1. Use the identifying stakeholder questions found in the book to come up with the list of stakeholders. Rank this list (Use HIGH-MEDIUM-LOW as the ranking system).

1. Who is paying for the system?
   1. Hospital administration, tax payers (public funding), patients, insurance companies
2. Who is going to use the system?
   1. Doctors, nurses, pharmacists, risk-management, consultants, patients, families
3. Who is going to judge the fitness of the system for use?
   1. Doctors, nurses, FDA, Hospital administration, FDA
4. What agencies (government) and entities (nongovernment) regulate any aspect of the system?
   1. FDA, internal hospital policies, Center for Devices and Radiological Health (CDRH)
5. What laws govern the construction, deployment, and operation of the system?
   1. FDA, state laws, Center for Devices and Radiological Health (CDRH)
6. Who is involved in any aspect of the specification, design, construction, testing, maintenance, and retirement of the system?
   1. (Software) Engineers, doctors, nurses, pharmacists, consultants, hospital administration
7. Who will be negatively affected if the system is built?
   1. Hospitals with lesser equipment (competitors), vendors of medical equipment that the system replace

**HIGH**

* Hospital Administration
  + In charge of selecting and paying for system
* FDA
  + In charge of approving and regulating the system

**MEDIUM**

* Doctors, Nurses, Pharmacists
  + Regular interactions with the system, need to be able to use the system effectively
* Patients
  + They’ll be directly affected by the system. Needs to be comfortable and provide accurate information to their support staff.

**LOW**

* Consultants, Risk-management
  + Analyze the data that is produced, not much direct interaction with the system
* Families
  + Will have limited interactions with the system during visits
* Engineers
  + Building the system, but not much decision making power over the direction of system

2. Identify any regulations, standards, guidelines, etc. that apply to the Course Project. Rank this list (Use HIGH-MEDIUM-LOW as the ranking system). You will need to research a little bit into the regulations, standards, and guidelines that may govern the patient monitoring system

**HIGH**

* Device must meet the marketed specifications so that it can be trusted to perform accurately by all stakeholders
* Has an LCD screen so we must meet all “applicable requirements of Title 21 Code of Federal Regulations (Subchapter J, Radiological Health) Parts 1000 through 1005”. This piece conveys all of the information to the user.
  + <https://www.fda.gov/radiation-emitting-products/home-business-and-entertainment-products/televisions-and-video-display-monitors#lrps>
* Data integrity is high because poor readings could negatively impact the patients well-being, even resulting in death

**MEDIUM**

* The battery should comply with “IEC 60086-4, Primary Batteries – Part 4: Safety of Lithium Batteries or IEC 62133, Secondary Cells and Batteries Containing Alkaline or Other Non-acid Electrolytes”. This is medium because the battery will only be used during transportation, which is a small window and there will be medical professional available during transportation to assist with any issues
  + <https://www.csagroup.org/article/making-sense-regulations-medical-device-batteries/>
* Any medical device system software should comply with “IEC 62304” to be sure that any code meets the standards. This is medium because this system will mostly visualize data from external components and allow for some minor configuration settings. The overall architecture shouldn’t be too complex
  + <https://en.wikipedia.org/wiki/IEC_62304>

**LOW**

* Data security is low because this is a real-time monitoring system, data should not be stored or transferred in any meaningful significance
* Biocompatibility of the materials used in the device is low because the device does not have any contact with the patient. However, its use in a medical environment shall still be taken into account
  + <https://www.fda.gov/medical-devices/products-and-medical-procedures/safety-metals-and-other-materials-used-medical-devices>