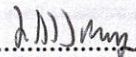
	DOC No: AEU00367	TITLE: WORK INSTRUCTION - CLEAN DOWN PROCEDURE – ELLIPTA MANUFACTURING AREA			Advanex Europe Ltd Head Office: Southwell Site Mill Park Way, Southwell Nottinghamshire, UK, NG25 0ET ☎ 00 44 (0) 1636 815555 ☎ 00 44 (0) 1636 817725 Bilborough Site ☎ 00 44 (0) 115 9293931 ☎ 00 44 (0) 115 9295773 Video Conference IP: 80.176.189.113 www.advanexeurope.co.uk general@advanexeurope.co.uk
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DOCUMENT APPROVAL


Author's Signature:

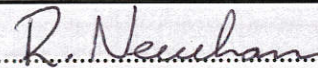
Your signature indicates that this document has been prepared in accordance with company standards or guidelines and adequately reflects the tasks and deliverables necessary.

Signature		Date	20-Mar-2015
Print Name	James Drury		
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Reviewer's Signature:


Your signature indicates that, you have reviewed this document and that it accurately and completely reflects the tasks and deliverables necessary.


Signature		Date	20-Mar-15
Print Name	Steve Harris		
Title	Head of M&P manufacturing		

Signature		Date	20-Mar-15
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Title	Operations Manager AEUS		

Quality Assurance/Compliance Approver's Signature:

Your signature indicates that this document complies with company standards or guidelines; and that the documentation and information contained herein complies with applicable regulatory, corporate, divisional/departmental requirements, and current Good Manufacturing Practices.

Signature		Date	20-Mar-2015
Print Name	Gary Crawley		
Title	Quality Manager		

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1.0 PURPOSE

- 1.1. The purpose of the document is to define the SOP (Standard Operating Procedures) to be followed by ADVANEX EUROPE Ltd, in order to ensure that the cleaning of the machines and working areas in the ELLIPTA manufacturing area is completed in a controlled and consistent manner.

2.0 SCOPE

- 2.1. For the purpose of this SOP machines and working areas concerned are in the ELLIPTA manufacturing area.
- 2.2. All equipment and processes on the ELLIPTA section have been formally qualified and validated. All personnel working on the ELLIPTA section are responsible for ensuring that no changes are made to the process without full change control as defined in SOP/PH001 (Document number AEU00226).

3.0 TERMS, DEFINITIONS & ABBREVIATIONS

- 3.1. None applicable.

4.0 HEALTH, SAFETY & ENVIRONMENTAL

- 4.1. GMP (Good Manufacturing Practice) guidelines apply (Document number AEU00389).
- 4.2. Within the factory area safety footwear is mandatory.
- 4.3. Hair covers must be worn in the ELLIPTA manufacturing area.
- 4.4. Within the factory area safety glasses must be worn at all times.
- 4.5. The machine must be turned off during the cleaning operation.

5.0 ASSOCIATED DOCUMENTS


- 5.1. Line Clearance Check List.
- 5.2. Works Order Instructions: Allowing full traceability for the batch.

6.0 PROCEDURE

6.1. General Instructions.

- 6.1.1. During the coiling, forming and cutting process, small amounts of particulate are generated.
- 6.1.2. Cleaning of the machines and working areas is required to ensure acceptable levels of cleanliness are maintained.

6.2. Procedure.

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- 6.2.1. **Prevent Contamination Of Product.** Before commencing with the cleaning operation, the operator must ensure that any product in the surrounding area is covered and / or sealed.
- 6.2.2. **Equipment Required To Clean Machine Face.** Brushes and airlines are used to disperse any excess oil and particulate from the machine face and surrounding area.
- 6.2.3. **Equipment Required To Clean Work Area.** Vacuum cleaners are used during this operation to ensure containment of the particulate and prevent contamination of the surrounding area.
- 6.2.4. **Schedule of Cleaning.** The cleaning operations defined in Table 1: will be performed:

AREA	FREQUENCY	METHOD
M/C face & De-Coiler area	Twice per day-a.m/p.m	Airline/Vacuum cleaner
	End of Batch	Airline/Vacuum cleaner
	Material Change	Airline/Vacuum cleaner
De-Coiler area Automation	Twice per day-a.m/p.m	Brush/Vacuum cleaner
	End of Batch	Brush/Vacuum cleaner
	Material Change	Brush/Vacuum cleaner
Sieve	End of Batch	Brush/Vacuum cleaner Airline/Lint free cloth
Collection bins	End of Batch	Brush/Vacuum cleaner Airline/Lint free cloth
General M/C area	Twice per day-a.m/p.m	Airline/Vacuum cleaner
	As Required	Brush/Vacuum cleaner

Table 1: Schedule of cleaning activities.

- 6.2.5. **Confirm Effectiveness of Cleaning.** Following the cleaning operations, the machine operator will visually check the area to ensure that the cleaning has been effective.

LINE CLEARANCE CHECKLIST

DATE	BATCH NO.	CHECKED BY	SIGNATURE

WORK ORDER

WORKS ORDER

FACE OF MACHINE IS CLEAR

OVEN IS CLEAR

SIEVE IS CLEAR

INSPECTION RESULTS CHECKED

☐
☐
☐
☐
☐

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Figure 1: Example of a Line Clearance checklist.

- 6.2.6. **Line Clearance Check List.** After the batch quantity has been produced, the machine operator will perform the cleaning activities outlined in Table 1: once completed they will fill out and then sign the Line Clearance Check List, as shown in Figure 1: to confirm that this has been completed.

