1. Executive Summary

Own Risk and Solvency Assessment (ORSA) processes sit at the heart of effective enterprise risk management (ERM). While regulators worldwide understand the value of the information communicated as a result of ORSA processes, ORSA is best thought of not as a regulatory requirement but as a collection of internal “own” processes, highly tailored to the nature, scale, and complexity of an insurer, that result in key strategic information for senior management and the board.

Key observations/findings from the chapter include:

- ORSA is an ongoing part of risk and capital management practices and has merit beyond any regulatory requirement;
- ORSA is not a “one-size-fits-all” process. Significant variations occur from company to company, and even within different organizational units of large groups;
- Both quantitative and qualitative analyses support ORSA processes;
- ORSA processes are most effective when integrated within other business processes, particularly strategic and business planning, capital management, and, as appropriate, product pricing and underwriting;
- Promoting ORSA disciplines has value at both a macro (i.e., industry-wide) and at a micro (i.e., company- or group-specific) level; and
- Actuaries are highly experienced in assessing complex topics and have the skills and professional processes and perspective needed to create valuable risk analysis frameworks for management, boards, and regulators.

2. Introduction

The last decade has seen some important advances in the development, use, and application of sustainable enterprise risk management (ERM) frameworks within insurance organizations. As the insurance supervisory community observed the benefits of ERM, many key ERM practices were incorporated into Insurance Core Principle (ICP) 16 Enterprise Risk Management for Solvency Purposes, promulgated by the International Association of Insurance Supervisors (IAIS) during 2011. Likewise, more general core risk management principles have been codified in ICP 8 Risk Management and Internal Controls. ICP 16
reaffirmed for insurance and reinsurance companies the key elements needed for strong and effective ERM practices, and reminds regulators and supervisors worldwide of the need to encourage strong ERM practices within their regulated entities.

ICP 16 requires that a company (defined as either a solo entity or group) establish an ERM framework that specifies the processes and techniques the company will use to maintain its risk exposures within predefined risk limits, and states that a company’s risk management framework is to include several key elements, with each element operating in a manner that is consistent with the company’s nature, scale, and complexity. Some of the key elements identified within ICP 16 for an insurer’s ERM framework include:

1. It must provide for the identification and quantification of risk;
2. It must include risk management policies to guide the company;
3. It must establish and maintain risk tolerances setting out overall quantitative and qualitative levels within which the company assumes and manages risk; and
4. It must be responsive to changes in the risk profile and the environment through the periodic conduct and communication of ORSA results, and management’s strategic response to these results.

Specifically, ORSA is the ongoing process by which a company's senior management and board routinely assess the key risks to which the company is exposed and the adequacy of capital held to support the risks underwritten or accepted after mitigation and management activities have taken effect, both now and in the future, under different scenarios and relative to the company's appetite for risk. Periodic discussions of ORSA results provide benefits to senior management and the board. Effective use of the ORSA also has wider implications for effective regulatory review and oversight.

The primary objective of the ORSA is to support the company's strategic decision-making, by providing insights into the risks the company chooses to accept in return for the reward that can be expected over the business planning horizon. Specifically, the ORSA will:

1. Enhance the information basis for board decisions;
2. Provide senior management with an understanding of the company's current and evolving risk profile relative to the company’s appetite for risk under the various stress events or scenarios and an understanding of the adequacy of the capital resources to support both current and emerging risks;
3. Help build/maintain risk awareness throughout the company; and
4. Increase credibility and insight with regulators or supervisors.

Elements of the ORSA may also help supervisors better understand the company’s risk profile, risk management framework, and capacity to face the risks to which the company is or may become exposed. More broadly, promoting sound ERM and specifically ORSA disciplines across the insurance industry is considered by many to likely result in businesses that are better able to face current and future risks and uncertainties that will, in aggregate, lead to better and more robustly managed outcomes for policyholders.
3. The ORSA Process

The assessment of key risks and capital adequacy, both current and prospective, under both anticipated (or “baseline”) and stressed conditions is fundamental to the ORSA process. While these assessments must pay close attention to regulatory requirements, they fundamentally represent a company's own view of the key risks and the level of capital it needs and the risk management framework it will use to achieve its strategic objectives. It thus goes well beyond the capital required to satisfy rating agencies (i.e., capital sufficient to maintain a targeted financial strength or credit rating) or to satisfy regulators that capital, together with the underlying risk mitigation strategies and control framework, is sufficient to mitigate the risk of insolvency.

The ORSA process generally consists of a variety of assessments that result in an overall understanding of a company’s key risks leading to decisions regarding the management of these risks and an understanding of capital adequacy at a given point in time, all communicated through ORSA reporting. The process is expected to be carried out using an overall approach selected by the company that it believes to be appropriate and adequate for its own risk profile and strategic objectives. The ORSA approach is part of the company’s risk management framework and needs to fit the company’s organizational structure and take into account the nature, scale, and complexity of the risks the company faces and its appetite for risk.

ORSA processes and techniques, which are part of the risk management system of the company, consist typically of the following basic steps that need to be carried out on a periodic basis and upon significant changes to the company’s risk profile:

1. Identification of key risks, including:
   a. Identification of the gross (inherent) and net (residual) risk profile of the company; and
   b. Identification and prioritization of material risks and emerging risks, that is, specific risk events with a potential for having a significant impact on business performance.

2. Risk and capital adequacy assessments, including:
   a. Stress and scenario testing for assessing the financial effect of the quantifiable material known and emerging risks identified, complemented by qualitative techniques for assessing non-quantifiable material and emerging risks;
   b. Quantification of required capital using an “own” risk measure (e.g., economic capital), required regulatory capital, and other relevant risk measures such as required rating agency capital;
   c. Identification and acceptance of the principal expert judgements underlying the assessments including the key weaknesses and limitations in the data and models used;
   d. Assessment of the resultant individual and aggregate risk profile relative to the company’s risk appetite framework; and

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e. Assessment of the adequacy of available resources to meet the required capital obligations.

3. Communication and reporting of ORSA results, including:
   a. The results of key risk and aggregate risk assessments relative to the risk appetite framework; and
   b. An ORSA summary report, prepared with the main findings of the different assessments and a description of the ORSA process.

4. Assessments of the ORSA process itself, identifying key expert judgements, potential weaknesses, and points of improvement.

It is important to emphasize that an ORSA is not just a report or an outcome. It is an ongoing process that a company carries out on a periodic basis and whenever the company experiences a significant change in its risk profile or before major strategic decisions are made. The true value of the ORSA can only be realized when ORSA becomes integral to management's strategic decision-making.

Complementing the basic steps of the internal ORSA process, the following regulatory expectations for the ORSA generally apply:

1. The ORSA is expected to include an assessment of the company's overall solvency needs (both regulatory requirement and the company’s own capital standard);
2. The ORSA is expected to be forward-looking, i.e., not merely assessing current solvency needs but also adopting a medium- or longer-term, forward-looking perspective where appropriate;
3. ORSAs take into account the company’s risk appetite, tolerance, and limits;
4. In certain jurisdictions, the ORSA is expected to explain any divergence between how assets and liabilities are valued and recognized in the ORSA and how they are valued and recognized in the company’s regulatory capital computations;
5. The results of the ORSA are expected to be taken into account in business decisions, including decisions relating to capital management, business planning, and product pricing and underwriting;
6. Group-wide ORSAs consider group-specific considerations, such as liquidity and fungibility of capital; and
7. The ORSA is expected to be adequately documented such that a third party of the appropriate level of expertise can understand the principal methodologies, processes, key assumptions made, and judgments applied in the ORSA process.

4. Conducting an ORSA

ORSAs are conducted on all material and relevant (“key”) risks; utilize appropriate processes for assessing risk and capital adequacy, both as of the evaluation or assessment date and over the business planning horizon; and are to be clearly and appropriately communicated to senior management, the board, and regulators.

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I. Identification of Key Risks

The risk profiles of insurance companies vary widely from company to company as a result of the significant variability in business models that they adopt and environments in which they operate. This means that the types of risks to which a specific insurer or reinsurer is most exposed can vary significantly. In general, insurance companies are exposed to different combinations of market, credit, insurance (e.g., premium, reserve, catastrophe, mortality, morbidity, expense, and lapse), and operational risks based upon the products they underwrite, the investments they hold, and the quality of and control over their operations. For example, a “pure” unit linked life insurance company (writing savings products that do not include any embedded guarantees and with minimal protection cover) may be, relatively speaking, heavily exposed to operational risk (and possibly lapse risk) but may only be relatively indirectly exposed to market risk via the fees it collects on the assets being built up by its policyholders. In contrast a long-tail property-casualty (i.e., nonlife) insurer may be more heavily exposed to “insurance” risk.

Given the heterogeneous nature of risks a specific insurer or reinsurer may face, qualitative methods for identifying the risks that are most significant to the insurer, both currently and prospectively, include:

- Discussions with senior management and the board, revealing the type of risks that are most likely to keep senior leaders “awake at night”;
- Workshops (usually facilitated by risk managers) during which business leaders explore and rank a range of risks they think are important to their businesses or functional areas;
- Review of risks that other similar companies believe they are exposed to or have suffered loss from, possibly supported by external advisers or data sources;
- Consideration of scientific and environmental reports; and
- Review of the company’s own past losses and “near misses” to understand past risk drivers, causes, and impacts.

The processes involved can often be iterative in nature and would include consideration of risks, both gross and net of risk mitigation (e.g., before and after reinsurance). The risks identified will range from those risks amenable to quantitative assessment to those that are more difficult to quantify.

Within all risk assessment methods, it is important to take into account a consideration of known or potential changes to the environment in which the company operates that might have a significant impact on the risks to which the company may be exposed. Typically, an assessment of the potential changes to the environment will include some form of “horizon scanning” for emerging risks, bearing in mind that the environment in which the company operates is rarely static.

II. Assessing Key Risks and Capital Adequacy—Current and Future

Risk and capital adequacy assessments involve the analysis of all material risks the company faces. As a result, companies apply an assessment technique or combination of techniques that are most appropriate for each key risk and for all risks in aggregate, understanding

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correlations between risks, the indicated levels of required capital relative to established capital targets, and the adequacy of available capital relative to both own and regulatory measures of required capital.

A. Techniques for Assessing Risk and Capital Adequacy

Risk and capital adequacy assessments may be conducted using a variety of quantitative techniques and tools, such as economic capital modeling and stress and scenario testing. Each type of quantitative approach has its strengths and weaknesses:

- Economic capital models (ECMs) can provide a robust view of a company’s future financial condition, and ability to fulfil obligations to policyholders. An ECM depends on a set of assumptions about the general economy, the environment in which the company operates, and the company’s operating situation. Economic assumptions are often derived from stochastic generators using parameters based on either historical experience or on current or recent conditions. The resulting models can be extremely complex. Assessing their reliability and validity can be a significant challenge.

- Stress and scenario testing is used either instead of or along with an ECM as part of the capital adequacy assessment process. These techniques can be critical in helping identify potential threats and developing resulting management actions. In contrast to economic capital models, scenario analysis and stress testing assess the financial effect of specific events. They can be used to enhance the understanding of a company’s vulnerability to highly uncertain tail risks, and develop suitable mitigating actions. Stress tests can be easier to communicate and be more easily understood by management, board members, and other stakeholders than the output of ECMs. Their use can enhance the risk culture of a company, as they can alert decision-makers to potentially problematic areas and provide a framework to enable companies to base their business strategies and risk mitigation activities on a range of forecasts, rather than on a single best-estimate projected result or an average of stochastic results. Insurers would typically supplement traditional types of stress tests with reverse stress tests that are designed to explore scenarios that result in the company’s business model being fatally damaged. One aim of reverse stress tests is to identify business models that are more robust to such scenarios, and also to develop triggers for mitigating actions when a potential threatening scenario may be developing.

- Factor-based models, which rely upon capital factors that are calibrated to a selected return period and applied to financial statement data, are straightforward to use, and can be beneficial for quick assessments of trends. However, they generally rely upon capital factors that have been developed considering industry experience as a whole, and therefore may not fully reflect the risk profile of any individual company.

While it is within the company’s discretion to determine the techniques and tools to be used for their “own” assessments of risk and capital, many regulatory regimes either require that companies perform stress and scenario testing for regulatory purposes (e.g., Australia, European Economic Area, Canada), prescribe certain stress tests and scenarios (e.g.,

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Bermuda, Canada), or strongly encourage stress testing as a means to communicate the potential impact of the most significant risks and vulnerabilities to which a company is exposed. In addition, companies of a certain size are subjected to stress testing by regulatory bodies (e.g., European Insurance and Occupational Pensions Authority (EIOPA), through National Supervisors), and those insurance companies in the United States that operate within a bank holding company or own a thrift will be subjected to Federal Reserve Board stress testing. Given the sharp increase in regulatory use of stress testing, companies may need to consider how best to incorporate this testing into their ORSA processes.

In addition, in certain regulatory regimes (e.g., Solvency II) the ORSA also needs to include an assessment of the appropriateness of the methodology the company has selected to determine its regulatory capital requirements. Companies subject to this particular regulatory framework can select different approaches for their regulatory capital computations (e.g., standard formula approaches versus internal models and/or use of undertaking-specific factors). Regulators expect the company to justify why the selected approach is reasonable.

B. Establishing Capital Targets

As an integral part of a risk appetite framework, companies establish capital targets that consider the adequacy of own levels of required capital, regulatory required capital, and in certain circumstances rating agency or other measures of required capital. Differences between these capital measures are often based upon different valuation or accounting bases, or are based upon varying time horizons (e.g., one year of new business) and risk measures (e.g., 99.5 Value at Risk). Companies need to understand and be able to reconcile between valuation differences in measures of available capital and defined differences in measures of required capital when establishing capital targets and performing capital adequacy assessments relative to these targets.

Typically, capital targets reflect capital buffers above certain binding capital constraints to allow for loss absorption capacity in the event of a significant stress and in consideration of volatility of profits, uncertainty in the models and data, dividend policies, access to capital, and the overall quality of capital. In certain jurisdictions, ORSA regulatory requirements include the justification that the company will continuously comply with regulatory capital requirements and with other elements (such as computation of liabilities) that influence the company’s overall regulatory capital position, i.e., it is not just a point-in-time exercise. The principle underlying this requirement is that companies will not want to be so thinly capitalized (versus their capital risk appetite, as well as regulatory minimum levels, relative to the risks that they face) that they risk becoming undercapitalized just a short time after any capital assessment is carried out.

C. Forward-Looking Assessments

ORSA processes generally consider capital adequacy over the business planning horizon from a given evaluation date, in addition to a point-in-time assessment of risk and capital adequacy. While many companies utilize sophisticated methods and tools that allow for detailed assessment of capital adequacy over a one-year horizon, conducting ORSAs beyond one year requires the design and implementation of approaches that reflect key risk behaviors and likely management responses to risk events when they occur while limiting the additional uncertainty with projecting potential outcomes over multiple years.

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There are several methods that can be used for performing multiyear assessments, including multiyear stochastic models, applying stress scenarios to the results of one-year models to reflect an additional year or years of stress events and the development of factor-based approaches based on more complex and granular one-year stochastic model results.

III. Communicating and Reporting ORSA Results

Although the risk and solvency assessments themselves, including the use of modelling and forecasting tools to support them, represent a significant part of the overall ORSA process, ORSAs will be conducted in vain if the results are not communicated and reported effectively and relied upon.

Communicating and reporting ORSA results require companies to distinguish between several distinct groups of users, all of whom may have different needs, both as a result of their own knowledge and the intended uses they have for the information received:

A. Senior Management, the Board, and the Business

To ensure effective communication of ORSA results, companies start by working with the ultimate owner(s) of the ORSA process so that the end results meet their needs. The owner may be designated by local legislation—for example, under Solvency II it is the company board—however, independent of who the owners are, the findings and insights developed through ORSA are carefully designed to meet the needs of the users. In addition to the structure and level of detail provided within ORSA reporting, the owners also approve key aspects of the methodology being used including the key judgements made (e.g., the design of the stress and scenario testing to be carried out).

As usage is not limited to board- or senior-management-level decisions, it is likely that business units may also want to/need to use certain ORSA results for their own decision-making and ORSA communications to satisfy the needs of the business may need to be taken into account.

The process of reporting to the board and senior management is likely to happen at multiple points in the year as various ORSA and other business processes are completed. Companies will need to develop communication plans that are responsive to the timing of ORSA processes, taking advantage of the opportunities to discuss various results more fully as they become available. This ORSA communication plan may need to include a final report that brings all the results together, ideally with references to any supporting documents so these can be accessed as required.

B. Supervisors

Where there may be a requirement, either formally or informally, to provide an ORSA summary report to the supervisor, use of internal reports generated for senior management or the board may be favored to encourage companies to avoid creating separate reports strictly for compliance purposes. However, as the supervisors typically do not have access to day-to-day ORSA processes and internal reporting of ORSA results, they will likely need to reference supporting documentation or the ORSA summary reports themselves will need to include some of this support.
C. Other External Parties

Because the ORSA delivers significant valuable information, such as the business strategy and analysis of key risks, external parties such as rating agencies (and even shareholders and policyholders if they have access to ORSA results) would find the information highly beneficial. However, given that the ORSA report will likely contain proprietary information that management would not want to disclose to competitors, confidentiality of the information must be given the highest priority. External disclosures are likely to be driven by any minimum regulatory requirements, and these may be consistent with the risk disclosures under accounting or investment securities standards.

ORSA internal reporting will aim to communicate at least the main conclusions of the ORSA to all relevant staff. An ORSA supervisory report (if different from internal reports) may need to be more highly tailored to the needs of the supervisor.

Key attributes of any ORSA report include:

- A succinct overview of all key insights arising from the ORSA and how they fit together;
- Analyses of the key scenarios considered, including any management actions that are assumed and confirmation of whether or not these have been approved by the board;
- Where there is "use test" as part of the local regulations, information on where the board has been consulted;
- Either explicitly within the report, or documented separately, descriptions of the methodology and key assumptions underlying ORSA results, including information on the principal limitations and judgements made in the assessment; and
- Cross-referencing to any relevant supporting documents so that additional supporting detail can be obtained if required.

5. Integration with Other Business Processes

The results of ORSA processes are to be taken into consideration in strategic and business decision-making, subsequently reflected in capital management plans, business plans, and decisions regarding product pricing and underwriting (where appropriate and relevant). The most significant phases of the integrated process are depicted in Figure 1 below.
Figure 1

Although the timing of the phases within the integrated process identified in Figure 1 appear to identify a single cyclical process, ORSA processes are to be integrated within the business cycle, e.g., risk and capital assessments are carried out in developing capital management plans. ORSAs are conducted both on a periodic, planned time frame as well as an ad hoc time frame, aligned with potential changes to business strategy or sudden changes to the company’s underlying risk profile.

This linkage between a company’s business strategy and decision-making processes with its ERM framework including ORSA processes is often referred to as the “use” test by independent reviewers of the ORSA process, including regulators. Ultimately, a strong ERM framework is dependent upon the company’s ability and willingness to take action based on the results of the ORSA process. Regulators would view a company’s ORSA process as less desirable if that company focuses strictly on understanding risks including implications for their capital and solvency position, but then ignores the insights uncovered in the process. Regulators often value the use test because it incentivizes companies to continue to enhance their risk management disciplines and processes, ultimately leading to further protections for policyholders.

The scope of the use test includes, but is not limited to, senior management and the board responsible for company oversight. Under the use test, senior management is expected to

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actively consider ORSA results when developing future strategies, and reliance upon ORSA results is to be clearly evidenced. Boards are expected to be actively involved in framing and overseeing how the company’s ORSA is to be carried out, and ORSA results provide valuable information for helping the board oversee the business, challenge activities that seem inappropriate in the context of the company’s overall risk appetite, and generally hold senior management accountable. Engaging the board in the ORSA process makes it more likely that the ORSA will address the needs of all stakeholders and not just those most closely associated with the perspectives of senior management.

6. Other Group Considerations

Group-wide ORSAs will need to reflect potentially differing risk perspectives arising from different parts of the group, including risks arising from exposures that one member of the group may have relative to other group members, and group-wide exposure to risks that could impact multiple entities at the same time. Group-wide ORSAs would be expected to consider the extent to which capital is available to, and fungible and transferable between, different companies within the group (including exposure to foreign exchange risk), as well as the impact of any planned transfers of capital around the group or other planned risk redistribution activities. Group-wide ORSAs would also be expected to cover the extent to which business strategy and risk management disciplines were aligned across the group.

As groups can span many different jurisdictions and business types, regulatory reporting of group-wide ORSAs clearly identifies the companies that are within or excluded from the scope of the ORSA. If applicable, group ORSAs need to spell out how any governance requirements and variations in risk management perspectives applicable to individual companies within the group have been addressed. For multinational groups some more practical administrative issues would also typically be specified by regulation, e.g., the language(s) in which regulatory reporting of group-wide ORSAs need to be prepared and how the group-wide ORSA addresses any differences in supervisory needs across the different jurisdictions involved.

If the head (or other significant part) of the group is not an insurer then the intrinsic merits of a group ORSA are not diminished. However, the details might need adapting to address any regulatory requirements applicable to non-insurer elements of the group.

7. Guiding the ORSA Process

Companies develop policies and procedures related to key business processes, and for Solvency II, ORSA processes will be captured within a documented ORSA policy that articulates how the ORSA is to be carried out, a record of each ORSA conducted, and both an internal and a supervisory report on the ORSA (although these two reports may be the same). Solvency II also requires a summary of the ORSA approach to be made publicly available, so that customers and other external stakeholders can better understand the company’s risk management disciplines and solvency needs. The ORSA policy is expected to include descriptions of the processes, procedures, methodologies, and data quality standards used by the company. This would typically include information on the frequency and timing of the ORSA and how associated stress tests, sensitivity analyses, reverse stress tests, and other

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relevant analyses are to be carried out. This ORSA policy is also expected to justify why the selected approach is suitable, given the company’s risk profile and how this profile might vary through time.

Public disclosures may also help to promote wider adoption of best practice ORSA disciplines, benefiting the industry and customers more generally. However, as stated earlier, since the ORSA reports would likely contain proprietary information that management would not want to disclose to competitors, confidentiality of the information must be given the highest priority.

8. Insurance Supervision and ORSA

In certain regulatory regimes, supervisors may have the authority to require enhancements to ORSA approaches if they be deemed to be deficient, or to penalize companies in specified ways.

Supervisors have the general authority to request information from insurers where that information is deemed important to understand the nature of the risks assumed and the adequacy of capital to provide for those risks. Supervisors may ask for additional information or analysis sufficient for this purpose if it is not already contained within the ORSA, or other relevant risk and capital assessment processes of the insurer. In some circumstances supervisors may also exercise their authority to affect capital targets by imposing additional external constraints to be taken into account by the insurer in its own capital identification process.

9. Actuaries and ORSA

Since the conduct of ORSAs is often highly technical, companies are likely to rely on actuaries and other professionals to lead or provide support for ORSA processes. While actuaries have a key part to play in ORSA processes, it is important that they work with other professionals who will also have a part to play, including other colleagues in risk, finance, legal, claims, and underwriting. In addition it is important actuaries in solo companies interact with their colleagues in group roles when applicable.

Actuaries are highly experienced in assessing complex topics, and have the skills and professional processes and perspective needed to create valuable risk analysis frameworks for management, boards, and regulators. Beyond their experience with ERM and ORSA, actuaries have practiced in areas in which they commonly assess the impact of low-frequency and high-severity events such as extreme market conditions, pandemics, or hurricanes. Traditional actuarial functions, such as pricing and reserving for insurance companies, include estimating the central tendencies of likely future outcomes and developing an understanding of the variability around those estimates. Pricing and reserving may require the estimation of margins for risk variability, and development of those margins requires a deep understanding of risk. Further, actuaries apply risk assessment techniques that account for the nature, scale, complexity, and correlation of a wide range of risks and that reflect risk-mitigation strategies.

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I. Recent Professional Milestones

1. In 2009, actuaries embraced tailored ERM education through the Chartered Enterprise Risk Analyst (CERA) program, which expands on the existing risk management education of actuaries. The CERA syllabus requires that the actuary master such topics as the drivers and practical aspects of ERM, relevant regulation and regulatory capital requirements, and ERM standards and leading practices that are in use around the world.

2. In 2013, the U.S. Actuarial Standards Board (ASB) formally adopted Actuarial Standards of Practice 46 and 47 in regard to actuarial services relating to the evaluation and treatment of risk. The ASB is currently considering whether further guidance is needed for the conduct of capital adequacy assessments, and expects to publish an exposure draft in the second half of 2016.

3. The Actuarial Association of Europe (AAE) is preparing European Standard on Actuarial Practice 3 on actuarial practices in relation to the ORSA process.

4. In 2014, a similar project was initiated by the International Actuarial Association (IAA) to prepare an International Standard of Practice in relation to ERM.

5. In 2015, an issue brief developed by the IAA on the “Value of the ORSA” to a board was formally approved for distribution.

Maryellen Coggins, FCAS, MAAA, CERA, is a Managing Director at PwC. She is located in Boston, Massachusetts, USA. Her principal areas of expertise include enterprise risk management and property & casualty insurance. She can be contacted at mary.ellen.j.coggins@us.pwc.com.

Nick Dexter, FIA, FSA, is a Senior Advisor at the Prudential Regulation Authority and is based in London, United Kingdom. His principal areas of expertise include life insurance and enterprise risk management. He can be reached at Nick.Dexter@bankofengland.co.uk.

Malcolm Kemp, FIA, M.A., CERA, is Managing Director of Nematrian Limited and is based in London, United Kingdom. His principal areas of expertise include risk, investment management, and quantitative finance. He can be contacted at malcolm.kemp@nematrian.com.

John Oost, AAG, RBA, is a Senior Risk Manager at Achmea. He is located in Zeist, The Netherlands. His principal areas of expertise include enterprise risk management and Solvency II. He can be contacted at john.oost@achmea.com.

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