FINAL DOCUMENT

Global Harmonization Task Force

Title: Comparison of the Device Adverse Reporting Systems in USA, Europe, Canada, Australia & Japan

Authoring Group: Study Group 2

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The document herein was produced by the Global Harmonization Task Force, a voluntary group of representatives from medical device regulatory agencies and the regulated industry. The document is intended to provide non-binding guidance for use in the regulation of medical devices, and has been subject to consultation throughout its development.

Preface

The document herein was produced by the Global Harmonization Task Force, a voluntary group of representatives from medical device regulatory agencies and the regulated industry. The document is intended to provide non-binding guidance for use in the regulation of medical devices, and has been subject to consultation throughout its development.

The purpose of this document is to provide general comparison information on the adverse reporting systems in existence in USA, Europe, Canada, Australia, and Japan. Manufacturers should refer to the current regulations and guidelines at each country or region for the reporting purposes.

GHTF Secretary's Note (June 2002): While endorsing this edition, Revision 3, to be added to the GHTF website (in place of R2), in order to recognise the total work effort involved with its development, the GHTF Steering Committee noted this version now contains outdated information. The document will not be continually updated as it was initially developed during the mid to late 1990's as a reference document to assist SG2 with its work on other Guidance Documents. The GHTF Steering Committee strongly encourages all readers to visit the Founding Member government websites to obtain information on the latest regulatory requirements for medical devices.

SECTION 1.
PURPOSE

Europe**	USA ***	Canada *	Australia	Japan
The purpose of the Vigilance System is to improve the protection of health and safety of patients, users and others by reducing the likelihood of the same type of adverse incident being repeated in different places at different times. This is to be achieved by the evaluation of reported incidents and, where appropriate, dissemination of information which could be used to prevent such repetitions, or to alleviate the consequences of such incidents. The Vigilance System is intended to allow data to be correlated between Competent Authorities and	The purpose of the Medical Device Reporting Regulation is to ensure that manufacturers, (including those foreign), and importers promptly inform FDA of all serious injuries, deaths or malfunctions associated with marketed devices. User facilities report deaths and serious injuries. As the principal US public health agency responsible for ensuring that devices are safe and effective, FDA needs such information to evaluate the risk associated with a device in order to take whatever action is necessary to reduce or eliminate the public's exposure to this risk.	The purpose of Mandatory Problem Reporting is to reduce the likelihood of recurrence of serious adverse incidents related to medical devices by evaluation of reported incidents and, where appropriate, dissemination of information which could be used to prevent repetitions or to alleviate the consequences of such incidents.	The purpose of the Incident Reporting and Investigation Scheme is to support the Post market monitoring processes under the Therapeutic Goods Act. Only a small, select group of high risk, registered devices are evaluated by the TGA prior to being approved for sale on the market, the majority of products being listed on the Australian Register of Therapeutic Goods without evaluation. Postmarket monitoring is considered an important process to evaluate on-going quality, safety and efficacy of therapeutic devices	The purpose is to ensure that safety and effectiveness have been carefully evaluated before approval time, and expected adverse events and contraindications must be described on the labeling. Before the approval stage, the number of patients is restricted and only narrow ranged group of patients is involved in clinical trial. After approval, the device is used for a wide range of patients, and there is the possibility of unexpected adverse events which can not be foreseen when the device is being approved. Therefore any adverse

manufacturers and so facilitate corrective action earlier than would be the case if data were collected and action taken on a State by State basis.			available in the market.	events must be tracked to ensure safety for marketed device.

* The following information is based on the proposed regulations.

** European directive (law) and guidelines (interpretation of the directive) are not interpreted in the same way throughout Europe. Thus reference to the directive doesn't reflect that other requirements do exist.

*** This information represents key features of the FDA regulations and does not encompass the full scope or intention of medical device reporting requirements.

SECTION 2.
APPLICABILITY

Europe	USA	Canada	Australia	Japan
These Guidelines cover the activities of: • the Commission • Competent Authorities • Notified Bodies • manufacturers (including their authorized representatives and persons responsible for placing on the market, see Article 14 of the MDD) • users and others concerned with the continuing safety of medical devices	The Medical Device Reporting Regulation establishes requirements for: • manufacturers • importers • user facilities Health professionals (physicians, physician assistants, pharmacists, nurses) and other consumers are encouraged to voluntarily report serious adverse events and product problems.	The Medical Devices Regulations cover the activities of: • Medical Device Bureau • Bureau of compliance and Enforcement • Manufacturers • Distributors	The Therapeutic Goods Act cover the activities of: • The Therapeutic Goods Administration • Manufacturers • Sponsors (manufacturers and importers) Postmarket reporting of adverse events is mandatory for device sponsors when they become aware of a serious injury or death involving a device. A device sponsor is generally the legal entity which manufactures or imports a therapeutic device. Postmarket reporting of adverse events is voluntary , but strongly encouraged, of healthcare institutions or practitioners.	These Guidelines cover the activities of: • MHW (Ministry of Health & Welfare) • Medical facility (voluntary) • Manufacturer/Importer/Domestic agent for foreign manufacturer

SECTION 3.
REPORTING TIMING

Europe	USA	Canada	Australia	Japan
Section 3.1 MANDATORY REPORTING	Section 3.1	Section 3.1	Section 3.1	Section 3.1
The report should be made as soon as possible. The time given below is the maximum elapsed time for determining the relevant facts and making an initial report. The time runs from the manufacturer first being informed of the incident, to the relevant Competent Authority receiving the notification from the manufacturer. Incidents: 10 days Near incidents: 30 days	Adverse event report: the time from the date the manufacturer or user facility became aware of information that reasonably suggests that a device has or may have caused or contributed to the event to the date of the report. • Manufacturer Death, serious injury, reportable malfunctions: to FDA within 30 calendar days • User facility Death: to FDA and manufacturer within 10 working days Serious injury: to manufacturer within 10 working days. (Such reports shall be submitted to FDA if the device manufacturer is not known) • Distributor Death, serious injury, and malfunctions: to manufacturer within 10	Manufacturers and Importers must report within the following time period the device related adverse events to the Bureau of Compliance and Enforcement. Incident: 10 days Near incident: 30 days	Reporting times are not specified, but are predicated on the phrase "…as soon as possible after the sponsor becomes aware…"	Medical Device manufacturers, importers and domestic agents for foreign manufacturers report within the following time period to the Safety Division of MHW after they become aware of an event: • Unlabeled serious incidents or near incidents – 15 days • Labeled serious incidents or near incidents – 30 days • Unlabeled medium level incidents or near incidence – 30 days • Serious incidents by infectious diseases that could be caused by using medical devices – 15 days.

	working days Death, serious injury to FDA within 10 working days <u>Manufacturer 5-Day Report:</u> the time runs (in working days) from the manufacturer became aware that a reportable MDR event necessitated remedial action to prevent an unreasonable risk of substantial harm to the public health to the date of the report; or becoming aware of a reportable event for which FDA has made a written request for the submission of a 5-day report. When such a request is made, the manufacturer shall submit, without further requests, a 5-day report of all subsequent events of the same nature that involve substantially similar devices for the time period specified in the written request. Manufacturer Baseline Report: to be submitted for a device when the device model is first reported and to be updated annually on the anniversary month of			

	the initial submission (Pending Guidance)			

SECTION 4.
REPORTING CRITERIA

Europe	USA	Canada	Australia	Japan
Section 4.1 DEATH/SERIOUS INJURY	Section 4.1	Section 4.1	Section 4.1	Section 4.1
Death or Serious deterioration in state of health: • Life threatening illness or injury • Permanent impairment of a body function • Permanent impairment to a body structure.	Death, or Serious injury, which means an injury or illness that: • Is life threatening • Results in permanent damage to a body structure • Results in permanent impairment of a body function (Permanent means irreversible, but not trivial, impairment or damage to a body structure or function.)	Death or Serious deterioration in state of health: • Life threatening • Permanent damage to a body structure • Permanent impairment to a body function	Death or Serious injury, is not specifically defined, but is taken to be: • Life threatening • resulting in permanent damage to a body structure • resulting in permanent impairment of a body function.	Death or Serious injury means an injury or illness that: • Is life threatening • Results in permanent damage to a body structure • Results in permanent impairment of a body function
Section 4.2 CONDITIONAL SERIOUS INJURY	Section 4.2	Section 4.2	Section 4.2	Section 4.2
A condition necessitating medical or surgical intervention to prevent permanent impairment of a body function or permanent impairment of a body structure.	An injury or illness that necessitates medical or surgical intervention to preclude permanent damage to a body structure or permanent impairment of	Condition which necessitates medical or surgical intervention to prevent: • Permanent damage to a body structure	Conditional serious injury is not specifically defined, but is taken to be: • An injury requiring clinical intervention to prevent serious injury.	Condition which necessitates medical or surgical intervention to prevent: • Permanent damage to a body structure

	a body function.	• Permanent impairment to a body function		• Permanent impairment to a body function
Section 4.3 Malfunction	Section 4.3	Section 4.3	Section 4.3	Section 4.3
All reportable adverse events require there to have been a malfunction or deterioration in the characteristics and/or performance of a device which led to or might have led to death or a serious deterioration in health. Where no serious injury/death occurred, it is sufficient that if the event occurred again in might lead to death/serious deterioration in health and is known as a near incident.	Device malfunction (or failure to meet performance specifications or otherwise perform as intended) such that the device or a similar device would be likely to cause a death or serious injury if the malfunction were to recur. • Performance specifications include all claims made in the labeling for the device. • Intended use may be shown by labeling claims; advertising matter; oral or written statements. A malfunction is considered likely to cause or contribute to a death or serious injury if: • the chance of it causing such an event is not remote or minute • it affects the device in a catastrophic manner that may lead to a death or serious injury • the manufacturer takes	Malfunction or deterioration in the characteristics and/or performance of a device which might have led to death or serious deterioration in health: • incident occurred and • is such that if it occurred again, it might lead to death or serious deterioration in health	Malfunction is not specifically defined, but is taken to be: A failure of the device to perform as expected which has the potential to compromise patient or operator safety. Such a failure may be caused by design, excessive claims, specification or labeling or device/component failure in which the device/system did not fail-safe.	Failure, malfunction, improper/inadequate design, manufacturing problem and improper/inadequate labeling which has led or may lead to death or damage if malfunctions re-occurs.

	or would be required to take action to prevent a hazard to health as a result of the malfunction • a malfunction of the same type has actually caused or contributed to a death or serious injury in the past two years.			
Section 4.4 USER ERROR	Section 4.4	Section 4.4	Section 4.4	Section 4.4
User errors are generally outside of the adverse reporting system except when; • Examination of the device or labeling (inaccuracies in the instruction leaflet or instruction for use include omissions and deficiencies) indicated some factors which could lead to an incident involving death or serious deterioration in health.	• Use error (errors induced by poor design, poor labeling, poor instruction, etc. which could lead to an incident involving death or serious injury).	• Examination of the device or labeling (inaccuracies in the instruction leaflet or instruction for use include omissions and deficiencies) indicated some factors which could lead to an incident involving death or serious deterioration in health.	User error is not specifically defined, but is taken to be: • A situation where patient or operator injury, or near injury, is caused by incorrect use, i.e. not following instructions or labeling when these are assessed as adequate for a "normal" or "reasonable" user. • "Off label" use when either the device is not specified for the application or specifically contra-indicated within the instructions for use or labeling.	• Recall provisions address inadequate labeling which could lead to an incident involving death or serious injury. There are no such definite provisions in adverse incident reporting.
Section 4.5	Section 4.5	Section 4.5	Section 4.5	Section 4.5

LITERATURE ANALYSIS				
No such guideline exists and the EU Vigilance guideline states "These guidelines make no recommendations on the structure of the systems by which manufacturers gather information concerning the use of devices in the post production phase". However, the directive indicates that "The manufacturer must undertake to institute and keep up to date a systematic procedure to review experience gained from device in the post production phase".	Reporting is required when the manufacturer becomes aware of a reportable incident regardless of its source such as literature reports.	The Regulations do not specify how the manufacturer or importer becomes aware of reportable incidents, but simply that they must report them within certain time limits based on when they become "aware".	The Therapeutic Goods Act does not specify how a sponsor becomes aware of reportable events, but conditions imposed under the Act require that" Where the goods are distributed overseas as well as in Australia, product recall or any similar regulatory action taken in relation to the goods outside Australia which has or may have relevance to the quality safety or efficacy of the goods distributed in Australia must be notified.. immediately the action or information is known to the sponsor".	Research literature which indicates the following items: • serious effect to human health • great change of the trend of adverse events • no effectiveness
Section 4.6 REMEDIAL ACTION	Section 4.6	Section 4.6	Section 4.6	Section 4.6
Not applicable	5-Day Manufacturer Report means a report submitted upon: • becoming aware that a reportable event or events, necessitates remedial action to prevent an unreasonable risk of substantial harm to public health; or	Not applicable	Not applicable	Not applicable

	• becoming aware of a reportable event for which FDA has made a written request for the submission of a 5-day report. When such a request is made, the manufacturer shall submit, without further requests, a 5-day report for all subsequent events of the same nature that involve substantially similar devices for the time period specified in the written request.			
Section 4.7 VOLUNTARY REPORTS	Section 4.7	Section 4.7	Section 4.7	Section 4.7
Voluntary reports may be submitted at any time and may be other than death, serious injury or malfunction as defined.	Voluntary reports may be submitted at any time and may be other than death, serious injury or malfunction as defined.	Voluntary reports may be submitted at any time and may be other than death, serious injury or malfunction as defined. Reports of incidents (including those involving death or serious deterioration in health) from those other than manufacturers and importers (for example, hospitals, coroners, the public, etc.) are also considered voluntary reports.	Voluntary reports may be submitted at any time and may be other than death or serious injury.	Voluntary reports may be submitted at any time and may be other than death, serious injury or malfunction as defined.

SECTION 5.
NOT REPORTABLE INCIDENTS/EVENTS

Europe	USA	Canada	Australia	Japan
• Single fault conditions for which the manufacturer has made provisions • Normal aging of the device* predicted in the information supplied with the device • Mishandling or user error* • Expected side effects.* Risk was foreseeable and clinically acceptable in view of potential patient benefit • Outcome of the incident was adversely affected by a pre-existing condition of the patient • Events occurred outside of the European Union. * If provisions are made in labeling information	• Adverse events for which there is information that would cause a person who is qualified to make a medical judgment (e.g., a physician, nurse, risk manager or biomedical engineer) to reach a reasonable conclusion that a device did not cause or contribute to a death or serious injury or that a malfunction would not be likely to cause or contribute to a death or serious injury if it were to recur. • FDA may grant exemptions, variances or alternatives from, or to, any or all of the reporting requirements	The Regulations have no provision for "Not Reportable Events". This topic may be covered in future guidance documents. • Events occurred outside of Canada.	The Therapeutic Goods Act has no provision for "not reportable events" but these will be conferred in future guidance documents. • Events occurred outside of Australia.	There are no definite provisions for "Not Reportable Events" except for mishandling or user error. Reporting is not required when an incident has obviously been caused by user's mishandling or error resulting from inadequate knowledge or techniques.

SECTION 6.
PROCEDURE TO REPORT

Europe	USA	Canada	Australia	Japan
The manufacturer normally performs the investigation following the initial report, keeping the Competent Authority informed of progress as appropriate. There should be a final report, in a given period of time, which is a written statement of the outcome of the investigation and of nay action to the relevant Competent Authority. The manufacturer should report to the Competent Authority in the country of the occurrence of the incident of the occurrence of the incident and for implantable devices a copy of the report should also be sent to the Competent Authority of the State where the implant was performed where known.	Required information must be included within the adverse event report. If any required information was not provided, an explanation of why such information was not provided and the steps taken to obtain such information must be submitted. Follow-up reports providing additional or corrective information may be submitted at any time after the initial report. Reports containing information requested by FDA must be submitted within timeframe stipulated by FDA.	Initial Incident Report within 10 or 30 days. Final report required based on time line given in initial report	Initial incident report "...as soon as possible after the sponsor becomes aware..." Sponsor is required to respond to request for further information within 15 days. Process of investigation and final conclusions is determined by level of investigation and type of remedial action, if any, required.	Initial report within 15 or 30 days, followed by final report as soon as possible after the investigation. Follow-up reports will be required monthly until final report is issued when investigations exceeds one month.

Notification of recalls should be made to each Member State in which the devices are being recalled, and copied to the Competent Authority of the State where the manufacturer's Notified Body resides, where applicable.				

SECTION 7.
APPLICABLE FORMS

Europe	USA	Canada	Australia	Japan
• Initial Incident Report • Final Incident Report	• Mandatory adverse event report (MedWatch Form 3500A) for manufacturers, user facilities and importers • Voluntary adverse event report (MedWatch Form 3500) for health professionals & others • Baseline report for Manufacturers (Form3417) • Annual User Facility	• A proforma incident reporting form (Medical Devices Problem Reporting Form; 1 July 1998) is available and preferred, but is not considered mandatory, providing that all information that would be required in the form is submitted.	• A proforma incident reporting form is available but is not considered mandatory.	• Initial and final reports as identified in form number 3-2.

	report (Form 3419)			

SECTION 8.
CONTENT OF THE FORMS

Europe	USA	Canada	Australia	Japan
The report should include the following details as appropriate:	Individual medical device manufacturer reports shall contain the following information, known or reasonably known to them :	The form has the requirement for the following information:	The report form requests the following information:	The report should include the following details as appropriate:
Section 8.1 MANUFACTURER INFORMATION	Section 8.1	Section 8.1	Section 8.1	Section 8.1
• manufacturer's name (and the name of the authorized representative, within EEA, if relevant) • address • contact point • telephone number, fax • Identification number of the notified body involved and the date of attestation.	• manufacturer name • manufacturer and device manufacturing site address • contact office name and address • telephone number	• Manufacturer and importer identity • Address • Contact point • Telephone number • Fax number • Establishment License number (if applicable)	• Manufacturer Name Address Telephone • Supplier Name Address Telephone (If known, or if different from sponsor)	• manufacturer/importer/domestic agent for foreign manufacturer name • address • contact point • telephone number/fax number
Section 8.2 DATE	Section 8.2	Section 8.2	Section 8.2	• Section 8.2
the date when the incident came to the attention of the manufacturer or importer	date received by manufacturer (month, day, year)	The date when the incident came to the attention of the manufacturer or importer	Date either of the incident if report is from a health care institution, or when sponsor is made aware of the incident.	date of manufacturer report to authority
Section 8.3 DEVICE INFORMATION	Section 8.3	Section 8.3	Section 8.3	Section 8.3

• medical device type • commercial name • catalogue number model • serial, batch, lot number • software version	• type of device • brand name • model number, catalog number • serial, lot or other identifying number • expiration date, if any • date of device implantation and explanation (month, day, year) • whether the device was available for evaluation and whether the device was returned to the manufacturer, and if so, the date it was returned • if the device was returned to the manufacturer and evaluated by the manufacturer, a summary of the evaluation. If no evaluation was performed, provide an explanation why no evaluation was performed • device manufacture date (month, day, year) • was device labeled for single use	• Name of the device • Model number or the catalogue number • Control number • age of the device • was it sterile? • Software version • device license number • from whom was the device purchased? • is device available for evaluation?	• identity of the device • product type/application • brand, trade name and model number • serial/batch/lot number • date of manufacture(if known)	• brand name • generic device name • device type name • model number, catalog number • authorization number such as approval number on document control number

	• whether use of device was initial, reuse or unknown			
Section 8.4 ACCESSORIES	Section 8.4	Section 8.4	Section 8.4	Section 8.4
associated devices and/or accessories involved in the incident (if known)	concomitant medical products and therapy dates (do not list products that were used to treat the event)	Associated devices and/or accessories involved in the incident (if known)	Not requested	Not applicable
Section 8.5 Incident description	Section 8.5	Section 8.5	Section 8.5	Section 8.5
details of the incident (to the extent known), including: • date • patient or user outcome • current location of device involved in the incident.	description of the event or problem to include: • date of event • outcomes, e.g. death or serious injury; patient follow-up, required treatment, or sustained permanent damage • patient age at the time of event or date of birth • patient gender and weight • how the device was involved • operator of the device (health professional, patient, lay user, other)	Details of the incident (to the extent known), including: • Date • Patient or user outcome • Incident reported to manufacturer? importer? distributor?	• Description of the incident, including history, consequences, circumstances and, where relevant, sketched or explanatory information.	Description of the event or problem, include: • date of event • patient of user outcome • patient age or date of birth • patient gender • how the device was involved and uses • if implanted, give name

	• nature of the problem • description of relevant tests, including dates and laboratory data • other relevant patient history including pre-existing medical conditions • any environmental conditions that may have influenced the event			
Section 8.6 REPORTER INFORMATION	Section 8.6	Section 8.6	Section 8.6	Section 8.6
• contact point of user where incident occurred (need not necessarily be the person who actually witnessed the incident. It is recommended that health-care facilities have a contact person witness the incident.)	• initial reporter information, including name, address and phone number of the reporter who initially provided information to the user facility, manufacturer or distributor; whether the initial reporter is a health professional; occupation; and whether the initial reporter also sent a copy of the report to FDA, if known	• Initial reporter information, including the name address and telephone number of the person submitting the information to the manufacturer or importer.	• Reporter information, including institution or sponsor organization, address and telephone contact details.	• reason why the device was used.

	• date of report by the initial source			
Section 8.7 MANUFACTURERS COMMENTS	Section 8.7	Section 8.7	Section 8.7	Section 8.7
• manufacturer preliminary comments	• manufacturers report number • evaluation codes, including event, method, result and conclusion codes; for each event code provided by the user facility or a distributor, a statement of whether the type of the event represented by the code is addressed in the device labeling	• The manufacturer's or importer's preliminary comments • The manufacturer's or importer's final comments (if form is used to submit final report)	• The bulk of reports are from healthcare institutions. Manufacturers/Sponsors comments are solicited when a request for information is sent to the device sponsor.	• detailed information of adverse events or device problem. - kind of device - date of the onset of the event, progress of the symptoms of the patient, etc. - final result of the patient • cautions on the labeling • opinion of the Doctor in charge • opinion of the manufacturer
Section 8.8 PATIENT'S IDENTITY	Section 8.8	Section 8.8	Section 8.8	Section 8.8
• National practices for protecting patient confidentiality should be respected.	• patient name abbreviation or other identifier (do not use full name or social security number)	• No requirement to report patient's identity.	• No requirement for patient identity to be supplied.	• Patients initials shall only be reported.
Section 8.9 Next steps	Section 8.9	Section 8.9	Section 8.9	Section 8.9

• manufacturer's proposed next action and timescale.	• whether remedial action was taken and type whether remedial action was reported as a removal or correction	• The proposed course of action the manufacturer or importer intends to follow respecting the incident and the timescale.	• Proposed course of action, if any, is requested when a request for information is sent to the device sponsor.	• manufacturer's comments • corrective action (include proposed action and time scale)
Section 8.10 REPORT TO OTHER CA'S	Section 8.10	Section 8.10	Section 8.10	Section 8.10
A statement of whether the manufacturer is aware of any other similar incidents having an impact on the current report, and (if yes) the name/s of that Competent Authority and the date of the report.	Not applicable	A statement of whether any report has been made previously to the Program on this product, and the date of the report.	Not applicable	Not applicable
Section 8.11 REPORT TYPE	Section 8.11	Section 8.11	Section 8.11	Section 8.11
Initial/Final Report	Type of report: Initial (30 day) Follow-up (supplemental, also 30 day), or 5-day.	• Mandatory 10-day • Mandatory 30-day • Voluntary	Not applicable	Not applicable
Section 8.12 BASELINE REPORTING	Section 8.12	Section 8.12	Section 8.12	Section 8.12
Not applicable	Manufacturer Baseline Reports: • Manufacturer MDR contact name, address and telephone number • Product identification • Identification of any	Not applicable	Baseline reporting is required only for registered devices, for the first three years of registration. A recent introduction of 10 year baseline reporting has	Not applicable

	device previously reported in a baseline report that is substantially similar to the device being reported • Basis for marketing, including 510(k) or PMA number and • Is the device currently the subject of an approved post-market study • Date the device was initially marketed and, if applicable, the date on which the manufacturer ceased marketing the device • Shelf life, if applicable, and expected life of the device.		been implemented for stentless tissue prosthetic heart valves.	
Section 8.13 Final Report	Section 8.13	Section 8.13	Section 8.13	Section 8.13
Manufacturer final report must include the results of the investigation and may identify any of the following actions: • no action • additional surveillance or follow up of devices in use • dissemination of information to users • corrective action on future	FDA uses a single report system. If the manufacturer obtains required information after filing the initial MDR, a supplemental report is required within 30 days.	A description of the incident, including the number of persons who have undergone a serious deterioration in the state of their health or who have died; a detailed explanation of the cause of the incident and a justification for the	No officially designated final reports required from sponsor. Event is closed off by mutual agreement between sponsor and TGA after discussion or negotiation of final outcome. final copy of TGA report, with outcomes is provided to sponsor.	Manufacturer's final report may include information such as investigation, corrective action and response to users.

production • corrective action on devices in use • recall		actions taken in respect of the incident; and any actions taken as a result of the investigation which may include: I. increased postmarket surveillance of the device II. providing users of the device with information III. corrective and preventive action respecting the design and manufacture of the device, IV. corrective action on any unit of the device still in use, and V. recall of the device		
Section 8.14 ANNUAL CERTIFICATION		Section 8.14	Section 8.14	Section 8.14
	Requirement removed by the FDA Modernization Act of 1997	Not applicable	Not applicable	Not applicable
Section 8.15 User facility semi-annual reports	Section 8.15	Section 8.15	Section 8.15	Section 8.15
Not applicable	• User facility's Health Care Financing Administration (HCFA)	Not applicable	Not applicable	Not applicable

	provider number • Facility's name and complete address • Date of report and the lowest and highest user facility report number of reports submitted during the report period • Name, position title and complete address of the individual designated as the facility contact person • Information for each reportable event that occurred during the annual reporting period, including user facility report number; name and address of device manufacturer; device brand name and common name; product model, catalog, serial and/or lot number; a brief description of the event reported to the manufacturer and/or FDA; and where the report was submitted • Summary of total number of reportable events, or • Attachment or the			

	original reportable event report.			

SECTION 9.
ROLE OF THE AUTHORITY

Europe	USA	Canada	Australia	Japan
The Competent Authority should acknowledge the receipt of the report to the sender.	FDA acknowledges receipt of voluntary reports only. All reports are entered into a database.	The Competent Authority should acknowledge the receipt of the report to the sender.	The TGA acknowledges receipt of all reports, voluntary and mandatory, from both user facilities and sponsors.	MHW makes record of the received reports. MHW evaluates the reports.
The Competent Authority should record the report - this should involve categorizing the incident, for example: • by date (of incident, receipt by manufacturer, receipt by Competent Authority) • by outcome (death, injury or near incident) • by manufacturer and model • by device type, using appropriate nomenclature • by "coordinating"	FDA treats device-related adverse events on a case-by-case basis. FDA's response is based on the number of reported adverse events, the actual effect of these adverse events and the potential health risk(s). FDA will conduct inquiries/investigations of manufacturers, user facilities, and importers. Firms may be contacted by	The Competent Authority should record the report – this involves categorizing the incident, for example: • by date (of incident, receipt by manufacturer, receipt by Competent Authority) • by outcome (death, injury or near incident) • by manufacturer and model • by device type, using	All reports are treated individually and assessed for risk based on potential and actual outcome, overseas reporting history and previous market history. Response is based on number of adverse events for the product, risk analysis of outcome, mode of failure, etc. TGA may conduct investigations of the device through the	

Competent Authority for this type of incident (if any) • by the date when the manufacturer's next action is due The Competent Authority monitors the investigation carried out by the manufacturer and should evaluate the report and intervene as appropriate. This may be by performing their own investigation with manufacturers consultation.	letter, telephone or via an FDA investigator. Follow-up options include: additional information letters, phone follow-up, site inspections, meetings, and compliance actions.	appropriate nomenclature • by the date when the manufacturer's next action is due The Competent Authority normally monitors the investigation carried out by the manufacturer and should evaluate the report and intervene as appropriate, in consultation with the manufacturer if practicable. The program has established guidance documents for processes such as the • procedure for medical device complaint handling and recalls • procedure for mandatory and voluntary problem reporting for medical devices The program has developed standard operating procedures for' • evaluation of reported mandatory medial device incidents, • investigating medical	sponsor or direct with manufacturer. Regulatory options include • Publication of general awareness bulletin • Reference to Adverse Drug Reaction Advisory Committee for follow up. • Action through GMP Section of TGA. • Product improvement (hardware, software, documentation, etc.) • Safety alert • Voluntary recall for product correction or removal • Mandated recall for product correction or removal.	

		device problem reports The program analyzes individual problem reports with the intention of focusing post-market surveillance audits		

SECTION 10.
DEFINITIONS

Europe	USA	Canada	Australia	Japan
Section 10.1 MANUFACTURER	Section 10.1	Section 10.1	Section 10.1	Section 10.1
...the natural or legal person with responsibility for the design, manufacture, packaging and labeling of a device before it is placed on the market under his own name, regardless of whether these operations are carried out by that person himself or on his behalf by a third party. The obligations (of this Directive) to be met by manufacturers also apply to the natural or legal person who assembles, packages, processes, fully refurbishes and/or labels one or more	...any person who manufactures, prepares, propagates, compounds, assembles, or processes a device by chemical, physical, biological, or other procedure. The term includes any person who: • repackages or otherwise changes the container, wrapper or labeling of a device in furtherance of the distribution of the device from the original place of manufacture • initiates specifications for devices that are	A person who sells the medical device under their own name, or under a trade-mark, design, trade name or other name or mark owned or controlled by the person, and who is responsible for designing, manufacturing, assembling, processing, labeling, packaging, refurbishing of modifying the device, or for assigning it to a purpose, whether those tasks are performed by that person or on their behalf.	Manufacturer - • To produce the goods; or • To engage in any part of the process of producing the goods to their final state, including engaging in the process of packaging, labeling, storage, sterilizing, testing or releasing for supply of the goods or of any component or ingredient of the goods as part of that process.	No definition exists but "manufacturer" is interpreted as "any natural or legal person who is authorized to manufacture a device for business by obtaining "kyoka" (license) from the local governor".

ready-made products and/or assigns to them their intended purpose as a device with a view to their being placed on the market under his own name. This sub-paragraph does not apply to the person who, while not a manufacturer within the meaning of the first sub-paragraph, assembles or adapts devices already on the market to their intended purpose for patient...	manufactured by a second party for subsequent distribution by the person initiating the specifications • manufactures components or accessories intended to be commercially distributed.			
Section 10.2 DISTRIBUTOR	Section 10.2	Section 10.2	Section 10.2	Section 10.2
Definition has not been established.	Distributor means any person, other than the manufacturer or importer, who: • furthers the marketing of a device from the original place of manufacture to the person who makes final delivery or sale to the ultimate user, but • does not repackage or otherwise change the container, wrapper, or labeling of the device or device packaging. The distributor has no	Distributor. • Not specifically defined.	Distributor - • not specifically defined as the Act applies only to sponsors or manufacturers. Sponsor - • A person who exports or arranges the exportation of the goods from Australia; or • A person who imports or arranges the importation of the goods into Australia; or • A person who, in Australia, manufacturers the goods, or arranges	No definition exists but "distributor" is interpreted as "any natural or legal person who is authorized to sell or rent a medical device for business by notifying the local governor of the requirements provided by MHW".

	adverse event reporting obligations.		for another person to manufacture the goods for supply (whether in Australia or elsewhere) but does not include a person who: • Exports, imports or manufactures the goods; or • Arranges the exportation, importation or manufacture of the goods, on behalf of another person who at the time of the exportation, importation or manufacture or arrangements, is a resident of, or carrying on business in Australia.	
Section 10.3 USER FACILITY	Section 10.3	Section 10.3	Section 10.3	Section 10.3
No definition exists but "user facility" is interpreted as "any facility which provides diagnostic or therapeutic services to patients".	User facility means a hospital, ambulatory surgical facility, nursing home, outpatient diagnostic facility, or outpatient treatment facility and which is not a "physician's office" (a facility that operates as the office of a physician or other health care professional for the primary purpose of examination,	Health care facility means a facility that provides diagnostic or therapeutic services to patients. It includes a group of such facilities that report to one common management that has responsibility for the activities carried out in those facilities.	User facility - not defined	No definition exists but "user facility" is interpreted as "any facility which provides diagnostic or therapeutic services to patients".

	evaluation and treatment or referral of patients.)			
Section 10.4 MEDICAL DEVICES	Section 10.4	Section 10.4	Section 10.4	Section 10.4
...any instrument, apparatus, appliance, material or other article, whether used alone or in combination, including the software necessary for its proper application intended by the manufacturer to be used for human beings for the purpose of: • diagnosis, prevention, monitoring, treatment or alleviation of disease • diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap • investigation, replacement or modification of the anatomy or of a physiological process • control of conception and which does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means...	...any instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which is: • recognized in the official National Formulary, or the United States Pharmacopoeia, or any supplement to them • intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or • intended to affect the structure or any function of the body of man or other animals, and which does not achieve any of its primary intended purposes through chemical action within or on the body of man or other animals and	..any article, instrument, apparatus, or contrivance, including a component, part or accessory thereof, manufactured, sold or represented for use in: (a)the diagnosis, treatment, mitigation, or prevention of a disease, disorder or abnormal physical state, or its symptoms, in a human beings; (b)restoring, correcting or modifying a body function or the body structure of human beings; (c)the diagnosis of pregnancy in human beings, or (d)the care of a human being during pregnancy and at and after the birth of the offspring including care of the offspring. It includes a contraceptive device but does not include a drug;	...therapeutic goods consisting of an instrument, apparatus, appliance material or other article (whether used alone or in combination), together with any accessories or software required for its proper function, which does not achieve its principal intended action by pharmacological, chemical immunological or metabolic means though it may be assisted in its function by such means.	..instruments and apparatus which are intended for use in the diagnosis, cure or prevention of diseases in man or animals, or intended to affect the structure or any function of the body of man or other animals, and which are designated by Cabinet Order.

	which is not dependent upon being metabolized for the achievement of its primary intended purposes. (Federal Food, Drug and Cosmetic Act)			
Section 10.5 ACCESSORY	Section 10.5	Section 10.5	Section 10.5	Section 10.5
...an article which whilst not being a device is intended specifically by its manufacturer to be used together with a device to enable it to be used in accordance with the use of the device intended by the manufacturer of the device.	...any finished unit distributed separately but intended to be attached to or used in conjunction with another finished device. (Medical Device Good Manufacturing Practices Manual)	...When a term is not defined in our Act or regulations, the customary meaning of the word should apply (i.e. - dictionary definition - a minor fitting or attachment)	...not specifically defined, but generally taken to be a part of the principal device, used in conjunction with the device, which is not an operation therapeutic device in its own right, which is supplied as an individual item.	No definition exists
Section 10.6 ADVISORY NOTICE / ALERT	Section 10.6	Section 10.6	Section 10.6	Section 10.6
A notice issued to provide information and/or to advise what action should be taken in the use, modification, disposal or return of a medical device (see also Recall)	Advisory notice means essentially the same in the US as in Europe. US regulators may issue safety alerts, public health advisories and urgent notifications.	The term “Advisory Notice” is not used in Canada. An alert is issued to provide information and/or to advise what action should be taken in the use, modification, disposal or return of a medical device (see also Recall)	Safety Alert - advice regarding a specific situation with respect to a therapeutic good which, while performing to meet all specifications and therapeutic indications, might present an unreasonable risk of substantial harm if certain specified precautions in regard to its use are not observed. .	A notice issued to provide information and/or to advise what action should be taken in the use, modification, disposal or return of a medical device (see also Recall)

Section 10.7 RECALL	Section 10.7	Section 10.7	Section 10.7	Section 10.7
When there is a risk of death or serious deterioration to the state of health, the return of a medical device to the supplier, its modification by the supplier at the site of installation, its exchange or its destruction, in accordance with the instructions contained in an advisory notice.	..a firm's removal or correction of a marketed product that the Food and Drug Administration considers to be in violation of the laws it administers and against which the agency would initiate legal action, e.g. seizure, or an action taken when the device poses a significant public health risk. Recall <u>does not</u> include a market withdrawal or a stock recovery. Remedial action means any action other than routine maintenance or servicing, of a device where such action is necessary to prevent recurrence of a reportable event. Remedial actions include recalls, repairs, replacements, relabeling, notification, inspection, patient monitoring and device modification/adjustment.	…in respect of a device that has been sold, means any action-taken by the manufacturer, importer, or distributor of the device to recall or correct the device, or to notify its owners and users of its defectiveness or potential defectiveness, after becoming aware that the device: • may be hazardous to health • may fail to conform to any claims made by the manufacturer or importer relating to the effectiveness, benefits, performance characteristics of safety; or • may not meet the requirements of the Food and Drugs Act or the Medical Devices Regulations.	Recall - Permanent removal of therapeutic goods from supply or use for reasons relating to deficiencies in the quality, safety or efficacy of the goods. Recall for product correction - The repair, modification, adjustment or re-labeling of therapeutic goods for reasons relating to deficiencies in the quality, safety or efficacy of the goods. The corrective action may take place at the user's or the sponsor's premises or any other agreed location. Hazard alert - The issuing of precautionary information about an implanted device where it has been proven there is no stock to be recalled and all affected devices are implanted (recently introduced, this category carried the same regulatory status as a recall,	No definition exists but the interpretation is very similar to the US.

			but has been introduced to remove any inference of explanation).	
Section 10.8 SINGLE FAULT CONDITION	Section 10.8	Section 10.8	Section 10.8	Section 10.8
Condition in which a single means for protection against a safety hazard in equipment is defective or a single external ,abnormal condition is present	IEC standard 601-1 "Condition in which a single means for protection against a safety hazard in equipment is defective or a single external, abnormal condition is present.	The EU definition is taken from IEC standard 601-1 "Medical Electrical Equipment" and is almost universally accepted, even outside the EU.	Not specifically defined, but taken to the same definition as specified in AS 3200.1.0 (IEC 601.1)	(JIS Standard) Condition in which a single means for protection against a safety hazard in equipment is defective or a single external abnormal condition is present.

SECTION 11.
RESPONSIBILITY ENTITY FOR THE INVESTIGATION OF THE ADVERSE EVENT

Europe	USA	Canada	Australia	Japan
The manufacturer normally performs the investigation, while the Competent Authority monitors progress. The Competent Authority may	Only manufacturers must investigate the complaint and, when filing an MDR report on methods, results and conclusions of the	The manufacturer normally performs the investigation, while the Competent Authority monitors progress. The Competent Authority	The manufacturer/sponsor normally performs the investigation, while the Competent Authority monitors progress. The CA	The manufacturer normally performs the investigation, while the Competent Authority monitors progress. The Competent Authority

intervene, or initiate independent investigation if appropriate. This should be in consultation with the manufacturer where practicable.	investigation. Manufacturer, User facilities or Importers are required to immediately review and evaluate any complaint pertaining to injury, death or risk to public health.	may intervene, or initiate independent investigation if appropriate. This should be in consultation with the manufacturer where practicable.	may intervene, or initiate independent investigation if appropriate. this should be in consultation with the manufacturer where practicable.	may intervene, or initiate independent investigation if appropriate. This should be in consultation with the manufacturer where practicable.