

<b>Confidentiality Level</b>	BL - Restricted for internal use	<b>TC ID / Revision</b>	00163567 / B
<b>Branch</b>	Q - Quality	<b>Document Status</b>	Document Released
<b>Level</b>	Process (M,Q,S)		
<b>Document Type</b>	Methodology		
<b>PBS Code</b>	N/A		
<b>WBS / OBS Code</b>	1.2 /		

## **INSTRUCTIONS FOR USE**

*(guide for preparation and specification of the content)*



### **Keywords**

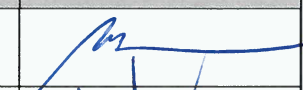

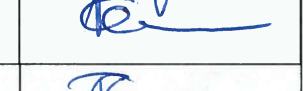

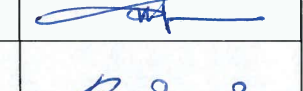
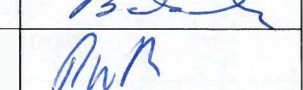
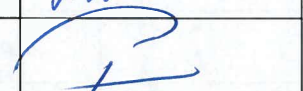

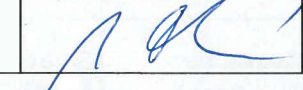

Product User Manual, Operating Manual, Operating Procedure

	<b>Position</b>	<b>Name</b>	<b>Signature</b>	<b>Date</b>
<b>Prepared by</b>	Quality engineer	Pavel Tůma		20. 2. 2018
<b>Agreed by (manager)</b>	Safety team Leader	Veronika Olšovcová		20. 2. 2018
<b>Quality Assurance</b>	Quality manager	Viktor Fedosov		20. 2. 2018
<b>Approved by</b>	Project Manager	Roman Hvězda		21. 2. 2018

### Revision History / Change Log

Change No.	Made by	Date	Change description, Pages, Chapters	TC rev.
1	Pavel Tůma, Viktor Fedosov	06.02.2018	Drafting the document	A
2				
3				
4				
5				
6				

### Reviewed By

Name (Reviewer)	Position	Date	Signature
Andrej Mlích	Technical Coordinator for L3	26.2.2018	
Franek Tomáš	Safety Engineer	22.2.2018	
Jaroslav Kašpar	Safety Engineer	20.2.2018	
Marek Bizdra	EHS Specialist	20.2.2018	
Martin Laub	Team Leader of Mechanics	20.2.2018	
Pavel Bakule	Team Leader Scientific	22.2.2018	
Pavel Bastl	Control System Team Leader	27.2.2018	
Petr Procházka	Biosafety Officer and Safety Expert	20/02/18	
Roman Kuřátko	Facility Manager	20.2.2018	
Veronika Olšovcová	Safety team Leader	20.2.2018	



## Table of Content

1. Purpose .....	4
2. Scope .....	4
3. Glossary of abbreviations and terms .....	5
3.1. Terms and definitions according to IEC 82079-1 (see [1]): .....	5
3.2. General ELI terms and abbreviations .....	6
4. Related/Reference and Applicable Documents .....	6
4.1. Applicable documents .....	6
4.2. Reference Documents .....	6
5. Roles and responsibilities .....	7
6. Content of instructions for use .....	7
6.1. Foreword .....	7
6.2. Expected Content of instructions for use .....	7
<1>. General .....	7
<2>. Identification of instructions for use .....	8
<3>. Identification (description) of the product .....	8
<4>. Modification of the product .....	9
<5>. Safety-related information .....	9
<6>. Product compliance .....	10
<7>. Preparing the product for use .....	10
<8>. Operation of the product .....	11
<9>. Maintenance of the product .....	11
<10>. Supplied accessories, consumables and spare parts .....	12
<11>. Information on special tools, equipment and materials .....	12
<12>. Information on repair of products and replacement of parts .....	12
<13>. Information required when the product is no longer needed .....	12
7. Annex 1. General ELI quality requirements for a supplier identifying necessity to provide Product Manual .....	14
8. Annex 2. An example checklist for review of Instructions for Use .....	15
9. Annex 3. Structure of instructions for use content .....	18
10. Annex 4 Types of hazards: .....	18

## 1. Purpose

The purpose of the document is:

- To identify the content of instructions for use for products to be developed (purchased) within ELI project in accordance with [2] and [3], see also Annex 1 of the document.
- To provide a reference frame for verifying the content of the instruction for use for products to be reviewed within the Technology Readiness Review Program (TRRP, see [4])
- To ensure that the content of instruction for use is suitable for the organization of compulsory personal training as required by the Labor Code of the Czech republic (see, [10])

## 2. Scope

This document was developed in accordance with IEC 82079-1 ([1]) principles and serves as a guide for specifying the content of all types of instructions for use (manuals) that will be necessary or helpful for systems (Device, Equipment) users to be developed and operated within ELI research programs to achieve required scientific objectives as well as to ensure relevant technical support solutions.

The document is intended for all parties involved in the preparation of instructions for use, for example:

- External and internal suppliers, technical writers, hardware/software designers or other people engaged in the work of conceiving and drafting such instructions for use.

As a guide, the document provides to the point, concise and specific information for authors of relevant technical documentation but does not define a complete set of the requirements for the contents of instructions for use.

Also, the document does not specify a fixed amount of documentation that has to be delivered with a product. The amount of documentation required, depends on the nature of the product, its complexity and the skills of the intended users.



### 3. Glossary of abbreviations and terms

*For the purpose of this document, the following terms, definitions and abbreviations apply:*

#### 3.1. Terms and definitions according to IEC 82079-1 (see [1]):

Instructions for use	<p>Information provided by the supplier of a product to the user, containing all the necessary provisions to convey the actions to be performed for the safe and efficient use of the product</p> <p>NOTE: Instructions for use of a single product comprise one or more documents, including product operating manual, maintenance procedure(s), getting started manual, etc.</p> <p>NOTE: The term Manual can be used as a synonym.</p>
Manual	<p>Document containing information for the use of a product</p> <p>NOTE: The term Manual covers such terms commonly used in ELI as: Product User Manual, Operating Manual, Operating Procedure or similar instructions and descriptions for equipment provided by external supplier as well as for equipment to be completed in ELI in accordance with a particular intended use.</p> <p>NOTE: The term Instruction for use can be used as a synonym.</p>
Product	<p>Intended or accomplished result of labor, or of a specific process, which could be a good or service</p> <p>NOTE: Instructions for use are seen as a part of a product.</p> <p>NOTE: The term "product" as defined in IEC 82079-1 relates to consumer, non-consumer, electrical, electronic, electromechanical, and mechanical, software and other products type.</p>
Equipment	<p>Associated assemblies intended to achieve a defined final objective</p>

### 3.2. General ELI terms and abbreviations

EHS team	Environmental Health and Safety team
Device	Any physical equipment, product or group of them which will be used and operated in ELI-BL
Device owner	Person who is responsible for the Device operation
DO	Device owner
TC ID	Teamcenter identification number. Unique ID given by Teamcenter as soon as the document is assign in to the TC
ELI-Beamlines (ELI-BL)	Czech pillar of the ELI project
EUN	ELI Unique Number
PBS	Product Breakdown Structure. Hierarchical breakdown (product tree) of the whole technology system providing details about the physical components of a particular product, or system, under consideration.
PBS code (PBS ID, PBS#)	A unique identifier (code) assigned to each component in a Product Breakdown Structure (PBS).

## 4. Related/Reference and Applicable Documents

### 4.1. Applicable documents

- [1]. IEC 82079-1-2012 (ČSN EN 82079-1 / 2013) – Preparation of Instructions for use - Structuring, Content and Presentation

### 4.2. Reference Documents

- |       |   |              |
|-------|---|--------------|
| [2].  | General Quality Requirements Category-A,B           | TC#00106507  |
| [3].  | General Quality Requirements Category-C,D           | TC#00106508  |
| [4].  | Technology Readiness Review Program                 | TC#00142889  |
| [5].  | Laser Safety Manual                                 | TC#00142979  |
| [6].  | Dangerous goods transportation                      | TC#00142977  |
| [7].  | Safety management system for lifting device         | TC#00152996  |
| [8].  | Waste Management                                    | TC#00142895  |
| [9].  | Electrical Safety Manual                            | TC# 00142981 |
| [10]. | Act No. 262/2006 Coll. (Paragraph 2 of Section 103) |              |



## 5. Roles and responsibilities

In according to applicable standard ELI quality requirements (see [2] and [3]) Device Owner shall ensure that each Device under his/her responsibility has to be completed by appropriate user documentation allowing safe operation of Device including required training of the operating staff (see [10]).

## 6. Content of instructions for use

### 6.1. Foreword

This methodology shall be applied as a guide to create the instructions for use for effective and safe operation of the product (Device, Equipment, System incl., software) to be developed and delivered within ELI project.

Instructions for use and its content shall be adapted to the scope and complexity of the product and its operation.

The instructions for use shall be developed in accordance with 3x ASAP.

1. as suitable as possible
2. as simple as possible
3. as soon as possible

Following chapters are focused primarily on the product manual creation but can also be applied for request specification for the appropriate documents from external suppliers or producers.

Each product manual has to be created with respect to intended use including expected operating conditions and define rules for product safe and reliable operation.

### 6.2. Expected Content of instructions for use

#### <1>. General

The instructions for use shall describe the functionality and characteristics of the product and provide answers to user questions such as: WHERE? WHO? WHAT? WHEN? HOW? This information shall correspond to the target group of users, conform to the product intended use and involve the required handling with the product at all stages of the product's lifecycle.

## <2>. Identification of instructions for use

The document shall enable unambiguous identification of instructions for use by following information:

- Unique identification number (TC ID and its revision);
- Date of issue;
- Identification of the publisher (author) of instructions for use including publisher's address if different from the supplier.

## <3>. Identification (description) of the product

The product identification shall include specification or description of the product and enable the user to identify the product through:

- Product identification number, i.e. serial number, version/model or/and type of the product including PBS and EUN, if required
- Supplier's name / identification, including contact details relevant for communication;
- Identification of providers of special tools, materials and technical assistance as the name, address, telephone number, fax number, e-mail address, and any other possible means of communication.

In addition, the product specification or product description shall provide a general overview of requirements, characteristics and performance and, If possible, provide the following information concerning the product:

- Complete measurements, such as weight, volume capacity and performance;
- Information on power consumption and input voltage, isolation category;
- Requirements for gas supply (e.g. type, pressure, etc.), water supply and for other relevant items as cleaning agents, cleaning consumables, lubricants, and electrical fuses (e.g., type, nominal value and characteristics);
- Operating conditions, operating environment specification and required interfaces;
- Emitted noise level;
- Electromagnetic compatibility;
- Qualification requirements for operating and maintenance personnel, etc.;
- Standard and optional accessories;
- Standards and legal requirements that the product meets;
- Expected product life and safe disposal at the end of the product operation;
- Notes on intended use and reasonably foreseeable misuse of the product.



**<4>. Modification of the product**

If the supplier does not allow for the product to be modified this shall be clearly stated in the instructions for use, including information about possible consequences resulting from a modification. Where applicable, it should be clearly stated that any product modification by the user is not recommended and any consequences will not be covered by support services or product warranties.

If the supplier allows users to modify the product, both permissible (and non-permissible) modifications, it shall be clearly described in the instructions for use. In this case, instructions for use shall clearly define and illustrate how to undertake permissible modifications (or direct the user appropriate to a source of relevant information), so as to allow the user to modify the product correctly and to ensure continuing safe and efficient operation.

**<5>. Safety-related information**

Safety information includes all potential risks and hazards. There has to be described each potential hazard related to the product. List of supposed types of hazards is in Annex 4 (chapter 10). In general, safety information should cover:

- The intended use of the product, the main function / purpose and scope of use and the basic safety principles to be observed; (also electrical safety [9])
- Limits of the use of the product regarding, for example, place, time, environment and mode of the operation, materials and additives, any necessary tools, as well as climatic conditions for operation and storage, such as temperature and humidity, explosive atmosphere, limits for outdoor operation...
- Clear defined information about personal protective equipment (for example, clothing, protective goggles);
- Protective features that need to be installed or activated by users;
- Potential hazards or precautions for specific groups of persons of which users shall be aware and which would not be immediately obvious without being pointed out;
- Description of the user type (e.g., level of experience and skills of persons)
- Specific indications that the product is no longer safe to use
- Information regarding safe disposal
- Explanation of graphical symbols used in safety-related information (ISO 7000, ISO 7010, IEC 60417);
- Signal words and/or graphical symbols including safety signs:
- Warning messages on hazards;
- Warning messages on reasonably foreseeable misuse:
- Warning messages on radiation, including any identified hazard, for example, sources of ionizing radiation, laser (in accordance with [5]) including related docs and IEC 60825-1), microwave, ultraviolet, infrared and lethal voltages etc.



**<6>. Product compliance**

Where applicable, the instructions for use shall contain information on product compliance with the legislation and other standards applicable to the product.

Where applicable, the purchased product shall have also the CE Declaration of Conformity.

**<7>. Preparing the product for use**

Where applicable, the instructions for use shall include information for product protection and the required safety of persons during transportation, manipulation and storage, installation and commissioning of the product.

**7.1. Transportation, manipulation and storage**

Instructions for use shall define requirements, appropriate methods for transportation, manipulation and storage of the product including:

- Dimensions, mass, and center of gravity (for large, heavy parts or for parts requiring difficult or dangerous manipulation or transport)
- Methods of lifting, handling and transportation that are ergonomically efficient and prevent damaging impacts and unexpected shocks (see also: [7] and [6])
- Qualification requirements for personnel which shall ensure or/and execute the manipulation
- Requirements for storage including specification of ambient conditions (temperature, humidity, cleanness...)
- Unpacking and Packaging the components for reuse
- Safe disposal of packaging

**7.2. Installation**

If necessary, the instructions for use shall define logic and identify the sequence of all activities to ensure and execute the installation of the product, namely:

- Sequence of the installation work (mechanical erection, assembling and integration of the system/equipment, interfacing with support building and engineering services, cleaning etc.,) to achieve required configuration of the product;
- Sequence of verification activities (inspections and tests) to provide evidence that stated installation requirements have been met.

Including the following information:

- Appropriate safety instructions
- List of all components (including assembly material)
- List of tools used needed for assembly and installation (including special tools)



- Conditions for unpacking, assembly and mounting (e.g. cleanness)
- Cleaning procedure
- Interface diagrams and requirements for interfacing the product with the power, gas, vacuum and other supplies

### 7.3. Commissioning

Where applicable, the instructions for use shall specify a procedure of product functional and performance verification to provide evidence that the installed and verified product (equipment) meets the operation requirements for determined level of the product (equipment) configuration.

## <8>. Operation of the product

The instructions for use shall contain information regarding normal and safe operation as well as abnormal operation of the product, specifically focused on:

- Definition of normal operating modes and regimes including description of relevant operation procedures
- Description of automatic and remote control of the product
- Indications of faults and warning signals
- Exceptional/emergency situations
- Troubleshooting and repair by non-skilled persons
- Troubleshooting and repair by skilled persons

## <9>. Maintenance of the product

The document shall contain information on product maintenance including required cleaning procedures. The maintenance can be carried out by both skilled persons and persons without professional qualification (non-skilled). Relevant specification of the maintenance focused on qualified and unqualified personnel shall preferably be presented as separate documents, or at least as separate chapters.

Instructions for use shall provide a list of possible maintenance and cleaning tasks including the frequency of tasks as well as inspection activities and related records. Materials and tools used for the maintenance and cleaning, for example, appropriate chemical substances, cleaning cloths and brushes. Risks arising from the use of inappropriate materials and tools shall be clearly specified. Following information shall also be specified in maintenance description:

- Maintenance plan including preventive and predictive maintenance to ensure continuous availability, reliability and safety of the product
- Cleaning plan (schedule)
- The nature and frequency of maintenance and cleaning inspections, related reporting and problem solving procedure



- Safety precautions and warnings needed when maintenance is carried out on powered on or operated product
- Drawings and diagrams enabling effective execution of maintenance task
- Regular inspections of alert equipment, related records, reporting and problem solving procedure
- Details of cleaning methods. Where there is a possibility of an improper cleaning or decontamination process, or the use of incorrect cleaning materials that lead to a safety hazard or problems resulting from corrosion or weakening of structural parts of a product, this shall specifically be stated
- Safe and documented disposal of waste, recycling, etc. (see [8])

#### **<10>. Supplied accessories, consumables and spare parts**

If required, the chapter shall specify accessories, consumables and spare parts required to ensure correct and safe operation and maintenance of the product.

#### **<11>. Information on special tools, equipment and materials**

If required, the chapter shall specify special tools, equipment and materials required to ensure correct and safe operation and maintenance of the product. Also, the chapter shall contain specific safety instructions for use of special tools, equipment and materials and appropriate requirements for needed personnel training.

#### **<12>. Information on repair of products and replacement of parts**

In case, the supplier and the law allow the customer to replace the parts of the product by himself, the following data should be identified in the instructions for use:

- method of repair or replacement; and
- a test method to verify the repair result

In case, the supplier does not allow the customer to replace parts by self-help, information about the relevant service organization shall be provided.

#### **<13>. Information required when the product is no longer needed**

Instructions for use shall contain information relating to handling, recycling or disposal of the product after it is no longer needed.

##### **13.1. Disassembly**

Disassembly by the customer shall only be permitted where this does not create a hazard. Where appropriate, the instructions of use shall include information, separately



or in combination, on correct disassembly of the product including handling of waste materials with due regard to safety and environmental considerations (e.g., see [8])

### 13.2. Recycling

Where specific procedures are necessary for recycling of the product or its components, these shall be specified in accordance with applicable legal requirements, safety regulations and/or relevant product standards.

### 13.3. Disposal

Instructions for use shall provide relevant information for the user on waste disposal and environmental protection.

In case the product contains any hazardous substance or if any hazardous substance is supplied together with the product, the necessary information on its constituents and the correct disposal procedure shall be involved in the instructions for use in accordance with safety and legal requirements.

## 7. Annex 1. General ELI quality requirements for a supplier identifying necessity to provide Product Manual

For products of category A and B (see [2]):

REQ-007179/A

The Supplier shall provide the Product Manual as part of the delivered Device. Completeness of the Manual shall be approved by the CA. The Manual shall include the instructions and descriptions regarding the following procedures:

- transport;
- handling;
- storage;
- installation and calibration (if required);
- safe operation and maintenance procedures

For products of category C and D (see [3]):

REQ-006935/A

The Supplier shall supply the following relevant manufacturing documents:

- Product Manual with instructions and descriptions regarding transport, handling, storage, installation, calibration, cleaning, safe operating (including step-by-step aligning procedure) and maintenance;
- Design supporting documentation (i.e. technical documentation);
- Breakdown list as built.

Verification method: R – review, I - inspection



## 8. Annex 2. An example checklist for review of Instructions for Use

A list, contained in a table A2.1, is based on EN 82079-1:2012 requirements for instructions for use of a product but should not be considered exhaustive.

This list includes verification criteria that could be applied during review of Product Manual (instructions for use of the product)

Table A2.1 – Checklist for conformity and comments  
(See TC\_00163567-A\_Annex\_2\_Instructions for Use\_Check List.xlsx)



TC\_00163567-A\_Annex\_2\_Instructions fo

Items of Product Manual to be checked		Compliance (Y/N)	Comments
<b>1.</b>	<b>Product (Device, Equipment) identification</b>		
1.1	Brand and type designation		
1.2	No. of model, version, type, subgroup		
1.3	Expiry date		
1.4	Up-to-date check / for example. date of publication of the handbook coverage of product modifications		
1.5	Supplier and provider of special tools, material etc. and technical assistance		
1.6	Contact details of supplier/service agency		
1.7	Certification references		
1.8	Requirements of specific product standards		
<b>2.</b>	<b>Product technical specification and its residual hazards</b>		
2.1	Functions and range of application		
2.2	Safe and correct use: principal residual hazards. general warnings about product or use		
2.3	Dimensions — mass — capacity		
2.4	Chemical composition		
2.5	Performance data		
2.6	Supply data for power, gas, water and other consumables (for example. detergents. lubricants)		
2.7	Energy consumption and methods of measurement used		

2.8	Emission of noise, waste water, etc., with methods of measurement used		
2.9	Expected product life and intended disposal		
2.10	Information on personal protection (for example. clothing)		
2.11	Information on dangers to particular vulnerable groups (for example. potential allergy or strobe effects)		
<b>3.</b>	<b>Preparing the product for use</b>		
3.1	Safely precautions before installation		
3.2	Unpacking		
3.3	Sale disposal of packaging		
3.4	Installation and assembly (for example. special tools. space for maintenance and repair)		
3.5	Storage and protection during intervals in normal use		
3.6	Repackaging to prevent damage in transport		
3.7	Information on operations to be carried out only by skilled persons. Separation of this information from instructions for use to users. Comprehensiveness of instructions for use to experts.		
<b>4.</b>	<b>Product operation</b>		
	- structure from basic to sophisticated operations/functions		
	- meaningful separation between basic product and optional modules		
4.1	Basic functions		
	- Complete for correct intended use		
	- Complete for safe intended use		
	- Complete for reasonably foreseeable misuse		
	- Conformity with minimum list in relevant product standard(s)		
4.2	Secondary functions (identical to 4.1 above)		
4.3	Optional modules and extras		
4.4	Personal protection		
4.5	Quick references		
	- by reminder cards, stickers or labels		
	- by reference to handbook. etc.		
4.6	Disposal of waste products		
<b>5.</b>	<b>Information needed by user</b>		
5.1	Explanations of visible and audible signals		
5.2	Distinctions between characteristics of normal and faulty/dangerous operation		
5.3	Trouble-shooting advice (for example. in the form of Frequently Asked Questions and fault detection procedures) - intelligible to consumers and paying due regard to safety		



<b>6.</b>	<b>Maintenance of the product</b>		
6.1	Safety precautions (for example. personal protection. special tools)		
6.2	Product maintenance by non-skilled persons		
6.3	Product maintenance by skilled persons		
6.4	Safety/deterioration checks during maintenance		
<b>7.</b>	<b>Critical information on safety and health</b>		
7.1	Warning messages <ul style="list-style-type: none"> <li>- correct locations <ul style="list-style-type: none"> <li>• on product and/or</li> <li>• on packaging and/or</li> <li>• in instructions for use</li> </ul> </li> <li>- it relevant, visibility at point of sale</li> <li>- correct use of terms</li> <li>- correct use of signal words</li> <li>- use of simple/standardized phrases</li> <li>- durability of warnings</li> <li>- conformity with requirements in relevant product standard(s)</li> </ul>		
7.2	Safety signals		
7.3	Information on residual risk		
7.4	Safe disposal of product at the end of its useful life		
7.5	Environmental impacts of using the product		
<b>8.</b>	<b>Consistency of the information presented in Product Manual with the design and intended use of the product</b>		
8.1	Integrated design of product and instructions for use <ul style="list-style-type: none"> <li>- No compensation for design deficiencies</li> </ul>		
8.2	Consistent terminology on the product itself: on the packaging: in accompanying material, on Web site resources and in marketing media		
8.3	Structure of text and graphics <ul style="list-style-type: none"> <li>- structure follows communication principles</li> <li>- meaningful headings used</li> <li>- unnecessary material excluded to avoid information overload (for example. sales promotion. extensive repetition. too many documents)</li> </ul>		
8.4	Location(s) and presentation of instructions for use		
8.5	Numbered pages and/or paragraphs with table of contents and/or index appropriate to length and complexity of text. Use of keywords		

## 9. Annex 3. Structure of instructions for use content

The Annex provides a structure of the content of instructions for use in Czech and English (see TC\_00163567-A\_Annex\_3\_Instructions for Use\_Content.xlsx)



TC\_00163567-A\_Annex\_3\_Instructions fo

## 10. Annex 4 Types of hazards:

- <1>. Laser radiation hazard
- <2>. Ionizing radiation hazard
- <3>. Electrical installation hazard
- <4>. High voltage hazard
- <5>. Flammable gases hazard
- <6>. Toxic gases hazard
- <7>. Inert gases hazard
- <8>. Vacuum hazard
- <9>. Ozone hazard
- <10>. Toxic substances hazard
- <11>. Biohazard
- <12>. Electromagnetic interference hazard
- <13>. Magnetic field hazard
- <14>. Radioactive materials hazard
- <15>. Cooling system hazard
- <16>. Pneumatic hazard
- <17>. Pressurized systems hazard
- <18>. Robotic systems hazard
- <19>. Waste management hazard
- <20>. Mechanical factors (maintenance) hazard