CELLAVISION **QUALITY ASSURANCE DOCUMENT**

TITLE	DOCUMENT NO	REVISION	PAGE
Environmental Manual for CellaVision AB	ECV-001	22.0	1 (27)

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REF	DOCUMENT NO	TITLE
[1]	SS-EN ISO 14001:2015	Miljöledningssystem – Krav och vägledning (ISO 14001:2015)
[2]	QCV-027	Risk Management
[3]	ER-002	Miljöaspektlista CellaVision
[4]	ER-039	Kontroll av lagefterlevnad
[5]	ER-038	Environmental Goals and Action Plans
[6]	QCV-090	Electronic Document Management System - CellDoc
[7]	QCV-006	Backuprutiner
[8]	ER-004	Riskanalys för nödlägesberedskap
[9]	QCV-016	Audit Procedure
[10]	QCV-031	Record Manangement
[11]	QCV-047	Nonconformity Management
[12]	QCV-010	Training Procedure
[13]	QCV-029	Product Development Process
[14]	QCV-098	Supplier Control
[15]	SFS 2022:1274	Förordning om producentansvar för förpackningar
[16]	SFS 2020:614	Avfallsförordning
[17]	EF-005	Logg som ska fyllas i då farligt avfall lämnas till annan part
[18]	QCV-005	Change Request
[19]	QCV-114	Handling of Environmental Certificates of Conformance

APPENDIX	TITLE
N/A	

Contents

1 Scope

The Environmental Management System (EMS) at CellaVision is used to organize, follow up, evaluate and account for the environmental work at the company. The EMS is based on standard SS-EN ISO 14001:2015[1].

This environmental manual describes the scope, responsibilities, and routines that control the environmental work at CellaVision AB.

2 Normative References

There are no normative references in standard SS-EN ISO 14001:2015[1].

3 Terms and Definitions

Standard SS-EN ISO 14001:2015[1] states a number of definitions. Those definitions have been used where they are considered applicable.

4 Context of the Organization

4.1 Understanding the Organization and its Context

CellaVision AB is a global company that develops and manufactures medical devices for the analysis of blood and other body fluids. CellaVision is mainly an office-based company with limited in-house manufacturing, since the manufacturing of systems is outsourced to a third-party manufacturer. The organization does not conduct any operations that are subject to notification or permitting according to the Swedish Environmental Code (Miljöbalken) but strives to minimize its negative impact. A detailed continuous evaluation of the environmental impact of CellaVision is documented in the Environmental aspects list, ER-002[3].

4.2 Understanding the Needs and Expectations of Interested Parties

The main interested parties, relevant for the EMS, are shareholders, the board of directors, employees, customers and authorities.

- Shareholders and the board of directors expect that the company fulfills requirements from the authorities and that the company is certified according to ISO 14001[1].
- Employees expect that the company fulfills applicable laws and regulations.
- Customers expect that the company fulfills requirements from the authorities and that the company is certified according to ISO 14001[1].
- The authorities expect that the company fulfills applicable laws and regulations that are listed in the laws list, see section 6.1.3.

Legal requirements are always binding and are listed in the laws list and transferred to product requirements for relevant product. The board of directors have decided that CellaVision shall have a certified EMS.

4.3 Determine the Scope of the Environmental Management System

The EMS covers the headquarters of CellaVision AB (further on mentioned as CellaVision). The headquarters are situated at Mobilvägen 12, 223 62 Lund, Sweden.

The operations of CellaVision span from product development to manufacturing and sales including:

- Software development and testing.
- Hardware development.
- Small production department that assembles simpler spare parts, accessories, and products, checks systems, and manufactures DVD boxes with software for sale.
- Sales organization in Sweden.
- Service and support organization.

The EMS encompasses all the operations.

The management of CellaVision is responsible for the definition and implementation of the EMS.

4.4 Environmental Management System

The EMS follows standard SS-EN ISO 14001:2015[1]. The overall process structure of the EMS is described in Figure 1.

The environmental policy states the overall vision of how CellaVision wants to work with its environmental commitment.

All activities, products and services that have or may have an environmental impact have been identified and are listed in the environmental aspects list ER-002[3]. The prioritized, significant environmental aspects have been identified and are the basis for the environmental goals. Routines have been implemented to control, measure and follow up the significant environmental aspects (see section 8.1 and 9.1).

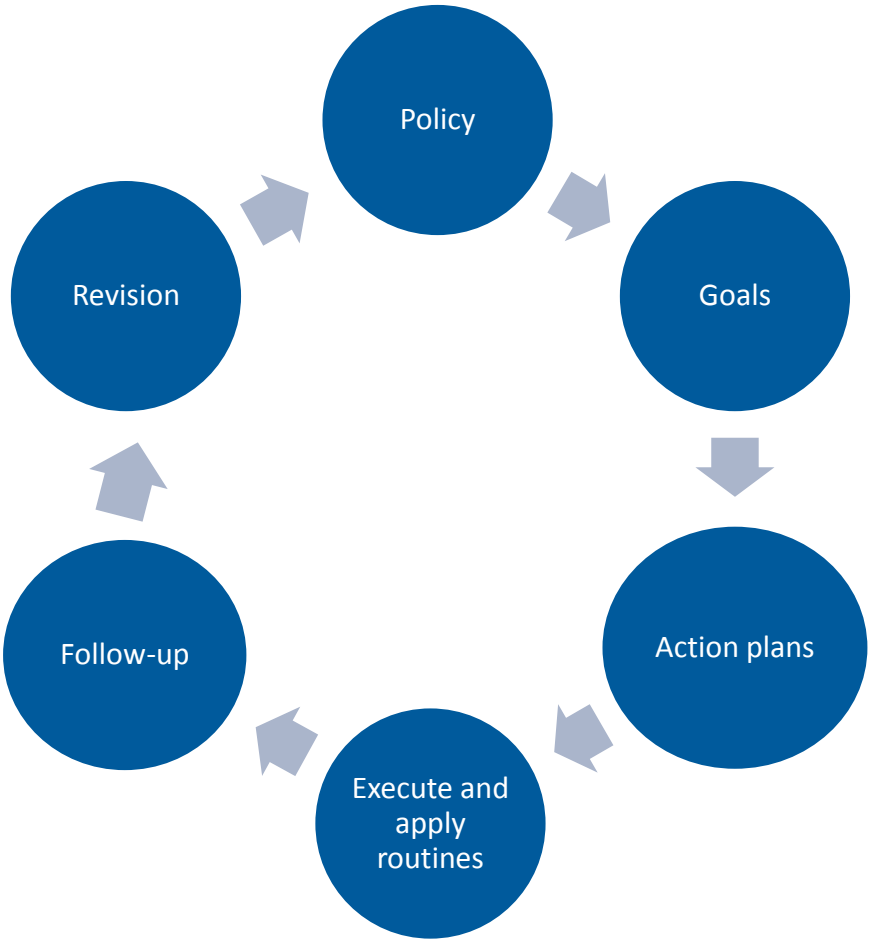

Figure 1 Process flow of CellaVision EMS according to SS-EN ISO 14001:2015 [1]

5 Leadership

5.1 Leadership and Commitment

The management of CellaVision has the ultimate responsibility for the EMS and the environmental commitment of the company. Management endorses communication of the importance of environmental work and ensures that resources and responsibilities are allocated to achieve effective environmental work.

5.2 Environmental Policy

CELLAVISION

CellaVision Environmental Policy

The operations of CellaVision span from product development to manufacturing and sales. The Environmental Management System encompasses all of the operations.

We base our environmental work on four ground principles:

1. CellaVision strives to make the employees aware of environmental issues and to stimulate concrete actions that support a sustainable future.
2. Cellavision strives to decrease the total environmental impact through a systematic environmental work during the development of processes and products. The Environmental Management System should be certified according to ISO14001.
3. Cellavision follows, and if possible, exceeds, environmental laws and regulations.
4. The environmental work of CellaVision shall continuously be improved and evaluated through internal audits.

The management of Cellavision is responsible for the environmental work.

Lund, September 20, 2021

Simon Østergaard

President & CEO

5.3 Organizational Roles, Responsibilities and Authorities

Management has the overall responsibility to:

- Establish environmental policy and goals for the organization.
- Determine the scope of the EMS.
- Ensure that the EMS is defined and established.
- Ensure that CellaVision is following current environmental laws.
- Ensure that sufficient resources are allocated to the EMS.
- Appoint the environmental officer.
- Ensure that internal audits are held and followed up.

The environmental officer has the responsibility to:

- Ensure that the EMS fulfills the requirements of SS-EN ISO 14001:2015 [1].
- Lead the environmental work to achieve the environmental goals.
- Report the status and performance of the EMS to management.
- Act as contact person for staff regarding environmental issues and spread environmental information.
- Keep track of laws and regulations regarding environmental work.
- Establish goals and action plans regarding environmental work together with management.
- Introduce new employees to the EMS.
- Conduct the revision of the environmental aspects list.
- Participate in the follow-up of the practical environmental work.
- Establish and maintain relevant EMS documentation.
- Ensure that review of emergency plan and risk analysis is done according to 8.2.
- Initiate review of improvement suggestions according to 10.3.
- Plan, lead and follow-up on revisions of the EMS on an overall level and ensure that appropriate internal auditors are available.
- Provide training material and conduct training according to 7.3.
- Follow-up on significant environmental aspects according to 9.1.
- Internal communication according to 7.4.

Department directors are responsible for:

- Staff having knowledge about relevant environmental laws and other requirements, and that these are considered when planning and performing work within each department.

CFO is responsible for:

- External communication according to 7.4.

Director Supply & Sourcing is responsible for:

- Reporting to NPA and El-Kretsen.
- Supplier assessment.

All personnel are responsible for:

- Following routines of the EMS.
- Following laws and other relevant regulations.
- Knowing about the environmental policy and the EMS.
- Reporting non-conformities and bring input to improvement suggestions according to established routines.

6 Planning

6.1 Actions to Address Risks and Opportunities

6.1.1 General

Risks and opportunities are identified in a SWOT analysis. The SWOT analysis shall be reviewed once a year and presented at Management Review, see 9.3.

The prioritized, significant environmental aspects and the environmental policy are the basis for the environmental goals. Overall goals are set and broken down into detailed goals.

Risk management is performed according to QCV-027 [2]. Risks and opportunities can be identified through review of the environmental aspects. Opportunities can also be identified through the Continual improvement process 10.3.

6.1.2 Environmental Aspects

Changes in the environment, either positive or negative, which are in part or completely a result of the environmental aspects, are called environmental impact. The EMS of CellaVision comprises activities, products and services which may have a direct as well as indirect environmental impact.

The environmental aspects relevant for CellaVision are documented in the environmental aspects list in report ER-002[3], where they are categorized as direct or indirect aspects. Direct aspects can be controlled by CellaVision whereas indirect aspects can only be influenced by CellaVision.

6.1.2.1 Significant Environmental Aspects

The environmental aspects which are considered to have a significant impact are called significant environmental aspects. They are rated (1-5) based on how critical the impact is (qualitative) and how extensive they are (quantitative). 1 signifies a low impact and 5 a high impact. Qualitative and quantitative values are combined and the higher the result the more important the environmental aspect. Environmental aspects with a score of 6 or higher are considered significant and are highlighted in ER-002[3].

6.1.2.2 Prioritized Significant Environmental Aspects

The significant environmental aspects are prioritized based on internal and external incentives. The external incentives are for example customer satisfaction, company image, and requirements from interested parties. The internal incentives are for example technological opportunities, investment costs, benefit for employees and lowering costs. The prioritizing is calculated as above, where 1 is a weak incentive and 5 is a strong incentive. A combined result of 6 and higher gives priority 1, a result 3-5 gives priority 2 and a result of 0-2 gives priority 3.

6.1.2.3 Revision of the Environmental Aspects List

The environmental officer is responsible for updating status of the significant aspects in the environmental aspects list, ER-002[3], once a year and reporting them at management review, see section 9.3.

A more thorough review of the environmental aspects list is done at major changes in the organization or at least every four years. The review is conducted by environmental officer, who is responsible for preparing adequate material for the review.

Agenda for the revision:

- Follow-up of current environmental aspects.
- Identifying possible new significant aspects.
- Review of internal and external incentives
- Determine the need for new training of the organization, or part of the organization.
- Possible suggestions of new environmental goals and action plans.

The environmental aspects list is kept as a record of the review, according to 7.5.3.

6.1.3 Compliance Obligations

CellaVision maintains a laws list that comprises laws and other regulations that are relevant for the environmental work at CellaVision.

Each law or regulation is considered and, if relevant, its application at CellaVision is described in the laws list. Compliance is checked according to 9.1.2.

CellaVision is not covered by ”Förordningen om miljöfarlig verksamhet och hälsoskydd” and therefore does not have to register according to this regulation.

6.1.4 Planning Action

All significant environmental aspects should be kept under surveillance and measured.

Planning of actions related to legal requirements is done in the laws list.

6.2 Environmental Objectives and Planning to Achieve Them

6.2.1 Environmental Goals

To improve the environmental performance of CellaVision, overall and detailed goals have been identified and action plans for these goals have been established.

Overall environmental goals are set based on the prioritized significant environmental aspects, see section 6.1.2. For each overall goal, detailed goals are set. At least two of the goals shall be clearly measurable. The measurable goals should be evaluated from year to year in order to identify the improvement of the environmental performance of the company.

The goals shall be compatible with the environmental policy. When setting the goals, consideration shall be taken to relevant laws and regulations as well as the commitment to prevent pollution. The goals should reflect our continuous improvement work and take consideration to economical, technological, operational and commercial requirements as well as input from interested parties.

6.2.2 Planning Actions to Achieve Environmental Objectives

The environmental goals and action plans are established during the revision of the environmental aspects list according to section 6.1.2 and 6.1.2.3. The plan for each detailed goal should contain the activities to achieve the goal, responsible for the activities, time frame, and resources. The environmental goals and action plans are listed in ER-038[5] and followed up at management review, see section 9.3.

7 Support

7.1 Resources

Management will allocate the resources that are needed to establish, implement, maintain and continuously improve the EMS.

7.2 Competence

CellaVision has established guidelines for environmental training and awareness.

Employees having basic understanding of how company activities and the actions of each individual can affect the environment and general health, serves to decrease the environmental impact of CellaVision. Training also contributes to minimize the risk of environmental accidents and ensures correct handling in case of an emergency.

Management is responsible to allocate sufficient resources for environmental training.

The environmental officer is responsible to ensure that relevant training is available.

Department managers/directors are responsible to ensure that personnel have the right environmental training for their assigned tasks and that necessary training is performed.

A digital training for “Environmental work and EMS” is available for all the employees on Cellavision Academy and is assigned to all new employees.

Table 1 Training

Training	Contents
Introduction of new employees (Is included in the QA Introduction according to QCV-010 [12])	• Introduction to ISO 14001[1] • Introduction to CellaVision’s EMS • Knowledge of the company’s impact on the environment • Knowledge of the individual’s role and responsibilities regarding environmental issues
Further training and skills development	The environmental officer plans sufficient training of personnel in connection with the revision of the environmental aspects list.
Changed position in the company	If an employee changes position within the company, this could mean that • Change to other part of the business where other environmental aspects are relevant • Increased responsibility regarding environmental issues

	Internal and/or external training should be performed if necessary
Consultants	Consultants working on behalf of CellaVision should receive relevant environmental training.

Conducted trainings and necessary environmental competence are documented on a training record according to QCV-010[12].

7.3 Awareness

All personnel shall be aware of:

- Relevant environmental laws and regulations.
- The importance of following the environmental policy, routines and requirements according to the EMS.
- The company's significant environmental aspects and associated, actual or potential, environmental impact related to work tasks.
- The positive environmental impact that each person can have by taking personal responsibility.
- The environmental goals.
- His/her role and responsibilities to fulfill the requirements of the EMS.
- Relevant routines and the consequences of not following these routines.

7.4 Communication

7.4.1 General

The organization shall establish, implement and maintain the processes need for internal and external communication relevant for the EMS.

7.4.2 Internal Communication

Internal information regarding environmental work is communicated through the internal communication channels. The following is published as internal communication:

- Environmental goals and relevant activities [5]
- Improvement suggestions according to 10.3

The environmental officer is responsible for internal communication regarding the EMS.

7.4.3 External Communication

CellaVision communicates its environmental work through the annual report and on the company website.

The environmental work is a part of CellaVision's sustainability work, which also includes human rights and community involvement.

CellaVision informs externally:

- The company's environmental policy and its importance for the environmental work.
- Within which prioritized areas the company is working to promote sustainability.

CellaVision does not communicate its significant environmental aspects externally.

CFO is responsible for the information in the annual report and on the website. The annual report is presented once a year and the website is continuously updated.

Contacts for the media and other external interested parties are referenced in the “Information Policy for CellaVision”.

7.5 Documented Information

7.5.1 General

The EMS contains both instructions and records, see section 7.5.3. The relevant records are described in each routine.

7.5.2 Creating and Updating

CellaVision environmental procedures are identified as ECV-XXX (Environmental CellaVision).

If there is need for a more specific instruction regarding a certain work task, this is described in an Environmental Instruction (EI). An EI should be easy to follow, with for example pictures and bulleted lists.

If there is a need to document something outside of the established instructions and records, this should be documented in an Environmental Report (ER). ERs are records.

Protocols and forms are documented as Environmental Forms (EF).

See Table 2 for document codes and functions and Figure 2 for an overview.

Table 2 Document codes used in the EMS

Document ID	Type	Procedure/Instruction	Record
ECV-XXX	Environmental Standard Operating Procedure	X	
EI-XXX	Environmental Instruction	X	
EF-XXX	Environmental Form	X	X
ER-XXX	Environmental Report	X	X

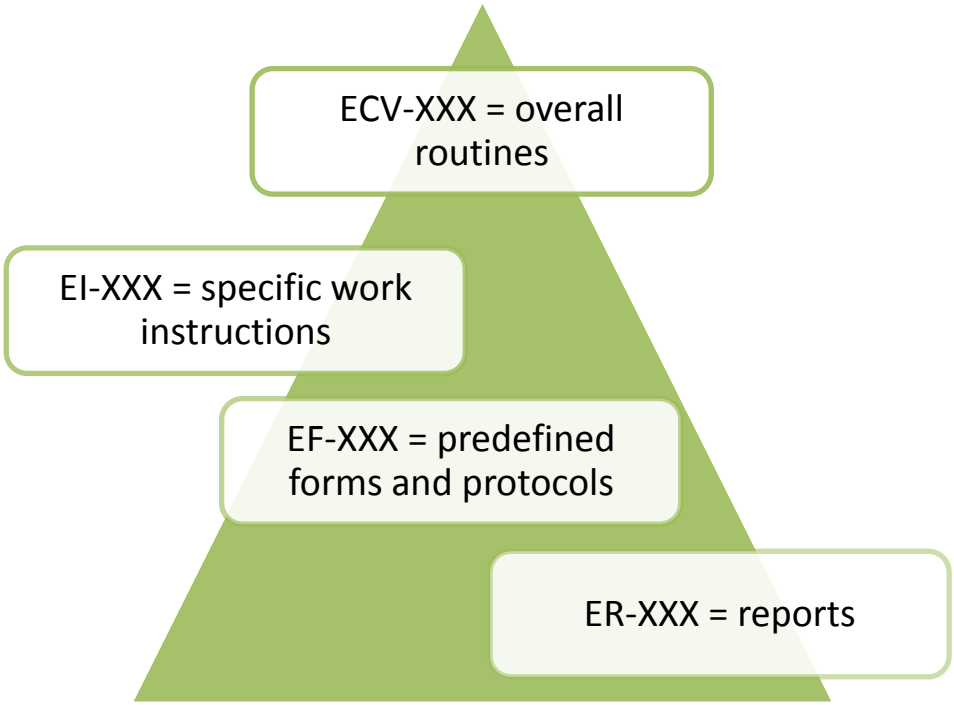

Figure 2. EMS document structure

All environmental documents related to the EMS shall be approved by Quality, either digitally through CellDoc or manually on paper.

In CellDoc documents are approved according to predefined requirements stated in QCV-090[6]. A digital signature is legally binding.

7.5.3 Control of Documented Information

Routines, instructions, and records should be stored in CellDoc. Documents that cannot be stored in CellDoc are kept in a binder marked “Dokument – Miljö”. Obsolete documents are stored for at least five years.

The documents in CellDoc are protected by CellaVision’s routines for data storage, as described in QCV-006[7].

8 Operation

8.1 Operational Planning and Control

In accordance with a life cycle perspective, routines to control the significant aspects of the following operations have been established:

- Design and development
- Purchase and procurement
- Production
- Transports
- Product responsibilities
- Office/administration
- Break- and lunchrooms
- Business travel

8.1.1 Design and Development

During the development phase, see QCV-029[13], the environmental work is integrated in the work process. For example, through the requirement specification, where the environmental aspects are weighed in.

8.1.2 Purchase and Procurement

One of the significant environmental aspects is suppliers of services and goods. By evaluating suppliers before approving them, CellaVision can ensure that the suppliers fulfill environmental requirements.

The evaluation of suppliers shall be performed according to QCV-098[14]. Supplier Declaration shall be handled according to QCV-114[19].

8.1.2.1 Environmental Consideration at Purchase

Purchase of services and goods that have been identified as having a significant environmental impact shall preferably be purchased from approved suppliers. Approved suppliers are handled in the business system Jeeves.

When purchasing services or goods the need should be considered, in order to prevent overconsumption.

8.1.2.2 Office Supplies

At headquarters there is a supply of office material. CellaVision has a contract with a supplier who restocks the supply regularly.

8.1.2.3 Printed Material

Printed material is ordered by purchasing from a suitable printing plant. Creation of printed material for printing of manuals is done by Technical Writing. Other printed material, such as product data sheets and marketing material is ordered by Global Marketing.

8.1.3 Production

8.1.3.1 Waste Handling / Recycling

Packaging material, such as cardboard and bubble wrap, is reused whenever possible. Packaging material that cannot be reused are sorted in designated containers and then transported to “Kretsloppsrummet”. Director Supply & Sourcing is responsible for that packaging waste is sorted correctly.

8.1.3.2 Service and Maintenance

Service of systems is typically performed by trained service technicians on-site at the customer site. The service technician is typically employed by a distributor of CellaVision products.

8.1.4 Transports

To be able to handle inbound and outbound shipping, the transports need to be planned well. All transports are ordered by Supply & Sourcing. The customers decide on which courier and type of transportation to be used.

When possible, transports should be coordinated to include as many systems as possible in one shipment.

8.1.5 Product Responsibility

8.1.5.1 Product Decommissioning

Since the systems contain both metals (including aluminum) and electronics it is important that these are decommissioned properly and in an environmentally safe manner.

8.1.5.2 Producer Responsibility Regarding Batteries

All companies selling electronic equipment containing batteries have a responsibility to decommission the product once it is expended. There are batteries in the systems that CellaVision sells. Director Supply & Sourcing is responsible for reporting the amount of batteries to El-Kretsen through their homepage.

8.1.5.3 Producer Responsibility Regarding Packaging

All companies producing, importing or selling a packaging or packaged item have a responsibility for the packages that end up on the Swedish market, according to SFS 2022:1274[15]. This is applicable for CellaVision. CellaVision is connected to “Näringslivets Producentansvar” (NPA) and shall report the amount of packaging used annually. Kitron reports the packaging materials used by Kitron for CellaVision’s systems and other CellaVision related packaging. If Kitron changes its contract with NPA they must inform CellaVision. Contact information to NPA is filed in the “Producentansvar för förpackningar – Miljö” binder.

The environmental officer and Director Supply & Sourcing are responsible for reporting to NPA.

8.1.5.4 Product Register of the Swedish Chemicals Agency

CellaVision is importing immersion oil and this is reported to the product register of the Swedish Chemicals Agency. The Environmental Officer along with Director Supply & Sourcing are responsible for reporting the annual imported amount in Q1 every year. Contact information is filed in the ”Kemikalieinspektionen” binder.

8.1.5.5 Importer Responsibility Regarding CBAM Reporting

The Carbon Border Adjustment Mechanism (CBAM) is an EU instrument to put a fair price on the carbon emitted during the production of carbon intensive goods that are entering the EU, and to encourage cleaner industrial production in non-EU countries.

CBAM sets rules and requirements for reporting of embedded emissions in CBAM goods for importers, authorities, and non-EU producers.

CellaVision, as an importer, has responsibility to submit a quarterly report of imported CBAM goods to the EU Commission. Reporting to the EU Commission is performed in Tullverket. Finance & Administration is responsible for submission of the CBAM report.

8.1.5.6 Summary of reports to authorities due to producer responsibility

A summary of required reports to authorities due to Cablevisions responsibility as a producer and importer is presented in Table 3 bellow:

Table 3 Summary of reports to authorities due to producer/importer responsibility

Report	Associated law/regulation	Authority	Responsible	Frequency / Time frame
Producer Responsibility for Packaging	SFS 2022:1274	NPA (Näringslivets Producentansvar)	Director Supply & Sourcing	Annually
Producer Responsibility for Batteries	SFS 2008:834	El-Kretsen	Director Supply & Sourcing	Annually
Producer Responsibility for Electrical Equipment	FFS 2014:1075	El-Kretsen	Director Supply & Sourcing	Annually
Hazardous waste	SFS 2020:614	Naturvårdsverket (Avfallsregistret)	Ragn-Sells AB reporting on behalf of CellaVision (according to a power of attorney)	N/A
Importer Responsibility for Registeration of imported chemicals	Reach regulation	Swedish Chemicals Agency	Environmental Officer along with Director Supply & Sourcing	Annually, in Q1
Importer Responsibility Regarding CBAM Reporting	Regulation 2023/956	EU Commission (Through Toolverket)	Finance & Administration	Quarterly

8.1.6 Office/Administration

8.1.6.1 Print-outs

The keep down the amount of printed paper, two side printing should be applied as much as possible.

The electronic document handling system also reduces the need for printing significantly, see QCV-090[6]

8.1.6.2 Copying

To reduce the number of copies on paper, documents should be scanned and sent electronically instead of taking paper copies. When copying it is appropriate to print on both sides, if possible. Instructions for two-sided copying is presented on the display of the printer.

8.1.6.3 Energy Saving Computer Work

In order to save energy, all computers and screens should be turned off or put in energy saving mode when leaving the office for the day.

8.1.6.4 Energy Saving Lighting

Bathrooms have movement-controlled lighting to ensure that the lights are not on unnecessarily. Other rooms do not have movement-controlled lighting and therefore it is important to turn off the light when it is not needed.

8.1.7 Break-/Lunchroom and Waste Sorting

8.1.7.1 Waste Handling / Recycling

The landlord at Mobilvägen 12 provides containers for paper, electronics, lights, metal, cardboard, plastic, glass and battery waste sorting.

Besides those containers, in Makrofagen there are containers for paper packages, organic, combustible, and assorted waste. The supplier is responsible for taking the waste from Makrofagen to the general waste area in the building, “Kretsloppsrum”.

8.1.7.2 Hazardous Waste

Slides with methanol fixed and denatured smears are discarded in yellow cans for hazardous waste, see Figure 3. The boxes are sealed with tape and transport to destruction is ordered. The Biomedical Scientist in Clinical Affairs is responsible for ordering transport to destruction. Hazardous waste is reported and transported according to 8.1.7.4.

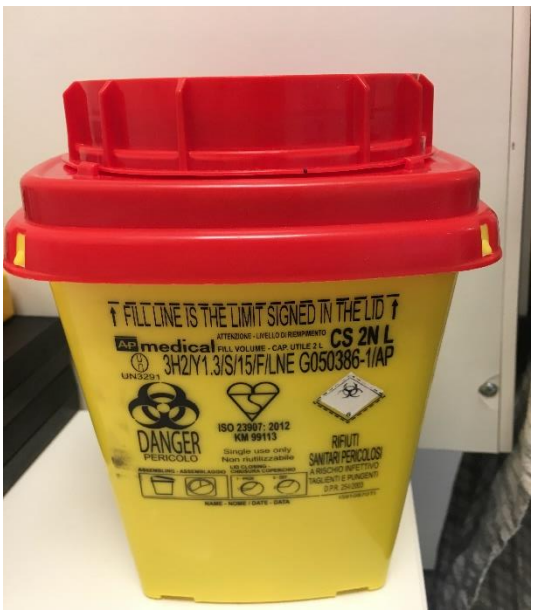

Figure 3. Can for hazardous waste

Waste contaminated with immersion oil is thrown in boxes with black plastic bags and marked with “Oljeavfall” (“oil waste”), see Figure 4. This type of waste is classified as “farligt avfall” (“hazardous waste”) according to SFS 2020:614, Appendix 3[16].

Figure 4. Box with a black plastic bag for oil waste

8.1.7.3 Methanol and Staining Fluid

Possible residual methanol after use is collected in a container and should be put in a fumed hood (located in the laboratory on floor 4) to evaporate.

Staining fluids that do not contain methanol are poured down the drain. Make sure to follow local guidelines for chemical disposal.

8.1.7.4 Transportation of Hazardous Waste

Pick-up of hazardous waste is ordered from Ragn-Sells AB by the Biomedical Scientist in Clinical Affairs. All necessary information should be written on the box.

Ragn-Sells AB

Tel: 010-723 40 00

Transport documentation is obtained at pick-up and is documented on form EF-005[17]Pick-up of hazardous waste, >The forms should be stored in binder “Farligt avfall” that is placed in the lab.

Digital reporting is done by Ragn-Sells AB according to a power of attorney.

Director Supply & Sourcing is responsible for ordering new containers for hazardous waste if needed.

8.1.7.5 Toners

Empty toner cartridges shall be returned to each manufacturer for recycling. If possible, use the same packaging material in which the toner was originally shipped. Usually there is an instruction on how to handle the empty cartridge when packaging and returning it.

8.1.8 Business Travel

Cellavisions global guidelines on business travel are stipulated in the “Business Travel Policy”. Additionally, there are certain local procedures to follow when making travel arrangements for a company-paid trip, which are described in the “Procedure for Business Travel & Expense Reporting”.

8.2 Emergency Preparedness and Response

To minimize environmental impact in case of accident there is a risk analysis mapping out environmental risks and defined actions, see report ER-004 [8]. Review of emergencies and risk analyses is done every four years.

The Environmental Officer along with management is responsible to summon appropriate functions for the revisions. The Environmental Officer prepares the meeting by providing requirement data, for example previous risk analyses, statistics of accidents. If an emergency or accident has occurred, the Environmental Officer shall assess the need for an additional review of emergencies and risk analysis.

The results are concluded in a report which is stored according to 7.5.3.

8.2.1 Protection and Alarm Routines

Cellavisions “Work Environment Handbook” embraces the routines for Systematic Fire Protection including “Fire Protection Organization” and “Fire Protection Policy” and also ruins to follow In the event of fire or danger.

A digital Basic Fire Protection Training is available for all employees on Cellavision Academy.

This information is communicated to all new employees.

The systematic fire protection work regarding the building is done by the landlord, while CellaVision is responsible for fire protection related to the operations of the company. This is done along with an external company specialized in fire protection.

There are smoke detectors and water sprinklers in every room. If a fire is detected, the fire alarm will sound. The landlord is responsible for annual inspection of the sprinkler system.

There are fire extinguishers and blankets placed on several locations. The fire extinguishers use either foam, water or carbon dioxide. The extinguishers are checked on a yearly basis by an external company.

9 Performance Evaluation

9.1 Monitoring, Measurement, Analysis and Evaluation

9.1.1 General

Overall and detailed environmental goals are continuously monitored by the Environmental Officer.

Management review is performed according to 9.3.

CellaVision has defined applicable environmental laws in a laws list, see section 6.1.3, and the compliance at CellaVision is followed up according to 9.1.2. Status is reported at management review.

In addition to goals related to the prioritized environmental aspects, the significant aspects are followed up according to 6.1.2.3.

9.1.2 Evaluation of Compliance

New Environmental laws and changes in existing laws that may affect CellaVision are identified through Ramboll's online service "Lagbevakningen" and are presented as "Ändringar".

The Environmental Officer, along with Director Quality and other relevant functions, review the law list and evaluate how applicable environmental requirements have been addressed within the organization.

The Environmental Officer is responsible for defining who is affected by the change and for communicating the information to relevant functions. If the impact of a change is uncertain, management or Director Quality shall be involved in the assessment.

Compliance of all applicable laws and requirements shall be evaluated once a year. The evaluation result and evidence of the compliance shall be documented using the "Revision" function at Ramboll's "Lagbevakningen".

The Environmental Officer summarizes the results of the review in ER-039[4] which shall be approved through a change request according to QCV-005[18]. The results are presented at management review and archived as records according to 7.5.3.

Any nonconformities arising from the review shall be handled according to section 10.2.

Log-on information is documented in the "Lagbevakning- Miljö" binder.

9.2 Internal Audit

9.2.1 General

Auditors are appointed according to QCV-016[9].

Internal environmental audits are performed according to QCV-016[9].

Internal audits are performed with a risk-based approach to allow a certain flexibility in order to focus on higher risk areas if needed. There shall be an internal audit of the EMS every year, the whole EMS must be covered within a three-years period.

The purpose of internal audits is to verify:

- that laws, regulations and the requirements of the organization are followed.
- that the requirements of standard ISO 14001[1] are fulfilled.
- that the EMS is implemented and maintained.
- the purpose and effectiveness of the EMS.
- continuous improvement.

9.2.2 Internal Audit Program

The Environmental Officer gives input to the planning of the overall audit program according to QCV-016[9]. The program is updated at least once a year.

The purpose and scope of each audit shall be defined in the program. Purpose and scope can vary depending on need to focus on certain areas, such as organization, offices, processes, ISO 14001[1] requirements, or laws and regulations.

The audit program is approved according to QCV-016[9] and stored according to QCV-031[10].

Results of the internal audits are presented at management review according to 9.3.

9.3 Management Review

Management review is held once a year, or more frequently if needed. The Environmental Officer, CEO, VP Devices & Software, and at least one more Executive Management representative should attend the management review. The Environmental Officer summons the meeting.

The following is compiled by the Environmental Officer and shall be the basis for the review:

- Status and follow up of open issues from previous reviews.
- Internal and external audit reports.
- Training status and training need.
- Review of changed laws and requirements.
- Risks and opportunities, based on a SWOT analysis.
- Improvement suggestions and nonconformities (including CAPAs).
- Follow up of significant environmental aspects, goals, and training needs.
- Adequacy of resources.
- Current environmental policy and goals.
- Evaluation of how environmental laws and other requirements are followed.

The following shall be evaluated at the review:

- Effectiveness of the EMS.
- Validity of policies.
- Goal fulfillment.
- The need for new or revised environmental goals.
- The need for new or revised environmental KPIs.
- Implemented actions.

The evaluation should consider:

- Changed laws.
- Changed expectations and requirements from interested parties.
- Changes in the company’s services or operations.
- Progress in the scientific or technical fields.

Minutes from the management review are documented. The minutes shall be approved and signed by the CEO and distributed all meeting participants and possible absent participants. The signed minutes are kept as records as described in 7.5.3.

Management review should result in decisions about corrective and preventive actions, including actions related to new laws and regulations, evaluation of goal fulfillment, internal audit reports, and improvement suggestions.

Decisions related to changes or updates of the EMS should be communicated to all affected parties.

9.4 Monthly Environmental Meeting

Monthly Environmental Meeting is held once a month for follow-up, monitoring, and evaluation of actions from different tasks in the EMS. The Environmental Officer summons the meeting and invites the appropriate functions depending on the tasks to be followed up. Minutes from the meetings shall be documented and saved.

10 Improvement

10.1 General

The organization shall establish routines for improvement and to carry out sufficient actions to continuously improve the EMS.

10.2 Nonconformity and Corrective Action

Environmental nonconformities are handled according to QCV-047[11]. The nonconformities are nonconformities to the EMS and only related to CellaVision AB. This routine is also applicable if an employee receives a customer complaint related to CellaVision's environmental work.

The person identifying the nonconformity shall immediately report the nonconformity on form QCV-047 App-A[11]. The form is immediately handed to the Environmental Officer. The nonconformity is logged in the NC log list and identified by a serial number. Both the Environmental Officer and department director shall be informed directly if the conformity is considered serious, the nonconformity is documented afterwards. Nonconformities that are not considered proper nonconformities by the Environmental Officer are handled as improvement suggestions according to 10.3.

Decisions regarding actions are taken together with the person responsible for the operations related to the nonconformity.

Responsibility for each action is assigned. If the action cannot be completed on time, the Environmental Officer and department head shall be informed.

A status summary of environmental nonconformities and CAPAs are presented at management review, see section 9.3.

10.3 Continual Improvement

Improvement suggestions do not require any actions but are very important in order to fulfill the requirement of continuous improvement. The improvement of the EMS will lead continuous development of the operations and contribute to improved environmental performance and awareness within the organization.

Suggestions for improvement can come from anyone in the organization, by sending an e-mail or verbally communicating it to the Environmental Officer. The Environmental Officer is responsible for documenting the suggestion in the Environmental Improvement Suggestion List in CellDoc. The suggestions will be reviewed by the environmental responsible along with persons responsible for the improvement area and a decision will be made if the suggestion should be implemented. If so, a responsible person will be appointed and an action plan will be documented in the suggestions list. The Environmental Officer should inform relevant functions of the decision.

11 Revision History

Rev.	Description of revision
14.0	Uppdaterat CellaVisions logga och lagt in logga på första sidan. Korrigerat dokumentnamn i referenslista. Lagt in referens till ER-039 i brödtext. Lagt in referens till ISO 14001 i avsnitt 1. Tagit bort upprepning av information som stod flera gånger. Förtydligat att CellaVision uppfyller lagkrav i avsnitt 1.1. Uppdaterat VP Supply & Sourcings ansvar i avsnitt 5.3. Delat upp informationen i avsnitt 6.1.2, 8.1.2-8.1.3, 8.1.5-8.1.7, 8.2, 9.1.2, och 10.3 i underavsnitt. Förtydligat arbetet i avsnitt 6.1.2.3 och ändrat så grundlig revidering av miljöaspektlistan görs minst vart 4 år. Reviderat avsnitt 6.1.4 för ökad relevans. Förtydligat att miljömål ska vara mätbara om praktiskt möjligt i avsnitt 6.1.5. Tagit bort hänvisning till formulär för avvikelser och dokumentation av utbildning från avsnitt 7.4.2 då detta dokumenteras inom kvalitetsledningssystemet. Tagit bort att pärmen står i labbet i avsnitt 8.1.5.3 då det inte stämmer. Uppdaterat vilka kärl företaget har i avsnitt 8.1.7.1. Uppdaterat figurnummer i avsnitt 8.1.7.2 och 8.1.7.3. Ändrat referens till förordning i avsnitt 8.1.7.3 då tidigare refererad förordning utgått. Lagt till att pärm märkt ”Farligt avfall” står på labbet i avsnitt 8.1.7.5. Ändrat frekvens för inventering av nödläge i avsnitt 8.2. Tagit bort stycke om utrymningsrapporter då sådana rapporter inte sammanställs och tagit bort referens till avsnitt i personalhandboken i avsnitt 8.2.1. Förtydligat att även CellaVisions egna krav på miljöledningssystemet följs upp vid internrevision i avsnitt 9.2.1. Uppdaterat deltagare vid ledningens genomgång för att korrelera med QCV-024. Refererat till avsnitt 9.3 i de avsnitt med information som redovisas på ledningens genomgång.Tagit bort äldre revisioner från revision-historiken. Mindre editoriella förändringar.
15.0	Ändrat titlar och avdelningsnamn pga omorganisation. Uppdaterat avsnittet om farligt avfall enligt nya regulatoriska krav på elektronisk rapportering. Lagt till Environmental Sustainability Group under 5.3

16.0	Document translated to English. Section 5.3, changed that CFO is responsible for external communication instead of VP Human Resources. Section 6.1.2.1, the requirement that only significant aspects with priority 1 can be used for environmental goals has been removed. It should be possible to derive goals from any environmental aspect. Section 6.1.2.3, the requirement that the review of the environmental aspects list should be done by the environmental officer, VP Human Resources and Corporate Communications and Director Quality has been removed and replaced with only the environmental officer. This is changed since the environmental aspects list is presented at management review and there reviewed by the other functions. Sections 6.1.5 and 6.1.6 have been renamed 6.2.1 and 6.2.2 respectively in order to fit with the chapters of the standard. Section 6.2.1 has been updated to to more clearly define the requirements for the environmental goals, according to NCA21-003. Section 7.5.2, the three-year check if documents still are relevant is removed. Relevant documents are continuously used and updated and irrelevant documents are withdrawn. Section 8.1.2, details regarding different items that are purchased has been removed since this does not add any useful information Section 8.1.7.2, “contagious waste” is removed since the waste is not considered contagious according to ER-002 rev. 9.0. Reference to EI-002 under 8.1.7.5 removed since Ragn-sells AB is reporting dangerous waste to the authorities. Section 9.2.1 states that internal audit of the EMS should be carried out on a yearly basis, according to NC21-004.
17.0	Removed “Form for evaluation of the environmental work of a supplier” under 7.4.2. since this is documented and handled in QCV-098 “Supplier Control”, it is not relevant to reference QCV-098 in this section. Form EF-001 “Form for evaluation of the environmental work of a supplier” should be made obsolete since it is not used. Clarified references in 7.4.2. According to audit observation 22-009. Form EF-004 “Förbättringsförslag” is made obsolete since improvement suggestions are documented in the Environmental Improvement Suggestion List, according to 10.3 Added links to document references in reference list. Revision history for the last five revisions added, according to QCV-002, sec 7.3.
18.0	Corrected a typo under 8.1.5.2. 9.3. Changed “should” to “shall” in 9.3. 9.3 Changed composition of Management Review based on CA22-009. 6.1.1. and 9.3 added “Risks and opportunities” SWOT analysis according to CA22-011. Editorial changes. 9.1.2 Updated and clarified the process for yearly review of the Laws list according to CA22-010

19.0	4.2 Updated how Legal requirements are considered within projects by “transferred to product requirements for relevant product” 5.3 Definition of “Environmental sustainability group” was removed since the adequacy and dedication of resources will be evaluated by management review. Responsibility for bringing input to improvements emphasized for all employees. 7.2 Training of consultants in Table 1 updated and “by the environmental officer” removed since the relevant environmental training could be provided in other ways, such as reading this Environmental Manual. 8.1.2 Added “Supplier Declaration shall be handled according to QCV-114” 8.1.8 Reference for information regarding “Business Travel” updated according to OBS23-001 8.2.1 Reference to “Routines regarding fire and evacuation” updated according to OBS23-001 8.1.5.3 Updated the section with the current applicable law - SFS 2022:1274 8.1.5.3 Changed responsible from “Application & Clinical Support” to “The Biomedical Scientist in Clinical Affairs” 8.1.7.2 Responsibility changed from Application & Clinical Support to Biomedical Scientist in Clinical Affairs. 8.1.7.3 Handling of methanol and staining fluid updated 8.1.7.4 Updated with the Biomedical Scientist in Clinical Affairs as the person ordering Pick-up by Ragn-Sells. “Supply & Sourcing” changed to “Director Supply & Sourcing” as responsible for ordering new containers for hazardous waste. 9.1.2 Section revised to clarify the compliance evaluation using Ramboll’s “Lagbevakningen”. The time interval for evaluation of compliance of all applicable laws and requirements changed to once a year. 9.2.1 Interval for internal audit revised to “the whole EMS must be covered within a three-years period”. 9.3 Added “Adequacy of resources” according to CA23-001 9.3 Added “Training status and training need “as its own point Changed who to sign the meeting minutes from “VP Devices and Software” to “CEO”.
20	Added information to Sec 7.2 Table 1 to clarify that Introduction of new employees to EMS is included in QA Introduction according to QCV-010 [12] due to CA23-004.

21	Section 1 revised by removing the text that deemed to be redundant. Section 4.1 Updated with brief description of CellaVisions products due to OBS24-001. Section 4.3 Updated with brief description of CellaVisions activities with effect on CellaVisions environmental commitment due to OBS24-001. Sections 5.3 and 8.1.5.3 revised with the chane of FTI to NPA for reporting due to "Producer Responsibility for Packaging". Section 7.2 revised and information regarding digital training for "Environmental work and EMS" added. Section 8.1.8 revised due to updates in documentations regarding business travel. Section 8.2.1 revised due to updates in documentations within Work Environment Handbook" and outputs from review of ER-004 Rev. 3.0 to 4.0 "Risk analysis for emergency preparedness". Section 9.4 added with information regarding "Monthly Environmental Meeting" because of action within CA24-001.
22	Section 4.1 updated to clarify the environmental impact of CellaVision regarding to Swedish Environmental Code (Miljöbalken). New Section 8.1.5.5 added regarding Importer Responsibility Regarding CBAM reporting as an action from NC24-022. New Section 8.1.5.5 added with a summary of reports to authorities due to producer/importer responsibility. Section 9.4, link to the X folder removed since this type of links do not work in CellDoc document.

For complete revision history, see ECV-001 rev. 13.0 and 15.0.

Signature Page

The document ECV-001 revision 22.0 has been electronically signed by:

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The document was included in Change number 24-0795 owned by Behnaz Mostafavi.