LO3 Tutorial – week 1

Recall LO3: **Given an example system and standard or regulation, justify what evidence would be needed to comply with the regulation or standard.**

The tutorial on this topic will take place on Tuesday 12 March and Wednesday 13 March. In many cases demonstrating that you have correctly implemented appropriate processes provides evidence that a product complies with the standard. You should bear this in mind while you are working on this LO.

Week commencing 4 March you should do some preparatory work. I will not be attending either tutorial this week, but you could meet in your groups to discuss this activity. The table below lists some relevant software development standards. Recall you can download personal copies of any of these standards at: https://bsol-bsigroup-com.ezproxy.is.ed.ac.uk/ (you will be required to authenticate to the University to access BSI information).

STANDARD	MEDICAL DEVICE	GENERIC SOFTWARE
LIFECYCLE	IEC 62304	ISO 12207
RISK MANAGEMENT	ISO 14971	ISO 16085[1]
QUALITY MANAGEMENT	ISO 13485	ISO 25002 (also 25010, 25019)

You have already decided on a domain and class of product you are interested in. Here you will consider what is necessary to manage risk in your product. Do the following:

1. Choose one of the three risk management standards considered in this note. Your choice should be relevant to your choice of domain and product.
2. Read your chosen standard. In general these are quite short. Try to look at the Appendices if you can.
3. For your chosen domain and product try to follow the standard to see what kind of risks need to be managed for your system.
4. Consider all the risk management processes and activities. To limit the amount of work, take one or two risks and work through all the activities for these risks. These are the process and activities:
   - 4.1. Risk Assessment
     - 4.1.1. Risk identification
     - 4.1.2. Risk analysis
     - 4.1.3. Risk evaluation
   - 4.2. Risk treatment
     - 4.2.1. Selection of risk treatment options
     - 4.2.2. Preparing (and implementing) risk treatment plans
5. Document you activities on a new wiki page and discuss with one of your other group members to try to identify gaps or issues in what you have done.

[1] Many of you may be interested in systems with embedded AI components. The risk management standard for this is ISO 23894:2023.