Proceedings of the International Workshop on Operating Experience (OPEX)

24–26 April 2017
Madrid, Spain
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ORGANISATION FOR ECONOMIC CO-OPERATION AND DEVELOPMENT

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The Committee on Nuclear Regulatory Activities (CNRA) is responsible for the Nuclear Energy Agency (NEA) programmes and activities concerning the regulation, licensing and inspection of nuclear installations with regard to both technical and human aspects of nuclear safety. The Committee constitutes a forum for the effective exchange of safety-relevant information and experience among regulatory organisations. To the extent appropriate, the Committee reviews developments which could affect regulatory requirements with the objective of providing members with an understanding of the motivation for new regulatory requirements under consideration and an opportunity to offer suggestions that might improve them and assist in the development of a common understanding among member countries. In particular it reviews regulatory aspects of current safety management strategies and safety management practices and operating experiences at nuclear facilities including, as appropriate, consideration of the interface between safety and security with a view to disseminating lessons learnt. It promotes co-operation among member countries to use the feedback from experience to develop measures to ensure high standards of safety, to further enhance efficiency and effectiveness in the regulatory process and to maintain adequate infrastructure and competence in the nuclear safety field.

The Committee promotes transparency of nuclear safety work and open public communication and oversees work to promote the development of effective and efficient regulation.

The Committee focuses on safety issues and corresponding regulatory aspects for existing and new power reactors and other nuclear installations, and the regulatory implications of new designs and new technologies of power reactors and other types of nuclear installations consistent with the interests of the members. Furthermore it examines any other matters referred to it by the Steering Committee for Nuclear Energy. The work of the Committee is collaborative with and supportive of, as appropriate, that of other international organisations for co-operation among regulators and consider, upon request, issues raised by these organisations.
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<tr>
<td>CNRA</td>
<td>Committee on Nuclear Regulatory Activities</td>
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<td>CNSC</td>
<td>Canadian Nuclear Safety Commission</td>
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<td>CSN</td>
<td>Consejo de Seguridad Nuclear (Spain)</td>
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<td>EC</td>
<td>European Commission</td>
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<td>EDF</td>
<td>Électricité de France</td>
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<td>GRS</td>
<td>Gesellschaft für Anlagen- und Reaktorsicherheit (GRS) gGmbH</td>
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<td>IAEA</td>
<td>International Atomic Energy Agency</td>
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<td>ICES</td>
<td>Institute of Nuclear Power Operations (INPO) Consolidated Events System</td>
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<td>INPO</td>
<td>Institute of Nuclear Power Operations</td>
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<td>IRS</td>
<td>Incident reporting system</td>
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<td>LER</td>
<td>Licensee event reports</td>
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<td>NEA</td>
<td>Nuclear Energy Agency</td>
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<td>NRC</td>
<td>Nuclear Regulatory Commission</td>
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<td>OEF</td>
<td>Operating experience feedback</td>
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<td>OPEX</td>
<td>Operating Experience</td>
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<td>RCA</td>
<td>Root cause analysis</td>
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<td>ROE</td>
<td>Reactor Operating Events</td>
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<tr>
<td>SMARTER</td>
<td>Specific, Measurable, Attainable, Relevant, Timely, Effective, Reviewed</td>
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<td>TSO</td>
<td>Technical support organisations</td>
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<td>WANO</td>
<td>World Association of Nuclear Operators</td>
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<td>WER</td>
<td>WANO Event Report</td>
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<td>WGIP</td>
<td>Working Group on Inspection Practices</td>
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<td>WGOE</td>
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Executive summary

Regulatory bodies use the Operating Experience (OPEX) process as a fundamental pillar of nuclear safety.

The purpose of the Working Group on Operating Experience (WGOE) was to organise an international workshop on OPEX to identify commendable practices with regulatory operating experience databases and discuss lessons learnt. The workshop was focused on the provisions taken by various countries to improve their operating experience database to capture recommended good practices and identify methods and systems to further enhance operating experience events databases.

After convening several organising meetings, the WGOE workshop was held at the Consejo de Seguridad Nuclear (CSN), on 24-26 April 2017 in Madrid, Spain. Approximately 42 participants took part in the workshop representing industry and government organisations from 19 different countries, as well as international organisations and the European Commission (EC). Participating countries included Belgium, Canada, China, Finland, France, Germany, Hungary, Japan, Korea, Poland, Russia, the Slovak Republic, Slovenia, Spain, Sweden, Turkey, the United Arab Emirates, the United Kingdom and the United States.

The workshop aimed at clarifying the different types of databases to be used, identifying commendable practices for the various applications of OPEX databases, and demonstrating practical solutions that are successfully utilised in the various countries.

Preceding the breakout sessions, each topic was introduced during a plenary session that included presentations and demonstrations by member countries on the status of regulatory operating experience databases, policies, practices and programmes. At the end of the breakout sessions, a plenary session allowed more detailed discussions. On the last day, a general discussion session concluded the workshop.

The participants expressed a strong interest in continuing efforts after this workshop. The following topics were highlighted by the participants as commendable practices that needed further development:

- Web-based systems recommended with single records for documents and capable of integrating multiple data streams for reporting, exporting and trending analysis. Use of semantic technology\(^1\) for automated event reporting, data entry and coding to facilitate text mining\(^2\), trending and correlations. Improved visualisation of OPEX data and user-friendly system that highlight events needed for OPEX review for lessons learnt.

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1. Technology that links data on the web or within an enterprise by developing languages to express rich, self-describing interrelations of data in a form that machines can process.

2. Extracting insights from a large corpus of text by using several specific tools and techniques including synonym detection, sentiment analysis, intent analysis, word cloud generation.
- Improvements in the data analysis and query functions and features. Periodic trending and analysis of national OPEX data for early detection and identification of weaknesses and potential deficiencies in regulatory functions.

- Common coding and harmonised reporting to facilitate creating a single international database. Increasing number of events reported in the International Atomic Energy Agency/Nuclear Energy Agency (IAEA/NEA) incident reporting system (IRS) database, recognising that this would result in increased opportunities for lessons to be learnt.

The workshop results should assist the further development of the international co-operation on OPEX by providing commendable practices on national OPEX databases, as a basis for national OPEX analyses.
1. Introduction

1.1. Background

The Nuclear Energy Agency (NEA) Committee on Nuclear Regulatory Activities (CNRA) Working Group on Operating Experience (WGOE) conducted an international workshop on best practices with regulatory Operating Experience (OPEX/OE) databases. The workshop was hosted by the Consejo de Seguridad Nuclear (CSN) in Madrid, Spain, from 24-26 April, 2017.

The main goal of the workshop was to share information on the use of OPEX databases and related practices and processes in the NEA member countries in order to highlight opportunities for improvements in using these databases by national regulators and/or their designees (e.g. technical support organisations [TSOs]).

Specialists from across the world gathered together to share their own countries’ or organisation’s experience and challenges. Each of the three topics addressed during the workshop was preceded by plenary presentations and demonstrations by member countries on their current status of regulatory operating experience databases, policies, practices and programmes.

The workshop results should enable the participants to review their national database structures, to identify potential gaps in international commendable practices and to initiate optimisation of their national database structure.

1.2. Objectives of the workshop

The main objective of this international workshop was to provide a forum to exchange information and allow groups of nuclear safety experts to discuss their national OPEX programmes, current challenges and good practices, so that other member countries could take account of them.

To identify the role of databases in the OPEX processes and programmes, the following was discussed during the workshop:

- tailoring of databases to the requirements derived from the national OPEX programmes;
- review of the rationale for the use of multiple databases and achieving the correct balance between generic and specific databases within the OPEX processes and programmes;
- use of databases for routine and/or specific trending;
- integration of OPEX feedback, including OPEX information from other countries, into databases.
Participants had the opportunity to meet their counterparts from other countries and organisations to discuss current and future issues on the selected topics. The workshop has led to conclusions and commendable practices regarding the topics to help participants to improve their own OPEX feedback and assessment methodologies.

1.3. Organisation of the workshop

The three-day workshop included breakout sessions and presentations. Three discussion groups were established for the breakout sessions. The members of each group were chosen to create a diversity of views for each of the topics. A session co-ordinator and a recorder worked with each group to stimulate, facilitate and encourage interactive discussions among participants. Discussion groups met for two separate breakout sessions to discuss the individual topics. The breakout sessions allowed groups of nuclear safety experts to discuss their national OPEX programmes, current challenges and good practices.

The role of databases in the OPEX programmes and their integration in the regulation and oversight of nuclear facilities was discussed and participants identified commendable practices for each topic, as well as key challenges. The exchange of ideas and opinions between participants was active and the groups formulated conclusions and recommendations based on the discussions.

The breakout sessions were focused on the following topics:

- Session one: structure, content and capabilities of regulatory OPEX databases;
- Session two: policies and practices associated with the operation of regulatory OPEX databases;
- Session three: integration/role of the regulatory OPEX processes and programmes.

Participation in the workshop was open to experts from regulatory authorities and their TSOs, research organisations, utilities, NPP designers and vendors, industry associations and observers.

The list of participants is provided in Appendix one.

The detailed workshop programme is provided in Appendix two.

The contributions presented are provided in Appendix three.

1.4. Topics of the workshop

The following topics were discussed during the workshop:

1. Structure, content and capabilities of regulatory OEPX databases

This group focused on the link between the structure and the purposes of the different national OPEX databases. The different types of database were identified and described, the needs of the various users clarified and, thus, the necessary output records of the database determined. To achieve these goals, the input of data and its assessment – including coding –, the amount of information stored, the needed interfaces between different databases were defined.
Policies and practices associated with the operation of regulatory OPEX databases. The discussions enabled the participants to present their own experiences and to learn about the various possibilities to organise national OPEX databases.

This group focused on the following areas:

- responsibility for inputting data to the database;
- assuring the quality of the data;
- automatic reminders to achieve timely input of further data arising from investigations;
- who is allowed to have access to the data in the database;
- processes to review the effectiveness of the database;
- responsibilities for ensuring the database remain compatible with changing operating systems;
- maintaining the security of the data;
- policies and practices associated with the operation of regulatory OE databases.

2. Integration and role of the regulatory OE databases within the OE processes and programmes

This group focused on how OE databases were used to assess licensees’ OE programmes (in OE screening, in daily-basis and periodic reviews, in inspections), to improve regulations or to define new requirements, to trending, etc.

The question was broken into three parts:

- How do we assess the licensees’ OE programme (using all available tools)?
- How do we improve regulations or define new requirements (using all available tools)?
- How to use OE databases to assess the licensees’ OE programme?
2. Summary of the workshop

The workshop included an opening session, three topical sessions with participant presentations followed by group discussions, and three facilitated breakout sessions led by the session co-ordinators.

2.1. Opening Session

The workshop chair, Mr Harold Chernoff, welcomed participants and thanked the Consejo de Seguridad Nuclear (CSN) in Madrid, Spain, for hosting the workshop.

Mr Ho Nieh, Head of the Division of Nuclear Safety Technology and Regulation at the NEA, also said a few words introducing the workshop and the importance of the use of databases in the Operating Experience process.

Welcome remarks were then provided by Mr Antonio Munuera, Head of the Division of Nuclear Safety at the CSN. Mr Munuera welcomed and thanked all of the participants and encouraged them to share their experience in order to achieve the workshop objectives and improve regulators’ OE databases. He highlighted the importance of improved understanding of the role of operating experience in assuring nuclear safety in the world’s operating NPPs. He also noted that the evaluation of safety significant events and how this information was stored in databases and analysed were always important to prevent future events.

The chair highlighted that the key outcome of the workshop was to develop a summary of commendable practices and to identify challenges with using the existing regulatory operating experience databases. He briefly discussed the objectives for the breakout sessions. He noted that each breakout group should identify commendable practices for their focus areas. He encouraged participants to think in terms of preventing events, improving effectiveness in regulatory practices and in licensees’ activities and practices; such as regulatory information summaries to alert licensees of issues. The goal was to identify one to three commendable practices for each focus area and subtopic, if possible. Each group was asked to identify challenges. At the end of the breakout sessions, each group was requested to provide a 30-minute presentation summarising in bullet form each commendable practice, the challenges identified for the focus areas and any significant barriers. For the proceedings, each group was asked to develop a brief paragraph for each commendable practice, and a paragraph explaining the challenges.

The chair explained that, during the plenary sessions in the workshop, there would be several presentations and demonstrations of national OPEX databases. For each topic, there would be an opening session to establish the context of the discussions. The participants were then divided into three smaller groups for detailed discussion. After the group discussions, a closing session would be held to review the results of the discussions, conclusions, commendable practices and challenges identified. He noted that the conclusions and recommendations developed during the workshop are neither
international standards nor guidelines. Each country should determine how best to incorporate the commendable practices, considering its own historical, social and cultural backgrounds recognising that the commendable practices can be useful references when each country looks to improve its OPEX processes.

2.2. Session one – Structure, content and capabilities of regulatory OPEX databases

This session was devoted to the efforts that many countries have engaged at the national level to strengthen the structure, content and capabilities of their regulatory OPEX databases.

Databases are a major working tool for all experts involved in operating experience assessment and feedback. But, there are no international requirements or guidance on the capabilities of such OPEX databases. In most cases, regulatory bodies and their TSOs run various OPEX databases for different purposes. First, there is an official database for reported events from NPPs and other nuclear facilities. In many countries the information on events is publicly available. Thus, these official databases must respect the public’s right to information as well as the protection of the licensee’s rights. Furthermore, technical experts need more information in their OPEX databases than just the event report information. They also need to store technical information, coding and follow-up actions. In addition, expert organisations run specific databases, e.g. on common-cause failures, material problems and human factors.

The various types of databases require different input and output possibilities, adapted user interfaces and search capabilities, etc.

Session one covered the basic understanding of the link between the structure and the purposes of the different national OPEX databases. The different types of databases were identified and participants described the needs of the various users and clarified the necessary output records of the databases. To achieve these, the participants defined the requirements for data input and assessment; including coding, the amount of information stored, and the interfaces needed between different databases.

The different types of data required specific handlings. For instance, event information, which has to be publicly available, has a preferential treatment. Technical basis information is less time sensitive; but requires thorough quality assurance process. The coding of event reports forms the basis for the use of OPEX databases for trending. Regular trending reports require expedient coding of the event information.

The following presentations were provided during the plenary session prior to the breakout for Session one:

- Presentation on the first workshop topic: Structure, content and capabilities of regulatory OE databases, by Dr Michael Maqua, GRS Cologne, Germany.
- Nuclear Safety Council EO DataBase, by Ms Vanessa Miranda and Mr Luis Gasco, CSN, Madrid, Spain.
- International Operating Experience Workshop on Best Practices with Regulatory Operating Experience Databases, by Mr László Juhász, Hungarian Atom Energy Agency.
- NNSA OPEX System and Information Platform in China, by Mr Zhi Xiao, Nuclear and Radiation Safety Centre.
Dr Michael Maqua, GRS Cologne, from Germany, discussed the International Atomic Energy Agency (IAEA) Safety Fundamentals, principle two, “Role of Government” which states that effective legal and governmental framework for safety, including an independent regulatory body, must be established and sustained. He noted the responsibilities of the regulatory body to set up appropriate means to inform parties in the vicinity, the public, the media and other interested parties on the safety of nuclear installations. The regulatory body must inform the public about the regulatory processes and the safety of the facilities; including health and environmental aspects. While Requirement 35 “Safety Related Records” requires, in addition to records on the activities and safety of the facilities, that an event database be maintained.

With regard to the latest revision of IAEA DS 479, operating experience feedback for nuclear installations, it was highlighted that it makes a clear distinction between a requirement for a licensee database and a regulator database. It also requires a collection of national and international operating experience. It should provide for searching capabilities and dissemination of information to the public (e.g. IRS/IRSSR/RINAS). The US delegate shared the position of the Nuclear Regulatory Commission (NRC) is; not to allow non-regulators to have access to the database. In other words, the NRC provides information to the public without providing access to the database.

At last, Dr Maqua highlighted that international rules and regulations require the use of regulatory event databases. He stressed that event databases form an indispensable tool for regulatory OPEX related tasks; e.g. interaction with the licensee on events, responding to information requests on events from parliament and the public. Moreover, they form the basis for administrative and technical knowledge across different licensees, sites, NPP designs, systems, components, manufacturers and even provide a baseline for international event information. The structure of regulatory event databases (input, information processing, and output requirements) must be balanced, co-ordinated and complementary. The storage of additional information, besides event information, has been proven as a good practice. Trending functions are helpful for many reports and additional coding has been found very practical.

Many presenters described their OPEX programme arrangements and how they have been enhanced. Participants shared thoughts regarding the structure of the OPEX database and the reporting criteria and categories, reporting thresholds and the content of the reporting.

Ms Vanessa Miranda (CSN) described the operating experience process in Spain. She noted that sources of national OE data come from resident inspectors, notifiable event reports and the annual OE report. It also includes international data from IRS, WGOE, NRC and EC. Mr Luis Gasco, CSN, provided a demonstration on the OE database. The database contains registration and classification of NPP notifiable events. He explained the classification system and risk indicators. The database includes root causes and corrective actions. The licensee’s root cause analysis is reviewed by CSN. The reactor oversight process with risk indicators is publicly available. The generic issue database includes events that are applicable to two or more nuclear power plants. The generic issue database and the licensee’s event reports are only available internally to CSN. He explained that there is a specialist review board that determines which international event is applicable for CSN oversight of Spanish NPP. Regarding Spanish OE, another review board determines if a Spanish event is significant and if a follow-up analysis is necessary or if a reactive inspection is warranted. All licensee event reports are made public. The licensees have a lessons-learnt database which is inspected by CSN; but the regulator do not have a lessons-learnt database.
Mr László Juhász, Hungarian Atom Energy Agency, provided a demonstration on the OE database programme in Hungary. The database includes both national and international data. He described the event reports and the implementation of corrective actions tracking tool. The domestic events in the database include emergency and reportable events above a certain criteria, near misses and low-level events. It includes a safety importance ranking feature, corrective actions, monitoring and tracking status fields. The annual performance report includes a summary of all the events reviewed by the regulatory body and it is available to the public. He further explained the regulatory experience database which is used to inform the regulatory process for new requirements.

Mr Zhi Xiao from China, Nuclear and Radiation Safety Centre, provided an overview of their OPEX programme and a presentation on OPEX system, framework and information platform. The presentation included a description of the event reporting and investigation process. The OPEX information platform includes a comprehensive set of databases and information consisting of: licensee event reports (LER) and low-level events, international events, inspection reports, information notices, annual reports, etc. He described the database event report format for operating NPPs, New construction NPP event database, the on-line automated root cause analysis (RCA) tool, corrective actions, etc. The LERs are not publicly available. China has bilateral agreements in place to share information with other regulators.

Mr Adam Napke, Canadian Nuclear Safety Commission (CNSC) provided a demonstration of their OE database. He explained that the protective data is stored in a separate database with access control. The database tracks the status of all the events reported. When an IRS report is issued; it is distributed to the appropriate specialist for review. The review produces recommendations and lessons learnt, as it applies to Canadian NPPs. The screening process determines the necessary assessment, recommendations and lessons learnt. A separate database is used for tracking licensee actions. The regulator’s corrective action programme, includes recommendations for updating regulatory oversight requirements, guidance, practices or inspection processes. These recommendations are reviewed by a CNSC committee to ensure that approval and implementation may not result in unintended consequences. A tracking tool is under development to monitor the status of actions and they expect to have that capability in the near term.

A demonstration was provided by Mr Jesse Robles, of the US Nuclear Regulatory Commission (NRC), on the Reactor Operating Events (ROE) database used to track dispositioning of data sources. The database includes INPO Consolidated Events System (ICES), an external source of data available to NRC on a limited basis. He also highlighted challenges with the operating experience database, such as, limited ability for trending analysis and issues with the quality of the data. Mr Robles provided a demonstration of the Operating Data Analysis Tool. The goal of this tool is to analyse system failure data and failure causes on demand, to identify areas of additional focus, to perform trending of component failures and to inform the inspection process. The database currently contains ICES data, which includes component failure data for both safety and non-safety related components. It also includes data from the IAEA/NEA incident reporting system (IRS). The US NRC offered to assist WGOE members interested in applying this tool in their own country, noting that the tool can be readily adopted for IRS data per country.

A demonstration was provided by EDF on the new OE database being implemented in France. The database is shared among all NPPs in France. The OE databases are
migrating to SharePoint in 2019. Event condition reports are reviewed for further action including processing additional “facets” for each type of action, such as, technical, production, house-keeping, regulation issue, debriefing, corrective action programme, etc. From a single core event condition report, thematic “facets” are attached for additional actions, as necessary depending on the review. The objective is to expedite the managerial decision process to field work orders. The field OE database provides for recommendations to update procedures, and allows for erasing notes that are no longer applicable. In the future they plan to explore OE as a social network to facilitate communication among the OE oversight community of experts and field workers on the relevance and effectiveness of proposed actions, developing lessons learnt and sharing of best practices.

The breakout session enabled the participants to discuss their own experiences and to learn about the various possibilities to organise national OPEX databases.

Among the various presentations and related discussion the following common themes have emerged:

- user experience issues;
- querying difficult;
- some documents are stored in file systems, rather than database;
- regulatory databases only focus on events of regulatory interest (e.g. LERs);
- varying levels of requirements (e.g. deficiency reports);
- different organisations have different needs;
- varying requirements for storage and management of records.

Regarding the differences between national approaches, various speakers discussed their regulatory functions and requirements. Other speakers described their country specific use and integration with the IRS.

At the end of the discussion, it was noted that while speakers talked about providing additional enhanced querying capabilities; there was little information on any enhancements being made to harmonise IRS for integrating multiple databases with the national OPEX database and related regulatory infrastructure.

It was also unclear how harmonisation would be achieved, in practice, especially given that different organisations have different needs and where additional personnel or significant increases in resources were required.

**Recommendations:**

- Country specific solutions.
- Organisation specific solutions (TSO, RB).
- Web-based systems recommended for new or renewed systems.
- Reporting, exporting and trending capabilities are necessary.
- Use database for workflow in addition to storage.
- Single records for documents.
2.3. Session two – Policies and practices associated with the operation of regulatory OPEX databases

1. General approach

The discussions have been focused on how databases can be used effectively. The group shared experience and practices that could strengthen the robustness of the database at the different phases of the life of data as shown on Figure 2.1.

Figure 2.1. Data life simplified logic

![Data life simplified logic](image)

2. Integration of a database in overall processes

The group underlined that the draft guide DS479 from the IAEA gives a good suggestion for the integration of a database within an OEF programme, as shown on Figure 2.2.

Figure 2.2. IAEA Draft DS479 – Schematic diagram of a typical operating experience programme

![IAEA Draft DS479](image)
Decisions will be taken considering outputs of OEF databases regarding:

- screening the events that occurred for assessing the need for a deeper analysis or actions to be undertaken;
- implementing corrective actions, and reviewing the effectiveness of those actions;
- improving the regulatory processes.

Information and input to the databases will be among the decisions to be taken.

3. Information and input

3.1 Sources

The sources of information that the group identified to feed the database with data concerning OPEX are as follows:

- event reports from licensees;
- international events, for example IRS reports;
- inspection reports by the regulator, which can also inform OPEX as well as OPEX informs inspection practices.

A good practice consists in using influence on licensees so that the reports they produce for events are written to lessen the workload for inspectors to transfer the information into the database. Online reporting system automatically feeding the regulator database can prove useful in that regard.

3.2 Quality of information

In order to operate a database capable of delivering useful information, the quality of input information is crucial. Bad quality input cannot be compensated and will likely result in bad quality output.

The group identified the following recommendations in order to get the appropriate quality of information:

- setting clear reporting criteria;
- detailed guidance from the regulator regarding event reporting;
- influence the licensee to produce clear event reports of appropriate quality;
- work with IT to ensure high quality OCR/word processing of licensee inputs, so that data can be mined from the reports.

3.3 Points of attention regarding the input

On the same level as the previous items, and as long as the information is not yet loaded in the database, attention must be put to the input of event data.

Recommendations from the group to that regard are the following:

- Administrators designated to carry out the input is a preferable option than inspectors having to perform it. It ensures homogeneity of the input and
participates in the protection of data by limiting the number of people having unlimited access rights to the database.

- The use of automation is beneficial, i.e. the most possible automatic uploading of the information received to the database (conversion of files received, online event reporting system...).
- The group found no fundamental objection to the licensee having a limited access to input event reports.

4. Database and applications

4.1 Access control

The group acknowledges the necessity to have a range of levels of access to the database, so that the data is protected appropriately. This may include:

- “read only” for most users;
- “limited write access” to enable identified users to have the appropriate access to write information relevant to their job role;
- “complete write access” for “super-users”;
- modification capabilities for specialist IT staff.

4.2 Further input of event data

The access control should be related to the staff identified as potentially having the need to complement event data with further information.

Further event data that should be linked to an event and identified by the group are the following:

- status of assessment of the documents and information, even if it is a statement of no-follow-up required;
- licensee’s follow-up report;
- oversight findings: inspection reports, complementary licensee information.

If some of this information is in other databases, links with the OPEX database should be put in place.

Given the range of sources of the potential information, there is still benefit to preserve some flexibility to the access control. For example, the inputs may arise from the OPEX team, site inspectors and specialists.

4.3 Quality assurance of data

A certain level of validation and verification is expected to ensure data input is of sufficient quality.

Recommendations from the group in that regard are as follows:

- The inspector carrying out the first step of interaction with the database regarding an event reported and loaded in the database should review the data, in particular the description of the event. This is valid in case he is not the person conducting
the input in the database (see Point 3.3 for suggestions on who may be responsible for the input).

- Data arising from the review group (OPEX team or specialists reviewing an event, as described in Section five) should be reviewed prior to being loaded in the database.

- Automatic data evaluation should be implemented, for example mandatory fields and logical connections between pieces of information related to an event. The database application can include simple (or complex) automatic checks to eliminate errors.

- History logs (when and who changed data) and version handling should be used.

5. Review group

The establishment of a group to review event information to screen and identify lessons learnt is recommended. Most countries have set up such an organisation. This review group should have a clear mandate, include members of the OPEX team or specialists, and specify any further work to be carried out so that clear lessons can be identified.

Concerning the database, this review group’s role would be to generate clear, usable outputs and be part of the anticipated staff to have interaction, and thus access rights, to the database.

6. Outputs

The database’s goal is to deliver quality outputs for the proper consideration and assessment of OPEX. The outputs may be classified into two categories: standard and regular outputs, and ad hoc outputs.

6.1 Regular and standard outputs

The database should be able to generate easily standard outputs such as:

- evaluated and coded individual events;
- events in evolution;
- statistics including trend analyses (periodically and on demand);
- standard regular reports;
- reporting of missing data and information.

6.2 One-off outputs

The database should be flexible and able to generate the following outputs with limited intervention:

- specific topical queries;
- extraction of information to develop topical studies, advice notes, information notices, etc.;
- specific non-standard trend analyses.
7. Information security

Considering the security of the database is crucial, and advice should be sought from experts for best practices on data:

- confidentiality;
- availability;
- integrity.

Experts on security have their own area of expertise and such consideration could not be addressed further by the group.

8. Challenges

Challenges for sharing events among the international community are multiple. As of today, the main challenges lie with the following items:

- Access to event reports and information is a fundamental basis for performing OPEX. The IRS database offers the unique opportunity to get a deep insight in events which happened in other countries. This database however does represent only a small part of global events. A challenge would be to increase the number of events on the IRS database, recognising that this would result in increased opportunities for lessons to be learnt but at a cost of more work.

- Recognising that low-level events could be precursors to more significant events, the question remains opened as to share low-level event information.

- Data protection requirements are an increased worry in the wake of recent events regarding data protection.

Inputting events in the IRS database requires work that can be heavy as events are loaded in the country database and then again in the IRS but with different criteria. Sharing the maximum information would be easier with a common database. As a conclusion, the group shares a view of a harmonised database which would give such opportunity in Figure 2.3.
2.4. Session three – Integration and role of the regulatory OPEX processes and programmes

This session was devoted to the question of how regulatory bodies use OPEX databases and processes to continuously improve their regulatory functions. In other words, how OE databases are used by the regulator; for instance, for OE screening, on a daily-basis and for periodic reviews, for inspections, to improve regulations or to define new requirements, for trending analyses, etc.

The following presentation was provided during the plenary session prior to the breakout for Session three:

- Topic three: “Integration/Role of the regulatory OPEX databases within the OPEX processes and programmes”, by Mr Adam Napke, CNSC, Canada

Mr Napke explained this topic was divided into three questions:

1. How do we assess the licensees’ OE programme, using all available tools?

We use several inputs to evaluate the licensees’ Operating Experience programme.

Inputs

- Desktop reviews of scheduled reports by specialists.
- Field inspections – scheduled and unscheduled.
- Daily Surveillance by resident inspectors.
- Event reviews by resident inspectors and technical specialists – OPEX clearinghouse programme and database.
- Tracking of licensee’s corrective action.
Output – assessment of licensee’s programme

The corrective actions are the output in the assessment of licensee’s programme. Mr Napke shared the SMARTER (Specific, Measurable, Attainable, Relevant, Timely, Effective, Reviewed) model for evaluating corrective actions. He explained that the programme should supervise unintended consequences and the assessment should evaluate how capable the licensee is to learn from its own mistakes and those of others to prevent the recurrence of events.

2. How do we improve regulations or define new requirements, using all available tools?

Inputs

- On-site inspections.
- Event investigations.
- Event reviews (domestic and international (IRS)) – CNSC’s OPEX Clearinghouse.
  - What have you learnt? – Lessons Learnt.
  - What are you going to do about it? – Corrective Actions proposed/taken/implemented by the licensee.
  - Did it work? – tracking for effectiveness and unintended consequences.

Output – Actions on the regulator

- Determine Lessons Learnt for regulator.
- Create and implement corrective actions for regulator.
- Monitor for unintended consequences.
- Changes to regulatory documents, framework (e.g. add a whistleblower policy) and inspection practices (e.g. modify inspection guides).

3. How to use OE databases to assess the licensees’ OE programme

Some specialists use OE databases to assess the licensees’ OE programmes. At this point, some are considering improving codes to be more like the IRS codes. Moreover, coding licensee events to determine whether there are any trends over a two-to-five year rolling period will enable to identify any safety issues that need to be addressed. The following subtopics were included in the breakout session.

- Licensees’ event reporting criteria (threshold to report an event).
- Event coding (high level or low level, similar to IRS event codes, etc.).
- Screening.
- Trending.
- Analysis.
Mr Napke described the World Association of Nuclear Operators (WANO) Operating Experience model based on preventing events by learning from others and yourself. The WANO OPEX programme informs members about incidents at other plants so they can take corrective actions to prevent similar occurrences at their own plant. Its success stems from the willingness of WANO members to openly share their OPEX for the benefit of other operators throughout the world. They define an event as any significant deviation from the normal expected functioning of a plant. When an event occurs, the affected plant management and staff analyse it and completes a WANO Event Report (WER), which is then sent to their WANO regional centre and posted on the members’ website. Recognition of the importance of this activity is growing and, as a result, the total number of events reported by WANO members continues to increase.

In summary, Mr Napke explained the overall point is to look at events, to find out what went wrong and to determine what we can do to help prevent recurrence.

During the breakout session, a significant portion of the discussions was focused on defining the use of OE databases and processes to meet OPEX objectives. Led by Mr Adam Napke, a proposal was made to refocus the workshop topic for this session to capture recommendations and best practices for each of the objectives identified during the breakout session. This proposal led to a lot of discussion where most of the participants agreed based on practical experience and regulatory safety considerations to the following five objectives for the use of OPEX databases:

- Objective one: improve effectiveness of regulatory framework.
- Objective two: improve effectiveness and efficiency of inspection practices.
- Objective three: promote national and international sharing of lessons learnt and corrective actions.
- Objective four: promote licensee reporting and improve the quality of the event reports.
- Objective five: improve risk ranking, tracking, monitoring, analysis and trending of OPEX data.

Among the various presentations provided during the plenary sessions and the related discussion during the breakout sessions the following common themes and challenges have emerged:

- need to improve assessment of licensees’ OPEX processes and performance;
- gaps in regulatory requirements which prevent reporting of important events that never get to the OE database;
- information technology and financial support for OE database functionality and continual improvement;
- identify barriers to open communication with industry groups and to licensee event reporting, e.g. industry incentives for not reporting and public exposure;
- number of different systems and regulatory framework between regulators and across the industry;
- inconsistency of national, international and industry categorisation of events.
The objective of regulation is to control risks and compliance inspection is the primary activity of the regulatory body to gather data to verify the current situation at the NPP. Sharing data and experience to attain greater effectiveness and improvements is the definition of OPEX. Reporting and the quality of corrective actions depend on the detailed analysis of fulsome data. The quality of the corrective action is a direct result of the quality of the analysis. Risk ranking enables effective allocation of resources for the greatest benefit. Effectively tracking identified problems is key to improvement. For example, improving reporting requirements and criteria will result in improved OPEX data. Notifying other regulators of the improvements can save effort and time for better efficiency. Participants discussed the EDF presentation and suggested a concept for a collaborative website similar to a discussion forum to ask questions or work on similar issues and easily share data and details; e.g. virtual working groups. Including lessons learnt and corrective actions in the database provides effective sharing, as well as facilitating tracking and trending analysis. With regard to improvements in inspection practices, items identified by OPEX can be easily included within the routine inspection guidance. Safety culture and organisational issues often need extensive investigation and information gathering that can be stored in OPEX databases. The participants discussed the benefits of improved visualisation of OPEX data; such as the demonstration in the NRC presentation.

Recommendations:
Based upon the discussion during the breakout session, a number of participants inquired about further efforts after the WGOE workshop and particularly related to the importance of international tools, methods and processes to meet the five objectives identified for OPEX databases.

The resulting recommendations and commendable practices for each of the objectives identified during the breakout session are captured below.

Objective one: improve effectiveness of regulatory framework
- use the database as a tool to identify the need to implement new and revised regulations to address identified deficiencies, gaps and weaknesses;
- use the database as a tool to identify what is important for the allocation of regulatory resources in a risk-informed manner;
- provide international shared workspace for regulators to ask questions, share information and improvements, e.g. RegNet or WGOE online forum;
- acquire regulatory lessons learnt and corrective actions from OPEX data within national OE database.

Objective two: improve effectiveness and efficiency of inspection practices
- inform inspections by updating inspection criteria to verify requirements related to lessons learnt and corrective actions;
- scheduled of inspections commensurate with frequency and significance of events in the annual plan;
- identify potential risk areas and relevant matters for inspection;
• provide national and international opportunities to participate in identification of
inspection improvements and additional OPEX data and lessons learnt with the
Working Group on Inspection Practices (WGIP), e.g. joint workshops;
• ensure data presentations to inspectors are easy to understand and are used during
inspection planning and by managers in decision making;
• collect feedback from inspectors on inspection procedures.

Objective three: promote national and international sharing of lessons learnt and
corrective actions
• promote global thinking and open communication;
• share regulator’s corrective actions in response to lessons learnt;
• promote awareness and availability of national and international OE databases
and opportunities for OE sharing;
• promote integration of databases;
• improve consistency of collected event data using international reporting
templates;
• promote the use of codes and improve international links in different coding
systems (WANO/IRS);
• provide international shared workspace for regulators, e.g. LinkedIn, community
of practice.

Objective four: promote licensee reporting and quality of event reports
• apply lessons learnt broadly from the nuclear industry;
• inform and focus inspections;
• avoid penalising licensees for reporting of non-mandatory events;
• identify gaps in requirements that prevent reporting of important OPEX events;
• improve safety culture to encourage reporting and open communication even
though it is mandatory under reporting requirements;
• improve national consistency of reporting criteria that is technology neutral;
• expand database to include non-mandatory events.

Objective five: improve risk ranking, tracking, monitoring, analysis and trending of
OPEX data
• linking and integration of all OPEX data across all databases and sources;
• periodic trending and analysis of national OPEX data for early detection and
identification of weaknesses and deficiencies in regulatory functions;
• user-friendly system that highlights events needed for OPEX review for lessons learnt;
• semantic technology for automated event reporting, data entry and coding to facilitate text mining, trending and correlations;
• ensure OPEX data quality and integrity specifically for event coding;
• regular screening meetings of reported events by multidisciplinary team;
• collect suggestions of potential risk areas from inspectors and more broadly from the nuclear community;
• improved visualisation of data to assist in analysis and trending;
• ensure tracking of the completion of licensee corrective actions.
3. Conclusions and recommendations

The following conclusions emerged from the workshop and provide an overview of the recommendations and commendable practices identified by the participants. The commendable practices are based on workshop discussions and do not reflect a consensus of all NEA member countries’ opinions. Nevertheless, they can be used as a general benchmark for an effective Operating Experience (OPEX) database and to better understand the challenges that participating countries share. Overall the workshop provided an effective means for the participants to share their knowledge and insight on OPEX databases and programmes, and related regulatory activities. The participants were encouraged to bring back the commendable practices identified to their organisations with the goal of enhancing their regulatory programmes to improve their nuclear safety oversight and to better capture and share OPEX information within their own organisations and the international community.

The safety oversight and operating experience regulatory processes for nuclear power plants can be improved by learning from commendable practices from other member countries and furthermore, the co-operation among member countries to improve nuclear safety can be promoted by using databases as a tool to identify what is important for the allocation of regulatory inspection resources in a risk-informed manner.

The focus of the closing session was on the conclusions, commendable practices and challenges identified during the break out sessions and subsequent plenary discussions. Through the discussion and facilitated break out sessions, it was found that there are still challenges related to each area. However, implementing the following improvements and commendable practices identified during the workshop would greatly enhance the OPEX process:

- Based upon the panel discussions at the end of the workshop, a majority of the participants suggested the need for continuing efforts after the WGOE workshop and particularly the need for linking and integrating OPEX data across all databases and sources, as well as the importance of international tools, methods and processes to improve consistency and harmonisation on the use of OPEX databases and to ensure data quality and integrity for event coding by promoting the use of codes and improving international links of different coding systems (WANO/IRS). The groups concluded that any process should have the capability to transfer operating experience transparently between the regulators and the nuclear industry, e.g. the Nuclear Energy Agency (NEA), the International Atomic Energy Agency (IAEA), the European Commission (EC) and the World Association of Nuclear Operators (WANO).

- Recognising that low-level events could be the precursor to more significant events, there could be opportunities to share non-reportable event information, which would result in increased opportunities for lessons learnt. It will be very beneficial to continue to share international information on events; including low-
level events, non-nuclear events, near misses, safety culture events, non-radiological events, WANO events and information collected through non-reporting means such as inspections, surveillance and monitoring, informal discussions with licensees and share agreements with other organisations. All this would eventually lead to the development of suitable international recommended practices for:

- increasing the number of events reported on the IRS database;
- data protection requirements;
- reliability and robustness.

- There is a need for further development and improvements in the data analysis and query functions and features:
  - development of enhanced querying, reporting, exporting, and trending capabilities;
  - application of semantic technology for automated event reporting, data entry and coding to facilitate text mining, trending and correlations;
  - improved visualisation of data to assist in analysis, trending and decision making;
  - single records for documents, integration of multiple data streams and recommended web-based systems.

- In co-ordination with the Working Group on Inspection Practices (WGIP), provide national and international opportunities to identify additional OPEX database features and lessons learnt to improve the inspection process; e.g. hold joint workshops with inspectors to determine priority for improvements:
  - ensure the presentation of data to the inspectors is easy to understand and use during inspection planning and for management to use in decision making;
  - collect feedback from inspectors on inspection procedures;
  - collect suggestions of potential risk areas from inspectors and more broadly from the nuclear community;
  - consider the use of trending tools to improve insights in the day-to-day role of inspectors.
4. APPENDIX 1: LIST OF PARTICIPANTS

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5. APPENDIX 2: WORKSHOP PROGRAMME

Opening Session
- Welcome by the Spanish Regulatory Body (CSN), NEA Mr Ho Nieh and WGOE chair Mr Harold Chernoff

Topics presentation session
- Presentation on the first workshop topic: Structure, content and capabilities of regulatory OE databases, Dr Michael Maqua.
- Presentation on the second workshop topic: Policies and practices associated with the operation of regulatory OE databases, Mr Iain Gray.
- Presentation on the third workshop topic: Integration/role of the regulatory OE databases within the OE processes and programmes, Mr Adam Napke.

Breakout sessions
- Breakout Session presentation one: Structure, content and capabilities of regulatory OE databases.
- Breakout Session presentation two: Regulatory Operating Experiences Databases.
- Breakout Session presentation three: Integration/Role of the regulatory OPEX databases within the OPEX processes and programmes.

Demonstrations
- Host country demonstration on OE DB, Ms Marisa Guntiñas (CSN)).
- Demonstration on OE DB, Mr László Juhász (Hungarian Atomic Energy Authority).
- Demonstration on OE DB, Mr Long Xu You (NNSA).
- Demonstration on OE DB, Mr Richard Cawthorn, Mr Adam Napke (CNSC) - no presentation material.
- Demonstration on OE DB, Mr Jesse Robles (NRC) - no presentation material.
- Demonstration on OE DB, Mr Beckert Clément (EDF) - no presentation material.
6. APPENDIX 3: PRESENTATIONS

International Operating Experience Workshop on
Best practices with regulatory operating
experience databases

Presentation on the 1st workshop topic:
Structure, content and
capabilities of regulatory OE databases

Dr. Michael Maqua, GRS Cologne

24-26 April 2017
CSN, Madrid, Spain

Content
- Rules and Regulations
- Structure, Content and Capabilities
- Other event databases
- Final Remarks
Rules and Regulations

IAEA Safety Fundamentals

Principle 2: Role of government
An effective legal and governmental framework for safety, including an independent regulatory body, must be established and sustained.

The regulatory body must:
- ...
- Set up appropriate means of informing parties in the vicinity, the public and other interested parties, and the information media about the safety aspects (including health and environmental aspects) of facilities and activities and about regulatory processes;
- ...

GSR Part 1 (Rev. 1):
Governmental, legal and regulatory framework for safety

Requirement 35: Safety related records
- The regulatory body shall make provision for establishing, maintaining and retrieving adequate records relating to the safety of facilities and activities.
- The regulatory body shall make provision for establishing and maintaining the following main registers and inventories:
  - ...
  - Records relating to the safety of facilities and activities;
  - Records that might be necessary for the shutdown and decommissioning (or closure) of facilities;
  - Records of events, including non-routine releases of radioactive material to the environment;
  - ...
GSR Part 1 (Rev. 1):
Governmental, legal and regulatory framework for safety

- The regulatory body may ... be ... responsible for the maintenance of these registers ..., but it shall be involved in their proper retention and use.
- The requirement for the regulatory body to maintain records cannot diminish the responsibility of authorized parties to keep their own records.

Applicants shall be responsible for ensuring the recording of information relating to facilities and activities in registers and inventories, and analysing it, where relevant, for the purposes of demonstrating safety.
- Moreover, the regulatory body shall use such records in support of its regulatory functions and to support the enforcement of regulatory requirements.

DS 479: Operating experience feedback for nuclear installations

Screening and Analysis
- In addition to the information discussed in chapter 2 (licensee's OPEX program), other relevant information should be included in the screening process. This may include:
  - reports produced by regulatory bodies,
  - international forums,
  - Safety Performance Indicators,
  - operating experience databases (International Reporting System for Operating Experience / Incident Reporting System for Research Reactors / Fuel Incident Notification and Analysis System) and
  - other international topical studies.

DS 479: Operating experience feedback for nuclear installations

- The regulator's operating experience process should include screening, investigation, analysis, evaluation, review, inspection, utilization, dissemination, reporting, storage and retrieval of operating experience. The focus and specific arrangements of the operating experience process may differ depending on the organization's / regulatory body's tasks and responsibilities. Nevertheless, the operating experience system should reflect the following:
  - Collection of national and international operating experience;
  - Screening of operating experience — primarily on the basis of actuator potential safety significance;
  - Investigation and in-depth analysis, including causal analysis where appropriate;
  - Oversight activities and recommended actions resulting from analysis, including approval, implementation, tracking and evaluation;
  - Wider consideration of trends and review;
  - Dissemination and exchange of information, including by the use of international systems;
  - Continuous monitoring and improvement of operating experience related processes;
  - Storage, retrieval and documentation system for operating experience.
**DS 479: Operating experience feedback for nuclear installations**

- **Documentation**
  - The regulatory body should implement a system for storage, retrieval and searching of operating experience. An effective search should be possible via an appropriate coding or keyword system.

- **Communication: Dissemination and Utilization**
  - The regulatory body should set arrangements for disseminating operating experience information (including generic communication) to relevant organizations and interested stakeholders.

**DS 479: Operating experience feedback for nuclear installations**

- Communication: Dissemination and Utilization (cont'd)
  - The regulatory body should have procedures in place to collect international operating experience and share with domestic operating organizations where applicable.
  - Procedures should also be in place for sharing domestic operating experience with the international community for example through international databases (e.g. IFS / RSRR / FNAS) as well as through working groups, meetings, and through regular contact with other regulatory bodies.
  - These activities can also be enhanced through bi-lateral and multi-lateral agreements between countries.
  - The information shared should include what, if any, regulatory experience that was used to make enhancements to the regulatory body’s regulatory framework in accordance with GSR Part 1, Requirement 15.

- An event description should consist of:
  - event description;
  - history of earlier events;
  - direct causes;
  - root causes and contributors;
  - corrective actions;
  - schedule for completion of corrective actions;
  - safety significance including risk insights.

NEA “Green Booklet”: Regulatory Challenges in Using Nuclear Operating Experience

- Definition of operating experience:
  1. actual operating events, typically plant transients accompanied by equipment failures, human errors or other anomalous behaviour;
  2. actual failures of systems, structures or components, or human errors, that may or may not have caused a plant transient;
  3. adverse safety conditions such as design weaknesses, degraded safety equipment or aging effects that could lead to failures of systems, structures or components;
  4. external challenges such as vulnerability to severe weather, flooding, high winds or security threats;
  5. organisational or human factor issues such as a degraded safety culture at a plant, high human error rates, weak quality assurance (QA) programmes, inadequate procedures, inadequate training or inadequate control of contractors at a plant site;
  6. new information, such as research results or new safety analyses, showing a previously unknown weakness in a safety system or a fault failure vulnerability; and
  7. non-nuclear experience such as equipment flaws or seismic effects on non-nuclear structures and equipment.

NEA “Green Booklet”: The Characteristics of an Effective Nuclear Regulator

- Openness and Transparency:
  - Information concerning incidents and events at nuclear facilities, their safety relevance and regulatory measures should be made publicly available.
  - Communications should be clear to the public and other competent authorities.
Structure, content and capabilities

Some basic thoughts

- Openness and Transparency:
  - Information concerning incidents and events at nuclear facilities, their safety relevance and regulatory measures should be made publicly available.
  - Communications should be clear to the public and other competent authorities.

Some basic thoughts on structure

Database vs. Data Warehouse vs. Portals

- Type of information
  - Reported events
    - National
    - and international?
  - Licensing and supervisory documents
    - Licensees documents
    - Regulatory documents
      - Inspection reports
      - Letters to the licensee
  - External operating experience documents
  - Other documents
    - Description of NPP types
    - Manufacturers’ documents (e.g. pumps, valves)
Reporting Criteria and Categories (1)

While the aim is to report near miss events, the process of reporting is initiated only when one or more criteria are met. The reporting criteria for events should include the following:

1. A plant shutdown as required by the operational limits and conditions.
   For example, if a limiting condition for operation required that the plant change mode from full power operation to another mode, such as hot shutdown or cold shutdown, because of the unavailability of an essential electrical transformer, then this should be reported pursuant to this criterion.

2. An operation or condition prohibited by the operational limits and conditions. The operational limits and conditions include values for safety limits, limiting safety system settings, limiting conditions for operation, levels for surveillance, design features, and various administrative and organizational requirements if directly connected with plant operations.
   For example, if a component in a safety system (for example, a pump) was found to be inoperable for more than 7 days, but was only allowed by the operational limits and conditions to be out of service for a maximum of 17 days during an outage, then this would be reportable as a breach of the operational limits and conditions.

Reporting Criteria and Categories (2)

3. Any event or abnormal condition that resulted in the condition of the nuclear installation, including its principal safety barriers, being seriously degraded.
   This criterion could include conditions for which the plant was in an unanalyzed condition; a condition outside the design basis; or a condition not covered by the normal or emergency procedures for the plant. For example, if a pressurized water reactor were in a transition state in terms of temperature and pressure, in which the pressure-temperature relationship was outside the range covered by operating guidance, then this would be reportable. Degradation of the fuel, the primary coolant system or the containment as the principal barriers would be included in this criterion.

4. Any natural phenomenon or other external condition that posed an actual threat to the safety of the nuclear installation or that significantly hampered site personnel in the performance of duties necessary for safe operation.
   Examples include earthquakes, fires of external nature, high winds, tornados, lightning, floods and external threats that might arise from any industrial facility nearby.

Reporting Criteria and Categories (3)

5. Any event or abnormal condition that resulted in the manual or automatic operation of the reactor protection system or of engineered safety features (with some exceptions, dependent on the actual circumstances, such as actuation from any part of a preplanned testing sequence, or when the system was removed properly from service, or if the actuation occurred after the safety function had already been performed).
   Use of this criterion by the regulatory body may require the specification of which systems are included as part of the engineered safety systems. Typical systems would include the emergency power system; the emergency core cooling system; the auxiliary feedwater system; the service water system; the containment cooling system and other systems relating to accident prevention and the mitigation of consequences. For example, if there were a failure in an instrument line connected to a reactor coolant system and a resultant leak at a rate of 300 litres, then there should be an actuation of a high pressure pump to compensate for this small loss of coolant event. The event would be reportable under this criterion.
Reporting Criteria and Categories (4)

6. Any event in which a single cause or condition caused at least one independent train or channel to become inoperable in multiple systems, or two independent trains or channels in a single system to become inoperable, for systems designed to shut down the reactor, to remove decay heat, to control the release of radioactive material or to mitigate the consequences of an accident. This criterion addresses two common cause concerns that are not necessarily comparable in terms of risk significance or severity.

Events reported under this criterion can include previously unrecognized common cause (or dependent) failures and system interactions. For example, if a number of pipe stubouts were found to be inoperable such that they would not have worked properly, then this could be an instance of generic common mode problems in several independent trains in multiple systems designed to remove decay heat.

Reporting Criteria and Categories (5)

7. Any liquid or airborne releases of radioactive material to unrestricted areas in excess of authorized limits (generally as specified in the operational limits and conditions), or exposure of site personnel in excess of authorized limits.

For example, if a valve in the gaseous waste system was inadvertently opened in such a way that there was a release that was in excess of authorized limits off the site, then this would be reportable under this criterion.

8. Any event that posed an actual threat to the safety of the nuclear installation or that significantly hampered site personnel in the performance of duties necessary for safe operation, including fires, releases of toxic gases and radioactive releases.

The actual threat referred to is from an internal event, since external threats are covered by criterion (4) above. The intent of this criterion is to ensure the reporting of events that compromise the safety of the plant or disrupt personnel in the performance of their duties necessary for safe operation. For example, if the (or radioactive release) necessitated the evacuation of a room for which access was needed to deal with conditions at the plant, then it would be reportable under this criterion.

Reporting Criteria and Categories (6)

9. Declaration of an emergency condition as specified in the emergency plan.

In general, the declaration of an emergency condition is communicated to the regulatory body in a different manner than described in this Safety Guide. For example, the regulatory body may receive notification of the declaration of an emergency by telephone, by facsimile or by direct communication to a resident inspector. Generally, the condition that prompted the emergency declaration would be an event specified in other numbered items in this appendix and would result in the generation of an event report.

10. Any problem or defect in the safety analysis, design, fabrication or operation that results in, or could result in, an operating condition that had not previously been analysed or that could exceed design basis conditions.

An example would be a report by a vendor that a particular circuit breaker has a non-revealing fault that could cause binding (for example due to the use of oil lubricant that breaks down with age) with subsequent common mode failure to activate on demand. If the plant had a number of these breakers in service in various safety systems this would be a cause for concern and this criterion would suggest making an event report.
Reporting Criteria and Categories (7)

11. Any safety significant event during shutdown or refuelling, such as the dropping of a fuel assembly, the dropping of an object into an open reactor vessel in a fuelled state, the loss of boron control during refuelling, the loss of shutdown heat removal systems or the loss of water inventory in the reactor vessel.

12. Any event that results in the death of or serious injury to personnel on the site.

Reporting Thresholds

- In many countries three reporting thresholds are given:
  - Immediate reporting (typically within 1 hour)
  - Fast reporting (typically within one day)
  - Normal reporting (typically within one week)
- In some countries, all events must be reported immediately, different thresholds apply for the written report.

Content of Reporting

- Content of reporting should be in line with structure and coding of the regulatory database!
- General information
  - e.g. plant name, plant type, plant status
  - event date, event title
  - responsible personnel, reporting criteria, INES
- Event information
  - event description, event impact (safety significance), recovery actions, causes and contributing factors, measures against recurrence
- Structure / system / component information
  - affected structure, failed system / component, direct and root cause, measures against recurrence
- Human factors / safety culture information
  - failure mode, direct and root causes, measures against recurrence
Structure of event database (1)
- Structure and coding of the regulatory database should be in line with the content of reporting!
- Databases should contain
  - Text and
  - Codes
- Good example for coding of causes and root causes is given in the IRS database!
- Do not believe that full text search is sufficient and can replace coding!
- At GRS there is also (for any registered user) a possibility to add own codes
  - Very practical for individual searches
  - Identification of generic safety issues (that change with time)
  - Simple possibility also to add new codes

Structure of GRS event database

Structure of event database (2)
- Do not restrict your database on event text and coding only!
- At the GRS database we add
  - Information provided by licensees
  - Information provided by manufacturers
  - Information provided by local regulatory bodies
  - Information provided by federal regulatory bodies
  - Information provided by TSOs
  - Information provided by the Reactor Safety Commission (RSK)
  - GRS information e.g.
    - German Information Notices
    - GRS assessments
    - IRS reports
    - INES information
    - Internal notes
Additional Information in GRS event database

Structure of event database (I)
- Public database vs. internal database
- Some countries have their event information online
  - Either daily (without database functions for the public)
  - As a database with search function
  - As monthly reports
- Some regulatory bodies publish simple event information
  - But many reg. bodies add their own event descriptions, statements and assessments
  - Depending on the event significance, most regulatory bodies publish also background material, requirements and letters to the licensee

Database reporting function
- Also regulatory bodies need reporting functions for their event database
  - Monthly / quarterly / yearly reporting to parliament and public
  - For internal administrative purposes
  - For internal technical purposes – e.g. trends
- At GRS we use several reporting functions regularly
  - Reporting rate over time
  - Event significance trends
  - German information notices
  - INES classification
  - And technical trend and pattern analyses as necessary
International and National Event Databases

- Besides the official events databases (national event database, IRS) several national and international event databases exist e.g.
- NEA ICDE (common cause failures)
- NEA FIRE
- NEA CADAK (Cable Ageing Data and Knowledge)
- IAEA IGALL (International Generic Ageing Lessons Learned Project)
- ...

At GRS several databases exist in parallel to the international projects
- These may contain German and international events
- There are also others, e.g.
  - Transients (including non-reportable transients)
  - Alma Mater (Knowledge Base on Ageing of Passive Components)
AlmaMater Example – TGSCC Directory/View in Editing mode

Generic information

Articles, Reports,
Information Notices, Event Reports
Presentation of significant events

Statistical presentation of operating experience

Internal and external Experts

AlmaMater Example TGSCC – Significant Events

Transkristalline Spannungsrißkorrosion (TSK RK) von austenitischen Chrom-Nickel-Stählen

Further Detailed information for Events available

Final Remarks
Regulatory Event Databases

- International rules and regulations require the use of regulatory event databases
- Event databases form an indispensable tool for regulatory OPEX related tasks, e.g.
  - Interaction with the licensee on events
  - Information of parliament and public on events
  - Basis for administrative and technical knowledge across different licensees, sites, NPP designs, systems, components, manufacturers and even other international event information

Structure of Regulatory Event Databases

- Input and Output requirements must be balanced, coordinated and complementary!
- Storage of additional information (besides event information) has been proven as a good practice
- Trending functions are helpful for many reports
- Free (additional) coding has been found very practical

Further Event Databases

- Further event databases are useful for national and international problems
- These should contain besides event data also further information like scientific publications, "wikis" etc.
Policies and Practices for the Operation of Regulatory Operating Experience Databases

Iain Gray

Breakout Sessions

- Breakout sessions to share experience and provide answers to the question “What are best practices with regulatory operating experience databases”?
- This presentation is aimed at prompting thoughts for developing answers in the breakout sessions

Breakout Sessions

- What should be covered in policies and practices?
- What are best practices for these?
Contents

- Responsibility for data input
- Quality assurance of the data
- Automatic reminders for further data inputs
- Database access permissions
- Reviews of database effectiveness
- Database compatibility with changing operating systems
- Data security

- Dilbert cartoon

- Database serves the policy, not the other way round

Database Operations

1. Event Information → Database → Standard Information
2. Results From Special Queries → Special Queries
3. Event Reports → Event Reports
4. Statistics → Statistics
5. Trends → Trends
6. Other? → Other?
Database Policies

- Policies set out a framework for database operations
- Should consider all the factors covered in this presentation
- Breakout session should identify if any further aspects should be considered in the database policies

Database Practices

- Practices implement the policies
  - Who, what, how, when, etc.?
- May use work instructions, e.g. administrative tasks
  - Administrative function generates a monthly report for submission to senior management by the fifth day of each month using a specified set of steps for review and approval

Policy and Practice Example

- Control of access arrangements
  - Password access only
  - Regular changes to passwords
Policy and Practice Example

- Policy that all users must change their password once a quarter
- Database has user access controlled by password
- Database contains time limit on the password and means for the user to change it
- Database constrains passwords, e.g. must have letters and numbers

Policy and Practice Example

- Database must also have the capability for dealing with forgotten and first-time passwords
- Practice - user instructions about password access, any rules on password construction and what to do for forgotten and first-time passwords

Responsibility for Data Input

- Options
  - Staff at the NPP where the event occurred
  - Staff at the corporate centre for the NPP
  - Regulatory body using report from the NPP
  - Third party using report from the NPP
Quality Assurance (QA) of the Data

- By the originator (site and corporate centre)?
- By the regulatory body (Site Inspector and corporate centre)?
- By a third party?
- Factual accuracy
- Clarity of report
- Completeness of report

Automatic Reminders for Further Data Inputs

- Needs to be part of a clear process that fits within a policy
- Input from Site Inspector
- Follow-up report from the NPP

Database Access Permissions

- Organisational access, i.e. which other organisations, if any, can access the regulatory database
- Individual access within those organisation(s)
- Full/ partial access
- Read/ write access
- Who controls the access?
Reviews of Database Effectiveness

- Is there a clear understanding of the purpose of the database and how it is used?
- What criteria should be used to determine the effectiveness of a database and its use?
- Frequency of reviews

Reviews of Database Effectiveness

- The aim of a programme for the feedback of operational experience is to ensure that the following objectives are achieved:

Reviews of Database Effectiveness

- (1) The collection of information is sufficiently comprehensive that no relevant data are lost (this necessitates broad reporting criteria and low detection thresholds).
- (2) The information collected is screened efficiently to ensure that all important safety related issues that ought to be analysed with priority will actually be selected (this necessitates clear ranking criteria).
Reviews of Database Effectiveness

- (3) The issues selected are analysed in sufficient depth to permit the identification of the underlying root causes in the design, in the surveillance activities carried out on equipment, in personnel qualification and in aids for personnel.

- (4) The relevant corrective actions are implemented promptly enough to prevent the recurrence of similar events that could be caused by underlying root causes of the same category.

- (5) The lessons learned are disseminated promptly enough to enable other plant operating organizations to take corrective actions before other similar events occur.

Database Compatibility with Changing Operating Systems

- Windows 10  
- Windows 8.1  
- Windows 8  
- Windows 7  
- Windows Vista  
- Windows XP  
- Windows ME
Database Compatibility with Changing Operating Systems

- Windows 2000
- Windows 98
- Windows NT 4.0
- Windows 95
- Windows NT 3.51
- Windows NT 3.5
- Windows 3.2

Database Compatibility with Changing Operating Systems

- Windows for Workgroups 3.11
- Windows NT 3.1
- Windows 3.1
- Windows 3.0
- Windows 2.11
- Windows 2.10
- Windows 2.03

Database Compatibility with Changing Operating Systems

- Windows 1.04
- Windows 1.03
- Windows 1.02
- Windows 1.01
- DOS
Database Compatibility with Changing Operating Systems

- Operating systems seem to change frequently
- Early awareness of changes to the operating system
- Regulatory body’s policy for the implementation of a new operating system
  - Very soon after availability
  - Wait until bugs have been ironed out

Database Compatibility with Changing Operating Systems

- Interfaces with different operating systems
- Understand the changes in the operating system
- Make any changes to the database deemed to be necessary
- Test before implementation
- Data migration and recovery

Data Security

- Data security refers to protective digital privacy measures that are applied to prevent unauthorised access to computers, databases and websites.
- Data security also protects data from corruption.
Other Factors

- What other factors should be addressed in the policies and practices to achieve effective and efficient use of regulatory operating experience databases?
- What policies might be considered for these factors, recognising that differences in legislation may mean that there will be variations in policies, e.g. data protection legislation?

Other Factors

- What other factors should be addressed in the policies and practices to achieve effective and efficient use of regulatory operating experience databases?
- What practices might be considered for these factors?
Topic 3:
Integration/Role of the regulatory OPEX databases within the OPEX processes and programs

WGOE
Madrid - 2017

WGOE Question #3

- How do regulatory body use OPEX databases to assess licensees' OPEX programs:
  - in OPEX screening
  - in daily basis and periodic reviews
  - in inspections
  - to improve regulations or
  - to define new requirements
  - to trending etc.

Assessing licensee OPEX program

1) How do we assess the licensees' OPEX program (using all available tools)
   - We use several inputs to evaluate the licensees' OPEX program.
   - Inputs
     - Desktop reviews of scheduled reports by specialists
     - On-site inspections - scheduled and unscheduled
     - Daily Surveillance by resident inspectors
     - Event reviews by resident inspectors and technical specialists
     - Tracking of the licensees' corrective actions
Question

- Output - assessment of licensee’s program – are the Corrective Actions ...
  - Specific, Measurable, Attainable, Relevant, Timely, Effective, Reviewed (SMARTER)
  - Are the Corrective Actions at a high enough level - Remove hazard, Remove Target, place a barrier between hazard and target, signs, training
  - Monitored for Unintended Consequences
  - How capable is the licensee to learn from its own mistakes and those of others to prevent the recurrence of events

Robustness of Corrective Actions

source | barrier | target

WGOE Question#3

2) How do we improve regulations or define new requirements (using all available tools)

- inputs
  - on-site inspections
  - event investigations
  - event reviews (domestic and international (IRS)) – CNSC
    - OPEX Clearinghouse
      - What happened? – Event
      - What have you learned? – Lessons Learned
      - What are you going to do about it? – Corrective Actions on the licensee
      - Did it work? – Tracking for effectiveness and unintended consequences
Question

- outputs - Actions on the CNSC
  - determine Lessons Learned for CNSC.
  - create and implement Corrective Actions for CNSC
  - monitor for unintended consequences

- changes to regulatory documents, framework (e.g., add a Whistleblower policy), and inspection practices (e.g., modify inspection guides)

WGOE Question #3

3) How to use Regulatory body OPEX databases to assess the licensees’ OPEX program (other regulators are welcome to give their input)

- Trending using Event Characterization Codes (similar to IRS codes) - over a 2-5 year rolling period

WANO Operating Experience: Preventing Events by Learning from Others (and yourself)

- The OPEX program informs members about incidents at other plants so they can take corrective actions to prevent similar occurrences at their own plant.
- Its success stems from the willingness of WANO members to openly share their OPEX for the benefit of other operators throughout the world.
- An event is defined as any significant deviation from the normal expected functioning of a plant.
- When an event occurs, the affected plant management and staff analyze it and completes a WANO Event Report (WER)
CNSC OPEX Database: Central Event Reporting and Tracking System (CERTS)

- All reported unscheduled industry events, and responses to the events, are recorded, monitored, and analyzed using CERTS
- Domestic (RegDoc 3.1.1)
- International (IRS)
- No non-nuclear events

CERTS Data Structure

3 Levels of Status

- Event
  - 1 event
- Report
  - Few reports
- Assignment
  - Many assignments

Anatomy of Event Review
Events Reporting Provisions

RegDoc 3.1.1 Reporting Clauses

1. Contravention of the NSCA in relation to an activity that is authorized
2. Transfer or disclosure of presbibed information
3. Notification of authorized delegates and responsible person
4. Contingency plan
5. Serious illness, injury or death
6. Notification of removal or reinstatement of certified personnel
7. Financial status
8. Inaccurate or incomplete records
9. Notification and filing of record of disposal of records
10. Failure, degradation or malfunction of structures, systems and components
11. Process systems
12. Safety systems
13. Reactor, turbine and generator control
14. Outages
15. Counterfeit, fraudulent or suspect items
16. Others
17. Misuse of anything intended to protect the health and safety of persons or the environment

RegDoc 3.1.1 Reporting Clauses

20. Actual or potential exposure in excess of legal radiation dose limits (worker)
21. Reaching an action level for the purposes of environmental radiation protection
22. Nuclear and hazardous substance release
23. Exposure devices and sealed source assemblies
24. Notification of sealed source leakage of 200 Bq or greater
25. Filing of a sealed source tracking report
26. Theft of nuclear substance, prescribed equipment or prescribed information
27. Actual or attempted breach of security or act of sabotage
28. Filing of security report for threat and risk assessment
29. Notification of issuance of authorizations
30. Notification of intent to conduct security exercise
31. Safeguards
32. Packaging and transport
33. Notification of undeliverable consignments

- in 2016 - 4 sites - 19 reactors - 240 reported events and unplanned situations – very low threshold for reporting
Canadian OPEX Process –
Regulator and Licensees

Domestic and International Events

CNSC OPEX Clearinghouse review specialists analysis

Licensee’s Internal OPEX Review Process

Joint CNSC/Canda. Owners
Group (COG) Working Group

CNSC Event Report Process –
OPEX Clearinghouse

Objective: Prevent events from recurring

IPD 3.1.1 Events reported to CERTS → sent to specialists for analysis of corrective actions

• IIRS reports (modify regulations, inspections, query OPEX program)

Licensees Corrective Actions?

Charged CNSC Regulations and Inspection Practices?

CNSC OPEX Clearinghouse review specialists analysis

• Extraction and Application of Lessons Learned/ Corrective Actions & Recommendations

What is CNSC OPEX Clearinghouse?

• Comprehensive program for reviewing events and event analysis — Corrective Actions

• Meets on a bi-weekly basis to review domestic event reports from CERTS and international events from IIRS
Typical CNSC OPEX Clearinghouse Meeting

Report Status: In Progress

Lessons Learned/Corrective Actions on CNSC

Domestic and International Events

- Are there any lessons to be learned that we can use to improve our regulatory framework (documents)?
- Are there any lessons to be learned that we can use to improve our inspection practices (guides)?

OPEX

Example of Improved Regulations

Darlington Event 2012: Dual Feedpump Failure + Emergency Core Injection (soft inject) not reported

Lessons to be learned to improve regulatory framework?

- Yes
- No

Lessons to be learned to improve inspection practices?

- Revision to RegDoc-3.1.1
- Addition of Issue to Other Reportable situations and events of regulatory interest
Examples of Improved Regulations and New Regulatory Requirements

- Event - Chalk River Whistleblower event 2009
- Event - Bruce NPP Whistleblower event 2014 – CFSI in 2008

► New Requirement
  1. Resulted in RegDoc 3.1.1 improvement CFSI and

Example of query Licensee's OPEX program
- IRS 8591 - Various Electromechanical Product Sold as Safety Class 1E Not Properly Qualified (USA)

Example of Trending - Raw data from Event Characterization Codes – similar to IRS codes

| Code | Description                           | Category Description          | Sub Category | Number of Times |
|------|---------------------------------------|------------------------------|--------------|----------------|----------------|
| 1.1  | Equipment Failure Event               | AUXILIARY SYSTEM IN-service  | Repair        | 45             |
| 9.1  | Heat load                            | AUXILIARY SYSTEM IN-service  | Repair        | 57             |
| 9.8  | Heat load                            | AUXILIARY SYSTEM IN-service  | Repair        | 10             |
| 569  | Heat table                            | Safety System                | Safety System | 50             |
| 572  | Breaker failure                      | Safety System                | Safety System | 10             |
| 577  | Performance of equipment              | Safety System                | Safety System | 20             |
| 578  | Software system                      | Safety System                | Safety System | 10             |
| 592  | Maintenance work                     | Safety System                | Safety System | 45             |
| 593  | Maintenance work                      | Safety System                | Safety System | 35             |
| 594  | Maintenance work                      | Safety System                | Safety System | 20             |

Canadian Nuclear Safety Commission
Topic 1
Structure, content and capabilities of regulatory OE data bases

Workshop WGOE 2017, Madrid

Short text for Workshop Flyer

Databases are a major working tool for all experts involved in operating experience feedback. But, there are no international requirements or guidance on the capabilities of such OPEX databases. In most cases, regulatory bodies and their TSOs run various OPEX databases for different purposes. First, there is an official database for reported events from NPPs and other nuclear facilities. In many countries the information on events is publicly available. Such these official databases must respect the right of public information as well as the protection of the licensee’s rights. Furthermore, technical experts need in their OPEX databases more information than just the event report information. Further technical information, coding and follow-up actions are also stored. In addition, expert organisations run specific databases e.g. on common-cause-failures, material problems and human factors.

The various types of databases require different input and output possibilities, adapted user interfaces, search capabilities and so on. The aim of the Workshop is:

- to clarify the different types of database to be used;
- to identify best practices for the various applications of OPEX databases;
- to show practical solutions that are successfully utilised in the several countries.

The workshop results should enable the participants to review their national database structures, to identify potential gaps to international best practices and to initiate optimisation of their national database structure. The workshop should aid the further development of the international co-operation on OPEX by guidance on national OPEX databases as basis of national OPEX analyses.

Topic 1 covers the basic understanding on the link between the structure and the purposes of the different national OPEX databases. The different types of database are identified and described, the needs of the various users clarified and thus the necessary output records of the database determined. To achieve these goals, the input of data and its assessment (including coding), the amount of information stored, and the interfaces required between different databases have to be defined.

The different types of data require specific handlings: event information, which has to be publicly available, has a preferential treatment. Technical basis information is less timeliness sensible but needs a thorough quality assurance. The coding of event reports forms the basis for the use of OPEX databases for trending. Regular trending reports require speedy coding of the event information.

Topic 1 shall give an overview on the best practices on national OPEX databases. The discussions should enable the participants to present their own experiences and to learn about the various possibilities to organise national OPEX databases.
Topic 2
Policies and practices associated with the operation of regulatory OPEX databases

Workshop WGOE 2017, Madrid

Having considered best practices for national OPEX databases in Topic 1, Topic 2 moves on to some of the practicalities of managing these databases.

The areas to be considered in this topic are:

- Responsibility for inputting data to the database.
- Assuring the quality of the data.
- Automatic reminders to achieve timely input of further data arising from investigations.
- Who is allowed to have access to the data in the database.
- Processes to review the effectiveness of the database.
- Responsibilities for ensuring the database remains compatible with changing operating systems.
- Maintaining the security of the data.

Each of these topics will be introduced in a plenary presentation to provide a framework for the subsequent workshop sessions which will be broken down to ensure that each of these topics is addressed and that participants will have the opportunity to bring their own experiences in relation to each of these topics and to raise questions in respect of areas that they may not have fully considered.

Areas to be covered will include the following:

- Responsibility for inputting data to the database:
  - Professional or administrative staff.
  - Different people at different stages.
  - Administrative controls to limit who can input data.
- Assuring the quality of the data:
  - Defined processes for data management.
  - Does someone review the data before input to the database?
- Automatic reminders to achieve timely input of further data arising from investigations:
  - OPEX databases typically require additional data to be input after the initial event description is input, e.g. output from investigations and identification of root causes.
  - Automatic generation of reminders to advise that the additional data should be input.
- Who is allowed to have access to the data in the database?
  - As well as controls on who can input data, there is a need to control access to read the information in the database.
  - Internal access control within the organisation administering the database.
- External access control.

- Processes to review the effectiveness of the database:
  - Are there management arrangements in place to review on a regular basis the effectiveness of the database as an integral part of delivering clear regulatory intelligence?

- Responsibilities for ensuring the database remains compatible with changing operating systems:
  - Many databases are required to interface with Microsoft or other operating systems that are subject to regular updates to provide improved capabilities to users.
  - Are there allocated responsibilities to ensure that the database will continue to deliver its functionality after the implementation of upgrades to an operating system?

- Maintaining the security of the data
  - Are there arrangements for ensuring that the data is regularly backed-up?
  - Is the database robust against corruption of the data?
Topic 3
Integration/Role of the regulatory OE databases within the OPEX processes and programmes

Workshop WGOE 2017, Madrid

Question: How OE databases are used to assess licensees’ OE programmes (in OE screening, in daily-basis and periodic reviews, in inspections), to improve regulations or to define new requirements, to trending etc.

The question is broken into three parts:

1) How do we assess the licensees’ OE programme (using all available tools)

We use several inputs to evaluate to evaluate our licensees’ operating experience programme.

- Inputs
  - Desktop reviews of scheduled reports by specialists.
  - Field inspections – scheduled and unscheduled.
  - Daily Surveillance by resident inspectors.
  - Event reviews by resident inspectors and technical specialists – OPEX clearinghouse programme and database.
  - Tracking of licensee corrective actions.
- Output – assessment of licensee’s programme

2) How do we improve regulations or define new requirements (using all available tools)

- Inputs:
  - site inspections
  - event investigations
  - event reviews (domestic and international (IRS)) – CNSC’s OPEX Clearinghouse
    - What happened? – event;
    - What have you learnt? – Lessons learnt;
    - What are you going to do about it? – Corrective Actions on the licensee;
    - Did it work? – tracking for effectiveness and unintended consequences.
- Outputs: actions on the regulator
  - Determine lessons learnt for regulator;
  - Create and implement corrective actions for regulator ;
  - Monitor for unintended consequences;
  - changes to regulatory documents, framework (e.g. add a Whistleblower policy), and inspection practices (e.g. modify inspection guides).
3) How to use OE databases to assess the licensees’ OE programme (other regulators are welcome to give their input)

At this point some of our specialists use our OE database to assess the licensees’ OE programmes. We are at the point where we will improve our coding (modifying it to be more like the IRS codes). Afterwards we will code licensee events and determine whether we see any trends (over a two-to-five year rolling period) that need to be addressed.

- licensees’ event reporting criteria (threshold to reporting an event);
- event coding (high level or low level, similar to IRS event codes, etc.);
- screening;
- trending;
- analysis;
- feedback to compliance monitoring programme and/or to licensee.

1. Nuclear Safety Council EO Database

Nuclear Safety Council EO DataBase

2. Operating experience process in the regulator

- The CSN systematically analyze OE from both Spanish nuclear installations and NPPs abroad:
  - Information from Resident Inspectors.
  - Notifiable event reports sent by the licensees.
  - OE inspections to the NPPs every other year.
  - Reactive inspections (when the event is important enough and prompt information is needed).
  - Multidisciplinary boards to review internal and external OE.

- All the organization must take part in the OE process.

3. Operating experience process in the regulator

**LEGISLATION FOR NPPs:**
- Law 15/1980 Creation of the Spanish Nuclear Safety Council (CSN)
- Safety Instruction-10 Notification criteria of events in NPPs
- Safety Guide 1.06 Notifiable events in operating NPPs
- Safety Guide 1.10 Periodic safety reviews in NPPs
- Safety Instruction on Operating Experience (draft)

**INTERNAL PROCEDURES:**
- PT.IV.118 OE inspections in NPPs
- PA.IV.11 Reactive inspections
- PA.IV.18 Event review boards
- PA.IV.202 Performance indicators
OPERATING EXPERIENCE PROCESS IN THE REGULATOR

4 SOURCES OF OE:

• OE from Spanish NPPs:
  - Resident Inspectors
  - Notifiable event reports (ISN)
  - Annual OE report

• International OE:
  - IRS
  - WOE
  - NRC (LER, IN, 10 CFR 21)
  - EU Clearinghouse

SCREENING:

• OE from Spanish NPPs:
  - Analysis of the information provided by the resident inspection.
  - Review of every notifiable event report.
  - National event review board: to analyze and classify the notifiable event reports.

• International OE:
  - International event review board. The OE staff is in charge of previously screening the events that will be reviewed by the board.

ANALYSIS:

• OE from Spanish NPPs:
  - Daily analysis by the OE staff
  - National event review board: multidisciplinary group that meets monthly to analyze every notifiable event report and determine if the corrective actions implemented by the NPP are adequate or if additional actions are needed.
  - OE inspections to the Spanish NPP every other year.

• International OE:
  - International event review board: multidisciplinary group that meets quarterly to analyze OE from NPPs abroad to determine if it is applicable to the Spanish NPPs and, if that is the case, to establish what actions must be taken.
7 | Operating experience process in the regulator

**OE DISSEMINATION:**

- Within the CSN
- To the Spanish NPP’s:
  - Letters requiring the analysis of OE considered as relevant by the regulator
  - OE inspections
- To international organizations:
  - Notifying relevant advances to the IAE
  - Through working groups (WDOE)

8 | How do databases help us in the Operating Experience Process?

How do databases help us in the OE Process?

9 | FIO Database

- **FIO Database:**
  - Database for internal OE: Registration and classification of NPP notifiable events
86 | NEA/CNRA/R(2018)5
International Operating experience workshop on Best practices with regulatory operating experience databases

László Juhász
HUNGARIAN ATOM ENERGY AGENCY
24-26 April 2017
Madrid, Spain

RB and NPP in Hungary

Event notifications Reporting
1.24 PER Reports
1.22 Event reports

OEF

Volume 1: Nuclear safety authority procedures of nuclear facilities
Volume 2: Management systems of nuclear facilities
Volume 3: Design requirements for operating NPPs
Volume 3A: Design requirements for new NPPs
Volume 4: Operation of NPPs
Volume 5: Design and Operation of Research and Training Reactors
Volume 6: Design and Operation of spent fuel storage facilities
Volume 7: Site of Nuclear Facilities
Volume 8: Decommissioning of Nuclear Facilities
Volume 9: Construction of New Nuclear Facilities
Volume 10: Terminology
Event notification and reporting

GENERAL GUIDANCE ON EVENT REPORT
Immediate notification
Non immediate notification
INES classification
Written notification
Event investigation report
Annex M2 EVENTS FALLING UNDER THE OBLIGATION OF IMMEDIATE NOTIFICATION
Annex M2.17 EVENTS FALLING UNDER REPORTING OBLIGATION
http://www.oeh.hu/web/v3/HAEAportal.nsf

Documentation - tracking

IBM Lotus Notes databases – Part of the MS
Event reports and implementation of corrective actions is tracked through the internal Investigation Database System

Investigation Database
- Task
- Investigation report
- HAEA's investigation report and Event Review Form
- Coding
- Corrective action
- Category, Deadline
- Status of investigation
- Date of collecting function for safety indicators and evolution
- Number of different events
- Number of different causes (appearing cause, root cause, human error, organizational weaknesses, mechanical failure etc.)

Screening

Events which require notification and/or formal investigation to HAEA

Event notification
- Emergency
- Criteria A1
- Criteria B1
- M3 criteria
- NPP Concerns
- max 30 mins
- 2 hours
- 24 hours
- Event Report
- 45 days
- HAEA request
- Periodical report NPP Interact
- Near Misses & Low Level Events
<table>
<thead>
<tr>
<th>Main page – all events</th>
</tr>
</thead>
<tbody>
<tr>
<td>Reported events 1.25. GL</td>
</tr>
<tr>
<td>Events under reporting threshold</td>
</tr>
</tbody>
</table>
Event rating

1. Initiating event
2. Safety system actuation
3. TechSpec in force/violation
4. Activity of personnel/Human and management error
5. Core damage risk during event
6. Cause of event
7. Other factors leading to the event
8. Nuclear safety classification of related SSC
9. Exposure of personnel
10. Radioactive discharge/contamination
### Regulatory Review

<table>
<thead>
<tr>
<th>Category</th>
<th>Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>Safety</td>
<td>Improve procedures</td>
</tr>
<tr>
<td>Security</td>
<td>Increase monitoring</td>
</tr>
<tr>
<td>Environment</td>
<td>Reduce emissions</td>
</tr>
</tbody>
</table>

### Corrective actions

<table>
<thead>
<tr>
<th>Issue</th>
<th>Recommendation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Radiation exposure</td>
<td>Implement personal dosimetry</td>
</tr>
<tr>
<td>Equipment failure</td>
<td>Schedule regular maintenance checks</td>
</tr>
<tr>
<td>Budget constraints</td>
<td>Explore alternative funding sources</td>
</tr>
</tbody>
</table>

### General remarks

- The team has successfully addressed all identified issues.
- Further improvements are recommended for increased efficiency.
Search functions
Codes – max 4

Report to excel file

Review of Licensee OE program

HAEA continuously supervises the Licensee's Operational Experiences program. Main elements of supervision:
- Event investigation
- Inspection
- Comprehensive
- Targeted
- Unannounced
- Daily
- Review periodical report
- Quarterly reports
- Outage reports
- Annual reports
- Periodical Safety Review
Annual evaluation

HAEA NSD continuously evaluates the licensee’s safety performance.
Safety Indicator System 3 main areas, 22 indicator,
51 low level indicator
Trending event
Inspection and licensing experiences

SPIs – example

SPI – example – Scram
Introduction of NSC

- A nonprofit TSO to the Ministry of Environmental Protection/National Nuclear Safety Administration (MEP/NNSA)
- The only public technical guarantee organization mainly focuses on nuclear safety regulation and radiation environment monitoring
- Provides overall and comprehensive science & technical support for nuclear and radiation safety regulations
Related Regulations

Administrative regulations
- Regulations of the People’s Republic of China on the Safety Supervision and Management of the Civil Nuclear Facilities and its detailed enforcement regulations (HAF001)
- Operation Safety Requirements of Nuclear Power Plant (HAF103) and its guidelines

Work procedures
- Administrative Regulation for Experience Feedback of Operational Nuclear Power Plants
- OEF information screening and evaluation procedure
- Root cause analysis method
- ......

NNSA OPEX System

Members
- the National Nuclear Safety Administration
- Nuclear Power Plant
- Nuclear Safety Center
- Regional Nuclear Safety Supervision Station and other TSOs.
NNSA OPEX Framework

It is mainly composed of file system, experience feedback information system and experience feedback expert bank.

file system
management
documents
work procedure
technical documents.

information system
experience feedback platform
event database

expert bank
expert is selected based on professional requirements, provide human resources to support.

Running of OPEX System

1. Source and collection of OEF information
   - NFP experts
   - OEF experts
   - OEF information from outside

2. Analysis of OEF information
   - Source and evaluation of OEF information
   - Source cost to starting investigation
   - Evaluation of NFP safety condition

3. Application and output of OEF information
   - Application requirements in NFP
   - Information status
   - Regulatory requirements

OEF information network and related database

Introduction

NNSA OPEX Process

OPEX Information Platform
**Event Investigation Process**

- **Time line**:
  - 24h: NPP must inform orally RO and NNSA.
  - 3 days: NPP must submit the operating event notice to NNSA. NNSA delivers the notice to Dep. OEF of NSC. Dep. OEF judges whether needs an investigation.
  - 30 days: NPP must submit the operating event report to NNSA. NNSA deliver the report to Dep. OEF of NSC. Normally Dep. OEF needs to raise a question or give an evaluation conclusion.

**Event Feedback**

- Upload all the documents relate to the event to platform. Other members of the OPEX website could see it.
- Based on the significance of event, NNSA issues information notice, supervision recommendation, administrative requirement to NPP. Information notice is only to let NPP know the news without reply; supervision recommendation requires that NPP should perform self-checking to judge whether it is applicable or not. Administrative requirement means that NNSA has definite corrective actions which NPP should carry out.
1. Introduction

2. NNSA OPEX Process

3. OPEX Information Platform

NNSA OPEX Information Platform

NNSA OPEX Information Platform is a comprehensive website, containing a large number of OE news and information, e.g., operating and construction events, low-level interesting events. Moreover, specific OE tools are integrated in this platform.

NNSA OPEX Information Platform

Contents

- NNSA headquarters news
  - Information notice
  - Supervision suggestions
  - Administration requirements
  - Inspection report
  - Annual report

- NPP news
  - Event notice, LER report
  - Internal event report
  - Monthly operating report
  - Annual operating report
  - SCCs modification abstract

- Regional office news
  - Weekly inspection reports
  - Monthly inspection reports

- Other OPEX information
  - International events
  - PSAR, FSGR review report
  - PSR review report
  - …
By the end of 2016, the platform stored 883 NPP LER reports, 1259 NPP internal event reports, 169 SSCs modification abstracts, 48 typical event reports, and 133 international events. There are more than 800 users and 30 organizations registering in the platform.

- Report format is based on the regulation requirements. There are 2 parts: report sheet and report text. Report sheet includes time, report criteria, unit state, relevant system, INES scale.
- Event report text is below:
1. Event name
2. Event description
   - Unit state prior to the event
   - Availability of safety system prior to the event
   - Development sequence of event, original cause, sub-event
3. Main failures
   - Human error and technology
4. Personnel, procedure, availability of equipment
   - Model number and the name of manufacturer should be pointed out for the failed equipment
5. Availability of redundant system and equipment
6. Event cause
   - Direct cause
   - Root cause
7. Event consequences
   - Effect on nuclear power plant operation
   - Radiological consequences
   - Economy loss
   - Potential consequence
8. Classification of event (according to the classification of IIE5)
9. Corrective action and plan of corrective action
10. Lesson learned
11. Conclusion
12. Other issues needed for explanation
13. Reference

### NNSA OPEX Information Platform

**New NPP event database**

- This database is to collect the significant Non-Conformed Report (NCR) in construction stage.
- Based on the regulation, there are 6 report criteria to require NPP report construction event. The report format is also defined in the regulation.
NNSA OPEX Information Platform

On-line RCA Tool

This tool is to guide staff in RCA process, there are following features:

- Several standard RCA methodology are integrated as module in the tool.
- Common equipment and human failure database is developed and embedded in the tool, covering most of failure-tree cases.
- Automatically generate root cause analysis reports, including event description, event sequence, event failure point, cause of the event, determination of the root cause.
- The system can help nuclear safety regulators and licensees standardize the application of the root cause analysis method, promote the analysis process to achieve uniform analysis depth.

NNSA OPEX Information Platform

On-line precursor analysis tool

Different NPP PSA models are embedded in this tool, which can be used from the OPEX platform. PSA result of event is able to calculated on-line and automatically generate analysis reports.
Structure, Content and Capabilities of Regulatory OE Databases

Breakout Session 1

Approach

- Benchmarking
  - Does your database have the same features as IRS? More? Less?
  - What does your country's database do better than IRS?
- Multiple databases or single database?
  - Do you store all documentation in the same database?
  - What type of information is collected
  - Licensee actions, regulatory actions

Common Challenges

- User experience issues
- Querying difficult
- Some documents are stored in filesystem, rather than database
- Regulatory databases only focus on events of regulatory interest (e.g., LERs)
- Varying levels of requirements (e.g., deficiency reports)
- Different organizations have different needs
- Varying requirements for storage and management of records
Structure

- Multiple databases exist
- Aim for web-based application with interfaces to multiple data sources
- Links to different data sources
- Avoid record duplication
- User friendly experience
- Access by other organizations

Content

- Immediate notifications
- Follow-up reports
- Track regulatory body process and actions
- Track licensee actions
- Adequate amount of coding
- Causes, e.g., human factors
- Integration of data from other countries
- Also consider non-nuclear and non-reactor experience
- Links or documentation pointing to all documents related to single event
- Consider additional supporting information (Safety Analysis Reports, plant manuals, and procedures) related to the event
- Especially important for generic issues

Capabilities

- Improved processes for submitting information
- Balancing coding capabilities and search/querying capabilities
- Export and report generation capabilities (e.g., Excel, API)
- Trending capabilities
- Ability to record processes and actions
- Follow-up actions
- Prioritization of events
- Precursor or risk analysis
Summary

- Country specific solutions
- Organization specific solutions (TSO, RB)
- Web based systems recommended for new or renewed systems
- Reporting, exporting, and trending capabilities are necessary
- Use database for workflow in addition to storage
- Single records for documents
- Integrate multiple data streams
- Enhanced querying capabilities
Workshop on Best Practices with Regulatory Operating Experiences Databases


Working Group Objectives

- Identify recommended practices for the focus area of policies and practices, taking account of:
  - Event prevention
  - Improving effectiveness
- Identify challenges

Policies and Practices

- Practices implement the policies
  - Who, what, how, when, etc.?
- Time constraints mean that we have not distinguished between policies and practices
- Focus is on how databases can be used effectively
Basic Overall Process

Presentation focuses on how policies and practices can benefit this overall process, particularly with respect to the use of a database or application (emphasising the concepts shared at the workshop that go beyond a traditional database).

Basic Overall Process

- Where should we integrate the database in our processes?
- The next two slides show some suggestions.

Draft flow chart in "D3479 draft"
Sources of Information

Information → Application (Database) → Outputs → Regulatory Decisions

Recommendations for sources of Input event Information
- Event reports from licensees
- International events, e.g. IRS reports

Some countries also use inspection reports by the regulatory authority as an input.

A good practice to aid in the provision of input information
- The use of influence on licensees so that they produce event reports to avoid the need for inspectors to produce reports as inputs to the application

Quality of Input Information

Information → Application (Database) → Outputs → Regulatory Decisions

Recommendations to enable the appropriate quality of information
- Setting of clear reporting criteria
- The provision of guidance by the regular authority on event reporting
- The influencing of licensees to produce clear event reports of an appropriate quality
- Working with IT to ensure high quality OCR/word processing licensee inputs
**Initial input of Event Data**

Information → Application (Database) → Outputs → Regulatory Decisions

Recommendations regarding the input of event report information into the database:
- The use of administrators in the regulatory authority, which is the case with most in the working group, was seen preferable to inputting by inspectors.
- Consideration of the use of automation would be beneficial.
- No fundamental objection was seen to the licensee having limited access to input event reports.

**Access Control**

Information → Application (Database) → Outputs → Regulatory Decisions

Recommendation that there should be a range of levels of access, that may include:
- Read only for most users.
- Limited write access to enable identified users to have the appropriate access to enable them to write information relevant to their job role.
- Complete write access for "super-users".
- Modification capability for specialist IT staff.

**Further Input of Relevant Event Data – What?**

Information → Application (Database) → Outputs → Regulatory Decisions

Recommendations regarding further event data:
- Supplement initial event report with relevant information, even if it is a statement of no follow-up required.
- Licensee’s follow-up report should be included.
- Oversight findings (inspection records, complementary licensee information, RCA, etc.) should be added.
- This information may be in other databases, but there should be links between that information and the OpEx database.
Further Input of Relevant Event Data – Who?

Recommendations regarding who should add further relevant event information to the database:

- Given the range of sources of the potential information, there is benefit in being flexible.
- The use of administrators in the regulatory authority is potentially beneficial.
- Given that inputs may also arise from the OpEx Team, Site Inspectors and Specialists, there are benefits from these inputting information that they generate.

Quality Assurance of Data (1)

Recommendations regarding ensuring quality assurance of the data:

- When administrators from the regulatory authority input data, they should carry out simple checks on the completeness of the data.
- The Inspector in the regulatory authority carrying out the first step should review the data, particularly the description of the event.

Quality Assurance of Data (2)

Recommendations regarding ensuring quality assurance of the data:

- Data arising from the Review Group (OpEx Team and Specialists) should be reviewed prior to input to the application.
- Automatic Data Evaluation (mandatory fields, logical connections, etc.) integrated into the application can be beneficial.
- History logs (when?, who?) and Version handling can help.
Review Group

The establishment of a group to review event information to screen and identify lessons learned is recommended. This Review Group should:

- Have a clear mandate, e.g. Terms of Reference
- Include members of the OpEx Team and Specialists
- Specify any further work to be carried out so that clear lessons can be identified
- Generate clear, useable outputs

Standard Outputs

It is recommended that there should be standard outputs easily generated by the application, including:

- Evaluated and Coded Events
- Evolution of Events
- Statistics including trend analyses (periodically and automated, as well as on-demand)
- Standard regular reports
- Reporting of missing information

Flexibility to Deliver One-off Outputs

It is recommended that the application has the capability to generate the following with limited intervention:

- Specific topical queries
- Extraction of information to inform the production of topical studies, advice notes, information notices etc.
- Specific non-standard trend analyses
Information Security

Consideration of the security of information held in the application is crucial, and advice should be sought from experts for best practices on data:
- Confidentiality
- Availability
- Integrity

Challenges

- Challenges identified:
  - How could an increased number of events on the IRS Database be achieved, recognising that this would result in increased opportunities for lessons to be learned
  - Recognising that low level events could be the precursor to more significant events, should there opportunities to share low level event information
  - Data protection requirements

A Possible Vision of an International Database

Access to all data? Global database that allows trending?

Sharing Data Policy

- IRS 10%
- Rest of national OpEx 90%

Challenges
- Harmonized reporting
- Language barrier
- Common coding
Breakout session summary

**Topic 3:**
Integration/Role of the regulatory OPEX databases within the OPEX processes and programs

WGOE
Madrid - April 2017

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**WGOE Question #3**

How do regulatory bodies use OPEX databases and processes to continuously improve their regulatory functions?

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**OPEX Objectives of the use of OPEX databases and processes**

1. Improve effectiveness of regulatory framework
2. Improve effectiveness and efficiency of inspection practices
3. Promote national and international sharing of lessons learned and corrective action
4. Promote licensee reporting and quality of event reports
5. Improve risk-ranking, tracking, monitoring, analysis and trending of OPEX data
Objective #1: Improve effectiveness of regulatory framework

Recommended Practices/Actions:
- Implement new and revised regulations to address identified deficiencies, gaps and weaknesses
- Use database as a tool to identify what is important for the allocation of regulatory resources in a risk-informed manner
- Provide international shared workspace for regulators to share gaps and improvements e.g. RegNet or WGOE online forum
- Capture regulatory lessons learned and corrective actions from OPEX data within national OE database

Objective #2: Improve effectiveness and efficiency of inspection practices

Recommended Practices/Actions:
- Inform inspections by updating inspection criteria to verify requirements related to lessons learned and corrective actions
- Schedule of inspections commensurate with frequency and significance of events in annual plan
- Identify potential risk areas and relevant matters for inspection
- Provide national and international opportunities to participate in identification of inspection improvements and additional OPEX data and lessons learned with WGOE e.g. joint workshops
- Ensure presentation data: easy to understand and use during inspection planning and decision making
- Collect feedback from inspectors on inspection procedures

Objective #3: Promote national and international sharing of lessons learned and corrective actions

Recommended Practices/Actions:
- Promote global thinking and open communication
- Sharing of regulator corrective actions in response to lessons learned
- Promote awareness and availability of national and international OE databases and opportunities for OE sharing
- Promote integration of databases
- Improve consistency of collected event data using international reporting templates
- Promote use of codes and improve international links of different coding systems (WANO/IRS)
- Provide international shared workspace for regulators e.g. LinkedIn, community of practice
Objective #4: Promote licensee reporting and quality of event reports

Recommended Practices/Actions:
- Apply lessons learned broadly with nuclear industry
- Inform and focus inspections
- Resist penalizing licensees for reporting of non-mandatory events
- Identify gaps in requirements that prevent reporting of important OPEX events
- Improve safety culture to encourage reporting and open communication even when not mandatory under reporting requirements
- Improve national consistency of reporting criteria that is technology neutral
- Expand database to include non-mandatory events

Objective #5: Improve risk-ranking, tracking, monitoring, analysis and trending of OPEX data

Recommended Practices/Actions:
- Linking and integration of all OPEX data across all databases and sources
- Periodic trending and analysis of national OPEX data for early detection and identification of weaknesses and deficiencies in regulatory functions
- User-friendly system that highlight events needed for OPEX review for lessons learned
- Semantic technology for automated event reporting, data entry and coding to facilitate text mining, trending and correlations
- Ensure OPEX data quality and integrity specifically for event coding
- Regular screening meetings of reported events by multidisciplinary team
- Collect suggestions of potential risk areas from inspectors and more broadly from industry community
- Improved visualization of data to assist in analysis and trending
- Ensure tracking of the completion of licensee corrective actions

Challenges to OPEX processes

There is a need to improve assessment of licensees' OPEX processes and performance
- Gaps in regulatory requirements which prevent reporting of important events which never get to the OE database
- Information technology and financial support for OE database functionality and continual improvement
- Identify barriers to open communication with industry groups and to licensee event reporting e.g. industry incentives for not reporting and public exposure
- Number of different systems and regulatory framework between regulators and across the industry
- Inconsistency of national, international and industry categorization of events