

## Response Action to Regulatory Authorities

There are two potential sources of interaction:

1. The agency that regulates the sale and use of devices (the FDA in the USA, Health Canada in Canada, the TGA in Australia, South African Health Department in South Africa, the MHDA in the UK). These agencies have a two-fold requirement:-
  - a. That the device is appropriately registered, covering intrinsic safety and scope of use.
  - b. Who may use the device.

This information varies between countries and is available from the device manufacturer and generally the principal brokers in the country of use.

2. Regulators of health professionals – ultimately this responsibility exists with either the country's national government or in some cases state governing authorities (eg USA) which are empowered by the federal government to regulate in certain areas.

In terms of the EPFX/SCIO/QXCI device regulatory authority visits are rare. In order to remove a device or terminate the operation of it the agent should state specifically the reason for this, produce the documentation authorising them to do so, eg a warrant, and issue a receipt. Generally they may be empowered, with the appropriate documentation, to move the interface device but in general not the software. ?? Is this correct?

In terms of practitioner regulation this generally arises by a complaint by a member of public or other health practitioner who believes you may be practising beyond your legal scope. The most common reason is practising or pretending to practice medicine without a licence or implying that a specific qualification is different from what it is.

IMUNE will support inappropriate actions against health practitioners to whom it has issued qualifications provided that:-

- Full information about the nature of the event is provided.
- The following course of action is adopted.
  1. In the case of actions requiring a response ensure that you make a response within this timeframe or negotiate and have confirmed in writing an alternative response date. In law if you do not respond within the stated or agreed time period the inevitable consequence is that you will be found guilty.
  2. Have available and provide the following information.
    - a. Code of ethics.
    - b. Waiver/informed consent.

- c. All qualification documents.
  - d. Training certificates, attendance certificates, CEU certificates and any other documentation that relates to and supports your professional practice.
  - e. Syllabuses or the trainings that you have undertaken.
3. Any information, bearing in mind client confidentiality, that will clarify the specifics of the issue behind the complaint. Be very careful here in terms of confidentiality and disclosure of information that may be misinterpreted. This is the area where an attorney or person experienced in derailing with these issues is of value.
  4. It is recommended that you copy any information that is provided to a third party and sign and date it, provide a listing of such materials and get a receipt for them. If there is reluctance for the authority to issue a receipt, this is unusual and should be a red flag for you. This may flag up the benefits of involving an attorney.
  5. If files are returned ensure that this is a full return: notify any discrepancies as soon as possible and confirm this either by fax or letter.
  6. If you have professional malpractice insurance then advise the insurance company as soon after the event as possible. A particular function of malpractice insurance is to provide legal support.

The best defence is proaction to avoid a situation arising. The following course of action is recommended:

1. Understand the legalities of purchase and use of any device or materials that you use.
2. Ensure that your waiver/informed consent is robust and is used: equip the client with this information and ensure that you have a copy. If your device uses experimental software requiring an IRB it is recommended you incorporate this into your form. Whilst informed consent/waiver may not be an obvious legal requirement in many countries eg UK, it is very protective and can be phrased softly and as an information for the client. Do not start a session without this being in place.
3. Ensure that your qualifications are prominently displayed either in the waiting area or clinic area.
4. Ensure that your qualifications cover your scope of operation: many health professionals operating by a feedback or resonance devices offer more information than education to the client in terms of their lifestyle, nutrition, etc. If you are not specifically qualified in these areas then ensure that your terminology is appropriate, ie use client centred skill unless you have qualifications that permit assessment, treating, etc.
5. Review what you offer within a consultation and ensure that your qualifications cover this.
6. Understand your code of ethics and operate to them to the highest professional standards.

7. Ensure you have malpractice insurance.