

Tool: Guidelines for assessing the impact of divergence

(Step 3. Assess the impact of divergence on leveraging information)

Introduction to the tool

This tool (*Guidelines for Assessing the Impact of Divergence*) is intended to support implementation of Step 3 of the process introduced in the IAEA TECDOC-2098, *Collaborative Reviews and Effective Leveraging* [1].

First, the guidelines provide a discussion of four types of divergence (scope and detail of the review, application contents, design reference and regulatory expectations) that could impact the ability of the Recipient Regulator (Regulator B in Ref. [1]) to use the review carried out by the Source Regulator (Regulator A in Ref. [1]). Then, the guidelines qualitatively assess the impact of the divergence following three categories:

- Low impact;
- Medium impact;
- High impact.

For each one of the four types of divergence, actions that the Recipient Regulator could adopt to minimize the impact of the divergence in the review are suggested.

Guidelines for assessing the impact of divergence

Divergence in the scope and detail of the review

The Source Regulator’s review may cover different technical areas, site parameter envelopes, operational modes, or specific accident scenarios compared to what the Recipient Regulator requires. Furthermore, the depth or granularity of the Source Regulator’s review (e.g. level of analysis, sensitivity studies performed, validation methods) might differ from the Recipient Regulator’s standards or practices.

Potential impact of the divergence:

Scope gaps (high), detail of the review (low).

Discussion and examples:

- Scope:** Differences in scope often arise from national regulations defining the range of required assessments. For example, the Source Regulator might have reviewed a generic design against a site parameter envelope selected by the applicant to enable fleet deployment (at multiple sites), while the Recipient Regulator may require consideration of different or more challenging site characteristics which are area or country specific. A Source Regulator’s review might focus on the nuclear island, while a Recipient Regulator may require a broader review including plant areas of limited or no nuclear safety significance. The reverse situation is also possible. As seen in the World Nuclear Association (WNA) report [2], different national views on relevant internal and external hazards directly influence the scope of the design basis and required reviews.

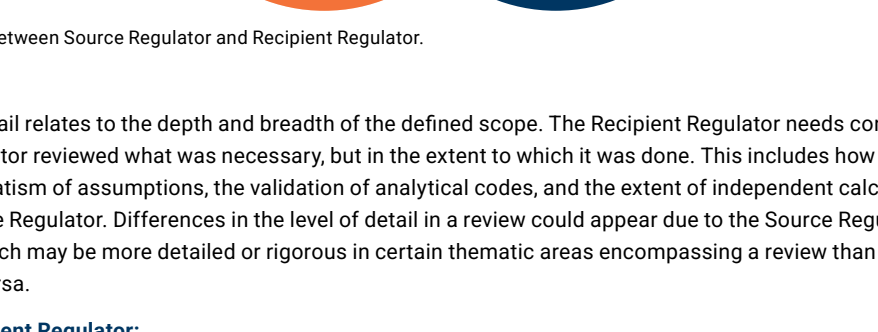


Figure 1. Different scopes between Source Regulator and Recipient Regulator.

- Detail:** The level of detail relates to the depth and breadth of the defined scope. The Recipient Regulator needs confidence not only in that the Source Regulator reviewed what was necessary, but in the extent to which it was done. This includes how the Source Regulator assessed the conservatism of assumptions, the validation of analytical codes, and the extent of independent calculations performed or reviewed by the Source Regulator. Differences in the level of detail in a review could appear due to the Source Regulator’s regulations or review procedures which may be more detailed or rigorous in certain thematic areas encompassing a review than those of the Recipient Regulator, or vice-a-versa.

Guidelines for the Recipient Regulator:

- Scope:**
 - The Recipient Regulator needs to clearly define first their own required scope based on their national regulations and context, recognizing that this scope can range from a focused, smaller area to a comprehensive whole-review assessment. This definition of scope should aim for workable information segments to facilitate effective review.
 - The Recipient Regulator needs to conduct a comparison between their own required scope and the actual scope covered by the Source Regulator’s review documentation. This would involve identification of specific areas reviewed by the Source Regulator but not needed by the Recipient Regulator (out of scope), areas needed by the Recipient Regulator but not reviewed by the Source Regulator (gaps to close), and areas where the scope overlaps but boundary conditions differ.
 - To address the gaps, the Recipient Regulator may conduct their own supplementary review, commission specific analyses, or potentially leverage relevant reviews from a third regulatory body, if available and practicable (see Steps 5 and 6 in Ref. [1]).
 - Information from the Source Regulator’s review that falls outside the Recipient Regulator’s required scope might still be useful contextually but should be leveraged cautiously and only after careful evaluation of its relevance and basis.
- Detail:**
 - The Recipient Regulator needs to gain a thorough understanding of the Source Regulator’s review procedures, internal practices, acceptance criteria, and quality management system for regulatory reviews. Direct engagement and information exchange with the Source Regulator are highly valuable.
 - The Recipient Regulator needs to determine their confidence level in the depth and rigor of the Source Regulator’s review. This is often subjective but can be informed by the Source Regulator’s reputation, experience, transparency, and the quality of the documented review basis (see Step 4 in Ref. [1] and the Tool of Assessment Checklist with a Scoring Matrix for Information Quality in *Regulatory Cooperation Toolkit: Resources for Leveraging Regulatory Reviews* [3]).
 - If confidence is high, the Recipient Regulator might leverage much of the Source Regulator’s detailed review, perhaps performing audits or targeted ‘deep dives’ on specific safety-significant or novel areas. If confidence is lower, more extensive independent verification by the Recipient Regulator might be necessary.

Divergence on the application structure, format and contents

The structure and format of a licensing application, as well as the expected content (type and level of detail of supporting evidence) included in the application, can vary significantly from country to country. Some regulatory bodies require highly prescriptive formats (e.g. specific chapters/sections in a Safety Analysis Report reflecting regulatory guidance), while others are more goal-oriented, focusing on the technical substance regardless of format.

Potential impact of the divergence:

The potential impact of divergence is medium in cases where the regulatory framework in the Recipient Regulator’s country is more ‘goal-oriented’, and high in cases where the regulatory framework in the Recipient Regulator’s country is more ‘prescriptive’.

Discussion and examples:

The Source Regulator may have accepted an application structured according to their national standards or vendor preferences (e.g. based on standards and formats common in the USA), while the Recipient Regulator’s regulations mandate a specific format aligned with their own guidance or, perhaps, IAEA standards. For a ‘prescriptive’ Recipient Regulator, simply receiving the Source Regulator’s reviewed documentation will often be insufficient, as finding and verifying compliance information mapped to the Recipient Regulator’s required structure can be extremely difficult and time-consuming.

The reviews performed by the Source Regulator may be based on certain structures of the application submitted for their jurisdiction. The Recipient Regulator needs to be aware of these structures or have confidence in the scope of the review conducted by the Source Regulator, i.e. what scope of applicant input was considered.

Guidelines for the Recipient Regulator:

‘Prescriptive’ Recipient Regulator:

- The primary challenge is mapping the information from the Source Regulator’s reviewed application to the Recipient Regulator’s required structure. This activity often falls to the applicant.
 - The Recipient Regulator may require the applicant to provide comprehensive cross-references, compliance matrices, or even supplementary documents that reorganize or bridge the information to meet the Recipient Regulator’s requirements. This can present a significant effort for the applicant but may represent less effort than re-writing or re-packaging all the information.
 - While focusing on their regulations, the Recipient Regulator needs to also consider the underlying technical substance. If the safety case is sound and adequately documented, minor formatting differences might be accommodated where regulations allow flexibility. However, significant differences in structure and underpinning may necessitate substantial applicant re-working.
- ‘Goal-oriented’ Recipient Regulator:
- A goal-oriented Recipient Regulator can streamline their assessment by leveraging the technical substance of an application already reviewed by the Source Regulator. The focus is not on accepting the Source Regulator’s review outright, but on determining if the documented information is sufficiently complete and clear to be incorporated into the Recipient Regulator’s own safety assessment and to support the Recipient Regulator’s independent findings. To assess the quality of the Source Regulator’s review, additional guidance is provided in Step 4 in Ref. [1] and the Tool of Assessment Checklist with a Scoring Matrix for Information Quality in Ref. [3].
 - It is important to ensure that the Source Regulator’s review basis and findings are clearly documented and accessible, even if the application format differs from the Recipient Regulator’s typical submissions.
 - The Recipient Regulator still needs to ensure all necessary technical information (design details, analyses, justifications) required by their own framework is present within the formal application submitted to them, regardless of where it resides structurally. A key consideration will be the degree to which the applicant’s and Source Regulator’s documentation show that the requirements/goals of the goal-oriented framework (Recipient Regulator) would be clearly met, or there is lack of visibility and additional work needed due to the different requirements of the Source Regulator.

Divergence on the design reference (impact on codes and standards changes)

The reactor design reviewed by the Source Regulator is based on a specific set of industrial codes and standards (C&S) for design, materials, construction, testing, and inspection (e.g. the American Society of Mechanical Engineers (ASME), French Association for Design, Construction and In-Service Inspection Rules for Nuclear Island Components (AFCEN), Institute of Electrical and Electronics Engineers (IEEE), International Electrotechnical Commission (IEC), the Nuclear Safety Standards Commission (KTA)). The Recipient Regulator’s national regulations or accepted practices may mandate or prefer different C&S.

Potential impact of the divergence:

High.

Discussion and examples:

This divergence is often a major hurdle. C&S are sometimes deeply embedded within national legal and industrial frameworks and supply chains. Regulatory bodies often prefer C&S that they are familiar with and that have been developed and applied within their national context (e.g. the United States Nuclear Regulatory Commission (U.S. NRC)’s preference for ASME/IEEE, the French Authority for Nuclear Safety and Radiation Protection (ASNR)’s preference for AFCEN/IEC, the UK Office for Nuclear Regulation (ONR)’s preference for IEC), or even mandate specific C&S. Differences are not necessarily about one C&S being ‘better’, but about established practice, familiarity, regulatory integration, and supply chain qualification. Divergence in C&S basis can result in:

- Extensive justification by the applicant demonstrating equivalence or adequate safety margins using the original C&S within the Recipient Regulator’s framework;
- Potential component or system redesign to meet the Recipient Regulator’s preferred C&S;
- The Recipient Regulator not being able to leverage the Source Regulator’s review due to technical discrepancies including quantitative acceptance criteria.

Guidelines for the Recipient Regulator:

- The primary responsibility to demonstrate that the C&S used in the design meet the safety objectives underpinning the Recipient Regulator’s legal and regulatory requirements lies with the applicant.
- It is crucial to differentiate between C&S (the ‘how’) and fundamental regulatory safety requirements or acceptance criteria (the ‘what’/ performance goal). The Recipient Regulator’s focus is on whether the safety outcome is achieved.
- The Recipient Regulator could, as a good practice, establish a clear process for applicants to demonstrate the equivalence of alternative C&S or justify their use. This requires expertise within the Recipient Regulator (or their Technical Support Organization(s) (TSO(s)) to evaluate such demonstrations. International efforts on C&S comparison (e.g. via the Nuclear Energy Agency of the Organisation for Economic Co-operation and Development (OECD NEA), the Multinational Design Evaluation Programme (MDEP), the Cooperation in Reactor Design Evaluation and Licensing (CORDEL) Working Group of WNA, the Industry Track Topical Group 2 of the IAEA’s Nuclear Harmonization and Standardization Initiative (NHISI)) can provide valuable input.
- Evaluate the significance of C&S divergence based on the safety function of the affected structures, systems and components (SSCs). Differences for highly safety-significant components (like the RPV) are more critical than for less significant ones.
- Encourage very early dialogue between the applicant and the Recipient Regulator on the proposed C&S basis to identify potential conflicts long before major design or procurement decisions are finalized.

Divergence on the regulatory expectations

This encompasses the specific interpretations, safety philosophies, analytical assumptions, and acceptance criteria applied by regulatory bodies, even when based on the same high-level international safety standards, for example, IAEA Safety Standards. It includes the way in which concepts like defence in depth (DiD), safety classification, common cause failure, human factors, and hazard assessment are implemented in practice.

Potential impact of the divergence:

High.

Discussion and examples:

This divergence can be a very challenging area, as it reflects deep-seated national regulatory culture, experience (including lessons from national incidents), and specific legal mandates. Several analyses have been conducted to assess how divergence in regulatory frameworks influence nuclear power plant design. For example, the WNA has identified specific areas where regulatory differences could affect design outcomes, as documented in report [2] and briefly summarized below. Additionally, the UK ONR has carried out a review of the EPR design, evaluating the influence of UK-specific regulatory requirements [4]. The UK ONR concluded that the regulatory decisions and approaches adopted during the EPR assessment were broadly aligned with those of other regulatory bodies. Nonetheless, divergences in the following have the potential to lead to design changes including:

- DiD:** Different requirements for independence and diversity between DiD levels (e.g. Western-European Level 3a/3b split vs. other approaches, which influences the instrumentation and control (I&C) design, as described in [2]).
- Design basis accident/design extension condition definition and analysis:** Differences in classifying events, required analytical methods (conservative vs. best estimate), crediting systems, and defining success criteria. For example, the differences performed by WNA [2] found that best estimates in event sequence analysis approaches lead to changes in the EPR design. These differences often stem from the underlying regulatory philosophy – whether goal-setting or prescriptive. The UK ONR report [4] outlines why and where changes in the UK have been adopted in other jurisdictions.
- Safety classification:** Different philosophies and numbers of safety classes, affecting the classification of specific systems and the associated requirements (e.g. US vs. UK classifications for AP1000 support systems or Advanced Boiling Water Reactor (ABWR) spent fuel cooling).
- Piping rupture criteria** (‘leak-before-break’ vs. ‘double-ended guillotine break’): Divergence in the fundamental approach to high- and moderate-energy piping safety, such as accepting an analytical ‘leak-before-break’ argument versus requiring postulation of most limiting failures (e.g. ‘double-ended guillotine break’) and applying a holistic ‘break preclusion’ philosophy, can lead to major design impacts. The acceptance of a ‘leak-before-break’ case by the Source Regulator is often insufficient for a regulatory body that bases their requirements on the postulation of full-bore breaks and the implementation of the ‘break preclusion’ concept, e.g. beyond code compliance for components of the highest reliability (where gross failure leads to intolerable consequences).
- Common cause failure:** Varying interpretations of required diversity and separation for mitigating common cause failure, especially in I&C (e.g. ABWR backup I&C requirements in the UK).
- Human factors:** Differences in crediting operator actions versus requiring engineered solutions (e.g. AP1000 spent fuel pool critically safety).
- Specific criteria:** Differing numerical acceptance criteria, interpretation of ‘as low as reasonably achievable’, or specific hazard resilience requirements (e.g. ABWR emergency diesel generator location).

Impact: These divergences often drive the most significant design changes, impacting hardware, software, plant layout, operational procedures, and the overall safety case architecture, even if the original design met the Source Regulator’s requirements derived from the same fundamental safety goals.

Guidelines for the Recipient Regulator:

- Understand the basis: The Recipient Regulator is strongly advised to invest effort to understand how and why the Source Regulator has reached their conclusions, including the specific criteria, interpretations, and assumptions applied. This requires transparency and detailed documentation from the Source Regulator’s review.
- Identify key differences early: Focus on identifying differences in fundamental safety philosophy and key acceptance criteria (e.g. safety classification boundaries, diversity requirements for key systems, severe accident management strategies) early in the process.
- Evaluate safety significance: Assess the practical impact of the identified divergences on overall plant safety. Determine whether the difference reflects a substantially different level of safety or is primarily a difference in approach or demonstration method.
- Risk-informed decision making: Employ risk-informed approaches where possible to evaluate the significance of divergences and the necessity of requiring design changes, weighing the safety benefit against the cost and complexity.
- Targeted review: Focus your own review resources on the areas of significant divergence in expectations and criteria, while potentially placing greater reliance on the Source Regulator’s review in areas of close alignment.
- Additional good practices are outlined in the *Regulatory Cooperation Toolkit: Approaches for Addressing Areas of Regulatory Difference* [5].

Examples of divergence for areas that have high impact on the design

Impact of divergence in safety classification schemes on the design reference

Divergence in the safety classification schemes between the Source Regulator’s jurisdiction and the Recipient Regulator’s jurisdiction can have a high impact on the design, from a design reference perspective, when attempting to leverage regulatory reviews. While codes and standards, for instance, ASME Section III, often detail specific requirements for different classes, the fundamental definition of the safety classes themselves, their number, and the specific criteria for assigning SSCs to these classes are typically established within national regulations.

These national regulations are generally developed considering high-level international guidance, such as that provided by the IAEA (e.g. IAEA Safety Standards Series No. SSR-2/1 [6], Requirement 22, which calls for classification based on function and safety significance). However, the high-level nature of IAEA guidance allows for variation in interpretation as Member States translate it into specific, legally binding national rules. Consequently, different jurisdictions establish distinct safety classification boundaries and hierarchies (e.g. three classes vs. four classes, differing criteria for criticality, decay heat removal importance, or hazard mitigation), leading to situations where the same SSC can be assigned to different safety classes under the Source Regulator’s regulations versus the Recipient Regulator’s regulations.

This divergence, rooted in differing national regulatory interpretations of international guidance, is particularly challenging for the Recipient Regulator, because the safety classification assigned to an SSC fundamentally dictates the required rigor and specific technical standards applied to its design, analysis, manufacturing, qualification, construction, inspection, and testing, as mandated by the respective national regulations (graded approach).

Challenges for the Recipient Regulator when considering the Source Regulator’s reviewed design reference:

1. Mismatch in required design rigor / graded approach (driven by regulation):

- If the Recipient Regulator’s regulations classify an SSC at a higher safety level than the Source Regulator’s regulations did, the original design reference reviewed by the Source Regulator is based on a regulatory foundation demanding less stringent requirements than what the Recipient Regulator mandates for that classification.

- Example: The Source Regulator’s regulations might place certain support systems in Safety Class 3 based on their interpretation of indirect safety impact. The Recipient Regulator’s regulations, interpreting the same IAEA principles differently, might place those same systems in Safety Class 2 due to a stricter view on defence-in-depth support functions, thereby imposing significantly higher regulatory requirements on their design and qualification basis.

2. Incompatibility with applicable C&S (as mandated by regulation):

- National regulations often link specific C&S (or types/classes within them, like ASME Class 1, 2, or 3) directly to their defined safety classes. A design referenced against the C&S deemed acceptable by the Source Regulator for their nationally defined safety class may not align with the C&S mandated by the Recipient Regulator for their national definition (and potentially higher) safety class for that same SSC. This requires the applicant to address the discrepancy dictated by the Recipient Regulator’s rules.

3. Inadequate qualification basis due to higher regulatory demands:

- The Recipient Regulator’s nationally defined higher safety classification typically carries with it more demanding regulatory requirements for seismic and environmental qualification. An SSC qualified to meet the Source Regulator’s regulatory requirements for its assigned class might not meet the requirements mandated by the Recipient Regulator’s regulations for its higher classification of that SSC.

4. Insufficient redundancy, diversity, or separation as required by regulation:

- The Recipient Regulator’s regulations might explicitly mandate specific levels of redundancy, diversity, or physical/electrical separation for SSCs belonging to higher safety classes based on their national interpretation of defence in depth and common cause failure mitigation. If the Recipient Regulator classifies a system higher than the Source Regulator did under their respective regulations, the original design might lack the safety characteristics legally mandated by the Recipient Regulator.

5. Impact on safety case reliance based on national regulatory framework:

- The Recipient Regulator’s overall safety review needs to demonstrate compliance with their own national regulatory framework, including their specific safety classification scheme. If the design reference reviewed by the Source Regulator utilizes components classified according to a different national scheme, the Recipient Regulator cannot directly adopt the Source Regulator’s finding. The applicant needs to perform due diligence to ensure compliance with the Recipient Regulator’s distinct regulatory framework.

When faced with differing safety classification schemes stemming from different national interpretations of international guidance, the Recipient Regulator needs to recognize that the design reference reviewed or approved by the Source Regulator was validated against a different set of regulatory requirements. The Recipient Regulator needs to require the applicant to demonstrate how the design meets the specific requirements tied to the Recipient Regulator’s own safety classification scheme, irrespective of the classification assigned by the Source Regulator. This may necessitate significant re-evaluation, justification, or re-design efforts focused on satisfying the demands of the Recipient Regulator’s national regulations, thereby reducing the efficiency of leveraging prior reviews.

Impact of divergence in defence-in-depth implementation on regulatory expectations and scope of review

Divergence in DiD implementation often stems from varying national emphases on preventive versus mitigation measures, influenced by historical events (e.g. post-Fukushima enhancements). This affects regulatory expectations (see Section ‘Divergence on the regulatory expectations’) by altering required layers of protection and intersects with scope of review (see Section ‘Divergence in the scope and detail of the review’) by expanding or contracting the events considered in safety analyses. IAEA SSR-2/1 [6] promotes DiD with five levels, but interpretations differ.

Challenges for the Recipient Regulator could include:

- If the Recipient Regulator mandates stricter DiD (e.g. explicit diversity in backups), the Source Regulator’s review scope may lack analyses of extended scenarios, requiring supplementary reviews.

- Differences in DiD philosophy lead to re-assessing redundancy, potentially affecting application contents (see Section ‘Divergence on the application structure, format and contents’), if new justifications are needed.

- Codes and standards related to DiD (e.g. IEEE for diversity) may not align, forcing equivalence demonstrations or changes.

For example, an integrated I&C platform acceptable to the Source Regulator may be rejected by the Recipient Regulator due to a lack of sufficient diversity or independence between safety functions, forcing a fundamental redesign of the plant’s control and protection systems. In another case, the Recipient Regulator may be more restrictive than the Source Regulator in allowing operator actions to be credited for fulfilling a specific level of defence, requiring the applicant to add engineered, automated systems instead.

The Recipient Regulator’s work might benefit from requiring the applicant to lead gap analyses with risk-informed justifications.

Impact of divergence in hazard analysis and assessment

Hazard analysis forms the foundation of the plant’s design basis. Divergence in how potential internal and external events are identified, screened, and characterized could be highly problematic because it directly dictates the physical robustness and safety systems required for the plant.

While guided by international boundaries, national regulations and practices dictate the specific list of postulated initiating events (PIEs) to be considered. Regulatory bodies may have different screening criteria or probabilistic thresholds for external events like seismic activity, flooding, extreme weather, and aircraft impacts. For example, the seismic spectra required by the Recipient Regulator may be more demanding than what was used in the design reference reviewed by the Source Regulator, invalidating the original qualification of structures and components.

The Recipient Regulator must not simply accept the Source Regulator’s review of hazard resilience if the fundamental hazard definitions differ. The applicant must re-evaluate the design against the Recipient Regulator’s specific hazard requirements. This can lead to significant challenges, which may include:

- The original design may be fundamentally inadequate to withstand the hazards defined by the Recipient Regulator, potentially requiring re-siting or significant structural and system redesign (e.g. strengthening buildings, relocating diesel generators).
- Equipment qualified for the seismic or environmental conditions of the Source Regulator’s framework may not meet the more stringent demands of the Recipient Regulator’s framework, requiring costly and time-consuming re-qualification or replacement.
- The Source Regulator may have screened out certain hazards (e.g. specific external floods or man-made events) that the Recipient Regulator requires detailed analysis, creating a major gap in the safety case that the Recipient Regulator must address with their own review.

References

[1] INTERNATIONAL ATOMIC ENERGY AGENCY, Collaborative Reviews and Effective Leveraging – The IAEA’s Nuclear Harmonization and Standardization Initiative, IAEA-TECDOC-2098, IAEA, Vienna (2025), <https://doi.org/10.61092/iaea-psrj-fkjj>

[2] WORLD NUCLEAR ASSOCIATION, Different Interpretations of Regulatory Requirements, Cooperation in Reactor Design Evaluation and Licensing – Licensing & Permitting Task Force, WNA, London (2021).

[3] INTERNATIONAL ATOMIC ENERGY AGENCY, Regulatory Cooperation Toolkit: Resources for Leveraging Regulatory Reviews – The IAEA’s Nuclear Harmonization and Standardization Initiative, IAEA, Vienna (2026).

[4] OFFICE FOR NUCLEAR REGULATION, ONR’s Regulatory Influence on the EPR Design in the UK, ONR, London (2024).

[5] INTERNATIONAL ATOMIC ENERGY AGENCY, Regulatory Cooperation Toolkit: Approaches for Addressing Areas of Regulatory Difference – The IAEA’s Nuclear Harmonization and Standardization Initiative, IAEA, Vienna (2026).

[6] INTERNATIONAL ATOMIC ENERGY AGENCY, Safety of Nuclear Power Plants: Design, IAEA Safety Standards Series No. SSR-2/1 (Rev. 1), IAEA, Vienna (2016).