Q&A instructions

- The questions will be addressed after the presentations have been delivered. During the presentations, the participants are invited to post their questions in the chat.

- When posting a question in the chat, please kindly indicated the speaker you wish to address your question.

- After the presentations, the Moderator will start the Q&A session by selecting the questions to be addressed, from the chat first.

- Once all the questions from the chat have been answered, the Moderator will give the floor to the participants to ask questions directly by raising their virtual hand. This part of the session will proceed in the order in which the participants have raised their hands.

- When the Moderator gives the floor to a participant, the participant is kindly requested to turn on the video, identify themselves and indicate the speaker they are addressing, and then proceed by asking a clear and concise question. Please kindly mute your microphone while the speaker is providing their answer.

- The participants are encouraged to courteously react to one another's questions and/or remarks by using the chat. This will help the Moderator identify topics that interest the audience the most.

- Please keep in mind that the Moderator will set a time limit for each question to keep things on track and to maintain a good pace.
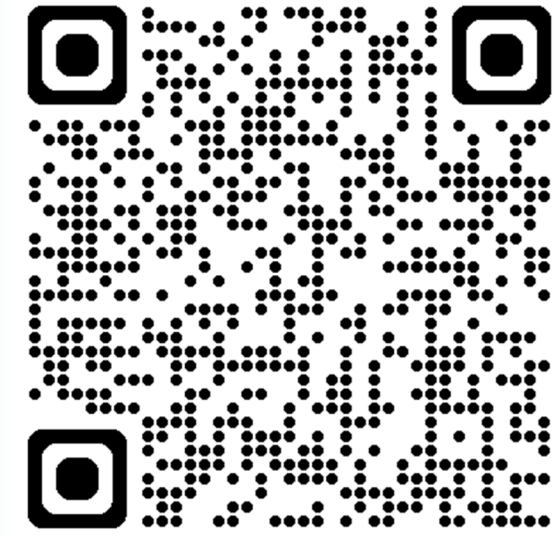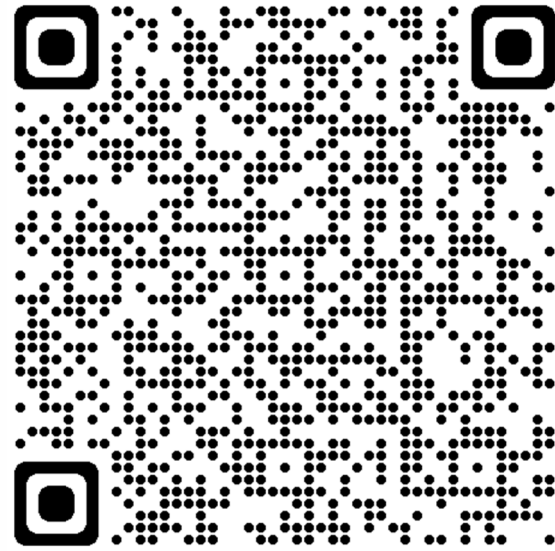
PLEASE KINDLY NOTE THAT THIS WEBINAR IS BEING RECORDED

SMR Regulators' Forum Webinar Series

WG 3 MANUFACTURING, CONSTRUCTION, COMMISSIONING AND OPERATION
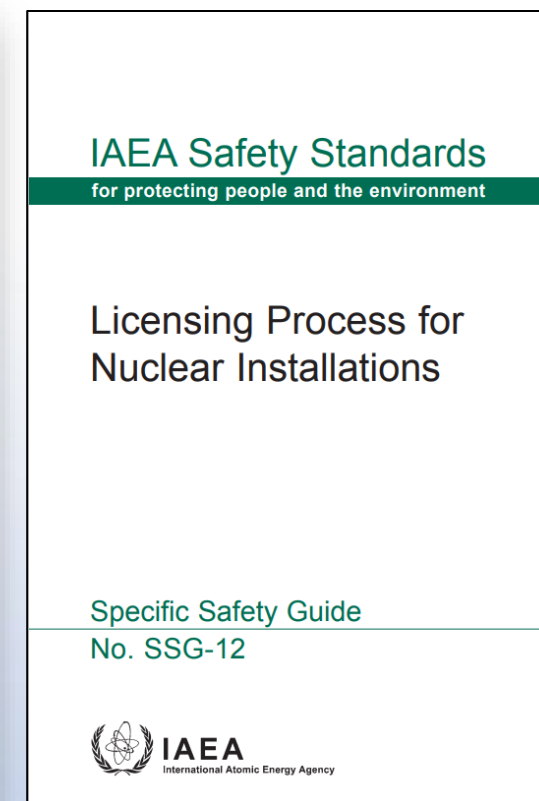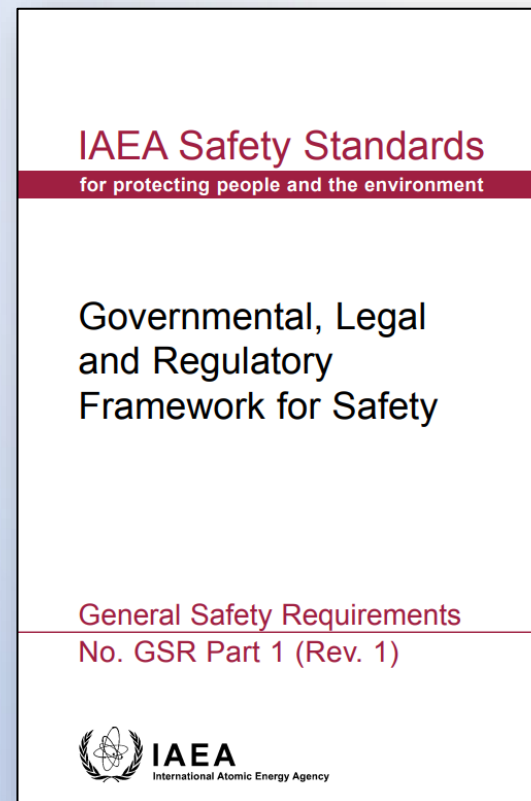5 April 2024

WG 1 LICENSING ISSUES

WG 2 DESIGN AND SAFETY ANALYSIS
03 May 2024

Introduction to the topic

- Current approaches :
  - ✓NPPs are licensed by the regulator in the country of operation
  - ✓Early regulatory engagement with vendor (prior to licensing or formal pre-licensing) not always the practice
  - ✓Cooperation among regulators during the review of a NPP design is not always the practice

IAEA Safety Standards
for protecting people and the environment

Governmental, Legal and Regulatory Framework for Safety

General Safety Requirements
No. GSR Part 1 (Rev. 1)

🅐 **IAEA**
International Atomic Energy Agency

IAEA Safety Standards
for protecting people and the environment

Licensing Process for Nuclear Installations

Specific Safety Guide
No. SSG-12

🅐 **IAEA**
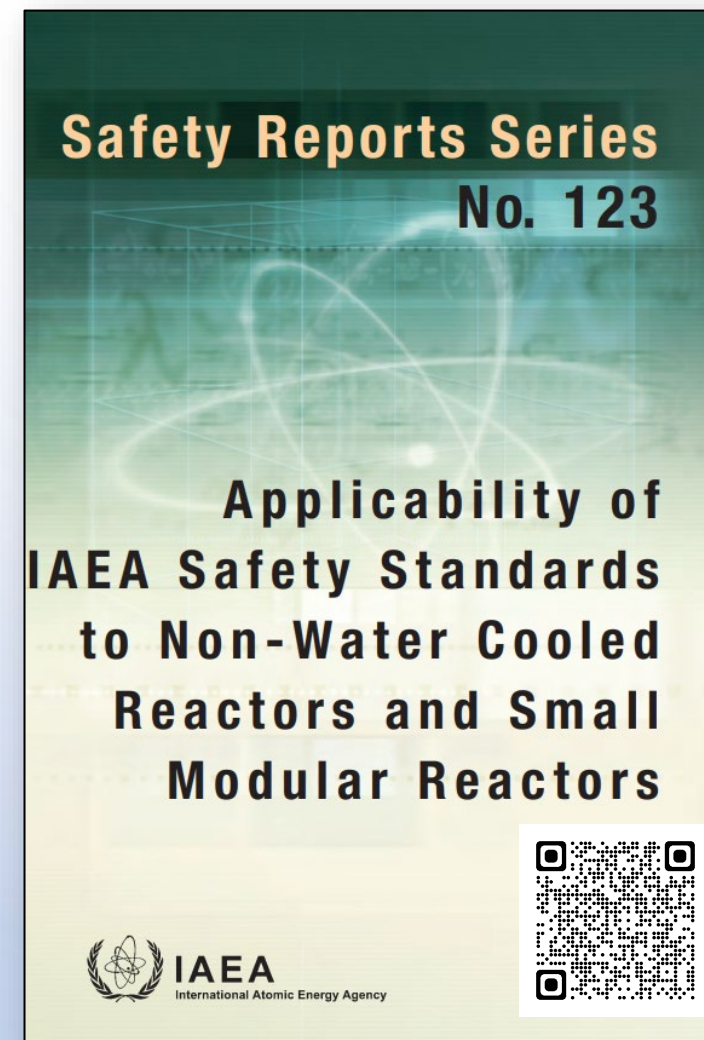International Atomic Energy Agency

Introduction to the topic

SMRs bring new deployment models:

- Potential increase on demand on regulatory resources due to high number of SMRs (with innovative features and limited operating experience)

- Some SMRs may be deployed as a standard design globally; this will require increase regulatory cooperation

- SMR lifetime stages could be located in different countries

How can regulators cooperate when reviewing the same SMR design to guarantee a high level of safety and to use resources efficiently?

Safety Reports Series No. 123

Applicability of IAEA Safety Standards to Non-Water Cooled Reactors and Small Modular Reactors

IAEA
International Atomic Energy Agency

Contents

The IAEA Nuclear Harmonization and Standardization Initiative (NHSI)

Ms Paula Calle Vives (IAEA)

The SMR RF and the Collaboration with NHSI

Dr Matthew Bamber (ONR), SMR RF Vice-Chair

Leveraging Regulatory Reviews

Dr Matthew Bamber (ONR), SMR RF Vice-Chair, NHSI WG3 member

Undertaking Collaborative Reviews

Mr Sean Belyea (CNSC), SMR RF Licensing / NHSI WG3 Chair

Addressing Differences in Regulatory Conclusions and Next Steps

Mr Sean Belyea (CNSC), SMR RF Licensing / NHSI WG3 Chair

Questions and Answers

Ms Volha Piotukh (IAEA)

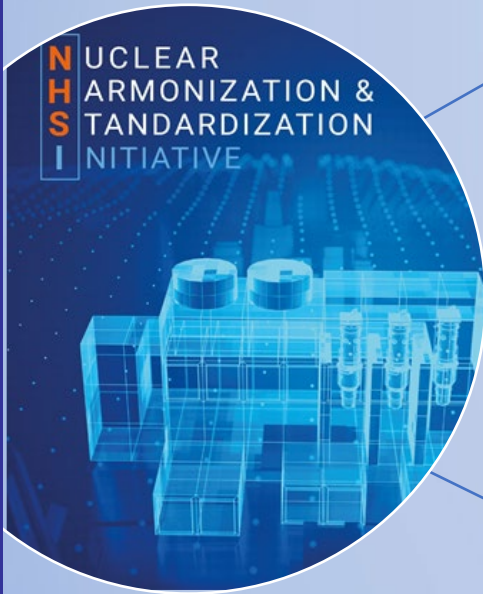# The IAEA Nuclear Harmonization and Standardization Initiative (NHSI)

The IAEA Nuclear Harmonization and Standardization Initiative (NHSI)

Effective Global Deployment of Safe and Secure Advanced Nuclear Reactors

Harmonization of Regulatory Approaches

- **WG1:** Framework for information sharing
- **WG2:** Towards harmonization - multinational pre-licensing joint review process
- **WG3:** Two processes increasing cooperation: leveraging existing regulatory reviews; collaboration between national reviews

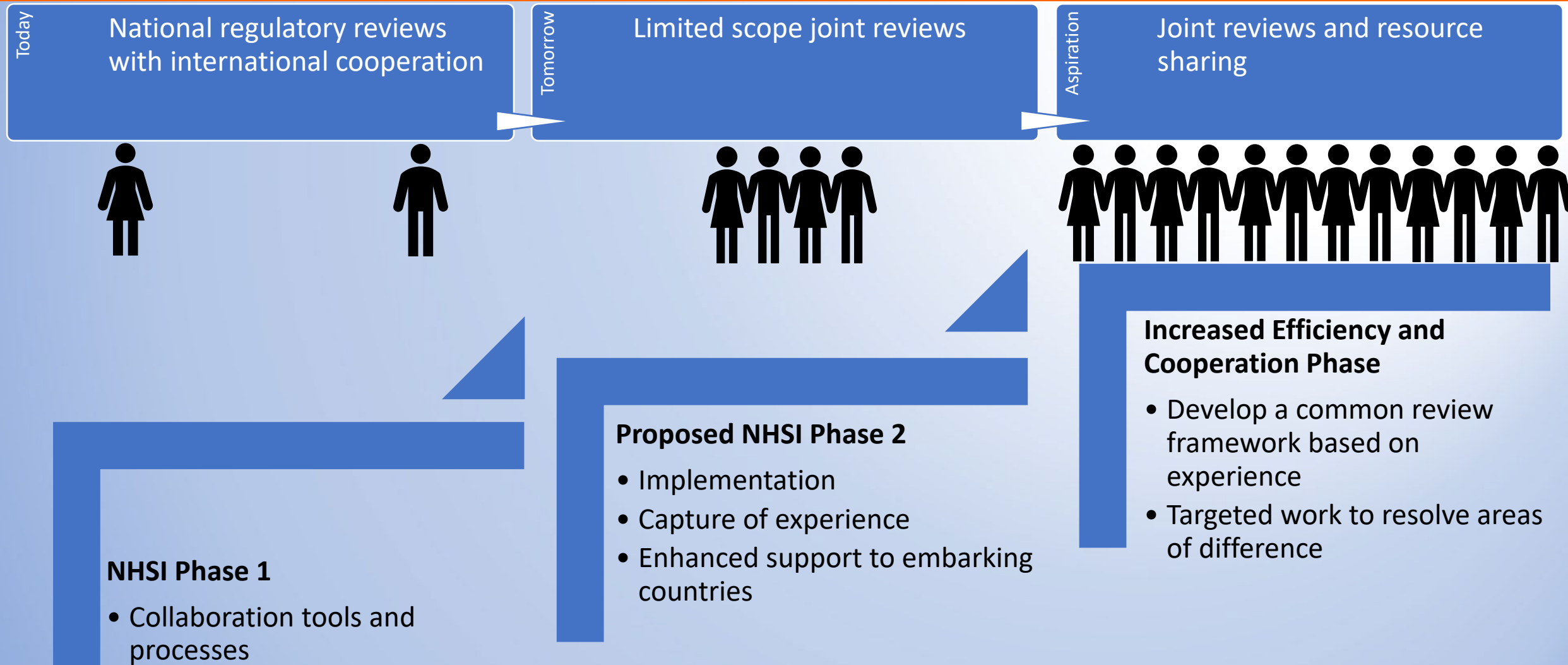**IAEA as facilitator**
within and between the tracks

Harmonization and Standardization of Industrial Approaches

- **TG1:** Harmonization of high-level user requirements
- **TG2:** Common Approaches to codes and standards
- **TG3:** Experimental testing and validation for design and safety analysis computer codes
- **TG4:** Accelerating the implementation of nuclear infrastructure for SMRs

NHSI Regulatory Track

ASPIRATION (Long Term) : Global framework for regulatory review of advanced reactors

Today — National regulatory reviews with international cooperation

Tomorrow — Limited scope joint reviews

Aspiration — Joint reviews and resource sharing

NHSI Phase 1

- Collaboration tools and processes

Proposed NHSI Phase 2

- Implementation
- Capture of experience
- Enhanced support to embarking countries

Increased Efficiency and Cooperation Phase

- Develop a common review framework based on experience
- Targeted work to resolve areas of difference

NHSI Regulatory Track Phase I (2022-2024)

TYPES OF COOPERATION

Collaborative reviews

Joint reviews

Leveraging regulatory reviews

NHSI WG1

Framework for **information sharing**

- Agreements to share controlled information and repository collating publicly available information
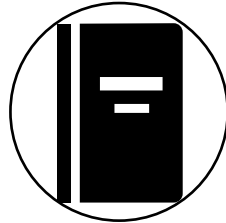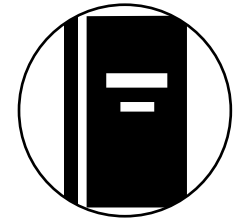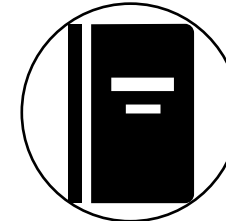
NHSI WG2

Towards harmonization: multinational pre-licensing review process

- A single team and a single review outcome
- Early identification of design "showstoppers"
- **Commitment to avoid duplication**

NHSI WG3

Two processes increasing cooperation – building on **current initiatives**

1. Leveraging existing regulatory reviews
2. Collaborative reviews: collaboration between national reviews (independent national reviews in parallel but with information exchange)
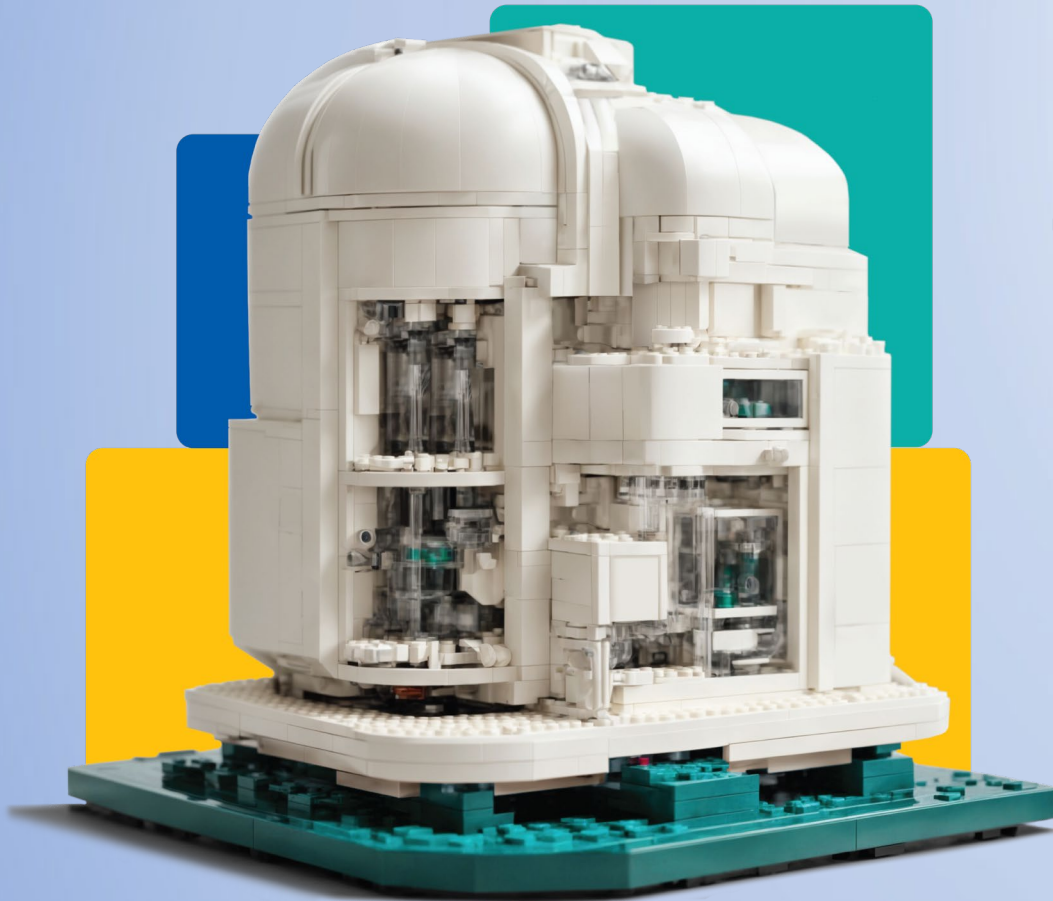
The Small Modular Reactor Regulators' Forum (SMR RF) and the Collaboration with NHSI

Objectives and Outcomes
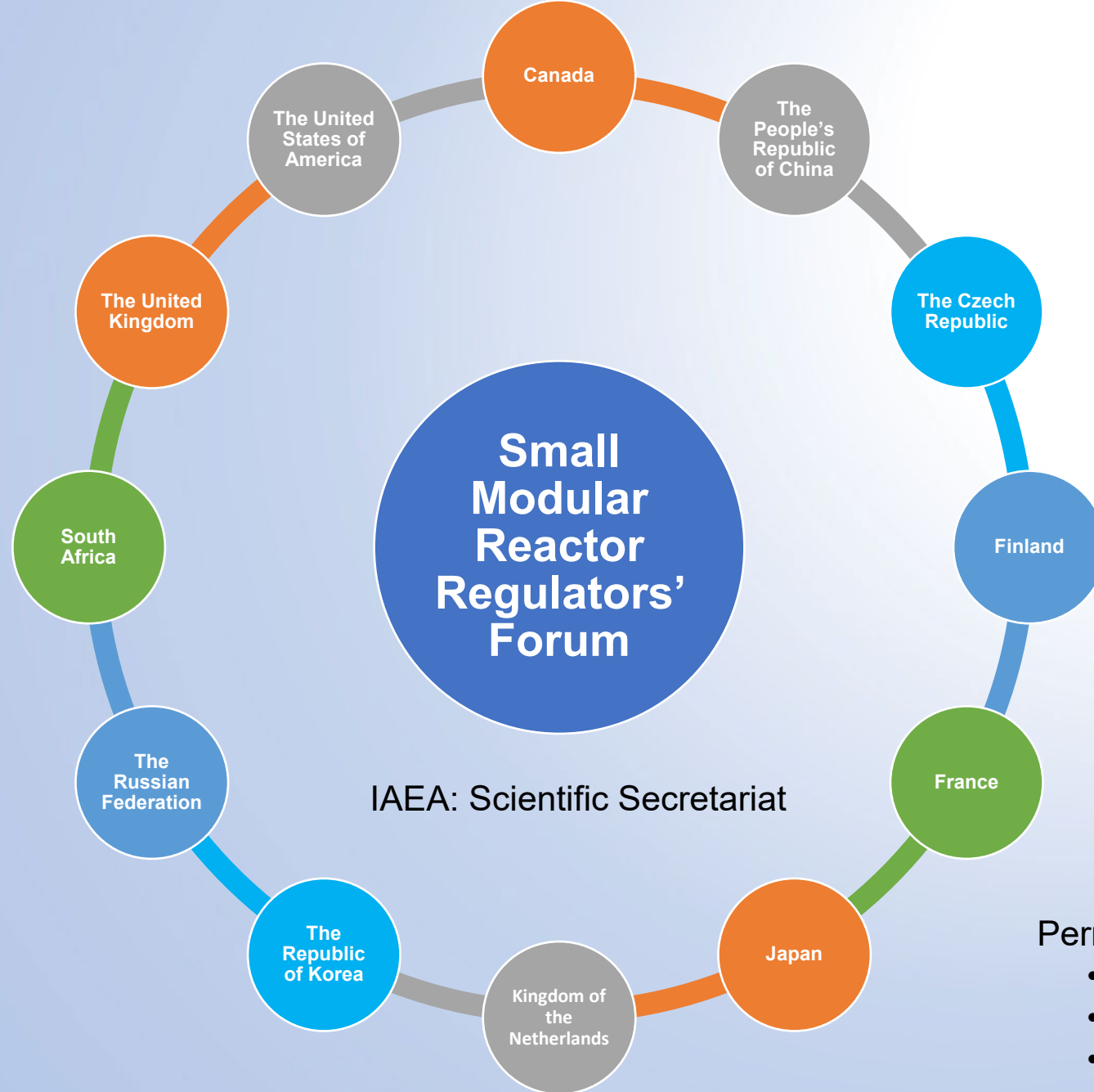
- Share regulatory experience among the Members to:
  - ✓ facilitate efficient, robust, and thorough regulatory decisions;
  - ✓ encourage enhanced nuclear safety and security;
  - ✓ facilitate international cooperation among regulators performing SMR-related assessments.

Generation and sharing of information that regulators can use to enhance their regulatory frameworks and activities

Description of regulatory challenges and discussions on paths forward

Common position statements on regulatory (policy and technical) issues

Suggestions for revisions to, or drafting of, the IAEA publications, especially the IAEA Safety Standards regarding SMRs

Suggestions for high level issues to be raised before international codes and standards organizations

The SMR RF and NHSI collaboration

- At the IAEA's invitation, the SMR RF Licensing WG leads the NHSI RT WG3, with its scope, objectives and membership adjusted accordingly

- Outcome is an IAEA TECDOC outlining:

  ✓ Proven processes for cooperation and lessons learned

  ✓ Exchange on good practices for cooperation among members, leading to improvements of the cooperation outside of NHSI

The SMR RF and NHSI collaboration

✓ A six-step process for leveraging regulatory reviews

✓ A process for collaborative reviews based on experience from ongoing and past cooperations

Collaborative reviews

Leveraging of regulatory reviews

Joint reviews (multinational pre-licensing joint review part of NHSI WG2)

Leveraging Regulatory Reviews
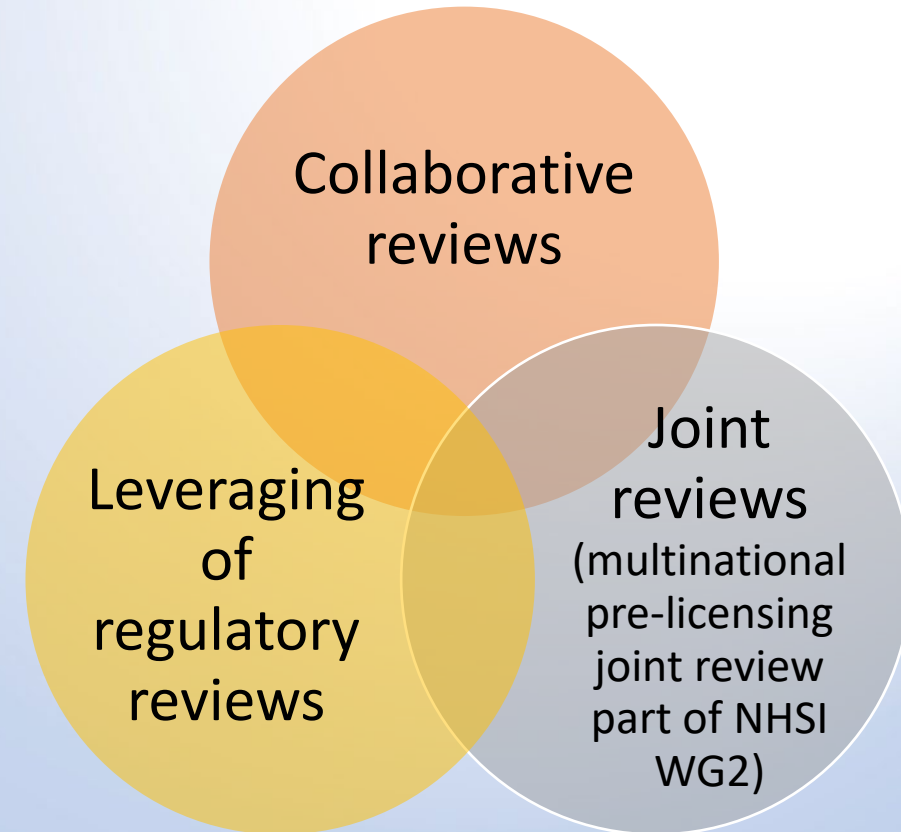
Preconditions to leverage reviews

Legislative Regulatory Regime

- Sufficiently developed and resourced nuclear safety/security infrastructure:
  - ✓ Legally mandated and independent regulatory body
  - ✓ Robust regulatory framework
  - ✓ Adequate and established nuclear safety/security knowledge base
  - ✓ Established regulations, standards and guidance
- Contracting Parties to the Convention on Nuclear Safety (CNS)

Process and Capability

- Clearly defined licensing and approval processes

Informed customer capability

- The capability to understand the basis of the leveraged review of the reference plant and the capability to assess any modifications to the reference plant design to suit country specific needs

Information

- Clear leveraged documentation to reduce potential for ambiguity, misunderstanding and misinterpretation
- Access to all necessary information with appropriate agreements and arrangements in place for the exchange of any sensitive information

Leveraging reviews

Step 1: Relevant source regulator

Step 2: Understand differences

Step 3: Assess impact of differences

Step 4: Assess information quality

Step 5: Categorize information

Step 6: Document

Approach to Leveraging Information

Step 1: Relevant source regulator

- Source regulator has reviewed the design and is experienced in reviewing and licensing NNPP
- Source regulator is experienced in regulating nuclear plant and sites
- Source regulator is engaged internationally with regulatory bodies, organisations and fora
- Source regulator has a transparent and accessible regulatory framework
- Source regulator has been the subject of IRRS missions

Approach to Leveraging Information

Step 2: Understand divergence

Identify and understand divergence in

- Regulatory frameworks
- Licensing processes
- Capacity and capability
- Reference design and application

Step 3: Assess impact of divergences

Divergence in Licensing process

- Extent of review may be insufficient requiring further assessment

Divergence in submitted application

- Areas of difference in submitted application will need to be reviewed

Divergence in requirements, expectations or approach

- These may be bounding or require additional measures

Areas of divergence need to be appropriately resolved

Approach to Leveraging Information

Step 4: Assess information quality

Is the information of sufficient quality for its purpose?

- The quality standard required across the scope of the information being leveraged needs to be defined

The Quality assessment of the information should consider

- Clarity – Coherent and intelligible
- Accuracy – Correct and error free
- Reliability – Trusted, suitably referenced, peer reviewed
- Completeness – All necessary information been provided
- Sufficiency – Meets or exceeds requirements and purposes
- Relevance – Relevant to the demands of the framework
- Currency – Information is current and valid

Step 5: Categorize information

Analyze the information to be leveraged

Understand the information, its context and how it will be used

Categorise the information

Type 1 – Needs additional work or detailed assessment to be leveraged
- Has high safety significance
- New findings or difference in design conditions
- Different regulatory requirements or thresholds

Type 2 – Can be leveraged readily
- Consistent with regulatory requirements or thresholds
- Consistent design conditions

Step 6: Document

The use of leveraged information and its outcome is to be documented, including:

- Date of the assessment
- Purpose of leveraging
- The process followed
- Assumptions made in leveraging
- Areas of similarity and difference across frameworks, design and approach
- Areas leveraged and areas needing additional measures
- Overall outcome

There is value in making this information publicly available where possible to demonstrate sovereignty of decision making
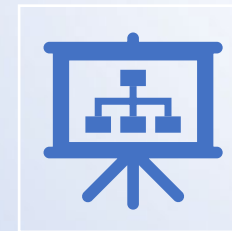
Undertaking Collaborative Reviews

Collaborative Reviews

Launching a review

Program of work

Organization

Process

Leveraging VS Collaboration
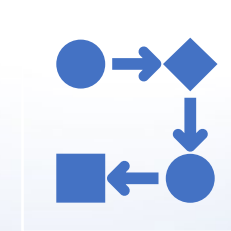
Leveraging — using another body's work and incorporating it into regulatory decisions

Collaboration — Two or more organizations working together on a review

Leveraging can be done as part of the Collaborative process

Launching a review

Decide on collaboration approach

- Working independently on all review aspects while sharing results
- Splitting up review tasks and integrating them
- Combination of the above

Setup project administration

- Establish Terms of Reference with clear objectives, outcomes, project schedule, costs and funding
- Ensure appropriate agreements are in place

Planning takes time - helps to ensure collaborative success

Program of work

Establish the topics that will makeup the program of work, while keeping in mind

- The safety impacts of established topics
- The impact each topic has on review objectives
  - ✓Also consider inter-topic dependencies or relationships
- The novelty of each topic
  - ✓Is the topical subject well proven or a new approach?

Organization

Establish an organizational structure

- Consider working group composition and working methodology
- Establish clear roles
  - Chair
  - Team leaders
  - Experts

Process

Distribute information from applicant

Assign work out

Analyze and review information

Share results and challenges

- Incorporate feedback

Each regulator performs due diligence on information to incorporate it into their own Framework

Address any differences in regulatory conclusions

Addressing Differences in Regulatory Conclusions

Sources of Differences

Different laws, approaches, regulations and philosophy	Technology and research advances	Operational experiences

New or changed codes or standards	Different siting challenges

Understanding the Differences in Regulatory Conclusions is key to addressing them!

How to Address Differences

Understand safety impact

- Greater impacts to safety imply more effort to address

Regulatory Differences

- Understand why difference exists
- Work towards a common regulatory position
  - ***** Harmonization! *****
- Minimize design changes needed
- Understand and document differences

Establishing high levels of universal safety with Regulatory flexibility

Next Steps

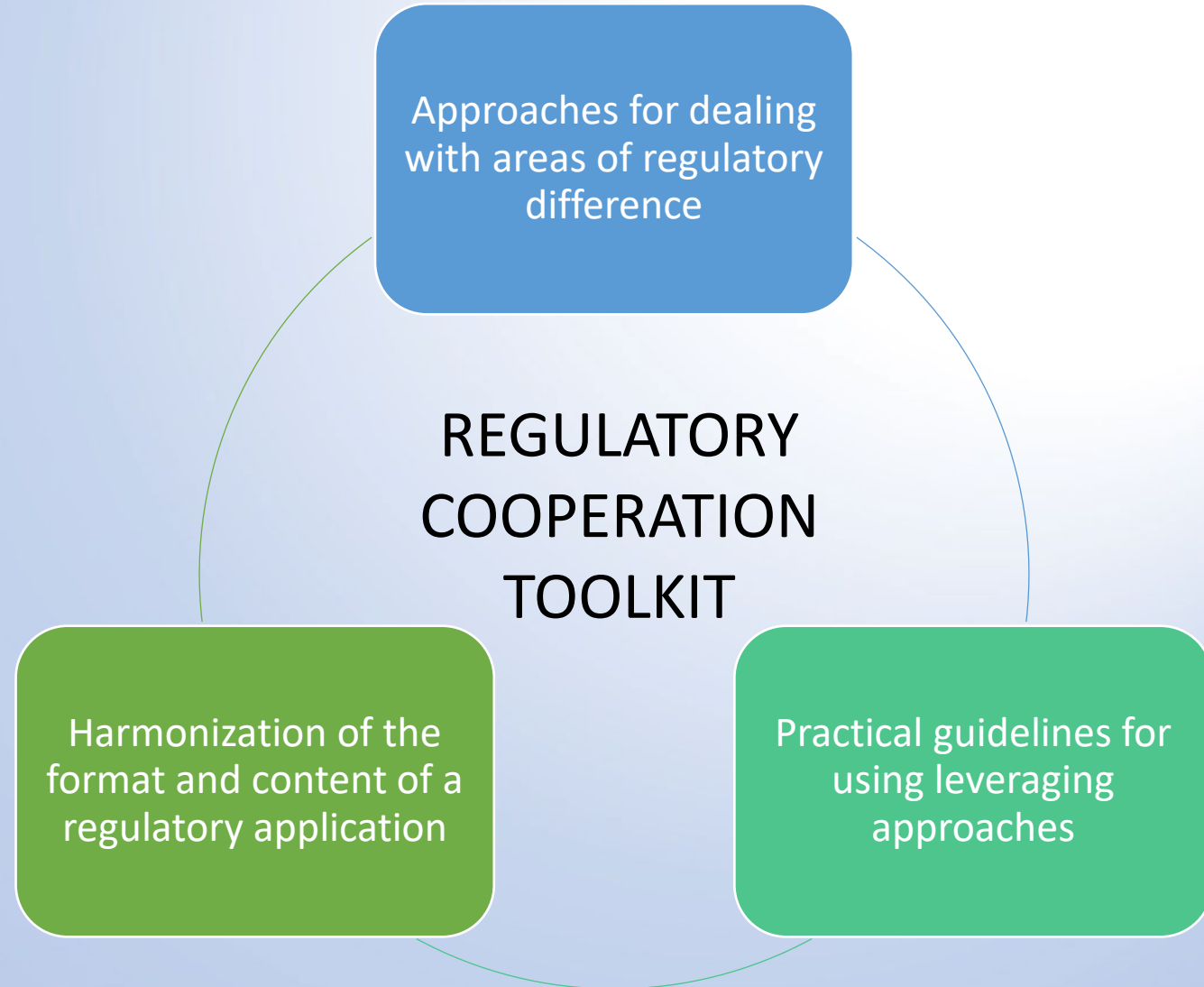Publication of (pre-print) IAEA TECDOC expected in 2025

For more information contact:
IAEA_NHSI_RT@iaea.org

Collaborative Regulatory Reviews and Effective Leveraging

Next Steps

Topics under discussion

Works starts in Fall 2024

REGULATORY COOPERATION TOOLKIT

Approaches for dealing with areas of regulatory difference

Harmonization of the format and content of a regulatory application

Practical guidelines for using leveraging approaches

Questions and Answers

Please visit the SMR RF web page:

https://www.iaea.org/topics/small-modular-reactors/smr-regulators-forum

and subscribe to the SMR RF Newsletter:

http://eepurl.com/iAZr0Q