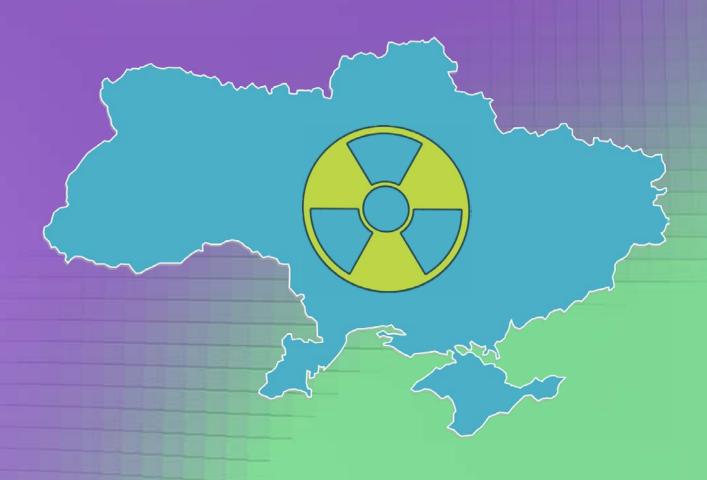
Achievements in the bilateral regulatory cooperation program between the Radiation and Nuclear Safety Authority of Norway and State Nuclear Regulatory Inspectorate of Ukraine in the period 2014–2020





Norwegian Radiation and Nuclear Safety Authority

Reference

Siegen K S and Sneve M K, Improvements in Regulatory Supervision of Radiation and Nuclear Safety in Ukraine arising from the DSA-SNRIU bilateral regulatory cooperation program in the regulatory enhancement and support of SNRIU in Ukraine 2014–2020

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Key words

Regulation, Radiation, Nuclear Safety, Ukraine, Cooperation

Abstract

The DSA established a bilateral cooperation program with the Ukrainian regulatory body, the State Nuclear Regulatory Inspectorate of Ukraine (SNRIU), in 2014. The cooperation has been financed by the Norwegian Ministry of Foreign Affairs under the Norwegian Action Plan for Nuclear Safety. This report describes the achievements resulting from the implementation of projects set up under that cooperation agreement in period 2014-2020.

Referanse

Siegen K S and Sneve M K, Improvements in Regulatory Supervision of Radiation and Nuclear Safety in Ukraine arising from the DSA-SNRIU bilateral regulatory cooperation program in the regulatory enhancement and support of SNRIU in Ukraine2014–2020

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Emneord

Myndighetssamarbeid, stråling, atomsikkerhet, Ukraina.

Resymé

DSA opprettet et bilateralt samarbeidsprogram med det ukrainske State Nuclear Regulatory Inspectorate of Ukraine (SNRIU) i 2014. Samarbeidet er finansiert av det norske utenriksdepartementet under den norske atomhandlingsplanen. Denne rapporten beskriver resultatene som følge av gjennomføringen av prosjekter satt opp under at samarbeidsavtalen i perioden 2014–2020.

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Contents

Ex	Executive Summary 4				
Lis	t of abbre	viations and acronyms	8		
1		INTRODUCTION	g		
2		PROJECT ORGANIZATION	13		
	2.1	Analysis as a primal tool for bilateral regulatory cooperation	13		
	2.2	Process for development of regulations and guidance	14		
	2.3	Compliance and enforcement	14		
3		THREAT - Threat Assessment Report 2015	16		
	3.1	Improvement of operational safety at nuclear installations	16		
	3.2	Safety regulation in the construction of new nuclear installations	16		
	3.3	Emergency preparedness and response	17		
	3.4	Improvement of safety in fabrication and use of radiation sources, radioactive wast	е		
		management, radioactive material transportation and uranium ore mining and m	nilling 17		
	3.4.1	Radiation sources	17		
	3.4.2	Uranium ore mining and milling	17		
	3.4.3	Radioactive material transportation	18		
	3.4.4	Radioactive waste management	18		
	3.5	Main threats and challenges	18		
4		WASTE - Development of General Safety Provisions for Radioactive Waste			
		Management in Ukraine	21		
	4.1	Project objective	22		
	4.2	Approach and achievements	22		
5		MEDICINE- Support of the SNRIU in the Amendment of Ukrainian Regulatory			
		Documents on the Radiation Protection in Medicine in Accordance with the IAE	A's		
		International Safety Standards and Council Directive 2013/59/EURATOM	26		
	5.1	Project objectives	27		
	5.2	Approach and achievements	27		
	5.3	Workshop for medical professionals and SNRIU staff members on the new set of requirements	gulatory 28		
6		URAN- Support of the SNRIU in the Amendment of Ukrainian Regulatory Docur	nents		
		on the Radiation Protection in Uranium Industry in Accordance with the IAEA's	i		
		International Safety Standards and Council Directive 2013/59/EURATOM	30		
	6.1	Project objectives	30		
	6.2	Approach and achievements	30		
7		SOURCE - Ukrainian Regulation on Radiation Protection in the Use of Radiation			
		Sources	33		
	7.1	Project objective	33		
	7.2	Approach and achievements	33		
	7.3	Workshop for SNRIU staff and professionals on presenting and discussing the new	set of		
		regulatory requirements of the General Safety Rules for Radiation Sources	34		

8		TRANSPORT - Revision of the Regulatory Document "Rules for Nuclear and Radiat	ion
		Safety in Transport of Radioactive Materials"	36
	8.1	Project objective	36
	8.2	Approach and achievements	36
9		DECOMISSIONING - Development of High-Level Regulatory Documents for Safe	
		Decommissioning of Nuclear Facilities	39
	9.1	Ukrainian legislation in the field of decommissioning	39
	9.2	Project objectives	39
	9.3	Approach and achievements	40
10		THREAT II - Ukrainian Regulatory Threat Assessment 2017	43
	10.1	Project objectives	43
	10.2	Approach and achievements	45
11		GUIDELINE - Development of Requirements for the Structure and Contents of	
		Emergency Documents	47
	11.1	Project objective	47
	11.2	Approach and achievements	47
12		EXPERIENCE- Development of Guideline for Assessment of Safety Culture and Hu	man
		and Organizational Factors in Operating Experience Analysis	51
	12.1	Project objectives	51
	12.2	Approach and achievements	51
13		PREPAREDNESS - Enhancing Emergency Preparedness and Response in Ukraine	54
	13.1	Project objective	54
	13.2	Approach and achievements	54
14		Current projects on-going through 2020	56
	14.1	COMPLIANCE - Improvement of Regulatory Framework on Safe Transport of Radioactive	ve
		Materials	56
	14.2	PROVISION - Development of Proposals/Recommendations on Procedure and Criteria the Recognition of the Radiation Protection Expert According to Council Directive	for
		2013/59/Euratom and IAEA Standards	56
	14.3	FRAMEWORK - Definition of Areas to Improve Regulatory Framework for Nuclear Secu	-
			57
15		Conclusions and Recommendations	59
	15.1	Conclusions	59
	15.2	Recommendations on next steps and international engagement	60
16		References	62

Executive Summary

The Norwegian Radiation and Nuclear Safety Authority (DSA, formerly the Norwegian Radiation Protection Authority (NRPA)) established a bilateral cooperation program with the Ukrainian regulatory body, the State Nuclear Regulatory Inspectorate of Ukraine (SNRIU) with support from State Scientific and Technical Centre for Nuclear and Radiation Safety (SSTC NRS), in 2014. The cooperation has been financed by the Norwegian Ministry of Foreign Affairs under the Norwegian Action Plan for Nuclear Safety, where one of the main objectives is cooperation with relevant authorities and organizations to reduce the risk of serious accidents and radioactive contamination.

The broad objective was, and remains, to support the development and maintenance of a broad-based radiation and nuclear safety culture through the development of a robust and independent regulatory process. The approach to achieving this was first to identify significant gaps in the current regulatory framework and then to draft relevant regulatory requirements, guidance and procedures to ensure protection of workers, public and the environment. A key feature of the program has been to address the challenges of nuclear legacies that developed prior to the development of modern safety standards.

The first stage in the cooperation program was the development of a Ukrainian Regulatory Threat Assessment to identify the primary nuclear and radiation threats to safety from a regulatory perspective, with the objective of identifying the current key challenges, threats and gaps in the Ukrainian regulatory framework. Three further joint projects were also initiated in parallel that were concerned with the regulation of radiation protection in the uranium industry, radioactive waste management, and radiation safety in medicine. Subsequently, additional projects were implemented in response to the findings of the Regulatory Threat Assessment. These included projects on safety during the transport of radioactive materials, radioactive source management, and decommissioning of nuclear facilities.

The first three years of the bilateral cooperation program saw a number of important measures and events take place in the Ukrainian nuclear sector. In light of this, the decision was made in 2017 to reassess the situation and a joint project was implemented with the objective of reviewing and update the findings of the first Regulatory Threat Assessment. This enabled new gaps existing in the Ukrainian regulation of nuclear and radiation safety to be recognized and further projects to address continuing and new threats were planned and implemented. A significant number of regulatory documents have been developed. Each document has been developed following review and analysis of the current regulatory position in Ukraine and with respect to international recommendations, best international practice and DSA experience. The following people were responsible for implementation of projects and outputs described in this report:

DSA Program Coordinator: Malgorzata Sneve;

DSA Project Manager: Katarzyna Siegien.

Short name	Project title and topic	Output documents	Person
THREAT	Regulatory Threat	Analysis of radiation and	Ganna Gorashchenkova,
	Assessment Report to	nuclear safety threats in	SNRIU Coordinator
	identify primary nuclear	Ukraine from a regulatory	
	and radiation threats to	perspective	Oleksandr Pecherytsia,
	safety from a		SSTC NRS Project
	regulatory perspective		Manager
WASTE	Development of	General Safety Provisions for	Nataliya Rybalka, SNRIU
	General Safety	Predisposal Radioactive	Coordinator
	Provisions for	Waste Management	

	Radioactive Waste Management in Ukraine	General Safety Provisions in Disposal of Radioactive Waste	Sergiy Kondratiev
MEDICINE	Support of the SNRIU in the Amendment of Ukrainian Regulatory Documents on the Radiation Protection in Medicine in Accordance with the IAEA's International Safety Standards and Council Directive 2013/59/EURATOM	General Safety Rules for Medical Radiation Sources Radiation Protection and Safety Rules in Brachytherapy	Ruslana Tripailo, SNRIU Coordinator Igor Shevchenko, SSTC NRS Project Manager Tetiana Lytvynska (SSTC NRS)
URAN	Amendment of Ukrainian regulatory documents on the radiation protection in the uranium Industry in Accordance with the IAEA's International Safety Standards and Council Directive 2013/59/EURATOM	General Radiation Safety Provisions for Uranium Ore Mining and Processing Operations and Their Termination Requirements for Institutional Control of Uranium Sites within Restricted Clearance from Regulatory Control	Viktor Riazantsev, SNRIU Coordinator Volodymyr Bogorad, SSTC NRS Project Manager
SOURCE	Enhancing regulation of radiation protection in the use of radiation sources	General Safety Rules for Radiation Sources	Ruslana Tripailo, SNRIU Coordinator. Tetiana Lytvynska, SSTC NRS Project Manager
TRANSPORT	Revision of the regulation of nuclear and radiation safety in transport of radioactive materials	Rules for Nuclear and Radiation Safety in Transport of Radioactive Materials	Volodymyr Sakalo, SNRIU Coordinator Oleksandr Pasyeka, SSTC NRS Project Manager
DECOMISSIO- NING	Development of high- level regulatory documents for safe decommissioning of nuclear facilities	General Safety Provisions for Decommissioning of Nuclear Facilities Requirements for the Structure and Contents of Operator's Documents for Licensing Application for Decommissioning of Nuclear Facilities	SNRIU Tamara Sushko, SNRIU Coordinator Sergiy Kondratiev, SSTC NRS Project Manager
THREAT II	Updated regulatory threat assessment	Updated analysis of radiation and nuclear safety threats in	Iryna Kostenko, SNRIU Coordinator

		Ukraine from a regulatory perspective	Yuliia Yesypenko, SSTC NRS Project Manager
GUIDELINE	Development of requirements for the structure and contents	Requirements for the Structure and Contents of Emergency Documents	Roman Khalenko, SNRIU Coordinator
	of emergency documents		Dmytro Gumenyuk, SSTC NRS Project Manager
EXPERIENCE	Development of guideline for assessment of safety	Guideline for Assessment of Safety Culture and Human and Organizational Factors in	Iurii Yesypenko, SNRIU Coordinator
	culture and human and organizational factors in operating experience analysis	Operating Experience Analysis	Dmytro Vorontsov, SSTC NRS Project Manager
PREPARED- NESS	Enhancing emergency preparedness and response in Ukraine	Updated radiation Emergencies Response Plan	Tetyana Kutuzova, SNRIU Coordinator
	response in ordanic		Svitlana Chupryna, SSTC NRS Project Manager

A holistic approach to cooperation requires clear ideas and good communication as well as a flexible and innovative approach to addressing challenges in order to produce tangible results. An important aspect of the cooperation program has been the organization of bilateral meetings and joint workshops that have allowed for the active involvement of experts from both DSA and SNRIU in the development of regulatory documents in line with the newest international recommendations and best practices. Experience has shown that this joint approach involving dialogue with the most relevant stakeholders provides a valuable opportunity to obtain opinions on the details in regulatory documents that can materially influence the effectiveness and efficiency of delivery of safety and security in everyday practices. These practically orientated opinions have been used directly in the further development of draft documents. At the same time, each organisation has clearly and transparently maintained its own responsibilities.

The regulatory framework for radiation safety and security in Ukraine has been considerably enhanced as a result of activities undertaken within the bilateral cooperation program between DSA and SNRIU. However, threats remain as detailed in the updated Regulatory Threat Assessment Report and three projects have already been established to address key priority areas:

- → COMPLIANCE Improvement of Regulatory Framework on Safe Transport of Radioactive Materials;
- → PROVISION Development of Proposals/Recommendations on Procedure and Criteria for the Recognition of the Radiation Protection Expert According to Council Directive 2013/59/Euratom and IAEA Standards; and,
- → FRAMEWORK Definition of Areas to Improve Regulatory Framework for Nuclear Security.

It is recommended that the cooperation program is continued in order to complete these projects and to address remaining and new threats. It is further recommended that the Regulatory Threat Assessment

report be periodically updated to take account of progress and to continue to ensure remaining threats are appropriately prioritized. In addition, while there has been considerable progress in developing regulations to address prioritized threats, further development of existing lower level regulations and guidance on their application may be required to align these with the new documents that have been developed, to align with on-going revisions to international recommendations and guidance, and to take account of continuingly growing international experience of best practice.

The DSA and SNRIU recognize the mutual benefits of the bilateral cooperation program as well as the wider benefits of sharing experience internationally. For example, the State Scientific and Technical Centre for Nuclear and Radiation Safety presented information on the implementation of a graded approach in ensuring safety of management of emergency and legacy radioactive waste in Ukraine at an international workshop on regulatory framework of decommissioning, legacy sites and wastes from recognition to resolution: building optimization into the process. This was reported alongside other substantial and valuable presentations and discussions in Sneve [2020]. DSA and Ukrainian organisations have contributed to international reports sharing experience and advising on characterization and management of legacy radioactive waste [NEA, 2016; NEA, in publication]. Following the recent publication of the Nuclear Energy Agency (NEA) report on legacy management [NEA, 2019], it is recommended that the results of the continuing DSA/SNRIU regulatory cooperation program are provided for consideration in the activities of the new Nuclear Energy Agency Committee on Decommissioning and Legacy Management and the recently set up Expert Group on developing a Holistic Process for Decision Making on Decommissioning and Management of Complex Sites.

List of abbreviations and acronyms

AOP Abnormal operating procedures
ChNPP Chernobyl nuclear power plant
CNS Convention on Nuclear Safety

CPPNM Convention on Physical Protection of Nuclear Material DSA Norwegian Radiation and Nuclear Safety Authority

EOP Emergency operating procedures

EU European Union HLW High-level waste

HOF Human and organizational factors IAEA International Atomic Energy Agency

ICRP International Commission on Radiological Protection

ILW Intermediate-level waste

INSC Instrument for Nuclear Safety Cooperation

LLW Low-level waste

NEA Nuclear Energy Agency of the Organisation for Economic Cooperation and

Development

NPP Nuclear power plant

NRBU Radiation Safety Norms of Ukraine
NRPA Norwegian Radiation Protection Authority

NRS Nuclear and radiation safety
NSC New Safe Confinement
RW Radioactive waste

SAMG Severe Accident Management Guideline

SAR Safety assessment report

SC Safety culture

SNRIU State Nuclear Regulatory Inspectorate of Ukraine

SSTC NRC State Scientific and Technical Centre for Nuclear and Radiation Safety

8

USSCP Unified State System on Civil Protection USSR Union of Soviet Socialist Republics

WENRA Western European Nuclear Regulators Association

1 INTRODUCTION

The Norwegian Radiation and Nuclear Safety Authority (DSA, formerly the Norwegian Radiation Protection Authority (NRPA)) established a bilateral cooperation program with the Ukrainian regulatory body, the State Nuclear Regulatory Inspectorate of Ukraine (SNRIU) in 2014. The cooperation has been financed by the Norwegian Ministry of Foreign Affairs under the Norwegian Action Plan for Nuclear Safety, where one of the main objectives is cooperation with relevant authorities and organizations to reduce the risk of serious accidents and radioactive contamination.

The broad objective was, and remains, to support the development and maintenance of a broad-based radiation and nuclear safety culture through the development of a robust and independent regulatory process. The approach to achieving this was first to identify significant gaps in the current regulatory framework and then to draft relevant regulatory requirements, guidance and procedures to ensure protection of workers, public and the environment. A key feature of the program is to address the challenges of nuclear legacies that developed prior to the development of modern safety standards.

The first stage in the cooperation program with SNRIU was the development of a Ukrainian Regulatory Threat Assessment (StrålevernRapport 2016:10 [Sneve et al., 2016]) to assess the primary nuclear and radiation threats to safety from a regulatory perspective, with the objective of identifying the current key challenges, threats and gaps in the Ukrainian regulatory framework (project THREAT). Three further joint projects were also initiated in parallel that were concerned with the regulation of radiation protection in the uranium industry (project URAN), radioactive waste (RW) management (project WASTE), and radiation safety in medicine (project MEDICINE). These projects were implemented to resolve the most crucial gaps of the Ukrainian regulatory system, in the areas of waste management, uranium mining and processing, and the use of radiation sources in medicine. Subsequently, additional projects were implemented in response to the findings of the Regulatory Threat Assessment. These included projects on safety during the transport of radioactive materials (project TRANSPORT), radioactive source management (project SOURCE), and decommissioning of nuclear facilities (project DECOMMISSIONING).

The first three years of the bilateral cooperation program between DSA and SNRIU saw a number of measures and events take place in the Ukrainian nuclear sector that, together, contributed to 45% of all regulatory threats recognized during the primary gap analysis being addressed [Sneve et al., 2016]. In light of this, the decision was made in 2017 to reassess the situation and a joint project was implemented (project THREAT II) with the objective of reviewing the current state of the Ukrainian legislative framework on nuclear and radiation safety and to update the findings of the first Threat Assessment Report. This enabled new gaps existing in the Ukrainian regulation of nuclear and radiation safety to be recognized. The revised Threat Assessment report (StrålevernRapport 2018:5 [Siegien et al., 2018]) provides information on current and planned SNRIU activities aimed at overcoming the identified threats and sets the basis for planning further activities. The approach and timeline for the cooperation program is illustrated in Fig. 1.

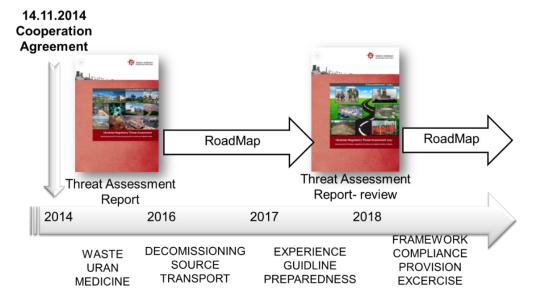


Figure 1. Timeline and progress in the DSA and SNRIU regulatory cooperation program.

In response to the findings of the updated threat assessment report [Siegien et al., 2018], SNRIU proposed further areas of cooperation to mitigate the most critical remaining issues and a number of new projects have continued to be implemented, including:

- → Development of requirements for the structure and content of emergency documents (project GUIDELINE);
- → Development of guidelines for the assessment of safety culture and human and organizational factors in operating experience analysis (project EXPERIENCE); and
- → Enhancing emergency preparedness and response in Ukraine (project PREPAREDNESS).

New regulatory documents are therefore under development to address key regulatory threats within each of the targeted projects (Fig. 2).

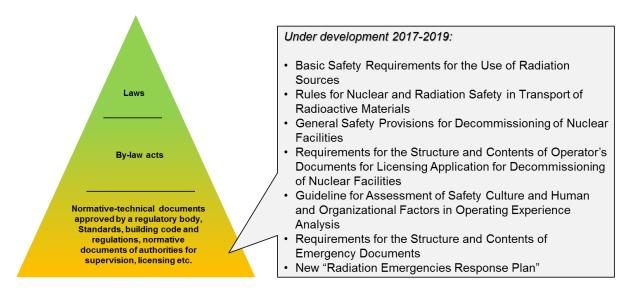


Figure 2. Regulatory requirements, rules, provisions and guidelines under development (2017 – 2019).

The current report provides an overview of each of the projects that have been undertaken as part of the bilateral regulatory cooperation program between DSA and SNRIU since its inception, see Table 1. The

objectives of each project, the approach taken, and key achievements are described in the following sections. The cooperation program has continued to grow each year since its inception and new projects continue to be implemented in line with prioritized threats. Current ongoing projects are therefore also described and conclusions and recommendations for the next steps in the cooperation program are provided, including international engagement.

Table 1. Projects and topics developed in the bilateral regulatory cooperation program

Short name	Title and topic	Start	Completion
THREAT	Regulatory Threat Assessment Report to identify primary nuclear and radiation threats to safety	2014	2015
	from a regulatory perspective		
WASTE	Development of General Safety Provisions for Radioactive Waste Management in Ukraine	2014	2016
MEDICINE	Support of the SNRIU in the Amendment of Ukrainian Regulatory Documents on the Radiation Protection in Medicine in Accordance with the IAEA's International Safety Standards and Council Directive 2013/59/EURATOM	2014	2016
URAN	Amendment of Ukrainian regulatory documents on the radiation protection in the uranium Industry in Accordance with the IAEA's International Safety Standards and Council Directive 2013/59/EURATOM	2014	2016
SOURCE	Enhancing regulation of radiation protection in the use of radiation sources	2016	2018
TRANSPORT	Revision of the regulation of nuclear and radiation safety in transport of radioactive materials	2016	2018
DECOMISSIONING	Development of high-level regulatory documents for safe decommissioning of nuclear facilities	2016	2018
THREAT II	Updated regulatory threat assessment	2017	2018
GUIDELINE	Development of requirements for the structure and contents of emergency documents	2017	2019
EXPERIENCE	Development of guideline for assessment of safety culture and human and organizational factors in operating experience analysis	2017	2019
PREPAREDNESS	Enhancing emergency preparedness and response in Ukraine	2017	2019

COMPLIANCE	Improvement of regulatory framework on safe transport of radioactive materials	2018	ongoing
PROOVISION	Development of proposals and recommendations on procedure and criteria for the recognition of the radiation protection expert according to Council Directive 2013/59/Euratom and IAEA Standards	2018	ongoing
FRAMEWORK	Definition of areas for improvement of the regulatory framework for nuclear security	2018	2020

2 PROJECT ORGANIZATION

Following review of the original work, the updated Threat Assessment Report allowed primary nuclear and radiation threats to safety from a regulatory perspective to be identified and prioritized and a roadmap for addressing those gaps and issues to be developed. Projects were then established in line with the roadmap to eliminate/minimize the threats. The strategy for each project was to undertake a preliminary analysis of the existing situation and, from this, develop the structure and content of the required regulatory document. Workshops would then be held following development of a first draft document to inform the finalization (Fig. 3).

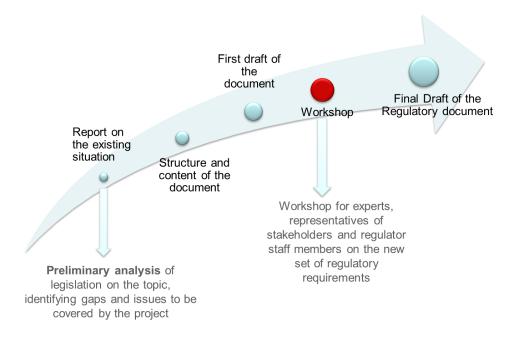


Figure 3. Project strategy for the development of regulatory documents.

2.1 Analysis as a primal tool for bilateral regulatory cooperation

One of the goals of preliminary analysis was to ensure that the benefits of actions justified the costs, and that an optimized solution was selected. The following questions were considered during preliminary analysis:

- → Is the problem one that justifies intervention?
- → If so, is regulation the most effective and efficient means of intervention?
- → What are the specific objectives in intervening?
- → Will the proposed regulation result in a reasonable balance of benefits and costs?
- → To whom will the benefits accrue? Who will pay the costs?
- → How were stakeholders consulted/ if they were, and what do they think of the proposed regulation and its likely impacts?
- → How will compliance with the regulation be monitored and enforced?

Where intervention in the form of regulation was justified, further joint activities were planned to develop the necessary regulation, taking into account the following:

- → **Benefits and detriments:** to identify and quantify the benefits and detriments, including financial costs, resulting from the regulation, using qualitative assessments if quantitative analysis is not feasible or possible.
- → **Consultation:** to summarize the stakeholders' consultation that should take place in identifying and characterizing the gap/problem, developing the regulation, and assessing benefits and costs.
- → **Compliance and Enforcement**: to explain the strategy being adopted to ensure compliance, and to describe the enforcement mechanisms in place or anticipated.
- → **Contact**: to identify who can be contacted for more information the requirement for stakeholder consultation.

2.2 Process for development of regulations and guidance

Output as stepwise improvements based on discussions and close examination of the prevailing circumstances

- Cooperation changes in time more decentralized and routine
- Confidence-building between regulatory counterparts is essential
- Regulatory cooperation is a technical work
- Focus on prospective regulations is far easier than existing regulations
- No "one shoe fits all" approach different country-specific norms and rules apply in different parts of the world.
- Replicate models that work well applied when beginning cooperation in new countries/regions
- Near-term, practical results are key to maintain support
- Expectations management: benefits accumulate robust over time
- Dialogue and informal exchange of information, by which regulators and various stakeholders meet to exchange views on regulatory issues, can help initiate cooperation.

Under the 2016 - 2018 program, the lessons learned from the first two years of implementing projects jointly with the State Scientific and Technical Centre for Nuclear and Radiation Safety (SSTC NRS) and SNRIU, led to introduction of several changes into the structure of work. The first important change was to add the in-depth analysis of the background situation to each project report to support the evaluation of documents from the angle of gaps revealed in the initial stage. Another lesson learned was the need to discuss draft documents with the operator and all the stakeholders who will be impacted by the new regulation. Such discussion can help to avoid the setting of requirements which are not practical, or possible to implement. The key issue is to ensure the level of safety rather than prescribe how that safety is achieved.

2.3 Compliance and enforcement

The long-term objective of DSA's regulatory cooperation programme in Ukraine, is to support the development of an enhanced safety culture, through planned, holistic and integrated regulatory activities in the field of nuclear and radiation safety. This implies that, when developing or updating existing documents, the whole cycle of regulatory activities needs to be taken into account. After approval, regulatory documents come into force and are applied to day-to-day operations in order to achieve safety policy objectives. Compliance inspection and enforcement then ensure the regulations are applied appropriately. Compliance and enforcement are under attention throughout the implementation of the cooperation program and underlies the need for involvement of stakeholders in both the process of development of the regulatory documents and in understanding the influence of those documents on operations.



particular rules are continuing to meet their specified objectives.

Figure 4. Cycle of regulatory activities.

3 THREAT - Threat Assessment Report 2015

The bilateral cooperation program between DSA and SNRIU began with the development of an initial "Ukrainian Regulatory Threat Assessment" Report in 2015 [Sneve et a., 2016]. The objectives were to provide a comprehensive analysis of the SNRIU activities, as the central executive authority entrusted with state regulation of nuclear and radiation safety and to identify the main threats faced by the SNRIU and the measures to eliminate or minimize them, with those measures being used as a roadmap for improving the SNRIU activities.

The Threat Assessment Project activities included:

- → development of the project proposals and definition of the structure and content of the "Ukrainian Regulatory Threat Assessment" Report;
- → review of the SNRIU activities on various directions and gathering of relevant information;
- → analysis and summarizing of collected information and development of the first draft of the "Ukrainian Regulatory Threat Assessment" Report;
- → considering SNRIU and DSA comments on the first draft of the Report with definition of areas for, and scope of, the Report modifications and amendments;
- → development of the final version of the "Ukrainian Regulatory Threat Assessment" Report and identification of the most important areas (i.e. threats and risks) requiring subsequent enhancement.

The main enhancement areas are described below. These enhancement areas were used as the basis for developing a roadmap for improvement of the SNRIU's activities in accordance with Governmental tasks and for implementation of the Association Agreement between Ukraine and the European Union, the European Atomic Energy Community and their Member States. It also allowed for improvement of the "SNRIU Action Plan for Implementation of the Program of the Cabinet of Ministers of Ukraine and Coalition Agreement for 2015" (Approved by the SNRIU Order of 15 January 2015) and advance planning of comprehensive measures to enhance the SNRIU's activities.

3.1 Improvement of operational safety at nuclear installations

State safety regulation of nuclear installations is of top priority in SNRIU activities. Based on the plans of the Ukrainian Government for long-term operation of nuclear power plants and the results of post-Fukushima stress tests, it was recognized that the regulatory authority needed to carry out a comprehensive assessment of the nuclear installation operator's safety justification, including checking associated calculations and the implementation of safety improvement measures.

3.2 Safety regulation in the construction of new nuclear installations

Ukraine is implementing a number of construction projects for new nuclear installations. They include Khmelnitsky nuclear power plant (NPP) units 3 and 4, a centralized spent nuclear fuel storage facility, a dry storage facility at the Chernobyl NPP (ISF-2), a nuclear fuel fabrication plant and a neutron source based on a subcritical assembly driven by a linear electron accelerator (neutron source). Safety regulation and compliance with nuclear legislation during construction of these installations are among the main objectives for SNRIU activities.

There is also a number of projects implemented on the Chernobyl site, such as construction and commissioning of the liquid radioactive waste treatment plant and industrial complex for solid radioactive

waste management and activities under the Shelter Implementation Plan, including construction of a new safe confinement. Therefore, there is a need for continuous regulatory control over compliance of design and technical documentation with regulations, standards and rules on nuclear and radiation safety, and for a proper safety level to be implemented and maintained in relation to each of the above-mentioned construction projects.

3.3 Emergency preparedness and response

Maintaining and enhancing emergency preparedness for nuclear and radiation accidents is another priority issue for the regulatory authority and other central executive authorities, including the State Emergency Service of Ukraine, local government bodies, and operating organization, etc. On the one hand, the importance of this area is caused by a high concentration of radiation and nuclear facilities in Ukraine, and on the other hand by escalation of the social, political and economic situation in the country: social and political instability increases threats related to terrorist acts, whilst economic factors lead to additional risks related to increased load on Ukrainian NPPs.

Ukraine has always paid serious attention to improvement of emergency preparedness for radiation and nuclear events, being the state that faced the first large scale nuclear accident at Chernobyl NPP. However, its accession to the Association of European Countries, as well as its internal social, political and economic situation, means it is necessary to analyse compliance of the national regulatory framework as regards emergency preparedness with European standards and assess the preparedness of Ukraine for new challenges related to increased terrorist threats.

3.4 Improvement of safety in fabrication and use of radiation sources, radioactive waste management, radioactive material transportation and uranium ore mining and milling

3.4.1 Radiation sources

State safety regulation of radiation sources is intended to ensure their regulatory control by applying a graded approach to various activities and radiation sources, taking into account potential nuclear and radiation hazards. The current state safety regulation is based on the following aspects:

- → an authorizing system (registration and licensing) has been implemented;
- → state supervision is conducted and sanctions are applied as appropriate;
- → a regulatory framework has been established and is being improved; and
- → resources are allocated in accordance with the graded approach depending on risks in the use of certain types of radiation sources.

3.4.2 Uranium ore mining and milling

The objective of state regulation in the field of uranium ore mining and milling is to ensure regulatory control over uranium ore processing, including termination of these activities and comprehensive assessment of radiation safety of existing and "legacy" uranium plants in order to provide radiation safety of personnel, the public and the environment against hazardous radiological factors. The strategic objective is to maintain a proper safety level in operation of uranium mining and milling plants during their liquidation, preservation and conversion.

Ukraine is extensively upgrading and modernizing basic industrial plants and auxiliary facilities of the Eastern Mining and Processing Plant (SkhidGZK), which deals with a complete cycle of uranium ore mining and milling on the territory of Ukraine and an up-to-date system of personnel dose monitoring is being introduced. Liquidation and reclamation of the former Industrial Association, Prindeprovsk Chemical Plant, is also underway and measures on upgrading, conversion and further operation of Section II of the Tailing Pit "Sukhachivske" are under revision by the State Enterprise "Barier" under a license for uranium ore processing.

3.4.3 Radioactive material transportation

Regulatory activities in radioactive material transportation are aimed at protecting the people, property and the environment against radiation and preventing accidents and incidents during transportation of nuclear fuel, radiation sources and radiation waste as well as individual doses associated with transportation. In the reporting period, there were no transportation accidents or incidents, and individual doses did not exceed the regulated values.

3.4.4 Radioactive waste management

The state safety regulation in the field of radioactive waste management covers licensing and oversight of operation of existing radioactive waste management facilities as well as safety enhancement, liquidation and reclamation of the existing "legacy" radioactive waste disposal facilities of the Radon State Association and facilities for Chernobyl-origin waste in the Exclusion Zone. It also covers construction of new radioactive waste management facilities for waste disposal, long-term storage, and processing.

Licensing and inspection require interface with applicants and licensees (including operators of radioactive waste disposal facilities) on issues of safety assessment and reassessment of the radioactive waste management facilities, implementation of an effective management system, identification of safety deficits and possible ways for their elimination, and ensuring the required safety culture in radioactive waste management. Regulatory control in this field is intended to check the capability of applicants and licensees to comply with safety conditions and rules in radioactive waste management activities and to provide administrative and technical measures and means for the safe implementation of activities and assessment of design and technical documentation for compliance with regulations, standards and rules on nuclear and radiation safety. The strategic objective is to ensure proper safety of existing and new radioactive waste management facilities and to determine the capability of applicants and licensees to implement radioactive waste management activities in compliance with appropriate conditions and rules.

3.5 Main threats and challenges

The analysis revealed the main threats and challenges for the SNRIU. Threats were categorized as highest, high or low priority in the following areas:

- → organization and general principles for activities of the regulatory authority;
- → safety of nuclear installations;
- → radioactive material transport;
- → emergency preparedness and response;
- → radioactive waste management and decommissioning; and
- → radiation safety.

The most common challenge related to an outdated or imperfect regulatory and legal framework governing certain activities in the above areas. Thus, improvement of the national legislation, including its adaptation to comply with European Union (EU) legislation, would require implementation of a number of measures, including in particular:

- → amending a number of legislative instruments;
- → developing new regulatory documents; and
- → reviewing regulatory documents in force, including Union of Soviet Socialist Republics (USSR) documents still in force, for consistency with international recommendations such as International Atomic Energy Agency (IAEA) Safety Standards.

At the same time, the analysis identified the main risks and challenges for the SNRIU that needed to be eliminated to ensure effective regulatory function. A summary of the identified challenging issues and ways to solve those issues is presented in Sneve et al. [2016].

The report also provides an overview of the main facilities and processes relevant to the use of nuclear energy in Ukraine and includes identification of the number of challenges for the industry as a whole (for example, the life extension of NPP units, construction of new units, construction of storage facilities for high level and long-lived radioactive waste, dealing with legacy sites., etc.). Altogether, there were 27 threats identified, 20 of which were of the highest priority and 7 fell within the high priority category. Those within the high priority category could have solutions postponed by a year or two. The distribution of threats across the key areas covered by the Threat Assessment Report are illustrated in Fig. 5.

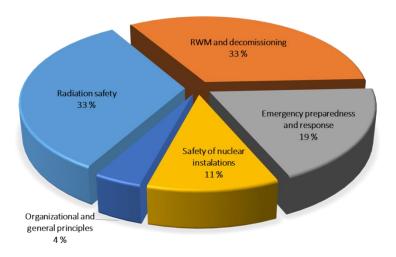


Figure 5. Statistics of Threats recognized.

Based on the prioritized threat assessment and measures identified to address those threats, a RoadMap was developed and a series of projects implemented with the objective of minimizing threats with the highest priority (Fig 6).



Figure 6. Timeline of project implementation to address priority issues.

4 WASTE - Development of General Safety Provisions for Radioactive Waste Management in Ukraine

Ukraine continuously carries out activities for development of the RW management system, including design, construction, and commissioning of processing facilities for all RW types at operating NPP sites and the site of the Chernobyl NPP (ChNPP) and of facilities for long-term storage and disposal of different RW types in the Chernobyl Exclusion Zone. The breakdown of types of RW throughout Ukraine is illustrated in Fig. 7.

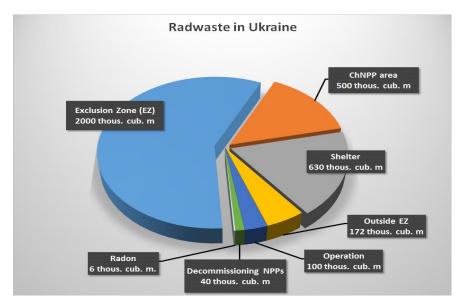


Figure 7. Radioactive waste in Ukraine (source: SNRIU)

Current and planned RW management facilities in Ukraine are as follows:

→ Exclusion zone

- storage of low-level waste (LLW) in temporary localization points of a trench type
- storage of intermediate-level waste (ILW) and high-level waste (HLW) in "Podlesnyi" and
 "3rd stage of the Chernobyl NPP" disposal facilities
- disposal of L/ILW in "Buryakovka" repository

→ Chernobyl NPP

- storage of operational RW
- storage of destroyed unit No.4 RW in the Shelter
- commissioning of plants for processing of liquid and solid RW
- storage of HLW and long-lived conditioned RW in a special repository

→ NPPs under operation (15 units at 4 NPP sites)

- storage of operational RW
- construction of complexes for solid RW processing on 2 sites (Rivne and Zaporizhzhya NPPs)
- designing of complexes for solid RW processing on 2 sites (Khmelnitsky and South-Ukraine NPPs)

→ RADON (5 regional state enterprises)

- storage of solid RW in containers and liquid RW in tanks
- storage/disposal of "historical" RW

→ Vector site in exclusion zone

 operation of near-surface disposal facilities for RW disposal from processing of the ChNPP waste (50 000 m³)

- construction of two SRW-1 and SRW-2 type disposal facilities (capacity of 11 200 m³ and 9 200 m³, respectively)
- 16 SRW-1 and 40 SRW-2 type disposal facilities are planned
- construction of a storage facility for disused radiation sources
- a repository to store long-lived and HLW is planned
- a complex for RW processing is planned

The 2016 threat assessment report [Sneve et al., 2016] revealed number of vulnerabilities in the Ukrainian waste management regulatory system. These included: a lack of regulatory documents with systemized safety rules and requirements for decommissioning, including the management system and safety justification for decommissioning; inadequate application of technical requirements for facilities at different decommissioning stages; incorrect determination of end states at different decommissioning stages; inadequate data on facilities required for decommissioning; and, insufficient application of the waste minimization principle, etc. Safety regulation of radioactive waste management in Ukraine was based on both regulations of the former USSR and those developed in the last 10-20 years and needed to be revised and harmonized with new requirements and the latest EU and IAEA standards. Therefore, based on the findings of the threat assessment, it was decided to launch project "WASTE".

4.1 Project objective

The objective of project "WASTE" was to develop two regulatory documents on radioactive waste management in accordance with the IAEA's International Safety Standards, Council Directive 2013/59/EURATOM, and considering the experience and best practices summarized in relevant publications of the Western European Nuclear Regulators Association (WENRA):

- → Regulation "General Safety Provisions for Predisposal RW Management" establishes objective, principles and safety criteria, as well as safety requirements for coordinated RW management during stages prior to radioactive waste disposal.
- → Regulation "General Safety Provisions in Disposal of Radioactive Waste" establishes objective, safety principles and criteria for human and environment protection against radiation risks from RW disposal facilities during their operation and after closure.

The two regulatory documents aimed to establish systematized nuclear and radiation safety requirements, to be met at mutually agreed RW management stages before and during disposal.

4.2 Approach and achievements

Documents were developed taking into account a graded approach to improve the effectiveness of safety regulation during RW management on waste generation sites and taking into account coordinated RW management stages and remote risks on the sites of facilities for RW processing, long-term storage, and disposal.

Both regulatory documents are based on general safety principles and consider the recommendations of IAEA Safety Standard Series (particularly, Predisposal Radioactive Waste Management, No. GSR, Part 5, [IAEA, 2009a], Classification of Radioactive Waste, No. GSR-1, [IAEA 2009b] and Disposal of Radioactive Waste, No. SSR-5, [IAEA, 2011]). The documents also take into account best international practices and Council Directive 2013/59/EURATOM, as well as experience and best practices summarized in relevant WENRA publications, such as the Report on Waste and Spent Fuel Storage Safety Reference Levels [WENRA, 2014a] and Report on Radioactive Waste Disposal Facilities Safety Reference Levels [WENRA, 2014b].

The presence of large volumes of RW in Ukraine including Chernobyl-origin RW and its peculiar characteristics required the development of specific safety requirements for predisposal management. In particular, it was necessary to establish regulatory safety requirements covering the following issues:

- → processing and conditioning of solid RW both accumulated and generated during nuclear facility operation and decommissioning;
- → processing and conditioning of liquid RW, including the development of technologies to process salt fusion cake, sludge and ion exchange resins accumulated at the sites of operating NPPs,
- → processing and conditioning of accident-origin solid and liquid RW with increased content of transuranic radionuclides resulting from activities in the Chernobyl Exclusion Zone;
- → long-term storage of long-lived intermediate- and high-level waste that will require further disposal in deep geological formations; and,
- → safety improvement of "legacy" RW management at Radon sites, and removal and processing of this RW to transfer it to the Vector site for disposal.

The following issues were considered when developing the document on predisposal RW management:

- → objective, principles, and safety criteria during predisposal RW management;
- → objective, principles, and safety criteria and requirements for the recovery of RW from legacy RADON facilities;
- → activities on predisposal RW management taking into account final disposal;
- → RW processing and conditioning technologies as regards safety and effectiveness of technologies for further RW storage and disposal;
- → RW characterization to ensure effective segregation of RW flows and adequacy of data to certify conditioned RW packages;
- → development and operation of processing/conditioning facilities (including safety issues during location, design, construction, commissioning, operation, as well as radiation protection, etc.);
- → criteria of RW acceptance for processing and quality requirements for conditioned RW packages taking into account long-term storage and disposal; and
- → safety improvement criteria and methodologies for storage of "legacy" RW.

To ensure safety at the final stage of RW management, safety criteria and requirements for disposal of all waste types needed to be established. These requirements were based on fundamental safety principles stated in the Joint Convention on the Safety of Spent Fuel Management and on the Safety of Radioactive Waste Management and should be met during RW disposal. Safety requirements cover development, operation, closure and post closure of RW disposal facilities, taking into consideration the potential hazard of waste in the long-term.

The following issues were considered when developing the General Safety Provisions in Disposal of Radioactive Waste document:

- → Objective, safety principles and criteria of RW disposal;
- → Safety requirements referring to RW disposal planning;
- → Safety requirements implemented in siting for disposal and designing disposal facilities;
- → Safety requirements at the stage of disposal facility operation;
- → Closure of disposal facilities;
- → Institutional control;
- → Aspects to ensure confidence in disposal facility safety (safety assessment and safety case; development of acceptance criteria, long-term safety substantiation, etc.);

- → Disposal of very low-level RW in trench-type disposal facilities;
- → Disposal of short-lived low- and intermediate-level RW in near-surface disposal facilities, particularly considering their location in the Chernobyl Exclusion Zone;
- → Disposal of long-lived and high-level RW in geological disposal facility; and
- → Approaches to safety improvement of "legacy" disposal facilities.

Both regulations developed under the project have been introduced into the regulatory system of Ukraine. Stakeholders participating in the process were the Ministry of Energy and Coal Industry, Ministry of Health, Ministry of Environment and Natural Resources and the State Agency of Ukraine on Exclusion Zone Management.

The "General Safety Provisions for Predisposal Management of Radioactive Waste" establishing the safety criteria and general requirements for nuclear and radiation safety at all stages that precede radioactive waste disposal has been in force since August 2017. Examples of application include:

- → Development of design documentation and preliminary safety analysis report for RW processing facilities;
- → Commissioning and operation of RW processing facilities at NPPs (development of testing programs, acceptance criteria, technical specifications, etc.); and,
- → Self-assessment of the licensees in the area of RW management for compliance with the regulation and subsequent development of respective action plans.

The "General Safety Provisions in Disposal of Radioactive Waste" establishing the general requirements for nuclear and radiation safety in radioactive waste disposal to protect personnel, the public and the environment against potential radiation impact in operation of disposal facilities and in long-term post-closure period have been in force since October 2018. The document is currently being used for the review of the design documentation for BURYAKIVKA disposal facility reconstruction.

The documents will be detailed/specified in lower-level regulations. According to the Regulatory Threat Assessment, the following structure of lower-level documents may be proposed as an option for predisposal RW management (Fig. 8) and disposal of RW (Fig. 9).

General Safety Provisions for Predisposal Radioactive Waste Management



Working title of regulation	Relation to existing regulations
Safety Requirements for preliminary treatment of radioactive waste prior to processing and conditioning	To replace SPAS-88, SPORO-85
Safety Requirements for RW processing and conditioning to the state acceptable for storage and/or disposal	New
Safety Requirements for long-term storage of radioactive waste	Revision of ND 306.4.143-2008
Requirements for the management system for predisposal RW management	New

Requirements for safety assessments and justification for RW treatment facilities and activities	New
Requirements for the structure and contents of SAR for RW treatment facilities	New to replace NP 306.3.02/3.043 - 2001, ongoing under INSC AP-2012
Requirements for safety assessments and justification for RW storage facilities	New
Requirements for the structure and contents of SAR for RW storage facilities	Revision of NP 306.4.142 -2008

Figure 8. Regulations under the General Safety Provisions for Predisposal RW Management.

General Safety Provisions for Disposal of Radioactive Waste



Working title of regulation	Relation to existing regulations
Safety Requirements for site selection for RW disposal facilities	Revision of NP 306.4.149-2008
Safety Requirements and rules for RW disposal in surface and near-surface facilities	New, to replace ND 306.604.95
General safety provisions for RW disposal in geological repositories	Revision of ND 306.4.133-2007
Requirements for the management system for RW disposal	New
Requirements for safety assessments and justification for surface and near-surface RW disposal facilities and activities	New
Requirements for the structure and contents of SAR for surface and near-surface RW disposal facilities	New to replace NP 306.3.02/3.043 - 2001, ongoing under INSC AP-2012
Requirements for safety assessments and justification for geological RW disposal facilities	New
Requirements for the structure and contents of SAR for geological RW disposal facilities	New

Figure 9. Regulations under the General Safety Provisions for Disposal of RW.

It is important when developing safety regulations not to include technical details on how to management the radioactive waste; technology should be in compliance with the national policy and strategy. The regulatory body sets safety requirements for the safe management of radioactive waste and it is then the responsibility of the operator to choose the best proven technology and to demonstrate safety according to the safety requirements in force.

Regulations developed under the project strongly depended on the existing regulatory framework currently in force in Ukraine. To avoid duplication, some requirements were not directly included but instead, references to the existing regulations were provided. Individual provisions of the existing documents may, however, also require revision in order to implement fully the developed documents. Furthermore, in some cases, existing, still in force regulations do not reflect the latest international safety recommendations that are encompassed in the developed documents.

5 MEDICINE- Support of the SNRIU in the Amendment of Ukrainian Regulatory Documents on the Radiation Protection in Medicine in Accordance with the IAEA's International Safety Standards and Council Directive 2013/59/EURATOM

Medicine is the largest sphere of radiation source use in developed countries, comprising 70% of general radiation sources in use, which equates to more than 18000 radionuclide radiation sources and generating equipment.

The level of nuclear medicine and nuclear medicine technologies in the developed countries ensures the possibility of achieving significant success in fighting oncological diseases. Up-to-date diagnostics using nuclear medicine technologies is widely used in clinical practices, including endocrinology, nephrology and urology, cardiology, neurology and psychiatry. The number of radiological studies carried out during a year per thousand people is considered as an important statistical parameter that shows development of this area within healthcare systems of countries. Developed countries perform, on average, 40-50 studies per thousand people per year whilst, according to different current assessments, Ukraine does not exceed three studies per thousand people per year.

Further development of nuclear medicine for healthcare of the Ukrainian population was restricted due to the absence of up-to-date foundations for control of radiation protection and safety of patients, medical personnel and the population in general during the use of ionizing radiation and radionuclides in medicine. The following areas of nuclear medicine and technologies needed to be covered:

- → medical services (X-ray and radionuclide diagnostics, radionuclide therapy, electron beam therapy, neutron and neutron capture therapy, proton therapy);
- → production and maintenance of equipment: gamma camera, photon emission computed tomography, positron emission computed tomography, magnetic resonance computed tomography, radiometric equipment, linear particle accelerators, radiotherapy equipment, brachytherapy equipment, cyber knife, gamma knife, cyclotrons, medical generators, equipment for synthesis of radiopharmaceuticals;
- → production of radiopharmaceuticals;
- → engineering services (personnel training, assistance by engineers in operation of medical centers).

Protection against negative impact of ionizing radiation under medical exposure is required for the more than 10 thousand medical staff performing treatments and diagnostic tests as well as the approximately 80 thousand patients per year that undergo therapeutic treatment and around 20 million people per year that undergo diagnostic tests in Ukraine. An additional issue within those numbers was that radiation accidents in medicine in Ukraine were not disclosed; they were not subject to investigation or analysis and preventive measures were not taken.

The International Atomic Energy Agency (IAEA) pays much attention to improvement and safety of nuclear medicine as an effective diagnostic and therapeutic instrument. An IAEA Mission "Integrated Regulatory Review Service" conducted in Ukraine in 2008, made a suggestion that the SNRIU should consider the adoption of a graded approach to the licensing conditions and requirements on safety of radiation sources, commensurate with the magnitude and nature of the associated hazard. In adopting such a graded approach, SNRIU developed a plan for development of documents on licensing conditions for various medical facilities, that took into consideration the importance of the activities in terms of risk to the public, patients and the environment.

5.1 Project objectives

Main objectives of project MEDICINE were to develop the following high-level regulations, category "Requirements", establishing systematized nuclear and radiation safety requirements in Medicine:

- → "General Safety Rules for Medical Radiation Sources" establishing the objective, principles, safety criteria, as well as safety requirements for medical sources. This document was to be based on general safety principles and consider the recommendations of IAEA Safety Series (particularly, Radiation Protection and Safety of Radiation Sources: International Basic Safety Standards Series No. GSR Part 3 [IAEA, 2014a]; Radiological Protection for Medical Exposure to Ionizing Radiation: Safety Guide Series No. RS-G-1.5 [IAEA, 2002a]) and recommendations of the International Commission on Radiological Protection (ICRP) [ICRP, 2007].
- → "Radiation Protection and Safety Rules in Brachytherapy" establishing the objective, safety principles, and criteria for personnel and patient protection against radiation risks in Brachytherapy. These safety requirements were to be based on recommendations of the IAEA and, particularly, Radiation Protection and Safety of Radiation Sources: International Basic Safety Standards Series No. GSR Part 3 [IAEA, 2014a].

The overall objective in developing these regulations was to improve the efficiency of safety regulation in nuclear medicine in Ukraine and update the regulatory basis for radiation protection and safety in accordance with the international safety standards and requirements.

The main goal of "General Safety Rules for Medical Radiation Sources" was to establish general rules for radiation safety of radiation sources used for medical purposes, ensure radiation protection of personnel, patients and the public, and prevent cases of accidental or emergency medical exposure. The objectives of the regulatory document were to define basic safety provisions for safe management of medical radiation sources and ensure a systematic approach to regulations and rules of radiation safety in use of medical radiation sources.

5.2 Approach and achievements

When developing the "General Safety Rules for Medical Radiation Sources" the first task was to analyse the regulatory framework existing in other countries and describe existing regulatory documents in Ukraine and describe existing structures and responsibilities. In the next step the draft document was developed covering the following issues:

- → requirements related to the justification of the medical exposure;
- → requirements related to the optimization of the protection and safety in medicine;
- → requirements for safety assessment of medical facilities and installations;
- → requirements for the allocation of responsibilities of responsible parties;
- → requirements for procedures and programs in the radiation protection in the medicine;
- → requirements for training and recognition;
- → requirements for equipment and software;
- → requirements for special practices, such as exposure of children, health screening programs, high dose/dose rate practices, biomedical research;
- → requirements for special protection during pregnancy and breastfeeding;

- → requirements for the release of patients from radiological departments and for protection of carers, volunteers, family members and general public;
- → requirements for the management of radioactive material and waste in medicine;
- → requirements for the control of discharges of the radioactive material to the environment from medical facilities and for the control of the direct public exposure from medical installations;
- → requirements for the prevention and investigation of accidental and unintended exposures;
- → requirements for reviews and records of medical exposures;
- → requirements for the workplace and environmental monitoring;
- → requirements for occupational dose records;
- → requirements for dose records for patients and estimates of population doses; and
- → requirements for licensing, reporting, inspection and enforcement.

The document "General Safety Rules for Medical Radiation Sources" therefore addresses issues of human health and safety, environmental protection and prevention of radiation accidents in the use of medical radiation sources. It applies to all entities dealing with medical radiation sources, state administrative bodies in the sphere of medical radiation sources and state regulatory bodies for oversight and licensing. The document is the main regulation that defines basic standards and rules of safety and radiation protection in the use of medical radiation sources.

The document "Radiation Protection and Safety Rules in Brachytherapy" defines requirements to radiation safety during the use of ionizing radiation sources in brachytherapy in relation to both the personnel, patients and the public and requirements to safety during design, commissioning and operation of new radiation technologies in brachytherapy.

The priority issues solved by developing "Radiation Protection and Safety Rules in Brachytherapy" was patient health and safety, environmental protection, and prevention of radiation accidents in use of radiation sources in brachytherapy. Efforts within the project ensured the approval of up-to-date rules of radiation protection and safety in brachytherapy, taking into account international standards and the best international practices.

The document applies to entities using medical radiation sources, state regulatory bodies for use of medical radiation sources and state regulatory bodies for supervision and licensing and establishes basic standards and rules for safety and radiation protection in use of radiation sources in brachytherapy.

Compliance with the requirements set out in these regulatory documents will contribute to improving the safety of applications of medical radiation sources.

5.3 Workshop for medical professionals and SNRIU staff members on the new set of regulatory requirements

On 10 August 2016, as a part of the project, a workshop was held to present and discuss with medical practitioners the two high-level regulatory documents, developed under the DSA-SNRIU cooperation, establishing systematized nuclear and radiation safety requirements in the medical practice, consistent with the latest international recommendations. The workshop was attended by representatives from DSA, SSTC NRS, Ministry of Health and relevant medical institutions.

The main objective of the workshop was to familiarize medical institutions and specialists with the new set of regulations and have their opinion on firstly, the necessity to introduce such documents in practice as

soon as possible and, secondly, on the documents themselves, their structure and their application to everyday practice. The structure and content of the documents were presented together with discussion on international safety recommendations (e.g. IAEA, GRS part 3 and 4) and their application and necessity of introduction into the Ukraine legislation system.

The workshop provided an opportunity for participants to raise and discuss issues in the field of nuclear medicine. Some issues raised and discussed concerning training of the medical physicists and the need to maintain experience and knowledge of radiation safety management in a difficult job market. All participants agreed that this issue needed further attention from all interested parties. Another important issue raised was the need for review of the currently in force Radiation Safety Norms of Ukraine (NRBU) that were developed many years ago and that are not totally coherent with current international recommendations and European Directives in the field of radiation protection.

All representatives agreed that the draft regulatory documents developed within the cooperation project were of a high standard and good quality. Following the workshop, the documents were to be sent for more detailed review and comments to the medical institutions and medical specialists.

Participants also agreed that this type of informational- working meeting, regarding newly developed documents was necessary when developing new regulations and regulatory documents. Such workshops provide a valuable opportunity to obtain opinions on the nuances from the viewpoint of the practitioners that are the main target of the documents and who would be using them in their everyday medical practices.

6 URAN- Support of the SNRIU in the Amendment of Ukrainian Regulatory Documents on the Radiation Protection in Uranium Industry in Accordance with the IAEA's International Safety Standards and Council Directive 2013/59/EURATOM

The uranium industry in Ukraine has developed through the increased production of natural uranium to the extent that will ensure nuclear fuel cycle needs. To achieve this, the industry required improvement in the following areas:

- → upgrade of mining technologies, opening and mining of existing reserves and mining of reserves at new sites; and
- → reconstruction of the Hydrometallurgical Plant (Zhovti Vody site) to increase the capacity of the tailings storage facility and contribute to the construction of new processing facilities in order to ensure the sustainability of the uranium industry in Ukraine.

The current Program for Uranium Production Development in Ukraine up to 2030 was developed according to the Energy Strategy of Ukraine. The objective of the Program is to define technical decisions and the scope of capital investments and ensure sufficient production of uranium concentrate for fuelling Ukrainian NPPs. The obligatory condition to meet the Program tasks is to comply with current requirements for protection of the public and the environment during the operation of uranium facilities, including the safe decommissioning and remediation of legacy sites.

6.1 Project objectives

An overall objective of the URAN project was to help the regulatory authorities of Ukraine to update the regulatory basis for nuclear and radiation safety in the uranium industry in accordance with international safety recommendations. Two draft regulatory documents establishing systematized radiation safety requirements in uranium industry in Ukraine were developed under the Project. The documents were intended to amend the existing obsolete set of requirements, which were mainly adopted during the Soviet era.

6.2 Approach and achievements

Taking into account the different tasks undertaken within the uranium industry and considering the current state of the Ukrainian regulatory framework, the two documents to be developed were considered to be of a high priority. The compliance with requirements of these documents would ensure a high level of radiation protection of workers in uranium mines and tailings facilities, as well as protection of the public and the environment through the implementation of up-to-date principles of radiation protection.

In the course of work and consensus building, and following requirements of the Ministry of Justice of Ukraine, the working titles of the regulatory documents were changed during the course of the project:

→ The title "General Provisions for Radiation Protection and Safety in Uranium Industry" was changed to "General Radiation Safety Provisions for Uranium Ore Mining and Processing Operations and Their Termination". The document established criteria, principles and general requirements for radiation safety during uranium ore mining and processing operations and their termination; criteria and principles of radiation safety for uranium facilities; and protection of uranium facility personnel, the public and the environment against potential radiation hazards caused by radiological factors

- occurring during uranium mining and processing, as well as the main technical and administrative measures aimed at their implementation.
- → The title "Safety Requirements to the Institutional Control at Former Uranium Processing Sites" was changed to "Requirements for Institutional Control of Uranium Sites within Restricted Clearance from Regulatory Control". This document established objectives and procedures for planning, implementation, correction, and termination of institutional control at uranium sites that have obtained restricted clearance from regulatory control after their closure or remediation.

The new set of requirements was based on up-to-date recommendations of the ICRP, incorporated the experience of DSA, and are in line with the IAEA International Safety Standards.

The "General Radiation Safety Provisions for Mining and/or Processing of Uranium Ore" established safety rules for all stages of uranium ore mining and processing and termination of these activities including design, siting, construction, upgrading, operation, decommissioning and partial closure of uranium mining and processing plants. The following issues were considered when developing the document:

- → Requirements related to the optimization of protection and safety in uranium industry;
- → Requirements for safe siting, design, construction, operation, closure, decommissioning and remediation when needed and safety assessment of uranium facilities at different stages and activities;
- → Requirements for the allocation of responsibilities between the parties involved;
- → Requirements for procedures and programs for radiation protection in uranium industry;
- → Requirements for radiation protection of the public, environment and workers;
- → Requirements for waste management;
- → Requirements for tail management and remediation of the site and the environment;
- → Requirements for the control of discharges to the environment from uranium facilities;
- → Requirements for radiation monitoring;
- → Requirements for occupational dose assessment and recording;
- → Requirements for assessment of public exposure; and
- → Requirements for licensing, reporting, inspection and enforcement.

Stakeholders involved in the approval process were Ministry of Energy and Coal Industry, Ministry of Health and Ministry of Environment and Natural Resources. The regulation was planned to be registered at the Ministry of Justice after introduction of appropriate amendments to Ukrainian nuclear legislation (i.e. the draft Law of Ukraine "On Amendment of Some Laws of Ukraine in the Area of Nuclear Energy Utilization").

Implementation of the requirements has greatly improved the radiation protection of workers of uranium facilities and the protection of the public and the environment.

The "Requirements for Administrative Control of Uranium Sites within Restricted Clearance from Regulatory Control" defines procedures for planning, conduct, revision and termination of administrative control of uranium sites that are under restrictive clearance from regulatory control. The document was approved by Ministry of Energy and Coal Industry, Ministry of Health and Ministry of Environment and Natural Resources and has been in force since March 2017. The requirements have been applied:

→ in development of design documents for decommissioning of uranium plants (Smolinska mine of the Eastern Ore Mining and Enrichment Plant, VostGOK); and,

→ in development of safety justification documents for remediation of the Prydniprovsk Chemical Plant.

Several uranium mining and processing facilities in Ukraine have terminated operations or have planned to terminate active operations and should be properly decommissioned. Efforts are taken within the framework of the State Target Program for putting former uranium facilities, namely Prydniprovya Chemical Plant, in a radiation safe state. The intention, by improving the regulatory framework, was to develop the requirements to achieve radiation safety and licensing conditions for the termination of uranium ore processing in accordance with up-to-date safety requirements. Such requirements were partially specified in the out-of-date document SP LKP 1991. However, the safety of former uranium sites after their closure is so important and socially significant that documents establishing the comprehensive requirements for the institutional control would become the key elements of the regulatory framework of Ukraine. The new regulatory document establishes requirements for the arrangement and implementation of basic types and mechanisms of institutional control at former uranium sites, which were previously used for uranium ore mining and processing (including tailing pits for uranium ore processing waste) and in their controlled area. The tasks of the regulatory document are to:

- → establish basic provisions on planning, and implementation and oversight of institutional control; and
- → identify basic provisions.

The new regulatory document applies to all entities of the uranium industry, state control bodies for the uranium industry and state regulatory bodies for supervision and licensing, and regional and local administrations.

32

7 SOURCE - Ukrainian Regulation on Radiation Protection in the Use of Radiation Sources

Prior to project SOURCE, the existing regulations and rules on radiation safety and protection in Ukraine were incomplete, and were, to a major extent, outdated when taking into account the latest international recommendations and EU Directives. The most recently developed regulatory documents in Ukraine only partially covered regulatory needs with regard to the management of radiation sources.

In general terms, control over radiation sources is provided through the state regulatory system that includes the following main elements: establishment of regulatory requirements; authorization of facilities and activities; and, inspections and enforcement. Authorization includes registration in the State Register of Radiation Sources and licensing of all radiation sources that are not exempted from regulatory control. An appropriate legal and regulatory framework has been established and in force. For example, specific safety requirements have been developed for teletherapy, radiography, accelerators PET/CT, brachytherapy, and similar development of specific requirements was needed for other aspects of nuclear medicine, well lodging, and other practices.

7.1 Project objective

The regulatory objective was to establish basic radiation safety requirements for activities using radiation sources to:

- → protect the health of the people and the environment;
- → ensure regulatory control of radiation sources throughout their lifecycle;
- → prevent radiation accidents and incidents, reduce or minimize radiological consequences of accidents or malicious actions using radiation sources;
- → apply graded approach to the regulation of activities with radiation sources considering potential danger of radiation sources.

This was to be achieved through the development of a document "General Safety Rules for Radiation Sources" to:

- → establish and maintain the regulatory framework for the control over radiation sources throughout their lifecycle, updated according to the latest international recommendations;
- → maintain occupational and public exposures from planned exposure situations at reasonably achievable minimal levels in the framework of established dose limits and dose constraints for respective categories;
- → prevent and diminish the probability of radiation accidents with radiation sources;
- → achieve and maintain a high level of radiation protection and safety for each radiation source, preventing unauthorized access, loss, theft or unauthorized transfer of radiation source; and
- → reduce or minimize the radiation consequences of any radiation accidents or malicious acts with radiation sources.

7.2 Approach and achievements

Harmonization with international and European standards is of a high priority in the development of the Ukrainian legal and regulatory framework for safety and security of radiation sources. As such, Standards

and Regulations for Radiation Safety in Ukraine are in the process of harmonization with the new IAEA Basic Safety Standards "Radiation Protection and Safety of Radiation Sources: International Basic Safety Standards, No. GSR Part 3" [IAEA, 2014a]. Legislation for radiation protection and radiation safety is also in the process of harmonization with EC legislation. In reviewing and developing regulations, an important issue that is being considered is the application of a graded approach whereby safety and security requirements are differentiated according to potential danger and use of particular type of radiation sources. This approach is implemented in the strategic plan of new safety regulations development.

The safety of life and human health, environmental protection, and prevention of radiation accidents in the management of radiation sources are the priority problems to be solved through the development of a new regulation. A draft document has been developed that establishes basic principles of ensuring radiation protection of personnel, the public and safety of radiation sources used in all sectors of the national economy. It applies to all entities involved in the use of radiation sources, state administrative bodies in the sphere of using radiation sources and those responsible for state oversight and licensing. It is the principal document establishing basic regulations and rules of safety requirements and criteria and radiation protection in the management of radiation sources.

From the perspective of the DSA, the developed draft document seems to be coherent and consistent and may help partially to solve the existing problem with the existing NRBU. Nevertheless, there remain some aspects that have not been completely addressed, such as "existing exposure situations". The document tries to include all radiation protection requirements but there remain some limitations in comparison with the GSR Part 3 [IAEA, 2014a] and EU Directive 2013/59/EURATOM setting our basic safety standards for radiation protection. The document represents a step forward but there is a further need to discuss how this document will fit into the national regulatory framework and how missing radiation protection requirements have been or will be addressed.

7.3 Workshop for SNRIU staff and professionals on presenting and discussing the new set of regulatory requirements of the General Safety Rules for Radiation Sources

A workshop was organized to present and discuss with representatives of the professional community and practitioners the document developed under the DSA-SNRIU cooperation, namely, the high-level regulation establishing systematized radiation safety requirements in the use of radiation sources. Representatives from SNRIU, SSTC NRS, DSA, Ministry of Health of Ukraine, Ministry of Ecology and Natural Resources of Ukraine, State Ecological Inspection of Ukraine, State Service of Ukraine for Food Safety and Consumer Protection, Government Agency "Public Health Center of the Ministry of Health of Ukraine", National Scientific Center for Radiation Medicine, State Enterprise "Izotop" and medical institutions participated in the workshop. The main objective of the workshop was to familiarize regional inspectors and the professional community with the new draft regulation and obtain their opinions on:

- 1. The document itself, its structure and application of new provisions in everyday practice.
- 2. The necessity to supplement and specify in more details certain sections of the document.

The structure and content of the document were presented along with discussion of international safety recommendations (IAEA, GRS Part 3 and COUNCIL DIRECTIVE 2013/59/EURATOM), their application, and necessity of their introduction into the legislative system of Ukraine. The main outcomes of the discussions were:

 There is a need for review of the Main Sanitary Rules on Ensuring Radiation Safety in Ukraine (OSPU-2005) and Radiation Safety Norms of Ukraine (NRBU-97) establishing the main radiation safety principles and criteria in Ukraine. These documents are currently in

force but were developed many years ago. As such, they are not fully coherent with international recommendations and European Directives in the field of radiation protection that are currently in force and are an obstacle for implementation of the provisions of the EU Directive in the legislative framework of Ukraine.

- 2. The regulation submitted for the consideration contains both new provisions established by COUNCIL DIRECTIVE 2013/59/EURATOM and IAEA GRS Part 3 and certain requirements of OSPU-2005.
- 3. The DSA experts noted the importance of updating both OSPU-2005 and NRBU-97 as basic safety standards of Ukraine. This should be the first priority.
- 4. All the meeting participants agreed that the presented document was relevant. Issues on implementation of specific document provisions into the Ukrainian regulatory framework were discussed, such as terminology, references, requirements for qualified experts, and provisions regarding other state bodies, for example medical survey, consumption products etc. As the next step, the document is due to be sent to representatives of the professional community, including participants of the workshop for more detailed review and comments.

8 TRANSPORT - Revision of the Regulatory Document "Rules for Nuclear and Radiation Safety in Transport of Radioactive Materials"

An important focus in the use of nuclear energy is placed on both the safe transport of radioactive materials applied in nuclear power, industry, and medicine and on the management of RW. Forty-seven enterprises in Ukraine have licenses for the transport of radioactive materials.

Prior to project TRANSPORT, the current "Rules for Nuclear and Radiation Safety in Transport of Radioactive Materials" that were in force had been developed based on the IAEA document "Regulations for the Safe Transport of Radioactive Material. Safety Requirements No. TS-R-1. 2005 Edition". Thus, these national rules did not fully comply with the latest IAEA Safety Standards on safe transport issued in 2012 [IAEA, 2012]. Furthermore, many changes in national legislation and international regulations concerning the carriage of dangerous goods took place since the development of current revision of the "Rules for Nuclear and Radiation Safety in Transport of Radioactive Materials".

8.1 Project objective

The objective of project TRANSPORT was to develop a new draft version of the regulatory document "Rules for Nuclear and Radiation Safety in Transport of Radioactive Materials" that would integrate international standards into the national regulatory and legal framework.

This regulatory document belongs to the category of requirements. The revised requirements were to cover all operations and conditions associated with the movement of radioactive material, and include design, fabrication, maintenance and repair of packaging; preparation, loading, shipment, transport, including transit storage, unloading and final receipt of radioactive material and packages.

8.2 Approach and achievements

The main tasks of the project were to analyse the national regulatory framework for the safe transport of radioactive materials for compliance with the IAEA "Regulations for the Safe Transport of Radioactive Material" No. SSR-6 [IAEA, 2012], and to develop the draft "Rules for Nuclear and Radiation Safety in Transport of Radioactive Materials".

The development of the draft of "Rules for Nuclear and Radiation Safety in Transport of Radioactive Materials" and its subsequent implementation will have a positive impact on ensuring nuclear and radiation safety in several vectors:

- → The regulatory framework for nuclear and radiation safety in Ukraine will be improved. Compliance of the new national rules with the international safety standards will ensure the adherence to international conventions on nuclear and radiation safety and will support the regulatory authority of Ukraine in safe and reliable international transit as well as in internal transportations.
- → the new rules will address gaps that have appeared during long-term application of previous rules or have been detected through analysis of legislation.
- → Regulatory and controlling authorities will receive a comprehensive and robust basis for inspection, supervision and management of operators, carriers and other entities involved in process of transportation.

- → The new rules will provide the stimulus to revise the legacy and develop new regulatory documents on specific matters of transportation of radioactive materials.
- → Licensees will obtain up-to-date, apprehensible and clear requirements for arrangement and performance of all the operations of safe transportation of radioactive materials.
- → The risk of inacceptable radiation consequences of any radiation accidents or malicious acts during transportation of radioactive materials will be reduced or minimized.

The national regulatory framework for safe transport of radioactive materials was analysed for compliance with the IAEA SSR-6 [IAEA, 2012] and against the regulatory framework existing in Norway and other countries. For example, the Set of Rules prepared by the Norwegian Institute for Energy Technology for the safe transportation of radioactive materials and corresponding documents of DSA were studied. Existing regulatory documents on transportation of radioactive materials in Ukraine were also analysed for compliance against relevant international transportation conventions to which Ukraine participates, as well as relevant documents of the European Commission and EURATOM, such as Council Directive 2006/117/Euratom of 20 November 2006 on the supervision and control of shipments of radioactive waste and spent fuel and international regulations regarding transport by road (ADR), sea (IMDG), rail (RID) and air (IATA).

The following national laws and other regulatory documents were analysed:

- → The Law of Ukraine "On Use of Nuclear Energy and Radiation Safety";
- → The Law of Ukraine "On Transportation of Dangerous Goods";
- → "The Provision on Procedure of Transportation of Radioactive Materials by Territory of Ukraine" approved by Resolution of Cabinet of Ministry of 15.10.2004 No 1373;
- → "The Procedure of granting Permit for transboundary shipments of radioactive materials approved by the Resolution of the Cabinet of Ministers of Ukraine of 03 October 2007 No 1196;
- → Rules for Nuclear and Radiation Safety in Transport of Radioactive Materials, approved by the Order of SNRCU of 30.08.2006 No 132;
- → Rules on Road Transportation of Dangerous Goods, approved by the Order of Ministry of Interior No 822 of 26.07.2004;
- → Rules on Carriage of Dangerous Goods approved by the Order of Ministry of Transport and Communication No 1430 of 25.11.2008;
- → Requirements to the quality assurance programs during radioactive materials transportation, approved by the order of SNRCU of 25.07.2006 No 110;
- → Provision on planning of measures and actions in case of accident during radioactive materials transportation, approved by the Order of SNRCU of 07.04.2005 No 38;
- → Procedure on issuing of certificates for safe transport of radioactive materials", approved by the Order of SNRCU of 06.09.2007 No 119;
- → Advisory material for the Nuclear and radiation safety regulations during radioactive materials transportation (PBPRM-2006), approved of 20.11.2009; and
- → Guidelines for the development of radiation protection program for the transport of radioactive material, approved by the order of SNRCU of 02.08.2010 No101.

Based on the results of the analysis, a list of identified gaps and issues was prepared.

Comparative analysis of the structure and content of the IAEA "Regulations for the Safe Transport of Radioactive Material" No. SSR-6, 2012 Edition and those of the Ukraine "Rules for Nuclear and Radiation Safety in Transport of Radioactive Materials" demonstrated that the structure and content of the Rules

considered those of IAEA Regulations 2005 Edition in outline, but there was a need to amend them in accordance with the list of identified gaps and issues, also taking into account requirements of national regulatory requirements. Based on the analysis results, a first draft of the structure and contents for the revised Rules has been developed, for consideration and review by relevant stakeholders. The next step will be to develop the draft document itself.

9 DECOMISSIONING - Development of High-Level Regulatory Documents for Safe Decommissioning of Nuclear Facilities

Ukraine operates 15 power units at the Rivne, Zaporizhzhya, Khmelnitsky and South Ukraine NPPs. Decommissioning of power units is planned to begin between 2029 and 2034, taking into account possible lifetime extension of 15 years. However, it is likely that not all NPP units will be subject to lifetime extensions. Therefore, decommissioning of some NPP units could commence as early as 2020 and currently the Chornobyl NPP units are being decommissioned.

A decommissioning program (final decommissioning plan) covering the entire decommissioning activity has been approved for ChNPP units 1-3. At present, there is a permit for activities at the stage of final shutdown and safe enclosure of ChNPP units 1, 2 and 3 and the wet interim spent fuel storage facility at the ChNPP site is being operated according to a license that is valid until 2025. A dry interim spent fuel storage facility at ChNPP is under construction.

Apart from NPPs, other nuclear facilities will require decommissioning at some stage in the future. At the Zaporizhzhya NPP site, a dry interim spent fuel storage facility is operational. There are also research reactors in Kyiv and Sevastopol. The Kyiv research reactor has a decommissioning program (final decommissioning plan) that has been approved by SNRIU. A neutron source based on a subcritical assembly driven by a linear electron accelerator is under construction.

9.1 Ukrainian legislation in the field of decommissioning

The general requirements for decommissioning of individual types of nuclear facilities are partly established in respective higher-level documents:

- → General Safety Provisions for Nuclear Power Plants (NP 306.2.141-2008);
- → General Safety Provisions for Interim Dry Storage Facilities for Spent Nuclear Fuel (NP 306.2.105-2004):
- → General Safety Provisions for the Nuclear Subcritical Assembly (NP 306.2.183-2012).

More detailed requirements for individual issues are established in the following documents:

- → General Safety Provisions for Decommissioning of Nuclear Power Plants and Nuclear Research Reactors (NP 306.2.02/1.004-1998); and
- → General Requirements for the Structure and Contents of the Safety Analysis Report on Decommissioning of Nuclear Power Plants and Nuclear Research Reactors (NP 306.3.02/3.040-2000).

9.2 Project objectives

The current in force regulatory documents partly provide general requirements for decommissioning of Ukrainian nuclear facilities, but do not include detailed requirements for decommissioning procedure, licensing and state oversight, contents of licensing documents etc.

Documents NP 306.2.02/1.004-1998 and NP 306.3.02/3.040-2000 entered force in 1998 and 2000, respectively. However, they neither take into consideration recent changes in the legislative framework in Ukraine nor the experience that has been gained both nationally and internationally in the area of

preparation for, and decommissioning of, Ukrainian nuclear installations. These documents therefore needed to be revised and updated to incorporate international safety standards in this field (e.g., GSR Part 6 [IAEA, 2014b] and both international and national experience. For example, specific requirements for management systems should be established for operators during decommissioning, in particular, taking into account the long-term decommissioning process and the constant changes in the facility during this period and the need for record keeping and information support throughout the entire decommissioning period.

The Ukrainian Regulatory Threat Assessment Report [Sneve et al., 2016] states that the elimination of identified threats requires a system of regulations for the decommissioning of nuclear facilities to be developed based on a comprehensive approach. Identified threats that were to be covered in the documents proposed for development were:

- → "7.4.6 Development of regulatory documents to establish specific safety requirements for nuclear installations in decommissioning.
- → 7.4.7 Lack of detailed requirements for nuclear installations in decommissioning after complete removal of nuclear fuel from their territory.
- → 7.4.8 Development of regulatory documents to establish specific requirements for the management system for decommissioning, in particular, taking into account long duration of the decommissioning process.
- → 7.4.9 Development of regulatory documents to establish detailed requirements for safety assessment and justification of nuclear installations in decommissioning and for structure and contents of licensing documents".

9.3 Approach and achievements

The SNRIU jointly with the SSTC NRS carried out a self-evaluation of Ukrainian regulations regarding decommissioning in terms of their compliance with WENRA reference levels for decommissioning [WENRA, 2012]. The following conclusions were made:

- → The requirements set forth in Ukrainian laws and regulations partially contain the main safety provisions for decommissioning of nuclear facilities.
- → The Ukrainian legislation should be brought into compliance with the associated WENRA reference levels and IAEA requirements through the review and development of regulations.

A series of new regulation documents were therefore developed. The new regulations establish:

- → objectives, principles, safety criteria, as well as safety requirements, including requirements for protection of the public and the environment, responsibilities associated with decommissioning, management of decommissioning, decommissioning strategy, decommissioning planning, conduct of decommissioning and completion of decommissioning actions and termination of the authorization for decommissioning;
- → requirements for structure and contents of required licensing documentation, in particular safety assessment and safety analysis reports, decommissioning strategies and plans, radiation protection programs, radioactive waste management programs, management systems and quality assurance programs and emergency plans.

Within the development of Draft Basic Regulatory Document "General Safety Provisions for Decommissioning of Nuclear Facilities" the following issues were considered:

- → Protection of people and the environment, including:
 - optimization of protection and safety in decommissioning;
 - graded approach in decommissioning; and
 - assessment of safety in decommissioning.
- → Integrated management system, including:
 - responsibilities;
 - organizational structure;
 - record and knowledge keeping;
 - implementation of quality assurance and compliance control system;
 - safety culture; and
 - staff competence assurance.
- → Decommissioning strategy/plans, including:
 - decommissioning strategy justification;
 - up-to-date insurance of financial resources for decommissioning strategy implementation;
 - radiological characterization of the facility;
 - decommissioning stages;
 - decommissioning plans and time frames;
 - updating of decommissioning plans;
 - final decommissioning plans; and
 - security aspects.
- → Conduct of decommissioning, including:
 - decommissioning procedures and regalement;
 - safety classification/reclassification of structures and equipment;
 - on-site emergency preparedness;
 - decommissioning experience feedback;
 - waste management;
 - on-site and off-site monitoring;
 - maintenance, testing and inspection; and
 - control of decommissioning activities.
- → Completion of decommissioning and safety verification, including:
 - completion of decommissioning actions and termination of the authorization for decommissioning;
 - decommissioning reporting;
 - license termination conditions; and
 - institutional control if needed.

The document takes into account the best experience of advanced countries in the safety regulation of decommissioning summarized in relevant IAEA and WENRA Publications. The following publications were used as a basis for development of the safety provisions:

- → Decommissioning Safety Reference Levels [WENRA, 2012];
- → General safety requirements for Decommissioning of Facilities (GSR Part 6) [IAEA, 2014b];
- → Decommissioning of Nuclear Power Plants, Research Reactors and Other Nuclear Fuel Cycle Facilities. Draft Safety Guide DS452, subsequently published as Specific Safety Guide SSG-47 [IAEA, 2018]; and,
- → Leadership and Management for Safety (GSR Part 2) [IAEA, 2016a].

The Draft Regulatory Document "Requirements for the Structure and Contents of Operator's Documents for Licensing Application for Decommissioning of Nuclear Facilities" describes requirements for the structure and contents of the required licensing documentation to be presented for decommissioning authorization. This includes, in particular, the need for safety assessment and safety analysis reports, decommissioning strategies and plans, radiation protection programs, radioactive waste management programs, management systems and quality assurance programs and emergency plans to be developed. The requirements consider the current approaches to safety assurance during decommissioning stages as set out in IAEA and WENRA requirements. The following issues were considered in developing the document:

- → structure and content of safety analyses reports and the respective safety assessment methodology, end states and criteria with account taken of different types of nuclear facilities and decommissioning stages;
- → structure and content of decommissioning plans (programs) on different life-time stages of nuclear facilities (design, construction, operation, shutdown and final decommissioning plan) with account of different types of nuclear facilities;
- → structure and content of the radiation protection and monitoring programs, radioactive waste management programs, integrated management systems for decommissioning stages with account of different types of nuclear facilities; and
- → structure and content of emergency plans.

The best experience of advanced countries in the safety regulation of decommissioning, as summarized in relevant IAEA and WENRA publications, was due to be considered during the development of the "Requirements for the Structure and Contents of the Operator's Documents for Licensing Application for Decommissioning of Nuclear Facilities". The following publications will be used as the basis for development of this document:

- → Decommissioning Safety Reference Levels [WENRA, 2012];
- → General safety requirements for Decommissioning of Facilities (GSR Part 6) [IAEA, 2014b];
- → Decommissioning of Nuclear Power Plants, Research Reactors and Other Nuclear Fuel Cycle Facilities (SSG-47) [IAEA, 2018];
- → Safety Assessment for the Decommissioning of Facilities Using Radioactive Material (WS-G-5.2) [IAEA, 2009c];
- → Leadership and Management for Safety (GSR Part 2) [IAEA, 2016a];
- → Safety Assessment for Facilities and Activities, GSR, Part 4 (rev 1) [IAEA, 2016b]; and,
- → Standard Format and Content for Safety Related Decommissioning Documents, Safety Reports Series No. 45 [IAEA, 2005].

10 THREAT II - Ukrainian Regulatory Threat Assessment 2017

Aiming to continue to maintain the cooperation between DSA (formerly NRPA) and SNRIU, and in order to provide a continued sound background for joint actions to ensure adequate response to the existing and/or new regulatory challenges faced by SNRIU, a decision was taken by these authorities at the beginning of 2017 to carry out a new Ukrainian Regulatory Threat Assessment. This new project was implemented during the summer-autumn of 2017.

10.1 Project objectives

The main project objective was to analyze the current (2017) situation in the field of nuclear and radiation safety regulation within the responsibility of the SNRIU and to identify the most significant threats requiring urgent improvements. In addition, it was also necessary to evaluate the progress achieved in regulatory activities during the period 2015-2017 under the bilateral cooperation project, as well as identify areas and topics for further joint DSA and SNRIU actions within the continued program for 2018-2020 to ensure adequate response to the existing and new regulatory challenges.

Since the first Regulatory Threat Assessment in 2015 [Sneve et al., 2016] and up until this second threat assessment, many important measures had been implemented in Ukraine's national nuclear sector (Fig. 10). For example:

- → Additional functions were assigned to the SNRIU such as clearance regulation and radiation control at national borders.
- → A Draft Law on National Commission on state regulation of nuclear energy safety is under preliminary review and approval.
- → The Governmental Decree on Approval of the SNRIU Action Plans on implementation of EU Directives (87, 117, 59) was issued.
- → Amendments of several basic Laws ("On Nuclear Energy Use and Radiation Safety", "On Authorizing Activity in Nuclear Energy" and "On Human Protection against Ionizing Radiation") have been introduced to the Parliament.
- → A set of top-level regulations on nuclear and radiation safety have been developed and put into force (including those mentioned above).
- → SNRIU became a full member of WENRA, which was an important step in Ukraine's transfer to EU standards in the regulation of nuclear and radiation safety. Within the framework of WENRA, Ukraine participated in the self-assessment and peer-review with respect to the WENRA Reference Levels. The outcomes of this self-assessment and its peer-review were put into the basis for developing the current SNRIU Plan for Development of Regulations.

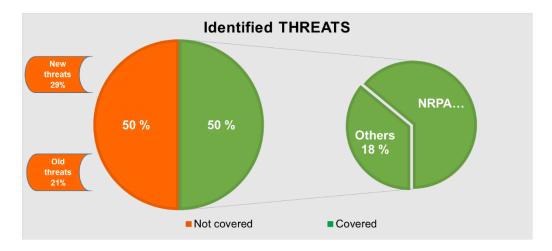


Figure 10. Progress in mitigating identified regulatory threats since the initial 2015 Regulatory Threat Assessment (source: SSTC NRS).

- → Operators have been finalizing the implementation of the IAEA recommendations related to resolution of safety issues. To resolve the safety issues identified in the reports, the operator, under continuous SNRIU supervision, had implemented a significant number of safety upgrades. Safety upgrades were implemented in line with the ongoing safety improvement programme, C(I)SIP, whose status was updated after the Fukushima Daiichi accident.
- → SNRIU has made a positive decision on the possibility of long-term operation of Zaporizhzhya NPP Units 1 and 2 for the next 10 years. This decision was preceded by a periodic safety review of these units, under which the operating organization took a series of substantial upgrading and modernization measures. Currently, the operating organization takes measures to prepare Zaporizhzhya NPP Units 3 and 4, Rivne NPP Unit 3 and Khmelnitsky NPP Unit 1 for long-term operation. The design-basis service lifetime of these units was due to expire in 2017-2018.
- → Westinghouse fuel is licensed in Ukraine in compliance with regulations, standards and rules on nuclear and radiation safety. All work stages and documents justifying operational safety are agreed in accordance with the established procedure with the SNRIU. After a successful trial operation, the new fuel assemblies were in operation at three units of Ukrainian NPPs, and three more units were planned to be loaded in the same way.
- → The progress with construction of the Centralized Spent Fuel Storage Facility, located in the Chernobyl exclusion zone, was highlighted in the state regulatory review of the facility's Preliminary Safety Analysis Report (the planned commissioning date was 2019).
- → The New Safe Confinement (NSC, "Arch") has been moved onto the Chernobyl Shelter facility. The completion of NSC auxiliary systems and NSC commissioning measures was planned for the end of 2017. After that, dismantling of the Shelter and Chornobyl Unit 4 structures was due to start.
- → In accordance with the provisions of the Convention on Nuclear Safety (CNS), Ukraine developed and submitted a National Report and attended the 7th CNS Review Meeting, which took place from 27 March to 7 April 2017. During the meeting, SNRIU representative gave a national presentation and Ukrainian delegation answered questions raised from its Country Group members. The Country Group identified a number of challenges for Ukraine. Progress in overcoming these challenges is to be reported at the next CNS Review Meeting.

The THREAT II assessment aimed to take into account the political and security situation in Ukraine and new challenges faced by SNRIU in order to maintain a solid basis for continued cooperation between DSA and SNRIU in ensuring an adequate response to the existing and/or new regulatory challenges in Ukraine.

10.2 Approach and achievements

The 2017 Regulatory Threat Assessment Report [Siegien et al., 2018] includes the following main chapters:

- 1. Background and introduction
- 2. Organization and general principles for activities of Nuclear Regulatory Authority
- 3. Safety of nuclear installations
- 4. Radioactive material transportation
- 5. Emergency preparedness and response
- 6. Radioactive waste management and decommissioning
- 7. Radiation safety
- 8. The main identified threats and proposals for their elimination
- 9. Overview and status of projects and activities directed to cope with the identified threats
- 10. Conclusions
- 11. Annex 1 Roadmap for cooperation between NRPA and SNRIU for 2018-2020

In developing Chapters 1-7 of the report, direct duplication of similar information presented earlier was avoided by referencing back to respective paragraphs of the original threat assessment report [Sneve et al., 2016]. Chapters 1-7 were therefore developed with an emphasis on describing changes that had occurred in Ukraine's national nuclear sector during the years since the original assessment, and on the actual or potential influences of those changes to regular SNRIU activities.

In Chapter 8 of the report, and consistent with the previous threat assessment report, the following information is presented for each identified threat:

- → description of the threat with reference to the particular chapter of the report where the relevant threat justifications are described in detail;
- → possible way(s) for threat elimination or mitigation of its influence on respective SNRIU activity(s);
- → priority of actions to be undertaken for the threat elimination or mitigation; and
- → risks stipulated by the threat existence and their propagation if the threat was not eliminated or mitigated.

Chapter 9 is then devoted to an overview of the on-going (and planed up to 2020) projects and activities directed to address the threats identified in previous chapter of the Report. Results achieved and the current (as of beginning of autumn 2017) status of projects being implemented under co-operation between DSA and SNRIU are presented. Other on-going and planned projects within SNRIU international co-operation (e.g. EU Instrument for Nuclear Safety Cooperation (INSC) projects and co-operation with the United States Nuclear Regulatory Commission and Department of Defence, the Swedish Radiation Safety Authority and the German Federal Ministry for the Environment, Nature Conservation an Nuclear Safety etc.) and relevant efforts and activities being undertaken by SNRIU using its own and SSTC NRS resources are also described in the same manner.

The 2017 report identified directions for regulatory enhancements in the area of safety of nuclear installations, radioactive materials transport, emergency preparedness and response, radioactive waste management and decommissioning, radiation protection, and nuclear security. In some cases, activities, which have to ensure aforementioned regulatory enhancements, are part of ongoing bilateral projects between DSA and SNRIU (a short description of those projects is provided in section 14 of this document).

In other cases, mitigation of the identified threats is an objective of ongoing or planned projects of SNRIU in cooperation with other international partners.

A Roadmap for continued cooperation between DSA and SNRIU was also developed and presented as Annex 1 to the report. The Roadmap contains a list of projects, along with brief descriptions, that were proposed under the continued bilateral cooperation program for the period 2018-2020. The projects were identified to:

- → deal with threats identified and assessed in the area of state regulation of nuclear and radiation safety under the regulatory threat assessment (and not covered by the on-going or planed national and international activities described in Chapter 9 of the report);
- → incorporate the results from a series of meetings between DSA and SNRIU representatives during 2016-2017:
- → take into account the SNRIU and SSTC NRS capabilities and resources; and
- → consider the current (as of beginning of autumn 2017) situation in Ukraine and worldwide.

All proposed projects were subject of detailed discussion following presentation of the Ukrainian Regulatory Threat Assessment during the progress meeting of DSA and SNRIU in October 2017.

While developing a Roadmap and defining the content of the proposed projects, special consideration was given to avoiding duplication and/or overlapping of the Roadmap proposals with other SNRIU activities at national and international levels that are either on-going or planned for 2018-2020. The Roadmap is a living document and will be updated as necessary. Finally, the threat assessment performed in 2017 enabled SNRIU to determine a number of new challenges, and support from DSA will be valuable in addressing them.

46

11 GUIDELINE - Development of Requirements for the Structure and Contents of Emergency Documents

The operation of NPPs is supported by documents, covering emergency procedures, guidelines, and plans. The development and implementation of NPP emergency plans and other documents are among the main elements required for defence-in-depth at all levels, which is recommended by international organizations, notably the IAEA and WENRA.

The Ukrainian operating organization (Energoatom Company and NPPs) develops and introduces emergency plans, procedures and guidelines for each unit of operating NPPs. These include event mitigation procedures, emergency operating procedures and severe accident management guidelines, etc. to implement organizational measures of the defence-in-depth strategy. In recent years, the scope of the emergency documents has been significantly extended; in particular, the following have been developed:

- → emergency operating procedures for low power and shutdown states;
- → emergency operating procedures for the spent fuel pool; and
- → severe accident management guidelines for different states of the reactor and spent fuel pool.

Further activities foresee the development and implementation of FLEX procedures, of the type discussed, for example, in https://www.neimagazine.com/features/featurea-global-response-4899802/.

Besides guidelines and procedures, the package of emergency documents for Ukrainian NPPs also includes justifications (technical and analytical) and deliverables with verification and validation results (including those obtained using NPP full-scope simulators).

The SNRIU oversees the development, implementation, and amendment of NPP emergency documents on a permanent basis. However, current regulations and standards on nuclear and radiation safety (NRS) establish only general requirements for the development, validation/verification, and agreement of emergency procedures and guidelines with the regulatory body. In particular, NP 306.2.141 2008 "General Safety Provisions for Nuclear Power Plants" and NP 306.2.145 2008 "Nuclear Safety Rules for Pressurized Water Reactors of Nuclear Power Plants" contained only general requirements for the structure and content of emergency documents. This situation resulted in different approaches being applied for the structure and development of emergency documents at different NPPs.

11.1 Project objective

The objective of project GUIDELINE was to develop a regulation to establish basic regulatory requirements for the development of NPP emergency documents (requirements for the contents, procedure for the development, implementation, and amendment of emergency documents, etc.). It was recognized that, following the development of the new regulatory requirements, improvement (updating) of existing emergency documents may also be needed.

11.2 Approach and achievements

The new document "Requirements for the Structure and Contents of Emergency Documents" establishes requirements for the structure and contents of emergency documents. The document also provides the basis for further development of regulatory provisions.

The operating organization is required to develop and introduce emergency procedures and guidelines for each NPP unit to implement organizational measures of the defence-in-depth strategy. The general diagram of existing emergency documents for Ukrainian NPPs is presented in Fig. 11.

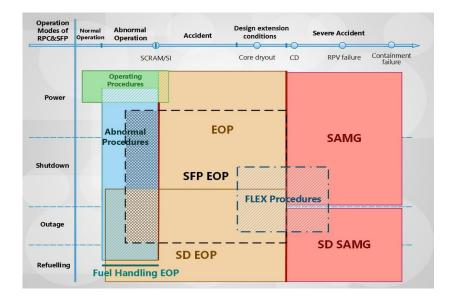


Figure 11 – Principal diagram of NPP emergency documents

According to the diagram, emergency documents consist of: Abnormal operating procedures (AOP); Emergency operating procedures (EOP) used for the management of design-basis and beyond design-basis accidents; and the concept of Severe Accident Management Guideline SAMG, https://www.iaea.org/topics/severe-accident-management/severe-accident-management-guideline-development-toolkit-samg-d.

The current national requirements for NRS established general provisions on the need for the development, validation/verification and approval of emergency procedures and guidelines by the regulatory body. In particular, NP 306.2.141-2008 "General Safety Provisions for Nuclear Power Plants" provides for the following requirements for the contents and format of emergency documents:

- → para. 10.9.1. "NPP administration based on the safety assessment report (SAR), technical specifications for safe operation and other operational documents shall arrange the development and approval of procedures and guidelines that determine the actions of personnel in case of abnormal operation, emergencies, design-basis and beyond design-basis accidents, including severe accidents".
- → para. 10.9.2. "Procedures and guidelines are based on symptoms and/or events, modes and states of a power unit that are expected during transients, emergencies and accidents. Emergency procedures and guidelines shall be in compliance with other operating instructions and procedures".
- → para. 10.9.3. "Requirements of emergency procedures and guidelines shall be justified by calculations, verified and validated in order to reflect the actual state of NPP (power unit) and conditions of its operation.
- → Validation of emergency procedures and guidelines shall be performed using full-scale simulators".

NP 306.2.145-2008 "Nuclear Safety Rules for Nuclear Power Plants with Pressurized Water Reactors" extends the abovementioned paragraphs regarding the approval of emergency documents, namely:

→ para. 4.3 "Reactor operation manual and guidelines that define actions of personnel in case of design-basis and beyond design-basis accidents, including severe accidents, shall be approved by the SNRIU".

Therefore, it is clear that national regulations established only general requirements, according to which emergency documents should be developed, and the approach to their development together with actions of personnel recommended in these documents should be justified. At the same time, there were no detailed requirements for the scope of emergency documents, approaches to their development and the required/sufficient scope of analytical and technical justifications, etc.

Within the development of emergency documents (in particular, EOP and SAMG), the operating organization has developed a set of guidelines with recommendations and methodology for the development, justification and verification/validation of EOP and SAMG. According to analysis results, the operating organization performed a significant scope of activities on the development of methodologies and recommendations to prepare, implement and support emergency documents. Experience gained will be taken into account in the development of a regulation on the structure and contents of the emergency documents for Ukrainian NPPs.

The regulation "Requirements for the Structure and Contents of Emergency Documents" establishes basic regulatory requirements for the development of NPP emergency documents:

- → requirements for the scope of emergency documents and justification deliverables (scope of justification, criteria for justification sufficiency, etc.);
- → requirements for the review, follow-up and amendment of emergency documents;
- → requirements for the interface between different components of emergency documents; and
- → general requirements for the allocation of responsibilities within the use of different components of emergency documents.

The document was developed based on provisions of the following Ukrainian and international documents:

- → NP 306.2.141-2008 "General Safety Provisions for Nuclear Power Plants".
- → NP 306.2.145-2008 "Nuclear Safety Rules for Nuclear Power Plants with Pressurized Water Reactors".
- → Safety of Nuclear Power Plants: Commissioning and Operation: Specific Safety Requirements, IAEA Safety Standards Series No. SSR-2/2 (Rev. 1) [IAEA, 2016c].
- → Severe Accident Management Programmes for Nuclear Power Plants, IAEA Safety Standards Series No. NS-G-2.15 [IAEA, 2009d].
- → Arrangements for Preparedness for a Nuclear or Radiological Emergency, IAEA Safety Standards Series No. GS-G-2.1 [IAEA, 2007].
- → Operational Limits and Conditions and Operating Procedures for Nuclear Power Plants, IAEA Safety Standards Series No. NS-G-2.2 [IAEA, 2000].
- → Accident Analysis for Nuclear Power Plants, IAEA Safety Reports Series No. 23 [IAEA, 2002b].
- → Implementation of Accident Management Programmes in Nuclear Power Plants, IAEA Safety Reports Series No. 32 [IAEA, 2004].
- → Development and Review of Plant Specific Emergency Operating Procedures, IAEA Safety Reports Series No. 48 [IAEA, 2006a].
- → Guidelines for the Review of Accident Management Programmes in Nuclear Power Plants, IAEA Services Series No. 9 [IAEA, 2003].
- → WENRA Reactor Safety Reference Levels [WENRA, 2008, with proposed updates].
- → WENRA Safety Reference Levels for Existing Reactors [WENRA, 2014c].

Within the scope of the project a working meeting with Energoatom and SS "Scientific and Technical Center" was organized. The meeting provided the opportunity for discussion of the draft document "Requirements for the Structure and Contents of Emergency Documents". The objective was to discuss of the current status of the GUIDELINE Project and familiarization with the draft document "Requirements for the Structure and Contents of Emergency Documents".

DSA Report

50

12 EXPERIENCE- Development of Guideline for Assessment of Safety Culture and Human and Organizational Factors in Operating Experience Analysis

In compliance with international guidelines and requirements, such as IAEA Safety Fundamental Principles [IAEA, 2006b] and NS-G-2.11 [IAEA, 2006c], ETSON Technical Safety Assessment Guide "Event Review and Precursor Analysis", as well as WENRA Safety Reference Levels for Existing Reactors [WENRA, 2014c], operating experience assessment, including operational event analysis, is one of the organizational and technical principles of ensuring NPP safety.

Operational event analysis for Ukrainian NPPs has shown that events caused by human and organizational factors (HOF) and drawbacks of safety culture (SC) were significant threats. HOF are factors that have significant influence, in a positive or adverse manner, on human performance. Therefore, HOF have a key importance for safety, keeping in mind that safety is the result of interaction of individuals, organization and technology. Safety culture (SC) is a set of characteristics and features in the activities of organizations and behaviour of individuals that stipulates that, as an overriding priority, safety issues of NPPs receive the attention warranted by their significance.

The updated Threat Assessment Report [Siegien et al., 2018] identified a number of threats in relation to HOF and SC. For example, no procedures had been established by the Ukrainian regulatory body to assess aspects of SC and HOF in the framework of operating experience assessment for Ukrainian NPPs. The absence of a clear analysis on SC and HOF, as well as an absence of practical guidelines on assessment, decreases the effectiveness of regulatory oversight. In response to the identified threats, a guideline for assessing the SC and HOF in operating experience analysis for Ukrainian NPPs was developed under the GUIDELINE project to improve effectiveness in identification of inspection areas, planning of inspections and general regulatory oversight.

12.1 Project objectives

The overall purpose of the project was to improve SNRIU activities in assessing the effect of SC and HOF on NPP safety. Analysis of operating experience was used to confirm that the root causes of abnormal events are determined correctly, to develop corrective measures and support monitoring of NPP safety. In undertaking operating experience analysis, safety at Ukrainian NPPs could be improved by preventing operational events caused by HOF, and efficiently using plant operating experience and enhanced operational safety. As such, the specific objective of project GUIDELINE was to develop and implement a guideline for assessment of SC and HOF in operating experience analysis of Ukrainian NPPs (operational events, safety performance indicators) and to improve effectiveness of regulatory oversight, including planning and conduct of inspections. The development of a new document "Guideline for Assessment of Safety Culture and HOF in Operating Experience Analysis" would contribute to enhancing the SNRIU capabilities and to improving nuclear safety.

12.2 Approach and achievements

The task was to define the regulatory requirements of Ukraine that were directly or indirectly related to the development and performance of the system for collection and use of experience in SC and HOF at NPPs. The next stage involved analysis of the IAEA documents on SC and HOF, as well as operating experience feedback presented in high-level documents and WENRA requirements. These requirements were compared with the current regulatory provisions of Ukraine. Further activities included analysis of operational events and safety performance indicators about SC and HOF. The analysis results were

finalized into a list of aspects to be considered in the Guideline. The following aspects were also considered:

- → SNRIU's system for assessing NPP safety performance indicators; and
- → individual Energoatom documents related to the system for operating experience feedback and investigation of NPP operational events.

The activities initiated at this stage were continued after the analysis of SNRIU and SSTC NRS documents on operating experience and safety performance indicators, considering the procedure developed in the Guideline. The final task was to define issues to be included in the Guideline and proposals on their structure.

Within preliminary review of documents related to investigation of NPP operational events, SSTC NRS experts defined that about 42% of the operational events at Ukrainian NPPs were associated with HOF and SC. The IAEA indicates that this percentage in other countries is much higher and can reach 80%.

At the same time, analysis of the operator's practices showed that the existing operator's system was largely focused on the analysis of technological problems in the event investigation process. Therefore, the SNRIU's system for HOF and SC analysis needed to be improved together with the operator's system for collection and analysis of information on operating experience.

In the analysis of deficiencies and improvement areas, a number important aspects relating to HOF and SC assessment programs were identified to be implemented in the operating organization and SNRIU, namely:

- → more specific definition of the oversight subject related to HOF and SC, determination of a model for understanding this issue;
- ightarrow detailed provisions for HOF and SC analysis depending on the type of reporting document;
- → analysis of plant current safety performance indicators in terms of HOF and SC;
- → wider inclusion of HOF and SC indicators into the oversight regulatory practices; and
- → training of SNRIU inspectors for understanding the HOF and SC indicators, their identification and correct interpretation, including recommendations on the actions of inspectors in case of events associated with HOF and SC.

Taking into account the collected and analysed information, a number of important aspects were identified for the operator's HOF and SC program, namely:

- ightarrow paying particular attention to human and organizational factors is important for safety;
- → introduction of modern social and psychological teamwork practices aimed at encouraging staff to take an active position in compliance with requirements and safety improvement; and
- → identification of new operating experience aspects associated with HOF and SC: for example, experience that applies only to HOF and SC, but not to operation of systems or equipment failures.

In accordance with the IAEA Fundamental Safety Principles [IAEA, 2006b] para. 3.17, "...The precursors to accidents have to be identified and analyzed, and measures have to be taken to prevent the recurrence of accidents. The feedback of operating experience from facilities and activities – and, where relevant, from elsewhere – is a key means of enhancing safety. Processes must be put in place for the feedback and analysis of operating experience, including initiating events, accident precursors, near misses, accidents and unauthorized acts, so that lessons may be learned, shared and acted upon".

The Guideline was developed in order to take the full advantage of the opportunities to learn from HOF and SC in operating experience analysis. However, it is impossible to describe the analysis of the behaviour

of social groups and individuals with clear laws and formulas. Knowledge on HOF and SC can only be obtained empirically, the data obtained are of a statistical nature, and the process significantly depends on the experience of the analyst. Given such limitations, all records on HOF and SC under this Guideline are accompanied by a quantitative indicator of factor certainty. The experts involved into the development of such records shall avoid categorical allegations and be always open to communicating with the operating organization for in-depth understanding of the nature of the identified factors.

The developed Guideline covers current international experience, in particular, IAEA guidelines and best international practices provided within the project established in the frame of Ukrainian–Norwegian Regulatory Cooperation related to the Radiation and Nuclear Safety in Ukraine.

13 PREPAREDNESS - Enhancing Emergency Preparedness and Response in Ukraine

Measures on emergency preparedness and response in Ukraine are integrated into the Unified State System on Civil Protection (USSCP) established by Resolution of the Cabinet of Ministers of Ukraine No. 1198 dated 3 September 1998. Within the USSCP, measures on emergency planning and response to nuclear or radiological emergencies on the territory of Ukraine or beyond its boundaries are laid down in the regulatory document "Radiation Emergencies Response Plan, NP 306.5.01/3.083" issued in 2004. At that time, the provisions of the regulatory document were developed considering IAEA recommendations on emergency planning and response stated in IAEA Requirements "Preparedness and Response for a Nuclear or Radiological Emergency, GS-R-2" [IAEA, 2002c] and IAEA publication "Method for the development of emergency response preparedness for nuclear or radiological accidents, IAEA-TECDOC-953" [IAEA, 1997].

The regulatory document "Radiation Emergencies Response Plan" is of interagency importance, approved by the joint order of the SNRIU and the Ministry of Emergencies of Ukraine, registered in the Ministry of Justice of Ukraine in 2004 and reviewed in 2010.

After recent publication of new IAEA and Euratom requirements on emergency preparedness and response, it became necessary to review the regulatory document "Radiation Emergencies Response Plan" in order to introduce new international safety recommendations into Ukrainian legislation.

On 17 September 2014, the Cabinet of Ministers of Ukraine issued Resolution No. 847p that approved the Action Plan on Implementation of the Association Agreement between Ukraine and the European Union and its Member States. Paragraph 187 of this Action Plan envisaged development and adoption of national legal acts aimed at implementation of provisions of the Council Directive 2013/59/Euratom of 5 December 2013 laying down basic safety standards for protection against the dangers arising from exposure to ionizing radiation, and repealing 89/618/Euratom Directives, 90/641/Euratom, 96/29/Euratom, 97/43/Euratom and 2003/122/Euratom. Some provisions of the Council Directive 2013/59/Euratom are relevant to emergency preparedness and response.

13.1 Project objective

An overall objective of the Project "Enhancing Emergency Preparedness and Response in Ukraine" was to identify gaps and issues in the existing high-level regulatory document "Radiation Emergencies Response Plan, NP 306.5.01/3.083-2004" laying down requirements for planning arrangements for response to radiation emergencies against the recent IAEA Safety Standards in the field of preparedness and response to a nuclear or radiological emergency.

13.2 Approach and achievements

During the course of the project the following activities were carried out:

- → identification of gaps and issues in the current version of the regulatory document "Radiation Emergencies Response Plan" with regard to the IAEA general safety requirements (GSR Part 7) in the field of preparedness and response to a nuclear or radiological emergency, Council Directive 2013/59/Euratom and WENRA Safety Reference Levels for Existing Reactors, and development of a report on findings;
- → analysis of the lessons learnt from the SNRIU's emergency exercises and previous application of the current version of the regulatory document "Radiation Emergencies Response Plan";
- → analysis of the regulatory framework for emergency planning in Norway and other European countries;

- → development of a draft of the structure and contents of a new version of the regulatory document "Radiation Emergencies Response Plan";
- → development of the draft of a new version of the regulatory document "Radiation Emergencies Response Plan" which will address inter alia requirements for the following issues:
 - emergency planning;
 - hazard assessment;
 - classification of all types of nuclear or radiological emergencies;
 - establishment of emergency preparedness categories;
 - protection strategy for a nuclear or radiological emergency;
 - roles and responsibilities in emergency preparedness and response;
 - organization and staffing for emergency preparedness and response;
 - training, drills and exercises for emergency preparedness and response;
 - response to simultaneous emergencies at several facilities;
 - coordination of emergency preparedness and response;
 - consistency among contingency plans and security plans;
 - termination of an emergency;
 - communicating with the public;
 - timely and comprehensive analysis of emergency;
 - quality management program for emergency preparedness and response;
 - coordination of preparedness and response at the international level; etc.

The findings were taken into account in a new draft of the Ukrainian high-level regulatory document establishing systematized requirements for planning arrangements for response to radiation emergencies. The draft of a new regulatory document meets the following international requirements:

- → Council Directive 2013/59/Euratom;
- → IAEA General Safety Requirements "Preparedness and Response for a Nuclear or Radiological Emergency, GSR Part 7", issued in 2015 and superseding GS-R-2 [IAEA, 2015];
- → WENRA Safety Reference Levels for Existing Reactors, issued on 24 September 2014 [WENRA, 2014c].

As a result of activities within the framework of the PREPAREDNESS project, a draft of the new regulatory document establishing systematized requirements for planning arrangements for response to nuclear and radiological emergencies in Ukraine was developed.

An interagency working group was established in Ukraine to include representatives of SNRIU, SSTC NRS, State Emergencies Service, Ministry of Energy and Coal Industry, Ministry of Health, Ministry of Ecology and Natural Resources, State Agency on Exclusion Zone Management, Scientific and Research Institute on Radiation Protection and others. Involvement of such a large group of experts in discussions on the structure and contents and the first draft of the new regulatory document at the very beginning of the project assisted in reaching an agreement between the interested parties on the final draft of the regulatory document. The document is to be submitted for approval to the Ministry of Justice of Ukraine and the Cabinet of Ministers of Ukraine.

14 Current projects on-going through 2020

14.1 COMPLIANCE - Improvement of Regulatory Framework on Safe Transport of Radioactive Materials

The objective of this project is to develop two high-level regulations and two procedures, establishing systematized nuclear and radiation safety requirements, to be met in the transport of radioactive materials.

- → Regulation "Procedure of Issuing Certificates on the Safe Transport of Radioactive Materials" will establish requirements for the procedure of issuing certificates of the different types. Requirements for stage-by-stage certification will be established, as appropriate, with regard to approval certificates for special forms of radioactive material, low dispersible radioactive materials and packaging design. The regulation will establish requirements for the procedure of multilateral approval of certificates issued by regulatory authorities of other countries.
- → Regulation on the Structure and Contents of Safety Analysis Reports that are included into the Package of Documents for Obtaining Certificates will establish requirements for safety analysis reports that are submitted by the applicant to the SNRIU in the package of documents supporting the application for obtaining certificates of the different types.
- → Regulation "Procedure for Inspecting Licensee Activities on the Transport of Radioactive Materials" will establish procedures to carry out inspections of activities performed by the entity according to the license on radioactive material transport issued by the SNRIU.
- → Regulation "Inspection Procedure for the Management System of the Transport of Radioactive Materials" will establish the procedures to carry out inspection of the management system of radioactive material transport activities performed by the entity according to the license on radioactive material transport issued by the SNRIU.

14.2 PROVISION - Development of Proposals/Recommendations on Procedure and Criteria for the Recognition of the Radiation Protection Expert According to Council Directive 2013/59/Euratom and IAEA Standards

Over recent years, there has been a significant amount of activity to improve legislation in the sphere of nuclear and radiation safety regulation in accordance with provisions in new IAEA standards and EU/Euratom Directives. However, an issue on the recognition of radiation protection experts at a legislative level remains relevant. The practice of involving qualified experts who provide support in radiation protection has been widely and successfully used in international practice. Despite the availability of highly qualified experts in national practice, there are no mechanisms in Ukraine to recognize radiation protection experts and to involve them in the cooperation with licensees, registrants, other owners of radiation sources on safety issues in the sphere of professional exposure and exposure of the public. Development of state-of-the-art radiation technologies and tightening of safety standards have resulted in the need to have qualified expert support for these activities to ensure radiation safety of personnel, the public and the environment.

It is necessary to state that the Cabinet of Ministers of Ukraine with the Resolution No. 1106 dated 25 October 2017 "On Implementation of Association Agreement between Ukraine, on the One Hand, and the European Union, European Atomic Energy Community and Their Member States, on the Other Hand" approved the Action Plan on the Implementation of Association Agreement between Ukraine and the European Union and European Atomic Energy Community. According to this Plan, among others, it is

necessary to develop recognition criteria and provisions on radiation protection experts with regard to SNRIU competence.

This problem has been discussed recently with the view to defining the status of radiation protection experts, criteria for recognition and procedures, including the authority involved in the recognition process, criteria, and issues on corruption prevention, etc. However, no agreement has, to date, been reached on these issues. Taking this into account, it was deemed necessary to study and generalize international experience in the recognition and involvement of experts in radiation protection, provisions and recommendations of international organizations, and to analyse the national regulatory framework with respect to introducing such experts into the legal field and practices for recognition of experts in other spheres.

The objective of project PROVISION is therefore the development of specific recommendations for the procedure of recognition of radiation protection experts according to Council Directive 2013/59/Euratom. The main task of this project is to develop criteria and recommendations on the procedure to recognize radiation protection experts to improve radiation safety in nuclear energy use and harmonize the national regulatory framework with EC Directives and IAEA safety documents.

14.3 FRAMEWORK - Definition of Areas to Improve Regulatory Framework for Nuclear Security

Physical protection of nuclear installations, nuclear materials, radioactive waste and other radiation sources is an important area of activities in the sphere of nuclear energy use, along with nuclear and radiation safety. Recognizing this, Ukraine has been involved in the international process on maintaining physical protection starting from the first years of independence. Ukraine joined the Convention on Physical Protection of Nuclear Material (CPPNM) in 1993 and was among the countries initiating the International Convention for the Suppression of Acts of Nuclear Terrorism. Ukraine signed and ratified this Convention in 2005. In 2008, Ukraine ratified the Amendment to the CPPNM, which made a significant contribution to the development of the legal framework for physical protection in Ukraine. The fundamental principles of physical protection and a number of important concepts were implemented into the legislation, including physical protection regime, design-basis threat, state physical protection system and nuclear security.

Since 2010, nuclear security has been an important component of nuclear and radiation safety in Ukraine. During this period, one regulation has been developed and more than 20 regulations have been revised, including four resolutions of the Cabinet of Ministers on physical protection, and one lower level document on nuclear security has been developed. At the same time, the IAEA developed and issued 24 documents with recommendations on nuclear security, one of which is on physical protection. Such a shift of priorities in Ukraine has made it possible to strengthen the regulatory framework for physical protection and close a number of gaps in it. However, it also affected the state of nuclear security regulation, which includes, in addition to physical protection, cyber security, countering illicit trafficking and a set of other safety significant types of activities. At the same time, threats to nuclear security in Ukraine are real, as it is confirmed by periodic threat assessments performed according to the law, and they require effective counteraction. The current regulatory framework does not fully cover a large number of nuclear security issues. Therefore, detailed analysis of European documents and international recommendations on nuclear security, detection of gaps in the legislation and definition of regulations to be developed or updated are of a high priority.

Activities of the SNRIU, as a competent authority of the state physical protection system are mainly aimed at maintaining the physical protection regime, as one of the most important components of nuclear security. Current regulations of Ukraine on physical protection generally comply with relevant state-of-the-

art approaches. Nonetheless, it is advisable to familiarize with Euratom regulations on nuclear safety and nuclear security, as well as provisions of IAEA recommendations and guidance on the main components and arrangement of nuclear security regime for further extension and improvement of the regulatory framework for security of nuclear installations, nuclear materials, radioactive waste, other radiation sources and for using systemic approach to nuclear security. Based on results of a comprehensive study of the mentioned documents and comparison of their provisions with relevant regulatory framework of Ukraine, it will be necessary to define and develop a tentative list of national regulations on certain issues of physical protection and nuclear security that shall be revised or developed. It will also be necessary to justify the sequence of actions in this area. Implementation of this high-priority task is aimed at strengthening the national regulatory framework through the definition of the main components of nuclear security and definition of further activities in the regulation of this issue in Ukraine.

The main project objective of project FRAMEWORK is, therefore, to define areas to improve the regulatory framework for security of nuclear installations, nuclear materials, radioactive waste and other radiation sources in Ukraine. Experts will review current requirements for nuclear security presented in regulations of the EU and IAEA in order to define the main issues for developing and maintaining the nuclear security regime in the state and analyse the extent to which these issues are covered in current legislation. The activities will result in the definition of regulations to be developed and current documents to be revised and updated.

Project implementation will provide the possibility to:

- 1. define the main issues posing risks to the efficiency of nuclear security regulation in Ukraine, based on review of security threats and the current regulatory framework;
- 2. develop the comprehensive framework (hierarchy pyramid) of regulatory and legal documents for nuclear security, with regulatory requirements to address these issues;
- 3. define recommendations on the structure and contents of these regulatory and legal documents and identify their level; and

58

4. define current regulations, which became obsolete and require revision or cancellation and replacement by new regulations.

15 Conclusions and Recommendations

15.1 Conclusions

The bilateral cooperation program between DSA and SNRIU has proved highly successful in addressing regulatory threats in Ukraine since its inception in 2014. A structured and holistic approach has been employed that includes: completion of a Regulatory Threat Assessment to identify and prioritize the most significant threats to radiation and nuclear safety from a regulatory perspective; implementation of projects to address the most urgent identified threats; review and update of the Threat Assessment Report to take account of on-going achievements in the program as well as wider external developments, and setting up of further projects to address remaining and newly identified threats.

A holistic approach to cooperation requires clear ideas and good communication as well as a flexible and innovative approach to addressing challenges in order to produce tangible results. An important aspect of the cooperation program has been the organization of bilateral meetings and joint workshops that have allowed for the active involvement of experts from both DSA and SNRIU in the development of regulatory documents in line with the newest international recommendations and best practices. Experience has shown that this joint approach involving dialogue with the most relevant stakeholders provides a valuable opportunity to obtain opinions on the details in regulatory documents that can materially influence the effectiveness and efficiency of delivery of safety and security in everyday practices. These practically orientated opinions feed back directly into the further development of draft documents. At the same time, each organisation has clearly and transparently maintained its own responsibilities.

The cooperation program has, in the period 2014-2020, achieved the following:

- → Development of an initial Threat Assessment Report, an important output and great achievement in a relatively short time that supported development of further strategy and prioritization of tasks.
- → Analysis of the regulatory framework existing in western countries as well as existing regulatory documents in Ukraine in a range of radiation safety areas, including medicine, decommissioning and RW management, emergency preparedness and SC and HOF in operating experience analysis.
- → Enhancement of the Ukrainian safety culture through support in the development of new regulatory documents in various fields relating to radiation safety and security.
- → Development of a revised and updated Threat Assessment Report to take account of the progress and achievements in the first phase of the cooperation program, as well as wider developments in Ukraine policy and program involving radiation and nuclear safety and security, thus identifying and prioritizing remaining and new threats and developing a Roadmap to alleviate and mitigate those threats.

A significant number of regulatory documents have been developed. Each document has been developed following review and analysis of the current regulatory position in Ukraine and with respect to international recommendations (i.e., relevant IAEA safety standards and ICRP recommendations), best international practice and DSA experience. The documents produced are detailed in Table 2.

Table 2. Regulatory documents developed in the DSA / SNRIU bilateral cooperation projects in the period 2014 to 2020.

Project WASTE

General Safety Provisions for Predisposal Radioactive Waste Management

General Safety Provisions in Disposal of Radioactive Waste

Project MEDICINE

General Safety Rules for Medical Radiation Sources

Radiation Protection and Safety Rules in Brachytherapy

Project URAN

General Radiation Safety Provisions for Uranium Ore Mining and Processing Operations and Their Termination

Requirements for Institutional Control of Uranium Sites within Restricted Clearance from Regulatory Control

Project SOURCE

General Safety Rules for Radiation Sources

Project TRANSPORT

Rules for Nuclear and Radiation Safety in Transport of Radioactive Materials

Project DECOMISSIONING

General Safety Provisions for Decommissioning of Nuclear Facilities

Requirements for the Structure and Contents of Operator's Documents for Licensing Application for Decommissioning of Nuclear Facilities

Project GUIDELINE

Requirements for the Structure and Contents of Emergency Documents

Project EXPERIENCE

Guideline for Assessment of Safety Culture and HOF in Operating Experience Analysis

Project PREPAREDNESS

Updated radiation Emergencies Response Plan

15.2 Recommendations on next steps and international engagement

The regulatory framework for radiation safety and security in Ukraine has been considerably enhanced as a result of activities undertaken within the bilateral cooperation program between DSA and SNRIU. However, threats remain as detailed in the updated Regulatory Threat Assessment Report [Siegien et al., 2018] and three projects have already been established to address key priority areas:

- → COMPLIANCE Improvement of Regulatory Framework on Safe Transport of Radioactive Materials;
- → PROVISION Development of Proposals/Recommendations on Procedure and Criteria for the Recognition of the Radiation Protection Expert According to Council Directive 2013/59/Euratom and IAEA Standards; and,
- → FRAMEWORK Definition of Areas to Improve Regulatory Framework for Nuclear Security.

It is recommended that the cooperation program is continued in order to complete these projects and to address remaining threats within the Ukraine regulatory framework in line with the Roadmap reported in Siegen et al. [2018]. It is further recommended that the Roadmap and associated Regulatory Threat Assessment report be periodically updated to take account of progress and to continue to ensure remaining threats are appropriately prioritized. In addition, while there has been considerable progress in developing regulations to address prioritized threats, further development of existing lower level regulations and guidance on their application may be required to align these with the new documents that

have been developed, to align with on-going revisions to international recommendations and guidance, and to take account of continually growing international experience of best practice.

The DSA and SNRIU recognise the mutual benefits of the bilateral cooperation program as well as the wider benefits of sharing experience internationally. For example, the SSTC NRC presented information on implementation of a graded approach in ensuring safety of management of emergency and legacy radioactive waste in Ukraine at an international workshop on regulatory framework of decommissioning, legacy sites and wastes from recognition to resolution: building optimization into the process. This was reported alongside other substantial and valuable presentations and discussions in Sneve [2020]. DSA and Ukrainian organisations have contributed to international reports sharing experience and advising on characterization and management of legacy radioactive waste [NEA, 2016; NEA, in publication]. Following the recent publication of the Nuclear Energy Agency (NEA) report on legacy management [NEA, 2019], it is recommended that the results of the continuing DSA/SNRIU regulatory cooperation program are provided for consideration in the activities of the new NEA Committee on Decommissioning and Legacy Management and the recently set up Expert Group on developing a Holistic Process for Decision Making on Decommissioning and Management of Complex Sites.

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