

DRAWING NUMBER <b>90-2000-5.4.2</b>	REVISION <b>A</b>	TITLE <b>Quality Management System Planning</b>	PAGE <b>1 of 2</b>
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## 1.0 Policy

Product Resources management shall ensure that

- a) the planning of the Quality system is carried out in order to meet the requirements given in 90-2000-4.1 (General Quality Management System Requirements) including the requirements of stated regulatory Quality systems, and
- b) the planning of the Quality system is carried out in order to meet the quality objectives, see 90-2000-5.4.1, and
- c) the integrity of the Quality system is maintained when changes to the Quality system are planned and implemented, and
- d) the integrity of the Quality system is maintained when changes to the business are planned and implemented.

## 2.0 Responsibilities

The Chief Quality Officer (CQO) is responsible for Quality system planning and for identifying products for which regulatory Quality systems apply.

## 3.0 Procedure

Product Resources accomplishes Quality system planning through the Management Review process. See 90-2000-5.6.1, 90-2000-5.6.2, and 90-2000-5.6.3 for a description of the Management Review process.

In order to identify and communicate that a product is controlled by a regulatory Quality system, the CQO shall, contemporary with the Planning of Product Realization (90-2000-7.1), assign a Family Code in Product Resources' ERP system, SyteLine, to the affected product's Item in SyteLine; Product Resources' products for sale have item number prefixes 41 or 99 (see 90-2000-7.5.3, Identification and Traceability). This Family Code shall include one of the following designations as the last "word" of the Family Code, depending on the regulatory Quality system that applies:

DRAWING NUMBER	REVISION	TITLE	PAGE
<b>90-2000-5.4.2</b>	<b>A</b>	Quality Management System Planning	2 of 2

ATEX ... for product that falls under the ATEX Directive, intrinsically safe (IS) product

MD ... for product that falls under the Medical Device Directive, medical devices

Other parts of this Quality system will give special requirements when handling product and/or its documentation when a regulatory Quality system applies. It is by this Family Code – which is a data field associated with an Item (part) in SyteLine and viewable in the SyteLine “Items” form – that employees will be able to know that special requirements apply (by the presence of one of the above designations) and, if so, which special requirements apply (depending on which designation is present).

Product Resources’ Family Code Utility, a process which runs over the weekend, once a Family Code is assigned to a product propagates that Family Code from top down, i.e., throughout a product’s Indented Current BOM.