

REGULATORY

REGULATORY ENGAGEMENT PLAN
for
Submittal and Approval of an Application to
Construct
SOLO Micro Modular Nuclear Reactor

(Non-Proprietary)

Total Pages:13

Document Number: LTR-TINN-24-007

(Enclosure 4)

Revision 0

2025-01-17

Terra Innovatum s.r.l.

Via Matteo Trenta 117, 55100 Lucca (LU), Italy

TABLE OF CONTENTS

1. Introduction	3
1.1 Purpose of Regulatory Engagement Plan	3
1.2 Contact Information	3
1.3 Company Information	3
1.4 Project Financial Support	5
1.5 Summary of Licensing Approach.....	5
2. Technology Overview	6
2.1 General Architecture and Design Philosophy.....	6
2.2 Key Design Features	8
2.3 Production and Construction	9
2.4 Site Selection of the RTR (FOAK).....	10
2.5 Operation.....	10
3. Regulatory Strategy.....	10
3.1 Application Type.....	10
3.2 Licensing Strategy.....	10
3.2.1 Conceptual Design Phase	10
3.2.2 Reference Design and Licensing Phase.....	11
3.3 Pre-Submittal Interaction Plan.....	11
3.4 Pre-Application White Papers and Topical Reports	11
3.5 Planned Application Submittal Date.....	13
3.5.1 Construction Permit Application.....	13
3.5.2 Operating License Application.....	13
4. References	13

1. INTRODUCTION

1.1 Purpose of Regulatory Engagement Plan

The purpose of this Regulatory Engagement Plan (REP) is to manage communication and information exchange between Terra Innovatum s.r.l. (TINN) and the Nuclear Regulatory Commission (NRC) during the pre-application activities that support the development of the Licensing Application (LA) for TINN SOLO™ Micro Modular Reactor, SMR™.

SOLO fits with the definition of non-power reactor given in NUREG-1537 “Guidelines for Preparing and Reviewing Applications for the Licensing on non-Power Reactors” [2]. TINN intends to apply for the licensing of SOLO the path presented therein.

This REP identifies the planned regulatory approach and describes the interactions, the roles and the responsibilities between TINN and the NRC staff to establish open communications and minimize uncertainty with the licensing process.

This REP contains a register of anticipated pre-application engagement topics and an approximate schedule for each engagement. This REP is expected to be a living document and will be updated and expanded as plans evolve to support future licensing actions and NRC decisions. All changes to this REP will be discussed and communicated with the NRC staff. The structure of this plan is based on NEI 18-06, “Guidelines for Development of a Regulatory Engagement Plan” [1].

TINN will maintain this REP and solicit NRC staff input for consideration and inclusion into the REP.

1.2 Contact Information

The following are points of contact for all correspondence:

Dr. Cesare Frepoli
COO and Director of Licensing and Regulatory Affairs, SOLO
Terra Innovatum s.r.l.
Via M. Trenta, 117 - 55100 Lucca, ITALY,
Phone: +1 724-448-9615
Email: c.frepoli@terrainnovatum.com

Copy to:

Dr. Alessandro Petruzzi
CEO
Terra Innovatum s.r.l.
Via M. Trenta, 117 - 55100 Lucca, ITALY,
Phone: +39 340-465-3059
Email: a.petruzzi@terrainnovatum.com

Dr. Marco Cherubini
CTO and Director of Product, SOLO
Terra Innovatum s.r.l.
Via M. Trenta, 117 - 55100 Lucca, ITALY,
Phone: +39 338-193-9233
Email: m.cherubini@terrainnovatum.com

1.3 Company Information

Terra Innovatum s.r.l. was founded in 2021 by Alessandro Petruzzi, Marco Cherubini and Cesare Frepoli and leverage decades of experience of the co-founders operating successful companies in the nuclear industry. Dr. Petruzzi and Dr. Cherubini founded and operate NINE, a company incorporated in Italy and working in nuclear safety technology since 2011. NINE is specialized in safety assessment and licensing of Nuclear

Power Plant and contributed into the licensing process of different NPPs such as Atucha-II in Argentina (PWR), Hanhikivi-I (WWER-1200) in Finland for which the Company develops the Chapters 15 (accident analysis) and 19 (Probabilistic and Severe Accidents). NINE competences embrace primarily Thermal-Hydraulics and Reactor Physics, Containment analysis, Severe Accident Analysis, Fuel Performance and Probabilistic Safety Analysis. NINE also collaborated with Australian, Norwegian and Swedish Safety Authorities in Emergency Preparedness and Response subject. NINE is currently leading a consortium of company for the independent assessment of AP1000 NPP for the Polish Regulator.

Dr. Frepoli is the founder and CEO of FPoliSolutions (FPoli), a company incorporated in US, servicing the nuclear industry since 2012. FPoli is currently servicing different nuclear companies in the US from SMR, Microreactors developers as well as providing solutions for the operating fleet. FPoli has been also developing cutting edge software that facilitates the orchestration and adoption of risk-informed analysis techniques in line with the DOE-sponsored Licensing Modernization Project (LMP) methods as formulated in NEI 18-04.

Before FPoli, Dr. Frepoli devoted his career at Westinghouse Electric Company (WEC) where he led several initiatives in the area of safety analysis and core engineering. At WEC, Dr. Frepoli was the inventor and main developer of key technologies such as ASTRUM™ and FSLOCA™, methods currently used by WEC to perform safety assessment across the globe. During his WEC tenure Dr. Frepoli was also heavily involved in the licensing process of the AP1000 as well as its international deployment and licensing including the tech transfer and training to China where the first units were built and currently operated. During the 2000s, Dr. Frepoli led the safety assessments and the submittal of LARs to USNRC that enabled Extended Power Uprates for several PWRs serviced by WEC.

Leveraging these capabilities, expertise and passion in safety assessment and licensing, the Micro Modular Nuclear Reactor SOLO was conceived at NINE in 2018. A dedicated startup team was assembled with Terra Innovatum s.r.l. (TINN) in 2021 to further develop its design and reach to the point where it is possible today to initiate the licensing process by presenting our Regulatory Engagement Plan to USNRC with this report.

Dr. Petruzzi the CEO of company, Dr. Cherubini the CTO and Dr. Frepoli the COO forms the executive board. Other members of the management team include Dr. Massimo Morichi who serves as Chief Strategy Officer (CSO), Mr. Guillaume Moyen as Chief Financial Officer (CFO) and Mr. Giordano Morichi as Chief Business Development Officer (CBDO) & Investor Relations.

Dr. Massimo Morichi start his career designing the core of the PEC (Fast Test Fuel Assembly reactor at ENEA) in 1984, later move to OakRidge and was involved in the Backend of the fuel cycle and after was appointed CTO-VP R&D of AREVA BU Nuclear Measurements in USA where he launched and coordinated the development of many innovative nuclear measurement solutions for AREVA Fuel Cycle and reactors, IAEA, DOE, DNDO, CEA till 2012. During this period, he was also appointed in March 2011, Group Leader of the AREVA Fukushima Project for the site remediation plan in Japan in support to TEPCO in the frame of the crisis support collaboration between France and Japan. In 2012 was appointed in Paris at the headquarter of AREVA as ESVP-Director of R&D Innovation of the AREVA-Group, where he contributes to establishing the Nuclear Light Water Reactor Institute in collaboration with EDF and CEA developing the AREVA set of Technology Roadmaps and many new projects for waste non-destructive measurements and coordinating technical R&D for the development of the EPR and in support to his licensing. He has developed with his teams many technological solutions today in use by international nuclear safeguards and non-proliferation and realized many systems utilized today by the IAEA and many DOE laboratories. Dr. Morichi has been also Director of the international EU MICADO Project for the realization of the most innovative and expert nuclear waste characterization and digitization system that could represent the EU reference standard. He's member of the International Scientific Committee of the TRANSMUTEX project, is professor of Nuclear D&D Technologies & measurements. Dr Morichi has several International Patents related to innovative Nuclear Measurement Technologies.

Over the last couple of years Terra Innovatum has established a strong connection with the supply chain for the keys and major components of SOLO, especially with regards to the fuel, to the specialized metallic parts (like the containment and the reactor vessel) as well as for their qualified fabrication under ASME rules, the Instrumentation and Control, the radiation monitoring systems, the security and surveillance with integrated safeguards. These contacts are based on long term relationships and professional activities that have been established over many years of operation of the Terra Innovatum key management personnel in the most recognized nuclear industries (Westinghouse, AREVA, Framatome, Orano, ATB, CAEN, Paragon etc.).

The SOLO reactor is the first nuclear reactor that has been conceived since the beginning with the objective of the integration of nuclear safeguards: Safeguards by Design (SBD). Key members of the top Terra Innovatum management have been at the forefront of the latest technologies developed for IAEA that are today well implemented in the safeguard’s verifications and remote monitoring. Such technologies are made available and enhanced for the implementation within the SOLO microreactor creating specific multiple measuring channels that are capable to perform direct and on-line measurements reported and transmitted directly through multiple data transmission links (satellite, LTE, Ethernet, Radio) with encrypted protocol and in independent channels to IAEA or other assigned authority (EURATOM, NNSA, DOE etc.).

The SOLO reactor implements a fault tolerant double channel of communication to minimize the risk of cybersecurity attack and is implementing two levels of protection at the Hardware and Software level with data encryption and authentication to offer the most secure operational functionality of the microreactor. The physical barrier is offered by sealed containment access that is also secured with antitampering and sealing method like the one used for nonproliferation circumstances.

1.4 Project Financial Support

||

||

1.5 Summary of Licensing Approach

This REP will guide pre-application activities between TINN and the NRC staff. TINN plans to use these interactions to inform the pursuit of licensing process for the SOLO project. TINN intends to submit a non-power reactor licensing application (CPA) in adherence with NUREG-1537, “Guidelines for Preparing and Reviewing Applications for the Licensing on non-Power Reactors”. The initial SOLO unit reactor, the First of a Kind (FOAK) demonstrative prototype, will be designed, constructed and operated for the purpose of prototype testing, research and training.

TINN is currently negotiating with key potential industry partners a Letter of Intent (LOI) to submit an application for a Construction Permit (CP) of the FOAK Research Test Reactor (RTR) facility to be deployed on a site yet-to-be-determined in the US territory. The SOLO RTR will demonstrate the safe operation of the SOLO system.

TINN will be the owner-operator of the proposed reactor, to be licensed and operated as a Class 104(c) “production or utilization facility” described in 10 CFR50.21(c) at a thermal operating power level of 5.0 MWth, the reactor will be classified as a “Testing facility” as defined in 10 CFR 50.2. TINN will submit

the CP application as permitted under 10 CFR 50.23 and in accordance with the Atomic Energy Act (AEA) Sections 31 and 104(c).

2. TECHNOLOGY OVERVIEW

2.1 General Architecture and Design Philosophy

SOLO is a micro modular nuclear reactor designed for continuous operation over 15 years, delivering a constant nominal thermal power of 5 MWth. This configuration is labelled SOLO-X1.

||

||

||

||

||

||

The reactor is equipped with a redundant control system and four independent and diverse safety shutdown systems – each of them with several redundancy degrees – based on both active and passive actuations, providing robust protection against all conceivable accident scenarios.

||

|

||

||

The enclosure strengthens the traditional defense-in-depth principle considered in large scale reactors. ||

||

The reactor's design leverages commercially off-the-shelf (COTs) components to mitigate supply chain issues. Moreover, for safety-class Structures Systems and Components (SSCs), SOLO design maximizes use of SSC with robust licensing history and operation. Most notably, the fuel is traditional commercial LWR-type fuel (UO₂ pellets in Zirconium-based clad tubes) currently produced by vendors such as Westinghouse, Framatome and GE-Hitachi. U235 enrichment is kept below 4.95% (notably LEU nuclear fuel), ensuring compliance with established safety standards. The availability of an established supply chain allows TINN to enhanced commercial viability, a more predictive schedule and reduced uncertainties in costs estimation.

||

||

||

||

A single SOLO unit is designed to provide electrical and/or thermal power to cover the base load at an industrial site but it can be employed for other uses such as water desalination and production of medical radioisotopes (e.g., Tc-99m) as in this instance to serve as RTR. The production of medical radioisotopes is possible without changing the reactor design due to the designed reactor core configuration that features open channels accessible from outside the core. Moreover, leveraging the possibility to site SOLO close to hospitals

or medical centers the transmutation process of suitable targets can be used ensuring a radioisotope production avoiding the radioactive waste generated by the alternative fission process.

||

||

SOLO core cycle is flexible and ready to eventually load LEU+ and HALEU when they will become available in the market. Loading fuel with higher enrichment could extend the core operational life up to more than 50y. In addition, the use of LEU+ and HALEU would allow SOLO to receive ATF solutions such as FeCrAl cladding granting a more efficient thermal cycle and consequently increase the electrical output of the unit.

However, for the purpose of the RTR SOLO-X1 units considered in this licensing application, the baseline design will consider fuel commercially available today in the LWR market.

2.2 Key Design Features

The key design feature for the SOLO-based are summarized in Table 1.

Table 1: Major Characteristics of SOLO™ Based RTR Design ||

II

2.3 Production and Construction

On the long run the plan is to produce SOLO microreactors on a dedicated assembly line in a centralized manufacturing facility. This will require a standard design that can be generically licensed and deployed in both US and non-US market. A factory production is typically decoupled from the fluctuations in demand and it will require the ability to develop an inventory of such reactors. This will bring quality advantages and will

facilitate inspections (e.g. ITACC items, etc.) but it will also bring new regulatory challenges for managing such inventories of nuclear assets. The factory license is outside the scope of this REP and licensing of the FOAK RTR.

2.4 Site Selection of the RTR (FOAK)

As stated in Section 2.3, SOLO modules are intended to be factory built and there will be minimal activities for their installation on the sites where they will be deployed. Therefore the design will need to be robust and generic enough to be compatible with a wide variety of potential sites. For the FOAK, intended to be deployed as a RTR, TINN is currently negotiating with potential industry partners who own estate in the US territory. The initial site for the deployment of the first SOLO microreactor will emerge from those negotiations. TINN will inform USNRC once those determinations are made.

2.5 Operation

The REP is intended for the CP of a SOLO RTR. In the long run, a SOLO power plant will assemble several modules (microreactors) into a fleet. The reactors will enter the operational fleet mode upon activation and operate autonomously with remote monitoring of all microreactors from a central control room that will allow data collection and trend analysis, yielding improved levels of safety. The modules are designed to operate at constant full power over the life or fuel cycle of the system. Data from multiple units is collected and allow for design/operating as well as condition monitoring throughout the operation of the reactor.

SOLO is designed for an off-grid, behind-the-meter operation. The simplicity and small size of the reactor does not require traditional routine maintenance which are typical during the operation of large scale reactor, for refueling, on-line maintenance, changes in setpoint. If any unsafe condition occurs or predicted to occur by monitoring the reactor condition or even if connectivity to a microreactor is lost, safety-automation ensures that the system shuts down without the need for any external intervention. Once the reactor is shutdown, the removal of the decay heat can occur indefinitely by active means, operator actions, or passive means in case those are not available (e.g. loss of power).

3. REGULATORY STRATEGY

3.1 Application Type

NEI 18-06, Guidelines for Development of a Regulatory Engagement Plan (REP), Revision 0, 2018 [1], was used as a guidance to develop this REP. At this time, no firm decision has been made with regard to the most appropriate licensing path and early discussions with USNRC will help to make this determination. At this stage, the preferred path is an application for a non-power reactor, or Research Test Reactor (RTR), according to provisions stipulated in 10 CFR 50.21(c) or 50.22 for research and development.

Key attributes of the SOLO reactors such as the low power level and the ability to be used as commercial medical isotope production reactor justify the non-power reactor or RTR as an amenable path.

TINN has been following NUREG-1537 [2] as main references to define the expected content of the safety analysis report (SAR) to be submitted to USNRC. In addition, aspects of the NUREG-0800 are also considered as a complement to NUREG-1537 information.

Regardless, TINN will be using the REP pre-application engagement activities to further inform the development of the SAR elements.

3.2 Licensing Strategy

3.2.1 Conceptual Design Phase

The conceptual design phase began in 2018 and it is now completed. Key design choices have been made and documented.

3.2.2 Reference Design and Licensing Phase

The definition of the final design is in the progress and it will progress in parallel with the pre-submittal activities.

TINN intend to produce a list of white papers which will serve as instrument to guide the development of topical reports that will be submitted as part of the licensing application.

TINN plans to engage with the NRC staff during this phase on programmatic topics which may include the review of white papers, test plans, design plans and other pre-application licensing activities.

3.3 Pre-Submittal Interaction Plan

The type and frequency of NRC staff interaction will vary as the development of the SOLO Project evolves and new questions and issues arise.

TINN plans to coordinate routine project management discussions and technical meetings with the NRC staff on specific topics. The technical discussions will provide the opportunity for direct engagement with NRC staff reviewers in specific subject areas and will include reviewers and management. Meetings will be focused on the reports or white papers discussed in Section 3.4.

During the routine project management meetings, the NRC project managers and TINN will determine the necessity and value-add of holding pre-submittal and post-submittal meetings for each submittal.

3.4 Pre-Application White Papers and Topical Reports

Table 2 provides a preliminary list of Topics to be discussed during the pre-application phase. The Topics are communicated via White Papers and Topical Reports documents submitted to USNRC for review. An early endorsement or approval of the approach considered for these Topics will improve applications efficiency by facilitating the finalization of design and operational requirements and associated analysis methodologies. A tentative schedule for the submittal of White Papers (WP) and Topical Reports (TR) for the Pre-Application is also presented in the table.

Table 2: Topics for SOLO MR Pre-Application Engagement

||

3.5 Planned Application Submittal Date

The PSAR will be prepared during the pre-submittal phase. Concurrently activities will be pursued to secure site for the SOLO RTR final construction. The construction will consist in the final assembly and integration of pre-assembled components received and transported to the site from qualified suppliers of choice.

||

|

3.5.1 Construction Permit Application

||

||

3.5.2 Operating License Application

||

||

4. REFERENCES

- [1] "Nuclear Energy Institute (NEI) 18-06, Guidelines for Development of a Regulatory Engagement Plan (REP), Revision 0," 2018.
- [2] "NUREG-1537, Guidelines for Preparing and Reviewing Applications for the Licensing of a Non- Power Reactor," 1996.