



## The Development of Regulations

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### ABSTRACT

In October 2002, The Act on Protection Against Ionising Radiation and Nuclear Safety which regulates all aspects of protection against ionising radiation and nuclear safety entered into force in Slovenia. The Slovenian government and its responsible ministries shall issue several governmental and ministerial regulations to support the above - mentioned act.

The Slovenian Nuclear Safety Administration (SNSA) which acts within the Ministry of the Environment, Spatial Planning and Energy takes an active part in drafting the regulations which are defined in the act.

Due to a very comprehensive and pretentious task, that is to be completed in a relatively short period of time, taking into consideration the involvement of stakeholders and all competent ministries, the SNSA within the Quality Management System developed a special procedure that insures the systematic approach to the preparation of regulations.

The article will briefly represent the process that:

- defines the preparation, development, harmonisation, review, approval and issue of regulations and
- uniforms the format of developed regulations.

### 1 INTRODUCTION

The Slovenian Nuclear Safety Administration (SNSA) within the Ministry of the Environment, Spatial Planning and Energy acts as the national regulatory authority, whose mission is to prevent or restrict any harmful effects of ionising radiation to the public, workers and the environment and to ensure peaceful use of nuclear energy. One of the obligations as well as competence of the SNSA is drafting the regulations on behalf of the Government and the Ministry of the Environment, Spatial Planning and Energy.

According to the Act on Ionising Radiation Protection and Nuclear Safety which entered into force on 1<sup>st</sup> October 2002 number of regulations shall be issued by the government (governmental regulations) as well as by ministers (ministerial regulations). Due to that fact the Act establishes the comprehensive system of regulations that requires the involvement of several ministries. Further, some of ministerial regulations are to be prepared autonomously and some of them in agreement or in co-operation with other ministers, so the harmonisation among ministries is required.

### 2 PURPOSE OF REGULATIONS

As defined in the IAEA Safety Guide No.50-SG-G9 "Regulations and Guides for Nuclear Power Plants"[1], the principal purpose in establishing a system of regulations is to

codify safety requirements of general applicability. The regulations should define for each stage of issuing a licence the licensing procedures and the safety requirements that are considered essential from the standpoint of ensuring the safety of the operating personnel and the public. Further, the regulations should define at least the minimum of requirements considered necessary by the regulatory body for achieving and maintaining safety and must be fully harmonised with the legislative requirements.

### **3 ESTABLISHMENT AND IMPLEMENTATION OF REGULATIONS**

According to [1] and IAEA TECDOC-1090 “Quality assurance within regulatory bodies”[2], the regulatory body should consider the following in order to establish a system of regulations.

- A regulatory body needs three basic resources: manpower, experience and information. To develop regulations the regulatory body should select personnel or have access to consultants, who have specialised qualifications. The regulation must be based on legislation of a Member State, however all other applicable sources of information can be used such as:

- safety related standards and recommendations prepared by other international organisations,
- regulations, guides and other relevant information produced by regulatory bodies in other countries,
- national legislation of other Member States, nuclear industry experience as documented in licensee records and reports,
- results of nuclear safety researches,
- reports and studies describing experience of nuclear power plants in other Member States,
- industrial standards in other countries in areas related or adaptable to nuclear power plants.

- A regulatory body should prepare in advance a uniform procedure for establishing, revising and revoking regulations. Such a procedure should be efficient and flexible enough to permit revisions. In addition a work plan for development of single regulation in which adequate resources including financial resources are carefully considered should be prepared in advance. With reference to such a Work - Plan the development of regulations should be continually monitored.

- The regulations must be written in clear, understandable and precise language in accordance with previously defined requirements for format, content and revision. Regulations should contain appropriate definitions of the terms used. Defined terms should be used consistently throughout the system of regulations. When preparing regulations current domestic and international practices must be considered.

- A regulatory body must be in case of use of regulations issued by other Member States fully cognisant of the provisions and requirements of its own legislation and simultaneously have a very good understanding of the practice in the Member State, whose regulation is being adopted or modified.

- A regulatory body must predict that revisions of procedures are enabled for reasons as for example changes of legislation, changes in the organisation, responsibilities, policy and procedures of regulatory body, experience gained by the regulatory body in the licensing process, unusual occurrences and accidental conditions, the need to improve or eliminate inadequate or impractical regulations, the acquisition of new results from research and development in the fields relevant to safety.

- A regulatory body must create a current directory of valid regulations and keep it current.

- Regulatory staff must be trained on the use and interpretation of regulations.

#### 4 SNSA PRACTICE IN DEVELOPING THE PROCEDURE

The development of regulations and guides is one of the main functions of a regulatory body and presents a core work process of the regulatory body. According to the new law the SNSA is responsible for drafting a considerable number of governmental and ministerial regulations (twenty). To complete such a comprehensive and pretentious task in a relatively short period of time, simultaneously taking into consideration the involvement of several stake holders and competent ministries the SNSA developed within the Quality Management System a special procedure that documents a process of a systematic approach to the preparation of regulations which fall within the competence of the SNSA.

The procedure “The Development of Regulations” is divided into six subprocesses: Initiating Stage, Planning the Project, Performing, Harmonisation Stage, Approval and Archiving.

##### 4.1 Initiating Stage

The initiating stage consists of the following activities:

- appointment of the Project Management Team,
- defining the scope of work.

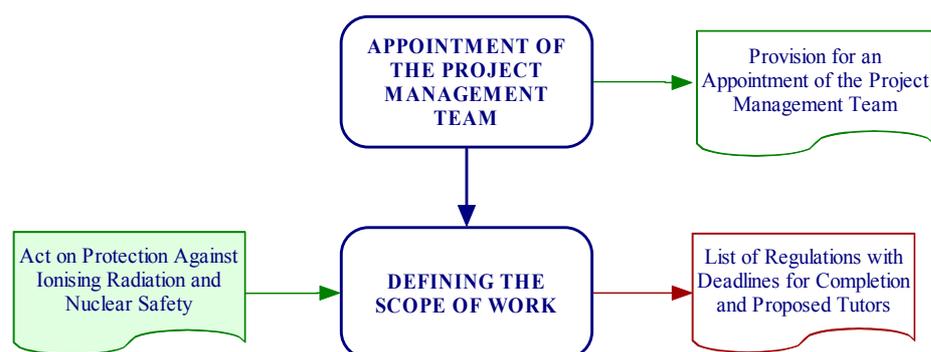


Figure 1: Initiating Stage

The purpose of Initiation stage of the project is to ensure that before significant resource is spent on the project, everything involved in the project is agreed [3].

The first activity of the initiating stage was the appointment of the Project Manager and the Project Management Team by the SNSA’s director. The Project Manager’s prime responsibility is to run the project of developing the system of regulations in a way which ensures that all project tasks are correctly fulfilled within the specified constraints of time and costs while the main responsibility of the Project Management Team is to provide support to the concerning Project Manager when required. The Project Management Team prepared the document “List of Regulations”, which was reviewed and approved by the SNSA’s director. The document defines:

- the working titles of regulations within the scope required by the law,
- deadlines for issuing the regulations,
- proposed appointed persons who are responsible, that the regulations are being drafted correctly and in time,
- proposed drafters and revisers and
- expected costs of the project.

## 4.2 Planning Stage

In the stage of planning the project the Project Manager makes the arrangements for:

- appointment of managers of regulations by the SNSA's director,
- preparation of the Work - Plan
- selection of drafters and revisers and
- making the contract with external drafters and external revisers.

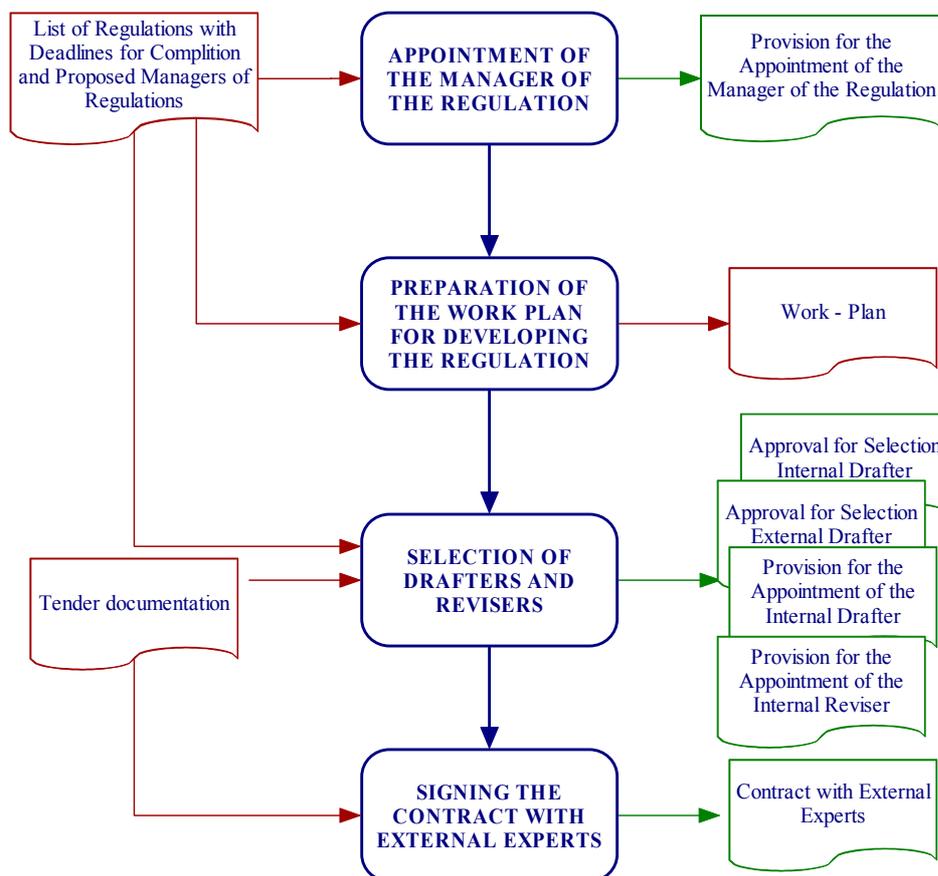


Figure 2: Planning Stage

The appointed managers of regulations are the SNSA employees, meanwhile the drafters and revisers can be the SNSA employees or external experts, however the selection of external drafters and revisers must be performed by public tenders according to the requirements of the Slovenian legislation. The Project Manager is responsible for preparation of a Work - Plan on the bases of input data gained from the document "List of Regulations" and from the "Provisions for Appointments". The Project Manager is also responsible for making arrangements for monitoring currently (once a week) proceeding of work against the Work - Plan.

## 4.3 Performing

The performing stage consists of:

- preparation and review of the document "Bases of the Regulation" ("Bases"),
- preparation of the draft,

- internal and external review of the draft,
- preparation of the proposal.

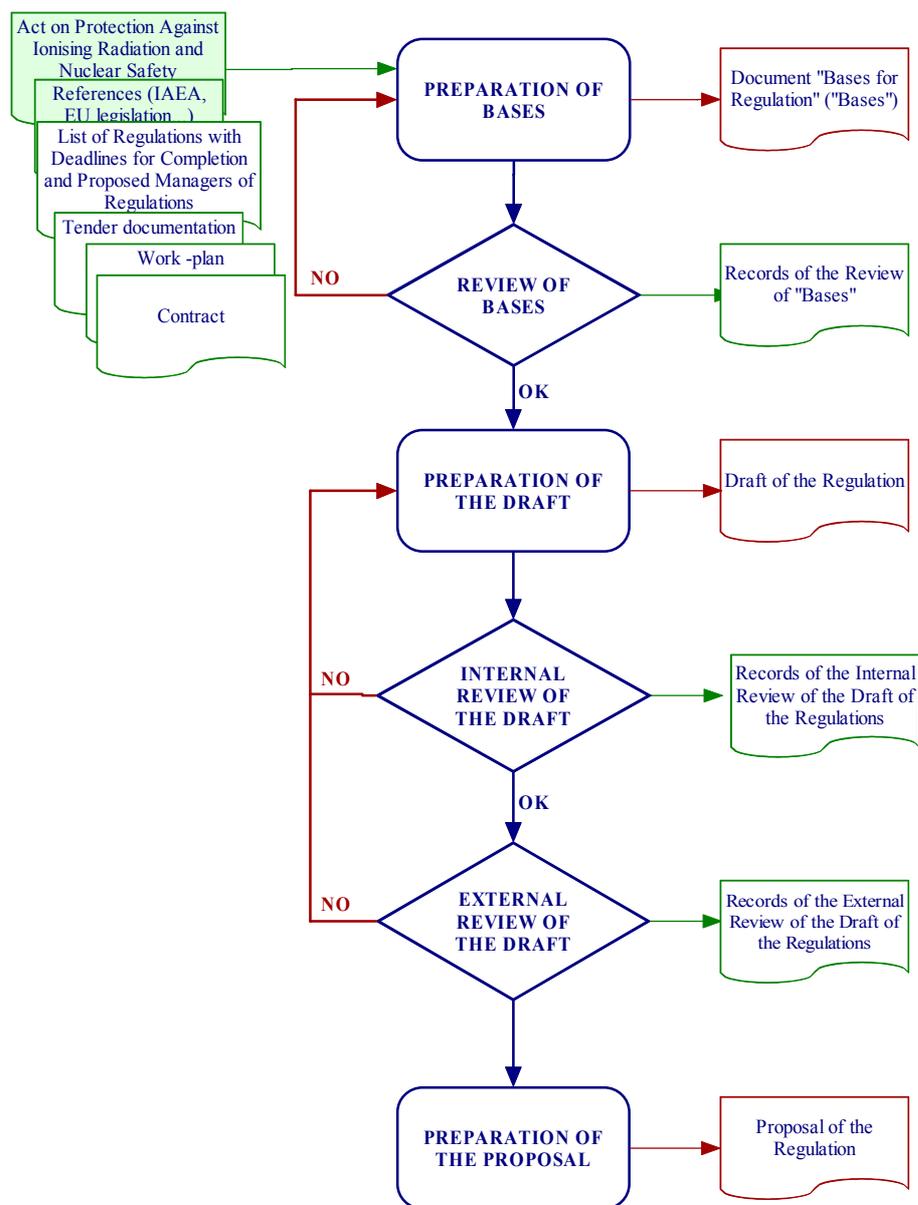


Figure 3: Performing of Development of Regulations

The appointed manager of the regulation is responsible for preparing the bases for developing the regulation. Adequate, sufficient and accurate inputs are a prerequisite for successful performance of the project.

All the input data are gathered in a special document “Bases for Regulation” and are handed over to the drafter of the regulation.

The document “Bases for Regulations” must as a rule define the following:

- Legal bases of the regulations
- Legislation which is substituted by the new regulation
- Structure of the regulation
- Definitions of terms
- Open expert questions

- Technical requirements for preparation the regulation
- Connection of single articles of the regulation with the source literature
- Deadlines
- References

The appointed manager of the regulation is responsible for making arrangements for the preparation of the draft, and for organising internal and external revisions as well as for the preparation of the proposal of the regulation on the bases of gained and accepted remarks.

#### **4.4 Harmonisation Stage**

The appointed manager for development of the regulation is responsible that the harmonisation stage is performed in accordance with accepted arrangements. The harmonisation stage to a high degree depends for example on type of regulations (ministerial or governmental), number of different participants that are engaged in preparation of regulations, etc. The harmonisation stage usually consists of the following activities:

- co-ordination inside expert working group (most time consuming),
- harmonisation among ministries in case of governmental regulation or inter-ministerial regulation,
- observations of stakeholders,
- proceedings within the framework of the round table,
- proceedings within the framework of the State Expert Council for Nuclear Safety,
- language review and finalisation,
- final review by the Legal Department of the Ministry, the Office for Legislation, the State Secretary, and other competent authority,
- preparation of the camera ready copy.

The preparation of the camera ready copy can be made only within consideration of all accepted observations and remarks

#### **4.5 Approval**

The Project Manager is responsible that the camera ready copy of the regulation is delivered to the state secretary for final approval according to the governmental procedures. The regulation enters into force after it is published in the Official Gazette of Republic of Slovenia.

#### **4.6 Archiving**

The appointed person for development of the regulation is responsible that all documentation in connection with published regulation is archived as defined in SNSA procedures for documentation requirements.

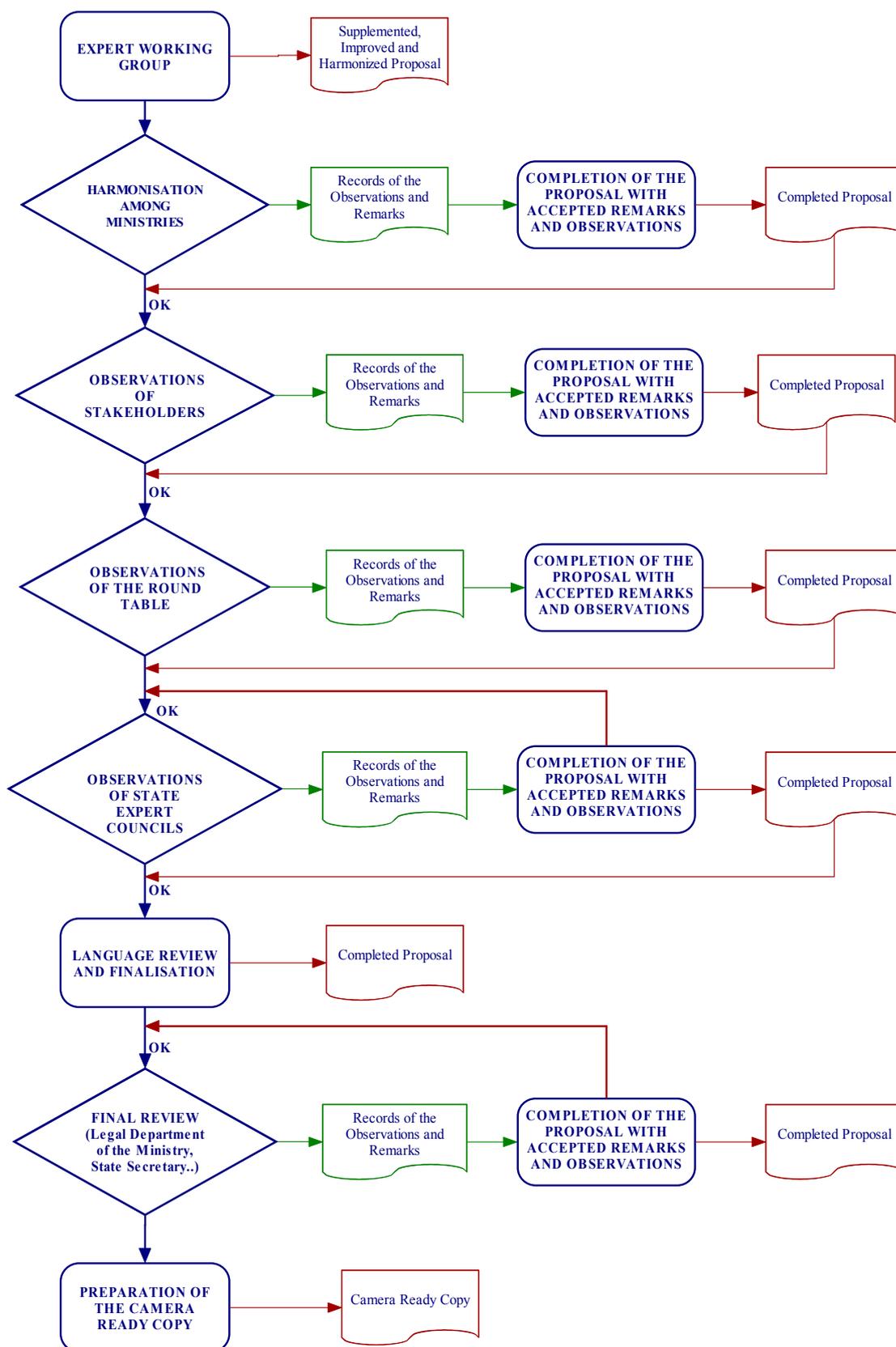


Figure 4: Harmonisation Stage

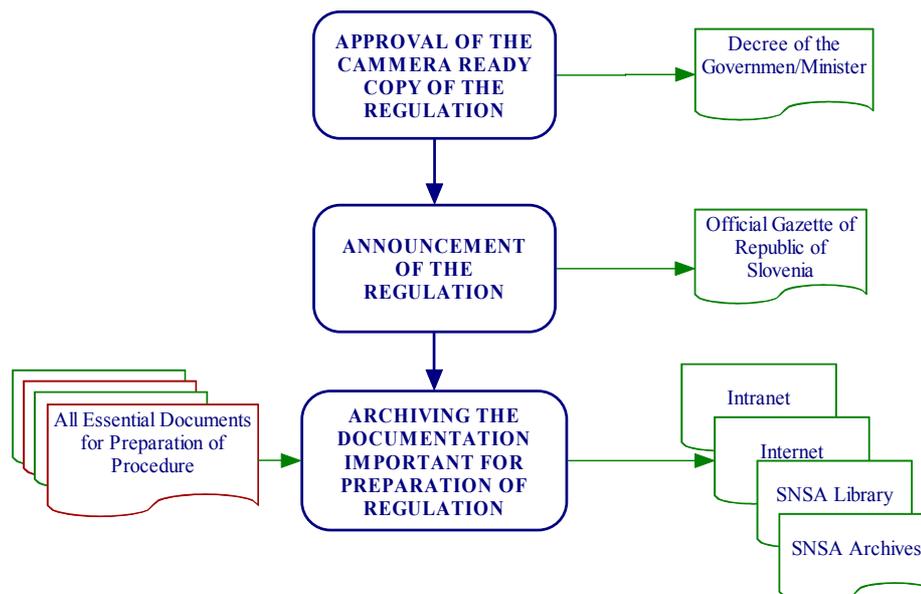


Figure5: Approval and Archiving

## 5 CONCLUSIONS

The establishment of the system of regulations is an integral part of the SNSA work and it will entail a development effort over two years, therefore more attention must be paid to the efficiency and effectiveness of regulatory work. For that reason the SNSA developed the quality management procedure on development of regulation in the form of the process approach which describes stages of the process as well as their inputs, outputs and feedback loops within the process. The advantage of such a written procedure with clear allocation of responsibilities, interfaces, resources and deadlines was recognised. Due to the limited resources the implementation of the described procedure is sometimes difficult so that according to the quality management practice the procedure is assessed and when necessary is improved.

## REFERENCES

- [1] IAEA Safety Guide No.50-SG-G9 “Regulations and Guides for Nuclear Power Plants”, A Safety Guide, Vienna, 1984, pp. 3-18.
- [2] IAEA TECDOC-1090 “Quality assurance within regulatory bodies”, Vienna, 1999, pp. 18-19.
- [3] CCTA, Managing a Successful Projects with PRINCE 2., pp 17-32.