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IMDA Recommended Health Care Industry Representative (“HCIR”) Credentialing Criteria

In the spirit of creating realistic, meaningful, nationally enforceable and comprehensive HCIR credentialing requirements, the following credentialing elements are recommended for “Clinical” HCIRs, defined herein as “individuals who represent a company (or companies) who require regular access to patient care areas, **and/or provide assistance to or consult with patient care staff while in the immediate vicinity of patients**”.

● **Health Vaccinations** – A statement from the vendor’s employer (hereinafter, “Company”), or submission to an approved Credential Verification Organization (hereinafter, “CVO”) proof:

- of performance of TB test (annually);
- that the Hepatitis B vaccine was offered per OSHA standard, or evidence of Adequate Response to Immunization;
- Mumps, Measles, Rubella (MMR) immunity, or documentation of 2 doses of the MMR vaccine, and;
- of Varicella immunity, or 2 doses of the adult Varicella vaccine.

Privacy concerns dictate that if these records are required by hospitals to be stored electronically by a CVO, said CVO should have sufficient security, defined as “[SAS70 LEVEL II](#)” controls around their internal databases to ensure privacy protection for participating HCIRs.

● **Background Verification**-- Letter from Company attesting that background verification was performed for each representative upon hire. This should include:

- criminal background check;
- sex offender registry;

This attestation of background check could also be provided through an approved CVO with sufficient security around their internal databases to ensure privacy protection. **At no time should Social Security, Driver’s license or Passport numbers be requested, nor provided. Furthermore, individual credit checks are irrelevant to patient safety and should not be requested nor provided.**

● **Training Documentation** – Letter from the company, or documentation from an approved CVO verifying that training was successfully completed by the HCIR in the following areas:

- **Product Training Certification for all FDA Class III medical devices and “Life Support Equipment”** (as defined by JCAHO in E.C. 6.20) that the HCIR sells or supports.
- HIPAA privacy & security for business associates;



- Conduct Policies and Procedures--letter from Company verifying adherence to a recognized applicable industry code of ethics such as the AdvaMed Code of Ethics;
- Exposure to bloodborne pathogens in the surgical environment;

and if appropriate, **dependent on patient care areas visited:**

- Sterile/Aseptic Control;
- AORN operating room protocol for sales representatives;
- Radiation safety.