Designation: F3527 – 21

Standard Guide for Assessing Risks Related to Implementation of Exoskeletons in Task-Specific Environments[1]

This standard is issued under the fixed designation F3527; the number immediately following the designation indicates the year of original adoption or, in the case of revision, the year of last revision. A number in parentheses indicates the year of last reapproval. A superscript epsilon (ε) indicates an editorial change since the last revision or reapproval.

1. Scope

1.1 When implementing exoskeletons in real-world work environments, exoskeleton interaction with various components of a given task and its environment can generate a number of risks. This guide provides guidance for conducting contextual risk assessment. A working document is provided in Appendix X1 to allow initiation of the risk assessment process. It can be used to describe tasks, break the tasks down into task elements, anticipate related harm scenarios (a series of typical harm scenarios are provided), assess related risks, and detect scenarios that may require further analysis or implementation of risk reduction measures.

1.2 This guide applies to exoskeletons administered by employers to paid workers or professionals to support work-related tasks and activities.

1.3 This guide addresses risks that may result in acute and observable injury and harm. This guide does not address the following topics and concerns related to exoskeleton use:

1.3.1 Assessment and prevention of risk factors that can lead to chronic, cumulative, or long-term injuries;

1.3.2 Use of exoskeletons to support rehabilitation and return to work;

1.3.3 Risks related to storage and use of personal information;

1.3.4 Risks that may result in damage of objects; and

1.3.5 Financial risks.

1.4 *Units*—The values stated in SI units are to be regarded as the standard. No other units of measurement are included in this standard.

1.5 *This standard does not purport to address all of the safety concerns, if any, associated with its use. It is the responsibility of the user of this standard to establish appropriate safety, health, and environmental practices and determine the applicability of regulatory limitations prior to use.*

1.6 *This international standard was developed in accordance with internationally recognized principles on standardization established in the Decision on Principles for the Development of International Standards, Guides and Recommendations issued by the World Trade Organization Technical Barriers to Trade (TBT) Committee.*

2. Referenced Documents

2.1 *ASTM Standards:*[2]

F3323 Terminology for Exoskeletons and Exosuits

F3427 Practice for Documenting Environmental Conditions for Utilization with Exoskeleton Test Methods

F3444/F3444M Practice for Training Exoskeleton Users

2.2 *Other Standards:*

EN 13921 Personal Protective Equipment - Ergonomic Principles[3]

ISO/IEC Guide 51 Safety aspects — Guidelines for their inclusion in standards[4]

ISO 31000 Risk Management — Guideline[4]

ISO 14971 Medical Devices — Application of Risk Management to Medical Devices[4]

3. Terminology

3.1 Many terms used within this guide are defined as in Terminology F3323 – 20. The following terms and definitions are used within this guide and are not defined within Terminology F3323 – 20.

3.2 *Definitions:*

3.2.1 *harm, n*—injury or damage to the health of people, or damage to property or the environment. **ISO/IEC Guide 51**

3.2.2 *harm scenario, n*—circumstance in which people, property or the environment is/are exposed to one or more hazards.

3.2.2.1 *Discussion*—Equivalent to "hazardous situation" defined in ISO/IEC Guide 51.

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[2] For referenced ASTM standards, visit the ASTM website, www.astm.org, or contact ASTM Customer Service at service@astm.org. For *Annual Book of ASTM Standards* volume information, refer to the standard's Document Summary page on the ASTM website.

[3] Available from British Standards Institution (BSI), 389 Chiswick High Rd., London W4 4AL, U.K., http://www.bsigroup.com.

[4] Available from American National Standards Institute (ANSI), 25 W. 43rd St., 4th Floor, New York, NY 10036, http://www.ansi.org.

3.2.3 *implementer, n*—natural or legal person responsible for purchase, administration and/or implementation of exoskeletons in task-specific environments.

3.2.3.1 *Discussion*—Legal person refers to a human or non-human entity that is treated as a person for limited legal purposes.

3.2.4 *producer, n*—natural or legal person with responsibility for the design, manufacture, assembly, packaging, or labeling of an exoskeleton, or adapting an exoskeleton before it is placed on the market or put into service, regardless of whether these operations are carried out by that person or on that person's behalf by a third party.

3.2.4.1 *Discussion*—Legal person refers to a human or non-human entity that is treated as a person for limited legal purposes.

3.2.5 *residual risk, n*—risk remaining after risk reduction measures have been implemented.

Adapted from ISO/IEC Guide 51:2014

3.2.6 *risk, n*—combination of the probability of occurrence of harm and the severity of that harm.

3.2.6.1 *Discussion*—The probability of occurrence includes the exposure to a hazardous situation, the occurrence of a hazardous event and the possibility to avoid or limit the harm (definition and discussion adapted from ISO/IEC Guide 51:2014).

3.2.7 *risk analysis, n*—systematic use of available information to identify hazards and to estimate the risk.

Adapted from ISO/IEC Guide 51:2014

3.2.8 *risk assessment, n*—overall process comprising a risk analysis and a risk evaluation.

Adapted from ISO/IEC Guide 51:2014

3.2.9 *risk evaluation, n*—procedure based on the risk analysis to determine whether tolerable risk has been exceeded.

Adapted from ISO/IEC Guide 51:2014

3.2.10 *risk reduction measure, n*—action or means to eliminate hazards or reduce risks.

Adapted from ISO/IEC Guide 51:2014

3.2.10.1 *Discussion*—Equivalent to protective measure.

3.2.10.2 *Discussion*—Examples of risk reduction measures are inherently safe design, protective devices, personal protective equipment, information for use and installation, organization of work, training, application of equipment, and supervision.

3.2.11 *safety, n*—freedom from risk which is not tolerable.

Adapted from ISO/IEC Guide 51:2014

3.2.12 *task element, n*—a component or constituent of a task to describe a certain part or the entire entity of the task.

3.2.12.1 *Discussion*—Equivalent to task component.

3.2.13 *task-specific environment, n*—the overall context in which a task is executed.

3.2.13.1 *Discussion*—Equivalent to operating environment.

3.2.14 *tolerable risk, n*—level of risk that is accepted in a given context based on the current values of society.

Adapted from ISO/IEC Guide 51:2014

3.2.14.1 *Discussion*—Equivalent to acceptable risk.

3.2.14.2 *Discussion*—Opposite to unacceptable risk.

4. Significance and Use

4.1 There is evidence to support use of occupational exoskeletons to support work tasks and activities. It is recognized that organizations, job responsibilities, and working contexts vary widely. Additionally, a wide array of exoskeletons are becoming available on the market. Exoskeletons vary in terms of complexity, form and mass, body coverage, and function. Certification programs for occupational exoskeletons are not available at this time. As such, at the present time no mechanisms exist to guarantee that circumstantial risk evaluation was performed on exoskeletons or whether these evaluations reflect the real working context in which exoskeletons will be implemented.

4.2 This guide provides a minimum baseline for assessing risks that may arise from exoskeleton interaction with existing and task-specific environments. The working document presented in Appendix X1 can be used to support decision making at different stages of exoskeleton implementation, such as:

4.2.1 *Purchase*—It can highlight safety concerns that may arise from introduction of a given exoskeleton technology in a specific work context;

4.2.2 *Implementation of Risk Reduction Measures*—It can highlight residual risks that require risk reduction measures;

4.2.3 *Detection of Unknowns*—It can lead to definition of additional steps that are needed to satisfy risk assessment for potentially hazardous situations;

4.2.4 *Risk Monitoring*—It can be used as a "living document" to monitor residual risks throughout the use period of the exoskeleton.

4.3 Harm scenarios described in this guide primarily reflect situations that may result in acute and observable injury or harm to a person. This guide is not suited for assessment of potential exoskeleton-to-task incompatibilities that may result in chronic, cumulative, or long-term injuries. However, these should be considered as part of any exoskeleton selection and implementation process. Guidelines on evaluation of risk factors that may lead to such injuries are currently under development and not yet published.

4.4 The user of this guide should evaluate the applicability of this guide for the given job context. The tool provided in Appendix X1 can be used as presented, can be adapted to reflect additional safety concerns, or elements of it can be used to supplement risk assessment tools existing in the enterprise where an exoskeleton is implemented.

4.5 The questions, statements, and harm scenarios provided in Appendix X1 are primarily targeted for assessment of risks that may endanger primary exoskeleton users. These can be modified to assess risks that may endanger secondary users, such as maintenance personnel, trainers, adjustment personnel, etc. It is recommended that risk assessment be conducted separately for each user type.

4.6 This guide can be used by non-specialized personnel to perform preliminary risk assessment, to aid, for example, pre-selection of exoskeleton models for purchase options. However, prior to implementing an exoskeleton in real-world

working contexts, risk assessment should be conducted by personnel having the knowledge and experience appropriate to perform such assessment. This should include detailed knowledge of user tasks, ability to perform task analysis, knowledge and experience with the particular exoskeleton model, and knowledge of methods and of limitations associated to risk analysis. As such, risk assessment may require involvement of multiple stakeholders, including ergonomists and human factors specialists, users, managers, producer representatives, and safety professionals.

4.7 This guide does not supersede any established laws or regulations of international, national, federal, state, tribal, local, or regional governments.

5. Procedure

5.1 Appendix X1 provides a series of questions and harm scenarios that can support initiation of the risk assessment process related to exoskeleton interaction with the user's task-specific environment. Additional blank forms are provided in Appendix X2, Appendix X3, and Appendix X4. The initiation of the risk assessment process relies on the following steps: (*1*) identify exoskeleton characteristics, (*2*) assess inherent risks related to the exoskeleton, (*3*) identify tasks and break down tasks into task elements, (*4*) assess risks resulting from the interaction of the exoskeleton with task elements, (*5*) detect harm scenarios that require additional analysis, and (*6*) detect harm scenarios that require implementation of risk reduction measures.

5.2 The process and applicable sections provided in Appendix X1 – Appendix X4 are illustrated in Fig. 1.

5.3 *Introductory Information:*

5.3.1 This section is used to record the following information: the date or period of assessment, the personnel who conducted the assessment ("assessors"), the exoskeleton make, model, and serial number, brief description of the exoskeleton user, and brief description of assessment results.

5.4 *Exoskeleton Description:*

5.4.1 This section is used to identify relevant information on the exoskeleton considered for implementation. Users of this guide should consult with the exoskeleton producer to ensure they have the latest and most relevant information on the exoskeleton, including its safety features, residual risks (for example, warnings), and recommended risk reduction measures.

5.5 *Harm Scenarios Inherent to Exoskeleton:*

5.5.1 This section provides a series of possible harm scenarios. It is used to detect and assess risks that may arise from exoskeleton use independently of a specific use context or interaction with specific task elements. These include harm scenarios that may arise from exoskeleton characteristics, such as release of hazardous media, uncertified electric components, damaged wiring, absence of emergency stop functions, etc.

5.6 *User Job Function and Tasks:*

5.6.1 These sections are used to list the user's job functions and tasks, and to anticipate tasks that would be executed in interaction with the exoskeleton. User job functions and tasks are identified by means of task analysis (references for fundamental notions of task analysis are provided in Appendix X5), and include:

5.6.1.1 *Essential Job Functions and Tasks*—Which correspond to the functions and tasks necessary to perform by the assigned position duties, such as manual handling of boxes in a warehouse, transport of military equipment, laying bricks, extinguishing fire with a firehose, and others.

5.6.1.2 *Non-essential Job Functions and Tasks*—Which correspond to accessory functions and tasks that may be unnecessary to perform the assigned position duties, such as walking down a hallway, use of staircases, adopting sitting rest postures, and others.

5.6.1.3 *Exoskeleton Specific Tasks*—Correspond to tasks related to general use, set up, and maintenance of the exoskeleton. These can include and are not limited to the following: retrieval from and disposal to storage, transport, assembly/disassembly, structural inspection, donning and doffing, and selecting modes of operation.

5.7 *Break Down into Task Elements:*

5.7.1 These sections are used to describe operating environments and task requirements.

5.7.2 Task elements should be captured for essential and non-essential tasks executed with the exoskeleton, as well as for exoskeleton-specific tasks.

5.7.3 Task elements are determined by means of task analysis (refer to Appendix X5), and include:

5.7.3.1 Personal characteristics of the user population,

5.7.3.2 Clothing and personal protective equipment,

5.7.3.3 Machinery and equipment,

5.7.3.4 Environment,

5.7.3.5 Handled and manipulated materials and objects,

5.7.3.6 Policies and procedures,

5.7.3.7 Social interaction,

5.7.3.8 Physical requirements,

5.7.3.9 Sensing requirements, and

5.7.3.10 Mental and cognitive requirements.

5.7.4 It is recommended that all listed task elements are carefully considered. The format of the tables can be modified and supplemented with additional items to reflect the user's operating environment and task requirements. A blank form for additional task elements is presented in Appendix X2.

5.7.5 Task elements may also be captured in the existing job assessment documentation (also known as job demands analysis and job analysis). In the case of existent job analysis documentation, the relevant information can be copied to or referred to in the applicable sections.

5.8 *Harm Scenarios Related to Exoskeleton Interaction with Task Elements:*

5.8.1 These sections are used to:

5.8.1.1 Detect potential harm scenarios based on task analysis which takes into consideration the addition of the exoskeleton in this context; and

5.8.1.2 Assess risks related to harm scenarios.

5.8.2 Harm scenarios presented in these sections address concerns related to a wide range of possible exoskeleton technologies and applications. As such, not all may be relevant to the implementation context. It is recommended that all harm

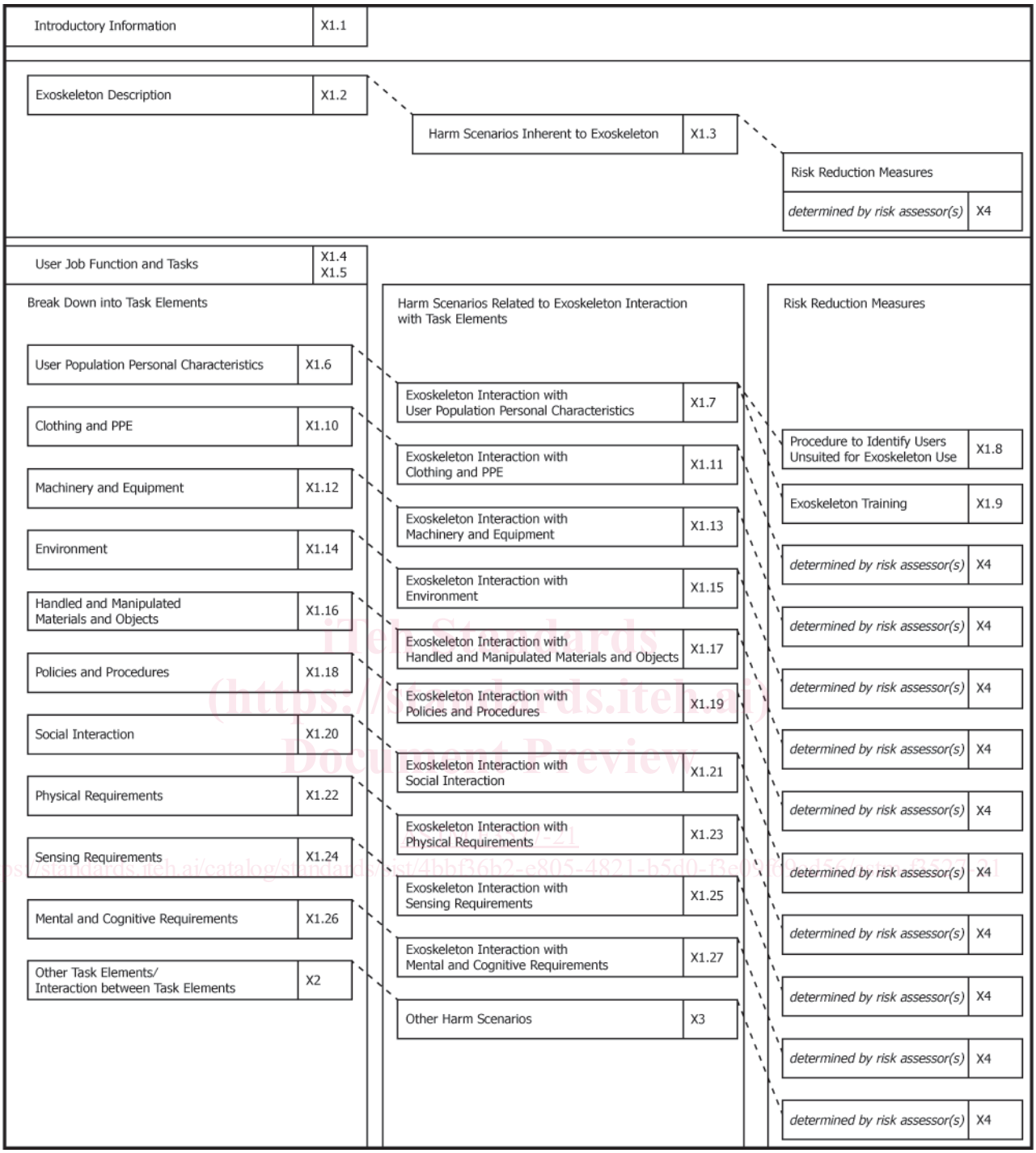

FIG. 1 Structure of the Working Document for Assessing Risks Related to Implementation of Exoskeletons in Task-Specific Environments

scenarios provided in these sections be considered for initial risk assessment. Unrelated harm scenarios may be omitted when a high confidence level is attained and is indicative of their irrelevance to the given exoskeleton technology and working context. Additional harm scenarios that reflect the implementation context should be included as necessary. A blank form for additional harm scenarios is presented in Appendix X3.

5.8.3 Risk assessment should be supported by an established risk matrix. Guidelines for defining a risk matrix are provided in Section 6.

5.8.4 Risks related to harm scenarios should be assessed for essential and non-essential tasks executed with the exoskeleton, as well as for exoskeleton-specific tasks.

5.8.5 While a number of risks can be anticipated, analysis of some risks may require considerable effort, including and not

limited to tests, simulations, and biomechanical analysis. Standard test methods to support risk analysis are being developed and are not yet published. Furthermore, caution is advised when assessing risks based on assumptions. Freedom from unacceptable risk should be supported and validated by simulations, limited field trials, and longitudinal field trials.

5.9 *Risk Reduction Measures:*

5.9.1 Risk reduction measures should be identified and described for all harm scenarios that present a medium to high level of risk, or as defined in the supporting "risk matrix" and "risk levels and required action" used by the assessor(s). Risk reduction measures can include and are not limited to the following: restrict the use of exoskeletons only for tasks or activities that are assessed as free of unacceptable risk, provide special training, define procedures that decrease risks to acceptable levels, modify and adapt task elements to exoskeleton use.

5.9.2 Appendix X1 includes two "risk reduction measures" sections that provide guidance to mitigate risks related to exoskeleton interaction with the personal characteristics of the user population:

5.9.2.1 Table X1.8: Procedure to identify users incompatible with exoskeleton, and

5.9.2.2 Table X1.9: Exoskeleton training.

5.9.2.3 These sections apply to any exoskeleton technology and application sector and should be addressed prior to exoskeleton implementation.

5.9.3 Risk reduction measures required to mitigate risks that arise from other exoskeleton-to-task elements interactions can be described in Appendix X4 or in a separate document.

5.10 *Additional Guidance:*

5.10.1 Some risks can be identified as they relate to a single class of "task elements," such as an exoskeleton that prevents the use of the fall arrest harness, related to the task element "clothing and PPE."

5.10.2 Risks may also arise from interaction of several "Task Elements" with an exoskeleton. For example, to assess whether the exoskeleton may cause acute and observable injury during a manual handling task, a more holistic analysis is typically required. That can include recording combinations of several task elements, such as the weight of handled objects and the posture that the user needs to adopt to complete the task, or other pertinent elements. It also implies consideration of exoskeleton weight supported on body segments and any assistance provided by the exoskeleton to the various articulations. Blank forms in Appendix X2 and Appendix X3 can be used to describe relations of "Task Elements" and to detail harm scenarios.

5.10.2.1 Certain risks may not be identified in the initial risk assessment stage, and become apparent only during the real use of the exoskeleton. Additionally, effectiveness of risk reduction measures should be validated prior to and monitored during real-world use of exoskeleton. It is, therefore, good practice to maintain and update risk assessment documentation after exoskeleton implementation.

6. Risk Matrix

6.1 A risk matrix, including definitions for severity, probability, as well as definitions for risk levels, are provided as examples in Table 1 and Table 2. They can be adapted and modified as relevant and necessary for the implementation context. If adaptation or modification is required, safety of the exoskeleton user and of persons interacting directly or indirectly with the user should be maintained as the primary goal.

7. Precision and Bias

7.1 The precision of risk assessment depends on the knowledge and experience of assessors as well as on the quality of data used for assessment. Furthermore, estimation of risk magnitude cannot be measured directly, and frequently requires use of assumptions. For this reason, it is recommended that absence of unreasonable risk be validated continuously, by progressively implementing the exoskeleton in complex real-world environments and monitoring potential harm scenarios after adoption of the exoskeleton for a job position.

7.2 The users of this guide should be aware of the limits of risk assessment, and that not all risk can be anticipated or eliminated for all use cases.

8. Keywords

8.1 accident; environment; exoskeleton; hazard; implementation; incident; injury; risk assessment; safety; task; use context; wearable robotics

TABLE 1 Risk Matrix[A]

		Severity		
		Minor Slight injury, that can be treated with first aid	**Moderate** Reversible injury which requires medical treatment (more than first aid)	**Significant** Permanent injury or injury resulting in death
Probability	**High** Likely to happen, often, frequently	Medium risk	High risk	Very high risk
	Medium Can happen but not frequently	Low risk	High risk	High risk
	Low Unlikely to happen, rare, remote	Very low risk	Low risk	Medium risk

[A] Additional information on risk matrix definition can be found in the following references:
ISO 31000 – Risk Management – Guideline
ISO 14971 – Medical Devices – Application of Risk Management to Medical Devices

TABLE 2 Risk Levels and Required Action

Risk level	Very low	Low	Medium	High	Very high
Action	No immediate action is recommended, but improve when feasible		It is recommended to redesign to remove hazard, or control with appropriate safeguards with a priority given to higher level risks		

APPENDIXES

(Nonmandatory Information)

X1. WORKING DOCUMENT FOR ASSESSING RISKS RELATED TO IMPLEMENTATION OF EXOSKELETONS IN TASK-SPECIFIC ENVIRONMENTS

X1.1 See Tables X1.1-X1.27.

TABLE X1.1 Introductory Information

DATE/PERIOD:		
ASSESSOR(S):		
EXOSKELETON	Make	
	Model	
	Serial number	
USER	Company/Agency/Institution	
	Department/Branch	
	Job title	
SUMMARY RESULTS		

TABLE X1.2 Exoskeleton Description

NOTE 1—Provide relevant description of the exoskeleton, based on information provided by the producer. Contact producer for missing information.

1. Exoskeleton:		Make
		Model
		Serial Number
2. Body coverage:		Full Body
		Upper Extremity
		Lower Extremity
		Torso
		Cervical
		Other, specify
3. Weight (kg):		
4. Actuation:		Electric, specify power source (ex: lithium-ion batteries):
		Pneumatic
		Hydraulic
		Spring
		No actuation
		Other, specify
5. Is the exoskeleton certified?		Yes, enumerate certifications:
		No
6. Was this exoskeleton model previously assessed for safety for this job position in the context of this company?		Yes, specify documentation related to the assessment
		No
		Unknown
7. Was this exoskeleton model previously assessed for safety for related job positions in the context of this or another company?		Yes, specify documentation related to the assessment
		No
		Unknown
8. Does the exoskeleton release oil or gases?		Yes, specify:
		No
9. Does the exoskeleton contain media under pressure (ex: oil, gases)?		Yes, specify:
		No
10. Does the exoskeleton contain hazardous substances?		Yes, specify:
		No
11. Does the exoskeleton contain easily flammable substances (solids/liquids)?		Yes, specify:
		No
12. Does the exoskeleton exhibit surfaces likely to become habitats for living organisms (fungi, germs, bacteria, mold)?		Yes, specify areas:
		No
13. Can explosive mixtures arise from the exoskeleton?		Yes, specify:
		No
14. Does the exoskeleton require wireless connectivity?		Yes, specify:
		No
15. Does the exoskeleton emanate radiation? Types of radiation include and are not limited to the following: nuclear, ultraviolet (UV), visible light, infrared (IR), microwave (MW), radio frequency (RF), extremely low frequency (ELF), particle (Alpha, Beta, Proton, and Neutron), magnetic fields and electric fields.		Yes, specify:
		No
16. Does the exoskeleton have an onboard emergency stop function that can be initiated by the user?		Yes, specify location and trigger (ex: button on chest):
		No
17. Does the exoskeleton have an emergency stop function that can be remotely initiated?		Yes, tethered
		Yes, wireless
		No
18. Does the exoskeleton have emergency doffing features?		Yes, specify:
		No
19. Can the exoskeleton be removed by another person if the user becomes incapacitated?		Yes
		No
20. Does safe use of the exoskeleton require supervision?		Yes, specify:
		No

TABLE X1.2 *Continued*

21. Check boxes of specific adjustments required for safe use of the exoskeleton		☐ Size adjustments ☐ Actuator adjustments ☐ Software adjustments ☐ Other, specify:

TABLE X1.3 Harm Scenarios Inherent to Exoskeleton

NOTE 1—Using the harm scenarios listed below and the information provided by the manufacturer, analyze and evaluate the inherent risks related to the use of exoskeleton. Verify hazards and warnings provided by the manufacturer to include respective risks. For severity, probability, and risk level determination, refer to Section 6 of this guide or any adapted risk matrix. Check boxes "control needed" for risks requiring risk reduction measures.

Harm Scenario	Severity	Probability	Risk Level	Control Needed
1. Exoskeleton can release media (oils, gases) that can poison or injure the user				☐
2. Exoskeleton can release media under pressure that can cause burns and injuries				☐
3. Exoskeleton employs tanks that can burst				☐
4. Exoskeleton exhibits mechanical failure hazards that may result in risk of injury				☐
Unsecured or loose nuts				☐
Damaged frame components				☐
Damaged elastic or spring components				☐
5. Exoskeleton exhibits electric hazards that may result in risk of injury				
Damaged wiring insulation				☐
Damaged equipment enclosures				☐
Faulty plugs and sockets				☐
Unsafe electrical equipment				☐
6. Exoskeleton exhibits engineering uncertainties that present an inherent risk:				
Uncertified electrical equipment				☐
Uncertified hydraulic mechanism				☐
Uncertified or no onboard emergency stop function				☐
Uncertified or no remote emergency stop function				☐
7. Exoskeleton contains hazardous substances that can poison or injure the user				☐
8. Triggering of the emergency stop function may require the user to support an excessive weight and cause falling or musculoskeletal injury				☐
9. Triggering of the emergency stop function may block exoskeleton articulations and cause falling or musculoskeletal injury				☐
10. Improper or no implementation of procedures may cause an unsafe set-up and state of the exoskeleton				
Size adjustment				☐
Actuation adjustment				☐
Software adjustment				☐
Maintenance and inspection				☐
Cleaning				☐
Storage				☐
Transportation				☐
Supervision				☐
Training				☐
11. Additional inherent harm scenarios:				
				☐
				☐
				☐
				☐
				☐

TABLE X1.4 User Job Function and Tasks

NOTE 1—Copy these from or refer to the Job Analyses document if available.

Company/Agency/Institution:		
Department/Branch:		
Job title:		
User type:		Primary User
		Secondary User, specify: (ex: exoskeleton maintenance personnel/training personnel)
Summary Description of the User's Job Functions and Tasks:		
Work shift(s):		

TABLE X1.5 User Job Function and Tasks (continued)

	Assisted by exoskeleton	Performed while wearing the exoskeleton but not assisted by it	Performed while not wearing the exoskeleton
Essential Job Functions & Tasks:			
Non-Essential Job Functions & Tasks:			
Exoskeleton Specific Tasks:			
Retrieval from and disposal to storage			
Transport			
Structural inspection			
Perform maintenance			
Assembly and disassembly			
Don and doff the exoskeleton			
Make adjustments to the fit			
Perform calibration			
Select modes of operation			
Select safety features specific to the job functions & tasks			
Provide images if necessary:			

TABLE X1.6 Task Elements - User Population Personal Characteristics

NOTE 1—Provide relevant description of the user population.

Age:	Between _____	and _____
Gender:		Female
		Male
		Other
Anthropometric characteristics of the user population:		
Height:	Between_____	and _____
Weight:	Between_____	and _____
If applicable, other critical measurements of the user population identified by the producer (ex: waist circumference, shoe size, etc.):		
1.	Between_____	and _____
2.	Between_____	and _____
3.	Between_____	and _____
4.	Between_____	and _____
5.	Between_____	and _____
6.	Between_____	and _____
If applicable, resting vital signs, Functional Outcome Measures or other relevant metrics of the user population (ex: resting heart rate, VO2 max, time to complete a task, etc.):		
1.	Between_____	and _____
2.	Between_____	and _____
3.	Between_____	and _____
4.	Between_____	and _____
5.	Between_____	and _____
6.	Between_____	and _____
Do the users suffer from musculoskeletal injuries, respiratory, circulatory, or other physical disorders?		No
		Yes, enumerate the injuries and disorders
		Unknown
Do the users suffer from mental or neurologic disorders?		No
		Yes, enumerate the neurological disorders
		Unknown
Do the users suffer from allergies?		No
		Yes, enumerate the allergies
		Unknown
Do the users have electrical implantable devices (ex: pacemaker, implantable cardiac defibrillator, bladder simulator)?		No
		Yes, enumerate implantable devices
		Unknown
Are users pregnant?		No
		Yes
		Unknown