority based on Risk Monitor information? What are the requirements for the contents of these reports?
  Szöveg beírásához kattintson ide.

3. *Do any requirements/guidance address* ***licensee decisions and permit requests*** *based on Risk Monitor information (differing from former practice)?*

(e. g. monitoring the effectiveness of maintenance, operation and maintenance planning and management decisions, changes to the licensing/design basis, LCO exemptions, etc.)

Szöveg beírásához kattintson ide.

4. *Do the requirements/guidance address the* ***Risk Monitor software****?*

Szöveg beírásához kattintson ide.

5. *Does the Authority establish requirements/provide guidance for the* ***process of introducing*** *a Risk Monitor at a licensee?*

- Are there requirements/guidance to ensure equivalence between the results of the baseline PSA and the model converted for Risk Monitor application?
  Szöveg beírásához kattintson ide.
- Are there requirements/guidance for a trial application period?
  Szöveg beírásához kattintson ide.
- Are there requirements/guidance for developing internal procedures at the plant?
  Szöveg beírásához kattintson ide.

6. *Are there decisions in relation to Risk Monitor applications which the Authority* ***entrusts to the licensees*** *provided that they are well established and sufficiently documented?*

(e. g. the measures to be followed at entering certain numerical risk bands)

Szöveg beírásához kattintson ide.

7. *Are the requirements* ***differentiated*** *(e.g. multi-levelled) according to the* ***kinds of Risk Monitor applications*** *the licensee wants to pursuit?*

Szöveg beírásához kattintson ide.

8. *What was the typical* ***share*** *of regulatory and licensee initiatives in developing the requirements or guides?*

(We are more interested in practical experience than in percentage values.)

Szöveg beírásához kattintson ide.

9. *Are there any insights or lessons learnt concerning Risk Monitor regulatory requirements and guides that do not fit any of our above questions?*

Szöveg beírásához kattintson ide.