Date revised 2/June/2005

			Implementation of SG2 Documents				
			Australia	**Canada**	**EU**	**Japan**	**USA**
N21	**Reportable event Sect 1.1-1.3**		Implemented in the law S41FN, S41MP, examples and plain english definition in TGA Guidance 11	Spirit of this have been in regulations from the begining	In the law, in MEDDEV2.12/1 rev4 (Guidance document). MEDDEV in line with N21	In the law. Law is compatible with N21 definition.	US Law and regulation definitions are compatible
	Section 2.1	**Deficiency of a New Device Found by the User Prior to its Use**	Implemented in TGA Guidance, but the guidance says "always instead of "normally".	Regulatory changes proposed. First draft to be public in summer 2005.	Implemented in MEDDEV	Exemption being applied no written guidance available. Having trouble with "normally as opposed to always"	US policy says “always” instead of “normally”; US feels “normally” is not enforceable.
	Section 2.2	**Adverse Event Caused by Patient Conditions**	Implemented in TGA Guidance	Regulatory changes proposed. First draft to be public in summer 2005.	Implemented in MEDDEV	Exemption being applied no written guidance available.	Substantially harmonized, but US does not agree with all examples.
	Section 2.3	**Service Life of the Medical Device**	Implemented in TGA Guidance	Regulatory changes proposed. First draft to be public in summer 2005.	Implemented in MEDDEV	Exemption being applied.	Not being applied. US manufacturers are not required to define service life.
	Section 2.4	**Protection Against a Fault Functioned Correctly**	Implemented in TGA Guidance	Regulatory changes proposed. First draft to be public in summer 2005.	Implemented in MEDDEV	Partly being applied. Life support devices are not exempted under this section.	Not being applied. US does not believe that the existence of an alarm necessarily guarantees patient safety.
	Section 2.5	**Remote Likelihood of Occurrence of Death or Serious Injury**	Implemented in TGA Guidance	Under discussion. Unlikely to be adopted into regs using current n21 wording.	Implemented in MEDDEV (Minor wording differences..negligible)	Interpretation of "remote" is difficult.	Harmonized.
	Section 2.6	**Expected and Foreseeable Side Effects**	Implemented in TGA Guidance	Under discussion. Unlikely to be adopted into regs using current n21 wording.	Implemented in MEDDEV. (minor wording differences)	Under consideration for future exemption	Not being applied as written, though manufacturers may apply for alternate summary reporting.
	Section 2.7	**Adverse Events Described in an Advisory Notice**	Implemented in TGA Guidance	Regulatory changes proposed. First draft to be public in summer 2005.	Implemented in MEDDEV	Not being applied	Partially harmonized. US regulations apply only to recalls.
	Section 2.8	**Reporting Exemptions Granted by NCA**	Implemented in TGA Guidance	Regulatory changes proposed. First draft to be public in summer 2005.	Implemented in MEDDEV	Not being applied, probably will never be applied.	Harmonized
N31		**Use Error**	Not implemented, user errors are reportable in Australia - this is explicit	Considering changes to regulations or guidance documents	Will be considered at next revision of MEDDEV (2nd semester of 2004)	Not being applied	Harmonized
N32		**Universal Dataset**	Implemented in TGA Guidance, minor local variations: ARTG#, ARTG Manufacturer#	Will be put into guidance	Will be considered at next revision of MEDDEV (2nd semester of 2004)	Have changed the form, with slight modifications to N32. In Guidance	Substantial harmonization. Six of 50 elements in 3500A not included in N32; 5 elements in N32 not required in 3500A.
N33		**Timing for Adverse Event Reports**	Implemented in the Medical Devices Regulations: Difference - "Immediate Reports" in 2 calendar days. "Death and Serious Injury Reports" in 10 Calendar Days	The current regulations are in alignment with N33	Will be considered at next revision of MEDDEV (2nd semester of 2004)	Not implement - "No vision to implement" because this impinges on regulation of medicines. 15 and 30 days is available.	Not harmonized. US regulation is less burdensome.
N36		**Trending of Adverse Event Reports**	Does not require implementation, trending mentioned in TGA Guidance	Does not require implementation, trending will be mentioned in Guidance	Does not require implementation, trending mentioned in MEDDEV	Implemented into Pharmaceutical Affairs Law in April 2005	Harmonized. Concept of trending in Quality System requirements.
N9		**NCAR Form**	In Use	In Use	In Use	In Use	In Use
N20		**NCAR Exchange Criteria**	In Use, Full Participation	In Use, Full Participation	In Use, Full Participation	In Use, Full Participation	In Use, Full Participation
		Legend:	Lt Green = Implemented		Lt Yellow = Partly Implemented		Orange = Not Implemented