6.1 qXR licensing model

<https://qure.ai/regulatory-and-privacy/#>

The two significant product licenses for qXR are from the USA FDA and European Economic Area. The product qXR-BT is FDA cleared under the 510(K) clearances which allows qXR to be on the market of the United States as Radiological Image processing software. This demonstrates that the FDA has already conducted some investigation on the performance of approved clinical benefits of the qXR product. The other clearance is that the product qXR is classed as a European CE medical device and it allows the product to be sold at European markets. This is also an indication that the effectiveness of qXR has been tested and recognized by the European Union independently.

Also, qXR follows a series of regulations regarding information security and privacy. Those protocols include HIPAA compliant, EU-GDPR compliant, ISO/IEC27000 certification, ISO13485 and IEC62304.

6.2 User training and follow-up

<https://qure.ai/how-we-deploy/>

There is a specific four-steps workflow that the company qure.ai follows when it comes to user training. The first step is the Orientation, the orientation works as a general introduction of the product and its functionality. During the orientation process the clients who are mainly the radiologists will gain a preliminary understanding of AI itself and how it is used in the medical imaging industry. The second step is technical readiness which is to guide the clients on the specific technical operation for qXR. The company is expecting the clients to fully understand how to operate the product and how to interpret the result at the clinical level. More importantly, the clients will learn to use the interface of the qXR application. The SLA, service level agreement, will be demonstrated and comprehended by the clients after the first two steps. Then the company will help the clients to deploy the system to their own devices including computers and chest CT scanner, mainly the computer since the chest CT scanner does not need additional deployments. The full deployment process takes approximately 6 hours, consisting of 2 hours for gateway deployment and 4 hours of on-precise deployments depending on the speed of the internet. Then the last step is volunteer training and support. If the clients encounter any problem while using the product, the support team will respond as quickly as possible. Also, the training at this stage is based on the client’s need instead of mandatory, which is that the client should come to the company and ask for the training he is willing to receive regarding the use of this product.

The process of client on-boarding workflow seems effective and could properly train the clients if implemented successfully. However, there are no user cases found on any platform rating this system. Neither the number of clients and the percentage of clients attending these four-step workflow are recorded as evidence, nor are the quality of the implementation recorded. Therefore, the actual effect of the practice of the workflow should be further examined.

As for the follow-up, there are two teams responsible for the communication with the clients, the client engagement team and project delivery team + technical lead. The clients can contact the client engagement team directly if they encounter any problem. The project delivery team can help the clients design the best technical approach of using this product for a specific task according to the nature of the task.