

行政院所屬各機關因公出國人員出國報告書
(出國類別：實習)

參加「ISO9000 品質管理執行研習會」

服務機關：經濟部標準檢驗局台中分局

報告人 職 稱：技士

姓 名：謝宗興

出國地區：印尼雅加達

會議期間：八十九年十月一日至七日

報告日期：九十年一月十八日

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壹、出國源起

- 一、亞洲生產力組織(Asian Productivity Organization)設置於 1961 年是由亞洲及亞太地區許多會員國組織而成，是一非營利性、且強調無區域性差別待遇之一跨國性組織。中華民國理事辦公處函轉亞洲生產力組織(APO)將於八十九年十月二日至十月七日於印尼雅加達舉行「ISO 9000 品質管理執行研習會」，經經濟部標準檢驗局推薦技士謝宗興參加，業獲該組織正式函覆接受推薦人選。
- 二、依據政府相關機構推動 ISO 9000 品保制度之分工職掌，經濟部標準檢驗局負責辦理 ISO 9000 認證及驗證業務。本研習班由亞洲生產力組織各會員國派員參與，包含推動 ISO 9000 成效良好國家，如我國、日本等國，亦包含剛剛起步推動 ISO 9000 之國家，如越南、高棉、斐濟、蒙古等；參加本研習會除可與相關國家之代表交換心得，亦可將本局推動 ISO 9000 品質管理之經驗提供給其他國家或給予協助。

貳、出國行程

一、八十九年十月一日

台北至印尼雅加達

二、八十九年十月二日至六日

印尼雅加達(WISATA INTERATIONAL HOTEL)

三、八十九年十月七日

印尼雅加達返回台北

參、課程簡介

一、八十九年十月二日

報到

開幕式(Open Ceremony)

各代表國學員自我介紹

品質管理基本觀念、使用技巧及工具之介紹

二、八十九年十月三日

各國學員論文發表(COUNTRY PAPER)及簡報
(PRESENTATION)

ISO 9000 執行經驗(by Mr. Arief Safari Indonesia)

ISO 9000 條文介紹(含 ISO 9000：2000 草案)

三、八十九年十月四日

案例研討(case study)

四、八十九年十月五日

工廠參觀(PT.HONORIS INDUSTRY 公司)

五、八十九年十月六日

內部品質稽核介紹

內部品質稽核演練

ISO 9000 驗證申請流程

問題研討

綜合討論

閉幕式

肆、研習紀要

一、論文發表及簡報

由來自 17 個國家之 23 個學員，輪流發表就自己國家目前推動 ISO9000 品保制度之概況作一簡要敘述，每一個學員皆需發表論文 20-30 分鐘簡報，並針對其他國家之代表所提之問題予以回答。

各學員關切的重點，大部份為各國 ISO 9000 品保驗證登錄情況(含廠家數、產業類別)推行困難點、政府及民間驗證機構之角色、驗證或輔導費用等實務的問題。

對於我國推行 ISO9000 品保制度之現況輪到本人發表時也依事先準備好之投影片做一詳盡介紹摘要如下：

ISO 9000 國際標準公布後，各工業先進國家紛紛採用，並轉定為其國家標準積極加以推動，逐漸形成世界潮流與趨勢。世界知名之產品標誌如英國 BS、美國 UL、日本 T 標誌、澳洲 AS 等，其對工廠品保制度之要求都已改採 ISO 9000 品保標準鑒於上述國際趨勢，可知推行 ISO 9000 品保制度，對於以出口為導向之我國經濟體制極具重要性。本局為促使品保制度國際化，提升我國品保水準，便利我國日後參與國際間之相互承認，自 1989 年即開始積極導入 ISO 9000 品保制度，並自 1991 年 1 月起接受國內廠商申請 ISO9000 品保驗證，而實行之初，許多廠商根本不知 ISO9000 為何物，經過本局六百多場次的說明會及不斷的宣導才逐漸讓廠商接受。其後，由於市場客戶的實際需要及確可獲得工廠管理體質改善，以致愈來愈多廠商開始推行 ISO9000 品保制度，截至目前，已獲得登錄 ISO9000 之廠商，已逾萬家。當然亦有因不同需求而向國外驗證機構申請登錄者。另外對於國內相

關驗證作業規定、費用、登錄廠商類別及如何取得國內認證機構(CNAB)之認證均作詳盡之說明(見附件論文)。最後也將本局未來努力方向做結論：

1. 擴大與國外驗證機構洽商雙邊之相互承認合作，使國外廠商可直接透過與本局有合作關係之國外驗證機構申請本局之 ISO 9000 驗證，本局(BSMI)不需派員出國辦理評鑑及追查作業。
2. 每年持續辦理「ISO9000 訓練」、「評鑑一致性訓練」、「評鑑技巧訓練」等相關訓練，有效提升本局稽核員專業知識以維持評鑑作業之一致水準。
3. 規劃派具資深稽核員赴工廠了解工廠因應 ISO 9001：2000 年版標準之調整情形，以便適時提供 ISO 9000 標準轉換之相關業務，使工廠能儘速於 2003 年前完成轉換。
4. 本局(BSMI)已接受全部製造業申請 ISO 9000 驗證外將逐步增加服務業驗證範圍並擴大政府機構及大眾運輸業之驗證服務

其間各學員對本局能投入如此多人力、心力，協助廠商導入 ISO9000 品保制度，讚譽有加，因此詢問更多有關本局如何推動的經驗，這也是本人深感對本次研習會有所貢獻的地方。

二、案例研討(case study)

由 Mr. Koichi Kumagai (服務於日本 Furukawa Electric 公司) 提供電子零組件製造廠之品質系統文件，將學員分成五組(類似稽核小組)，進行各類文件審查(包含品質手冊審查、程序書審查)及實際稽核模擬演練、如何找出問題並判定缺點，該項研討各學員表現均相當嫻熟且判定之缺點，應依據 ISO 9000

標準那一章節，觀點很一致。因此也顯示標準雖然於不同國家使用，但對標準之條文要求，認知是一樣的。Mr. Koichi Kumagai 特別強調一位合格成功之稽核員(Auditor)應具備以下特性 1.對事客觀 2.有耐性、禮貌 3.具專業性 4.機智且能應變 5.容易與人溝通 6.細心，但不吹毛求疵 7.沉著足以應付工作壓力 8.有充分準備(如備妥查核表)9.有原則、條理 10.守時、守機密。

三、工廠參觀

PT.HONORIS INDUSTRY 公司係一跨國公司，在印尼雅加達設立有照相機製造廠，為印尼當地之領導廠商。該公司已取得 ISO 9002(1995 年)驗證登錄，此外亦取得 QS9000(2000 年)驗證登錄，該公司實際為日本投資之海外分公司。期間好奇的問既然已有 ISO 9000 為何還申請 QS 9000，依該公司代表稱：因為受到客戶及日本總公司要求，因此公司才先後申請 ISO 9000 及 QS 9000 之驗證，於參觀製造現場時由張貼之各種報表及記錄，發現該公司具有相當濃厚日本式品質管理模式如運用 PDCA 管理循環、QC 七手法、SPC 統計品管等來落實 ISO 9000 品保制度。另外公司還就因建立 ISO 9000 品保制度後獲得以下幾項成就，如：1.強化公司體質 2.提升公司品質水準 3.建立標準化流程 4.提昇公司形象 5.滿足客戶的需求 6.提昇產品競爭力 7.拓展市場等作一完整之簡報。結束參觀後，心想一個公司要獲得一張 ISO 9000 證書或許不難，但要建立一個有效的 ISO 9000 品保系統及持續的落實執行並維持整個系統有效才是一大考驗，當然也惟有確實落實該系統，才能加強公司的競爭力及生產力。

四、問題研討及 ISO9000:2000 年版介紹

由日本籍講師(Mr. Koichi Kumagai)準備實際案例，將學員分成五組，進行問題討論及判定是否為缺點；各小組需派代表報告缺點，其他小組則提贊同或反對意見。這個單元類似模擬演練評鑑過程及召開評鑑總結會議。

新版 ISO 9001:2000 年標準之介紹主要針對新增加要求部份如 1.顧客為重(Customer Focus):公司內部如何將顧客之要求、期望轉換成品質管理系統要求 2.內部溝通:公司內部各階層對管理系統如何做有效之溝通 3.顧客溝通:如何與客戶有效做雙向溝通 4.顧客滿意度量測:滿意度可作為管理系統績效之一種量測 5.顧客要求之鑑別:顧客要求之服務、產品之規格、單價等鑑別 6.持續改善:運用 PDCA 管理循環模式 7.必要資源之可取用性 8.品質管理系統績效資料之蒐集與分析:強調統計分析於績效量化應如何運用以及資料蒐集方式等主要修訂條文要求逐一說明其真義。

五、綜合討論

將學員分成五組，提供各單元詳細的背景資料，針對本次課程各單元之講師表現、教材內容、績效展現、課程安排等，詳列評價之項目，由各小組自行討論、評估及打分數，並由各小組派代表進行報告及提供建言，以供 APO 秘書處作為訓練課程改善之參考。而本小組建議大致如下 1.與會代表均受過 ISO9000 訓練因此基礎課程可刪除 2.安排國際間目前最新之管理系統(如 TQM、TL9000、QS9000 等)3.邀請歐美先進國家之專家做專題討論，非侷限於亞洲國家。4.增加經驗交流時間，並設計相關課程。

伍、心得報告

綜合本次研習期間並與各國代表交換心得、經驗獲下列幾項心得：

一、各國辦理 ISO 9000 驗證之狀況

目前東南亞(含南亞)在推行 ISO 9000 績效方面，差異很大，推行成效較好之國家如我國、日本、菲律賓、馬來西亞、印度、泰國等國，至少都有幾千或幾百家廠商取得驗證登錄；但部份國家經濟起步較慢如越南、蒙古等，因此登錄廠數較少，亦有少數國家或許因地理環境關係經濟活動較不活絡如高棉、不丹、寮國等國，尚無驗證機構，因此無 ISO 9000 登錄廠商。本次研習會對上述國家是一個非常好向外學習的機會，或許這也正是 APO 舉辦會議的宗旨吧！

另有一個普遍現象，各國驗證機構大都屬跨國企業，市場佔有率高者俱屬國際知名驗證機構，如 SGS、DNV 等；此外由政府機構擔任驗證機構之國家，亦僅佔少數(如斯里蘭卡)。

二、登錄廠商管理

目前大多數東南亞國家之驗證機構，對登錄廠商均採每年追查二次，每三年重評乙次，故對本局每年僅追查乙次頗感興趣其運作模式。

另各驗證機構對於登錄標誌之使用，限制亦比國內嚴格許多，除本體、包裝材料或產品相關容器上不得使用登錄標誌外，亦不得在上述範圍使用文字敘述取得 ISO 9000 登錄，避免誤導消費者。

三、評鑑人員評鑑一致性(Compliance)維持

這是各驗證機構普遍遭遇的問題，例如：對同一類問題不同評審人員有不同見解；此外有些外銷廠商同時取得多個驗證機構之登錄（這現象在國內也很常見），不同機構間對類似問題之見解亦有差異。

綜合大家看法，人員一致性問題需透過一致性之訓練，由評審人員相互交流、研討可縮小彼此間對標準認知之差異，另透過認證機構之運作及解釋（如出版刊物或編輯指導綱要），亦是實務上可行的對策。

四、驗證機構(Certification Body)評鑑水準不一

各國之驗證機構普遍存有一個問題，只向外宣示驗證家數、廠商型態類別等表面績效或傾向以營利為目的，未真正要求評審員之評鑑素質水準，因此造成廠商只想速成獲取通過驗證證書，而無法落實 ISO 9000 品保系統，其實 ISO9000 管理系統只是國際間最低之管理系統標準，因此要使此管理系統發揮功效，企業應強化幾項工作 1.高階管理階層運用管理審查深入檢討品質系統的異常問題，並設定應改善之目標，由目標再衍生可量化之標的，再擬定可改善之計劃、方案(改善方法包括：固有技術的改善如製程能力(Cpk)之提昇、QC 七手法之落實運用等等)2.推動提升固有技術之活動，並將改善後效果所需之標準化活動再轉成 ISO9000 標準化文件，再結合 PDCA 管理系統，才能使品質不是口號。3.高階管理階層必須承諾、參與各項改善活動做到真正關心與監督的角色。至於驗證機構之評鑑水準也有待各國之認證機構 (Accreditation Body) 發揮其機能，加強管理監督。

五、教育訓練之評價

1. 大部份學員對本研習課程，皆給予滿意肯定之評價；APO秘書處在課程規劃、時間安排、講師遴聘等方面，可說用心良苦，尤其是最後面的綜合討論(課程整體評價)，藉由各國代表對課程充分討論後並提出改善意見，或許研討會就已定位ISO 9000品保，因此對於目前品質管理系統新趨勢TQM(全面品質管理)未列入課程討論為惟一缺憾。但於最後一天課程由馬來西亞籍講師Mr.Che Razali Che Ismail講解ISO9000:2000 DIS版算是較新之課程，以下摘要課程重點如下：為何要改訂標準？2000年ISO 9000標準改訂之主要理由是為了給使用者提升其活動價值的機會，並針對組織之主要過程，持續改進其執行績效。經由全球性廣泛的調查，瞭解所有使用者對品質管理系統標準的需求。新版標準將考慮把1987及1994年版品質管理系統標準之執行經驗，並融入新見解以成為一般性管理系統。如此，品質管理系統與組織的需求較為契合，也較能顯示組織業務運作的方式。國際標準組織(ISO)之指令也界定標準需定期修訂，以確保能維持最新及符合全球社會之需求。公元2000年ISO 9000標準改訂之主要理由包括強調量測顧客滿意度的需求、文件較易滿足使用者之需求、確保在品質管理系統與指導綱要之間的一致性，以及在組織中推廣一般性管理系統原則之應用。

2. 新版ISO 9001新規定要求：

新版 ISO 9001 將涵蓋大部分 1994 年版 ISO 9001 之要求事項，而新的以及較清楚的規定包括：

- (1) 持續改進。
- (2) 增加對高階管理者之角色的重視。
- (3) 在有關的部門與層級建立可衡量的目標。

- (4) 顧客滿意度及(或)不滿意度的資訊之監控，以作為一種系統績效之量測。
- (5) 強調對資源可取用性。
- (6) 訓練效果的確定。
- (7) 延伸對系統、過程及產品之量測。
- (8) 品質管理系統績效資料之蒐集與分析。

3. 新版標準之益處：

- (1) 適用各產業、類別及大小組織。
- (2) 易於使用，易於閱讀，容易了解。
- (3) 所要求之文件化數量大幅降低。
- (4) 將品質管理系統與組織之各項過程相連接。
- (5) 部分章節要求朝向組織績效之改善。
- (6) 朝向持續改善及重視客戶滿意之重要性。
- (7) 與ISO14001具相容性。
- (8) 考慮所有利害相關者之需求與利益
- (9) 一致性要求可涵蓋其他特定產業領域(如通訊、車輛)。
- (10) ISO9001與ISO9004各章節要求一致性配對，可進一步改善組織績效。

陸、檢討及建議

參與國際會議，能即時了解國際規範、標準制定之背景、觀念，並能適時表達國內現行做法；如無法達成國際上之要求，可於會中提出我國之看法及困難點。在廣泛之意見交換及討論過程中，所獲取之資訊及與各國代表建立相互交流關係，實對加速國內品保、產品驗證之推動有莫大助益。況且亞洲生產力組織係我國以「中華民國」名義加入之少數國際組織之一，目前 ISO9000 品保制度，為世界公認及接受之品質管理制度，透過國際認證組織多邊相互承認協議 (MRA)，將可使其他國家接受我國 ISO9000 驗證登錄結果，進而便利及促進我國產品外銷，因此，建議我國日後應繼續積極參加 APO 等國際組織所舉辦之各項會議或活動。

附件

一、Country Paper (The implementation of ISO9000 in Taiwan)

二、研習教材(ISO9000:2000 Guidance for the transition)

ASIAN PRODUCTIVITY ORGANISATION

COUNTRY PAPER

SEMINAR ON

IMPLEMENTATION OF ISO9000

(2-6, OCTOBER, 2000, JAKARTA, INDONESIA)

PRESENTED BY:
TSUNG-HSING SHIEH

BUREAU OF STANDARD METROLOGY AND
INSPECTION MINISTRY OF AFFAIRS(BSMI)
REP,OF CHINA

The implementation of ISO 9000 in Taiwan

TSUNG- HSING SHIEH

BSMI REP.OF CHINA

FORWORD

The Bureau of Standards, Metrology and Inspection (BSMI) subordinated to MOEA is the highest national agency for drafting CNS. It determines the national metrology policy and conducts commodity inspection. For years it plays an important role in promoting export, which in return earn a great deal of foreign exchange, and guarding public health from unqualified product.

Furthermore, BSMI has been promoting the adoption of the ISO 9000, helping Taiwan follow the global trend of internationalization and liberalization in economy. Many factories have made a leap in their management after they had been assessed by BSMI. Particularly, the service quality of some government agencies, assured by BSMI, have presented an entirely different perspective.

PROMOTION OF ISO 9000 QUALITY ASSURANCE SYSTEM

(1989~PRESENT)

ISO9000 has become the national assurance system for many advanced industrial countries since 1989. The renowned product marks of many countries, such as British BSI, American UL, Japanese T mark, Australian AS, and etc , have gradually been replaced by ISO Quality Assurance System. It is even more important for an export oriented country,

such as Taiwan, to adopt this system. In order to internationalize and raise the level of our Quality Assurance System also to facilitate the negotiating mutual recognition with other country in the near future, BSMI has actively introduced ISO9000 Quality Assurance System since 1989 and started accepting the domestic application of ISO 9000 in January 1991.

Following are the current situation of ISO 9000 implementation in Taiwan:

(1) Existence of the CNS equivalence to the ISO 9000 series

ISO code	issued date	CNS code	issued date
8402	1994	12889	1995.02.16
9000-1	1994	12680-1	1995.04.20
9000-2	1997	12680-2	1996.03.28
9000-3	1997	12680-3	1995.02.16
9000-4	1991	12680-4	1996.06.14
9001	1994	12681	1995.01.04
9002	1994	12682	1995.01.26
9003	1994	12683	1995.08.31
9004-1	1994	12684-1	1995.07.29
9004-2	1991	12684-2	1994.11.02
9004-3	1993	12684-3	1997.08.06
9004-4	1993	12684-4	1996.10.30
10005	1995	14177	1998.06.25
10007	1995	14238	1998.08.31
10011-1	1990	13351-1	1994.02.25
10011-2	1991	13351-2	1994.02.25
10011-3	1991	13351-3	1994.02.25
10012-1	1991	13827	1997.03.10

10013	1995	13657	1996.04.15
Guide 2	1996	13606	1997.10.21
Guide 61	1996	14119	1998.02.19
Guide 62	1996	13285	1998.02.19

2. Certification Bodies in Taiwan

There are about 23 certification bodies to promote the ISO 9000 registration in Taiwan. The certification bodies are as follows:

BSMI	AJA
SGS	BQR
DNV	ISC(Australia)
TUV Product Service	AQSR(U.S.)
RW TUV	OVQ(Austria)
Lloyd's	UICS
TUV Rheinland	NEMKO(Norway)
BSI-QA	QEC
BVQI	QMI(Canada)
UL	SF-ISR
Entela(U.S.)	JETT
KEMA	---

The **BSMI** is the biggest certification body and the only one authorized by the government in Taiwan.

3. Accreditation Body in Taiwan

The importance of quality management and environment management system certification has been widely recognized in the Republic of China in recent years. In view of the needs for ensuring

certification bodies continuously in compliance with the international standards, the **MOEA** promulgated “The Implementation Rules for the Chinese Quality Management and Environmental Management Accreditation System” and “The Points for the Establishment of Chinese National Accreditation Board” in March 1997. The Chinese National Accreditation Board (**CNAB**) was established to undertake related accreditation operations and began accepting applications for accreditation on July 30, 1998. The structure of the **CNAB**'s is shown in the Annex C.

The **CNAB** has accreditation programs for certification bodies or training course providers as follows:

- Quality Management System (QMS) Certification Bodies.
- Environmental Management System (EMS) Certification Bodies.
- QMS Auditor Training Course Providers.
- EMS Auditor Training Course Providers.
- Auditor Certification Bodies.

The accreditation operations of BSMI ISO9000 were formally certified by CNAB on April 20, 2000. They include “Chemicals, Chemicals Products and Fibers”, “Rubber and Plastic Products”, “Metal Products”, “Machinery and Equipment”, “Electrical and Optical Equipment” five categories. Nearly 70% of the factories have been certified and registered by BSMI. 1120 factories will be designated with CNAB mark in their certificate.

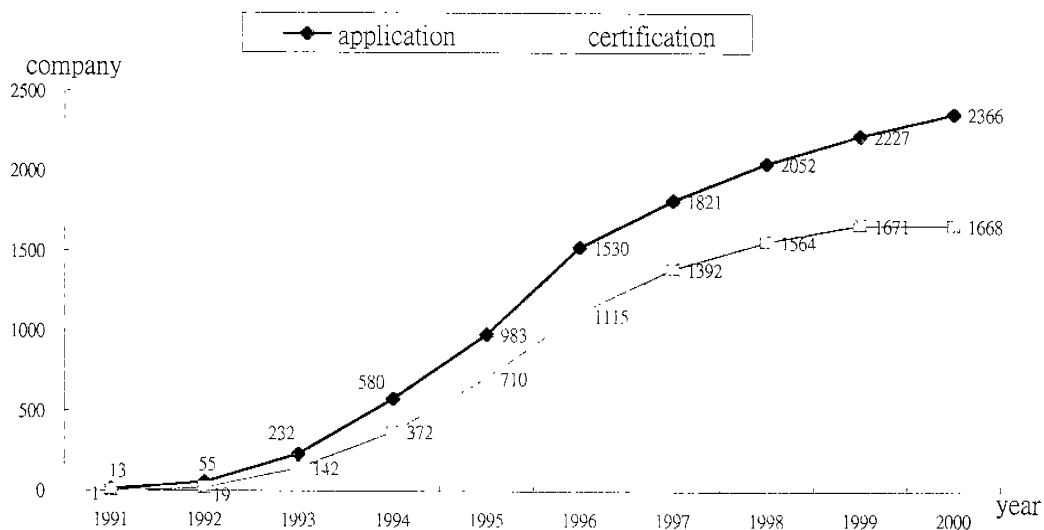
4. Number of ISO 9000 certified companies and from which business sector

Manufacturing and service industries may apply for ISO 9000

registration. Until Aug. 31,2000, the BSMI has received 2285 applications for registration and 1669 certifications have been granted in total, including 186 for ISO 9001 and 1483 for ISO 9002(see Figure 1).

At present, the scope is confined to the manufacturing and service industries. The statistic data shows that the industries most motivated to seek ISO 9000 registration are the chemical industry, the machinery industry, and the electronics industry (see Figure 2).

Figure 1



ISO 9000 registration for Taiwanese companies before June 30, 1996. Now, in accordance with the "Regulations for the Implementation of ISO 9000 Quality Assurance System Scheme", the fees of certification are as follows:

- (1) Application fee: NT\$ 10,000 per case;
- (2) Assessment, reassessment, and surveillance fees: NT\$ 7,000 per man-day;
- (3) Certificate fee (new or re-issued): NT\$ 2,000 per case;
- (4) Annual fee: NT\$ 15,000 per case. When the registered products of an organization are produced at different locations, the annual fee will be applied to each location.
- (5) Travelling and accommodation expenses of audits outside the country will be charged according to the "Travelling Expense Scales for Business Trip Abroad".

7. International cooperation

The import and export of commodities are closely related to the inspection system of the importing country.

Therefore international cooperation on product certification is an inevitable trend, and it may prevent repeated inspection. In view of this

The BSMI has promoted cooperation programs with famous certification Bodies of various countries with the aim of assisting domestic manufacture in obtaining the product marks of the importing countries and in competing more successfully in the international market.

The following international certification organizations have signed

Cooperative agreements or Memorandum of Understandings with the BSMI.

Foreign organization	Cooperation Program
1. German Management Systems Register Quality and Environmental management (DQS)	ISO9000 Quality Assurance and ISO14001 Environmental Management System
2. The British Standards Institution (BSI)	ISO9000 Quality Assurance
3. AIB-VINCOTTE Inter Belgium (AVI)	ISO9000 Quality Assurance
4. Italian Certification of Suppliers Quality Systems (CISQ)	ISO9000 Quality Assurance
5. The French Association for Quality Assurance (AFAQ)	ISO9000 Quality Assurance
6. The Austrian Association for the assessment and Certification of Quality Systems (QQS)	ISO9000 Quality Assurance
7. Underwriters Laboratories Inc.U.S.A (UL)	ISO9000 Quality Assurance
8. The Quality Management Institute Canada (QMI)	ISO9000 Quality Assurance
9. The Singapore Productivity and Standard Board (PSB)	ISO9000 Quality Assurance
10.SIRIM Berhad , Malaysia (SIRIM)	ISO9000 Quality Assurance
11.The south African Bureau of Standards (SABS)	ISO9000 Quality Assurance

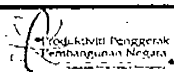
Conclusion (The FUTURE PERSPECTIVE)

1. Widening the bilateral mutual recognition agreement with foreign certificate agencies, in order that the foreign factories will be able to apply BSMI ISO9000 certificate from the local certificate agency, which had signed cooperative agreements with BSMI, directly. It will not be necessary for BSMI to assign its person to go abroad for assessments and surveillance.
2. Carrying out successively the “ISO9000 training”, “Uniformity assessment training”, “Assessing technique training”, so as to enhance the professional knowledge of BSMI’s inspectors to maintain the uniformity of assessing ability.
3. Projecting the assignments of senior inspectors to understand the adjustment of local factories to the ISO9000 2000 version, provide aids in time and ensure all the factories to complete their transfer into new version before 2003.
4. Although BSMI has conducted the approval of all the manufacturing industrials’ applications of ISO9000 certificate, it will extend the certificate business to service industrial, government agencies and mass transportation gradually.

SEMINAR ON IMPLEMENTATION OF ISO 9000

2-6 OCTOBER 2000

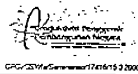
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Development*



ISO 9000 CLAUSES INTERPRETATION



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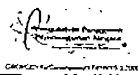


PRESENTATION OUTLINE

Part 1 : Introduction to the change

Part 2 : Details of the changes

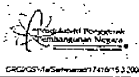
Part 3 : Guidance for the transition



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PART 1
Introduction to the changes



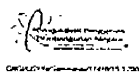
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**Revision currently being
undertaken by ISO/TC 176.**

**“Quality Management and
Quality Assurance”**

TC 176 formed in 1979.



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ISO - INTERNATIONAL ORGANIZATION FOR STANDARDIZATION

- World-wide federation of National Standards bodies with Secretariat in Geneva.
- Malaysia member since 1970s; represented by Dept of Standards Malaysia (DSM) since 1996.
- Standards prepared by ISO Technical Committees
- Every member body has right to be represented in the Technical Committees

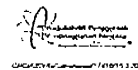


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WHAT DO WE MEAN BY YEAR 2000 REVISION?

- Revision to current ISO 9001:1994, ISO 9002:1994 and ISO 9003 : 1994
- Revision to ISO 8402 : 1994 and ISO 9000-1 (Clause 4 & 5); replaced by ISO 9000: 2000
- Revision to ISO 10011:1994 (part 1, 2 and 3)
- Reviewing and deciding on fate of existing documents in the ISO 9000 family
- Work is currently being undertaken by ISO/TC 176 its Sub-committees.



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WHAT IS THE CURRENT ISO 9000 FAMILY OF STANDARD?

ISO 8402	ISO 9004-3
ISO 9000-1	ISO 9004-4
ISO 9000-2	ISO 10005
ISO 9000-3	ISO 10007
ISO 9000-4	ISO 10011-1
ISO 9001	ISO 10011-2
ISO 9002	ISO 10011-3
ISO 9003	ISO 10012-1
ISO 9004-1	ISO 10013
ISO 9004-2	ISO 9000 for Small Business

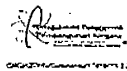


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MAIN REASON FOR REVISION

1. Under ISO protocols, all international standards shall be reviewed at least once in five years
2. Result of review will determine whether to reconfirm, revise or withdraw a standard
3. In 1990, ISO/TC 176 adopted two-phase revision process:
 - First phase, with limited change, resulted in publication of ISO 9000 : 1994 series
4. In 1996, ISO/TC 176 reaffirmed the two-phase process and began work on phase two, which is currently on-going



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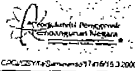


Y-2000 REVISION PLAN

4 Key standards to be developed/revised

1. ISO 9000 - Quality Management Systems
(Concepts and Vocabulary)
2. ISO 9001 - Quality Management Systems
(Requirements)
3. ISO 9004 - Quality Management Systems
(Guidance for Performance Improvement)
4. ISO 19011 - Guidelines for Auditing Management
Systems

To be supported by a number of Technical Reports.



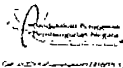
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TO ENSURE USER NEEDS TAKEN INTO ACCOUNT, GLOBAL SURVEY OF USERS AND CUSTOMERS CARRIED OUT IN 1997 BY ISO/TC 176

Questionnaire covered :

- Attitudes towards existing standards
- Requirements for revised standards
- Relationship of the Quality Management System Standards to the Environmental Management System Standards

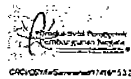


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**ANALYSIS OF SURVEY FINDINGS REVEALED
FOLLOWING USER AND CUSTOMER NEEDS:**

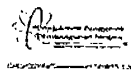
- Increased compatibility with ISO 14000 series of EMS standards
- Revised standard should have common structure based on process model
- Provision should be made for "tailoring" of ISO 9001 requirements to omit requirements that do not apply to an organization
- ISO 9001 requirements should include demonstration of continuous improvement and prevention of non conformity.
- ISO 9001 should address effectiveness while ISO 9004 should address both efficiency and effectiveness.



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- ISO 9004 should help achieve benefits for all parties, i.e. customers, owners, employees, supplier and society.
- The revised standards should be simple to use, easy to understand and use clear language and terminology.
- The revised standards should facilitate self evaluation
- The revised standards should be suitable for all sizes of organization, operating in any economic or industrial sector and the manufacturing orientation of current standard should be revised.

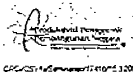


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TO ENSURE USER AND CUSTOMERS NEEDS ARE MET, A VALIDATION PROCESS HAS BEEN IMPLEMENTED:

- Allows for direct user and customer feedback at key milestones
- To determine how well the identified needs are being met
- ✓ To identify opportunities for improvement



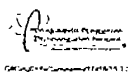
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SURVEY TO DETERMINE USER NEEDS 1120 PARTICIPANTS FROM 40 COUNTRIES

1 - 14	employees	12%
50 - 249	employees	24%
15 - 49	employees	8%
250 - 499	employees	14%
> 500 employees		42%



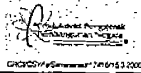
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SURVEYED ORGANIZATIONS/USER CATEGORIES

- 378
1. Product and Service
 2. Public Service
 3. ✓ Accreditation Body
 4. ✓ Certification Body
 5. Standardization Body
 6. Others

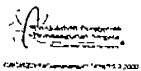


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USE OF ISO 9004 : 2000


- ISO 9001 : 2000 and ISO 9004 : 2000 are being developed as a consistent pair, with alignment of the classes.
- It is not intended to be a guide to the implementation of ISO 9001 : 2000
- Organizations are encouraged to use ISO 9004 : 2000 for the purpose of developing and enhancing systems beyond their immediate certification needs
- Title of ISO 9004 : 2000 has be revised to "Guidelines for performance improvement"

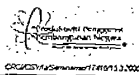


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**WILL A FULL REASSESSMENT BE CARRIED
OUT FOR THE PURPOSE OF UPGRADING
THE CERTIFICATE?**

- At this point, CBs have not made a decision
- Currently TC 176 is in discussion with IAF and CASCO
-  CBs will have to follow accreditation body guidance on this

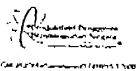


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WHAT DO YOU HAVE TO DO?

- Study draft to be ready in time
- Prepare to meet the new requirements
- unless you want to, do not change the structure of your QMS Manual to match the layout of the revised standard

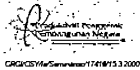


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SCHEDULE FOR DEVELOPMENT

1 Q 1998	Working Draft - for information
2 Q 1998	Working Draft - for information
3 Q 1998	Committee Draft (CD 1) - Comment by members of TC 176
1 Q 1999	Committee Draft (CD 2) - Comment & vote by members
4 Q 1999	Draft Intl Standards (DIS) - Comment & vote by members
3 Q 2000	Final DIS - Vote by members
4 Q 2000	Revised standard published



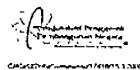
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CRG/CD/176/Service/176/15.3.2000

NEW ROLE FOR ISO 9004

- Based on 8 quality management principles
- Title revised to "QMS guidance for performance improvement"
- Towards "business excellence"
- Structure consistent with ISO 9001, but content not intended as a guide to its implementation
- To achieve benefits for all interested parties through sustained customers satisfaction



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CRG/CD/176/Service/176/15.3.2000

EIGHT PRINCIPLES ON WHICH NEW STANDARDS ARE BASED

- Customers focused organization
- Leadership
- Involvement of people
- Process approach
- System approach to management
- Continual improvement
- Factual approach to decision making
- Mutually beneficial supplier relationship



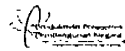
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GRC/CS/MS/Committee/1/1/19/13/2020

PRINCIPLE 1 CUSTOMER-FOCUSED ORGANISATION

Organisations depend on their customers and therefore should understand current and future customers' needs, meet customer requirements and strive to exceed customer expectation.



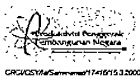
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GRC/CS/MS/Committee/1/1/19/13/2020

KEY BENEFITS:

- Increased revenues and market shares obtained through flexible and fast responses to market opportunities.
- Improved customer loyalty leading to repeat business and referrals

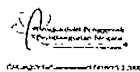


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APPLYING THE PRINCIPLE OF CUSTOMERS-FOCUSED ORGANISATION TYPICALLY LEADS TO THE FOLLOWING ACTIONS:

- Understanding customers needs and expectations.
- Ensuring goals and targets of the organisation are linked to customers needs and expectations.
- Ensuring customer needs and expectations are communicated throughout the organisation.
- Measuring customer satisfaction and acting on results
- Managing customer relationships
- Ensuring a balanced approach among customers and other interested parties.

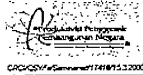


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**PRINCIPLE 2
LEADERSHIP**

Leaders establish unity of purpose and direction of the organisation. They should create and maintain the internal environment in which people can become fully involved in achieving the organisation's objectives.

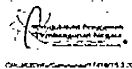


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KEY BENEFITS:

- People will understand and be motivated towards the organisation's goals and objectives
- Activities are evaluated, aligned and implemented in a unified way
- Leading by example thereby enabling continual improvement.

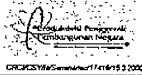


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**APPLYING THE PRINCIPLE OF LEADERSHIP TYPICALLY
LEADS TO THE FOLLOWING ACTIONS:**

- Considering the needs of all interested parties including customers, owners, people, suppliers, local communities and society at large
- Establishing a clear vision of the organisation's future
- Setting challenging goals and targets
- Creating and sustaining shared values and ethical role models at all levels of the organisation
- Establishing trust and eliminating fear
- Providing people with required resources, training and freedom to act with responsibility and accountability
- Inspiring, encouraging and recognising people's contributions.



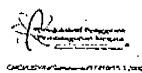
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CRK/2014/Seminar/17/16/15 3/2010

**PRINCIPLE 3
INVOLVEMENT OF PEOPLE**

People at all levels are the essence of an organisation and their full involvement enables their abilities to be used for the organisation's benefits.



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KEY BENEFITS:

- Motivated, communicated and involved people
- People feel accountable for their own performance
- People eager to participate and contribute to continual improvement.

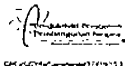


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APPLYING THE PRINCIPLE OF INVOLVEMENT OF PEOPLE TYPICALLY LEADS TO THE FOLLOWING ACTIONS:

- Understanding the importance of their contribution and role in the organisation
- Identifying constraints to their performance
- Accepting ownership and responsibility to solve problems
- Evaluating their performance against own personal goals and objectives
- Actively seeking opportunities to enhance their competencies, knowledge and experience
- Freely sharing knowledge and experience

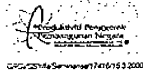


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**PRINCIPLE 4
- PROCESS APPROACH**

A desired result is achieved more efficiently
when related resources and activities are
managed as a process.

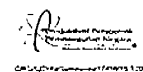


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KEY BENEFITS:

- Ability to lower costs and shorten cycle times though effective use of resources.
- Improved, consistent and predictable results
- Allows improvement opportunities to be focussed and prioritised.

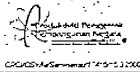


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**APPLYING THE PRINCIPLE OF PROCESS APPROACH
TYPICALLY LEADS TO THE FOLLOWING ACTIONS:**

- Using structured method to define the key activities necessary to obtain a desired result.
- Establishing clear responsibility and accountability for managing key activities
- Understanding and measurement of the capability of key activities
- Identifying the interfaces of key activities within and among the functions of the organisation
- Management focus on factors, such as resources, methods, and materials, that will improve key activities of the organisation,
- Evaluating risks, consequences and impacts on customers, suppliers and other interested parties.



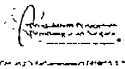
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**PRINCIPLE 5
- SYSTEM APPROACH TO MANAGEMENT**

Identifying, understanding and managing a system of interrelated processes for a given objective improves the organisation's effectiveness and efficiency.



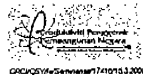
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KEY BENEFITS:

- Alignment of the processes which will best achieve the desired results
- The ability to focus effort on the processes that matter
- Provides confidence to key interested parties of the effectiveness and efficiency of the organisation.

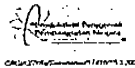


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APPLYING THE PRINCIPLE OF SYSTEM APPROACH TO MANAGEMENT TYPICALLY LEADS TO THE FOLLOWING ACTIONS:

- Structuring a system to achieve the organisations objectives in the most efficient way
- Understanding the interdependencies among the process of the system
- Targeting and defining how specific activities within the system should operate
- Continually improving the system through measurement and evaluation

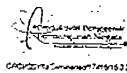


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✓ PRINCIPLE 6
- CONTINUAL IMPROVEMENT

Continual improvement should be a permanent objective of the organisation.



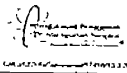
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0401/02/14/00000001/10/16/2/2000

KEY BENEFITS:

- Increased competitive advantage improved organisation capabilities
- Flexibility to react quickly to opportunities



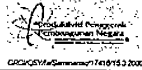
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**APPLYING THE PRINCIPLE OF CONTINUAL IMPROVEMENT
TYPICALLY LEADS TO THE FOLLOWING ACTIONS:**

- Employing a consistent organisation-wide approach to continual improvement
- Providing people with training in the methods and tools of continual improvement
- Making continual improvement of product, processes and systems an objective for every individual in the organisation.
- Establishing goals to guide and measures to track continual improvements
- Recognising and acknowledging improvements.

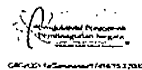


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**PRINCIPLE 7
FACTUAL APPROACH TO DECISION
MAKING**

**Effective decisions are based on the
analysis of data/information**

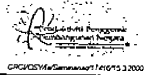


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KEY BENEFITS:

- Informed decisions
- An ability to demonstrate the effectiveness of past decisions through reference to factual histories
- Ability to review, challenge and change opinions and decisions.



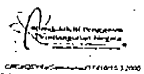
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GRK/CSM/Manpower/11/16/15.3.2010

APPLYING THE PRINCIPLE OF FACTUAL APPROACH TO DECISION MAKING TYPICALLY LEADS TO THE FOLLOWING ACTIONS:

- Ensuring, by analysis, that data and information are sufficiently accurate and reliable.
- Having data accessible to those who need it
- Making decisions and taking action based factual analysis balanced with experience and intuition.



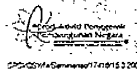
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GRK/CSM/Manpower/11/16/15.3.2010

**PRINCIPLE 8
- MUTUALLY BENEFICIAL SUPPLIER
RELATIONSHIPS**

An organisation and its suppliers are interdependent and a mutually beneficial relationship enhances the ability of both to create value.



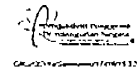
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KEY BENEFITS:

- Increase ability to create value for both parties
- Flexibility and speed of agreed joint responses to changing markets
- Optimisation of costs and resources.



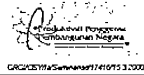
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**APPLYING THE PRINCIPLE OF MUTUALLY BENEFICIAL
SUPPLIER RELATIONSHIPS TYPICALLY LEADS TO
THE FOLLOWING ACTIONS:**

- Identifying and selecting key suppliers
- Establishing relationship that balance short-term gains with long-term considerations
- Pooling of expertise and resources with key partners
- Creating clear and open communications
- Establishing joint improvement activities
- Inspiring, encouraging and recognising improvements and achievements.



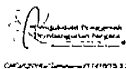
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GRUPO 1716 Setembro 1997 41/97 3.1/202

**INPUT FOR TC 176/SC2 MEETING IN SAN
FRANCISCO (SEPT. 1999)**

- CD2 released in March 1999
- Positive ballot by P-members of TC 176
- 4600 comments received from member organizations
- Results of (Validation) exercise involving 338 organizations.



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GRUPO 2042 Setembro 1999 11/99 3.1/202

**FROM COMMENTS AND VALIDATION
RESULTS FOLLOWING CRITICAL REVISION
ISSUES WERE IDENTIFIED:**

1. Clarify relationship between ISO 9001 and ISO 9004;
2. Clarify documentation requirements;
3. Ensure consistency of definitions and usage in standards;
4. Clarify "reduction in scope";
5. Ensure compatibility with ISO 14001;
6. Consider measurement of customer satisfaction requirement

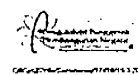


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PART 2

Details of the changes



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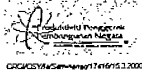
**ISO 9001:2000 (DIS)
Vs
ISO 9001:1994**

Scope (Clause 1.1)

It has been enhanced to specify that it is aimed at:

“achieving customers satisfaction through the effective application of the system, including the prevention of non-conformity and processes for continual improvement.”

ISO 9001:1994 requirements are aimed primarily at achieving customer satisfaction through prevention of non-conformity.



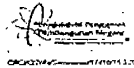
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SCOPE (CLAUSE 1.1 - GENERAL)

ISO 9001:2000 allows for certain requirements to be excluded in particular situations.

ISO 9001:1994, ISO 9002:1994 and ISO 9003 have different scopes clearly identifying particular situations where each standard applies.



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SCOPE (CLAUSE 1.2 - 01/12/2012)
PERMISSIBLE EXCLUSIONS)

Organizations may exclude requirements specified in ISO 9001: 2000 if the requirements are inappropriate due to:

- (1) The related processes not being performed by the organization as applicable to the product and/or service requirements or;
- (2) The nature of the product and/or service or;
- (3) The customers' or applicable regulatory requirements



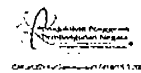
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SCOPE (CLAUSE 1.2 - 01/12/2012)
PERMISSIBLE EXCLUSIONS)

Exclusion permitted only of requirements that:

- (✓) Do not affect the organization's ability, or absolve it from its responsibility, to provide product that meets customers and applicable regulatory requirements
- (2) Are within Clause 7 of the standard: "Product and/or service realization"
- (3) Justified in the organization's quality manual.



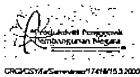
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(CLAUSE 2 - NORMATIVE REFERENCE)

Reference made to ISO 9000 : 2000 Quality Management System - Fundamentals and Vocabulary

This replaces reference to ISO 8402 : 1994 QM and QA - Vocabulary



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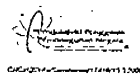


(CLAUSE 3 - TERM AND DEFINITIONS)

Term used to describe supply chain have been changed to reflect current vocabulary used by organizations

ISO 9000 : 2000 { supplier → organization → Customer

ISO 9000 : 1994 { subcontractor → supplier → Customer



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(CLAUSE 4 - QUALITY MANAGEMENT SYSTEM)

Organization shall establish, document, implement, maintain and continuously improve quality management system

- Identify and manage processes for QMS
- Determine sequence and interaction of these processes
- Determine criteria and methods for effective operation and control
- Measure, monitor, analyze process and implement action to achieve planned result and continual improvement
- Ensure availability of information to support effective operation and monitoring of processes.



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4.1 General documentation requirements

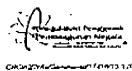
Extent of QMS dependent upon

- (a) Size and type of organization
- (b) Complexity and interaction of processes
- (c) Skills and training of personnel

4.2 General documentation requirement

QMS shall include:

- (a) Documented procedures required by the standard
- (b) Documentation required by organization for:-
 - Describing sequence and interaction of the processes
 - Ensuring effective operation and control of processes



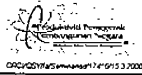
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TRANSITION GUIDELINE FOR CURRENT USERS (CERTIFIED COMPANIES)

To facilitate a smooth transition, key areas to be addressed are :-

- Internal Quality Auditor training focused on the relation between the versions and the new requirements
- Management awareness focused on structure of new version and the management role
- General staff awareness program
- Understanding of process management
- Clear understanding of the term "permissible exclusion" if you intend to exclude some requirements.

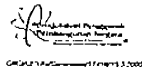


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TRANSITION GUIDELINE FOR NEW USERS

- In establishing your system, consider structuring based on new requirements
- Address new requirements based on ISO/DIS:2000
- Anticipated that a system based on ISO/DIS:2000 will also fully comply with ISO 9000:1994 (except for some documented procedures)
- If ready for certification before publication of new standard, audit will be to the current standard
- If ready for certification after publication of new standard, audit will be to new standard



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ISSUES FOR CERTIFICATION BODIES

To achieve a smooth transition, the following should be considered :

- Timing of audit and certification activities based on ISO 9001:2000
- Arrangement of audit schedule for each organization
- Training of auditors
- Protocol for encouraging users to adopt ISO 9001:2000 at their earliest convenience
- Timely administration of upgrade certification certificates



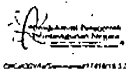
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WHAT WILL HAPPEN TO ISO 9002:1994 CERTIFIED ORGANIZATION?

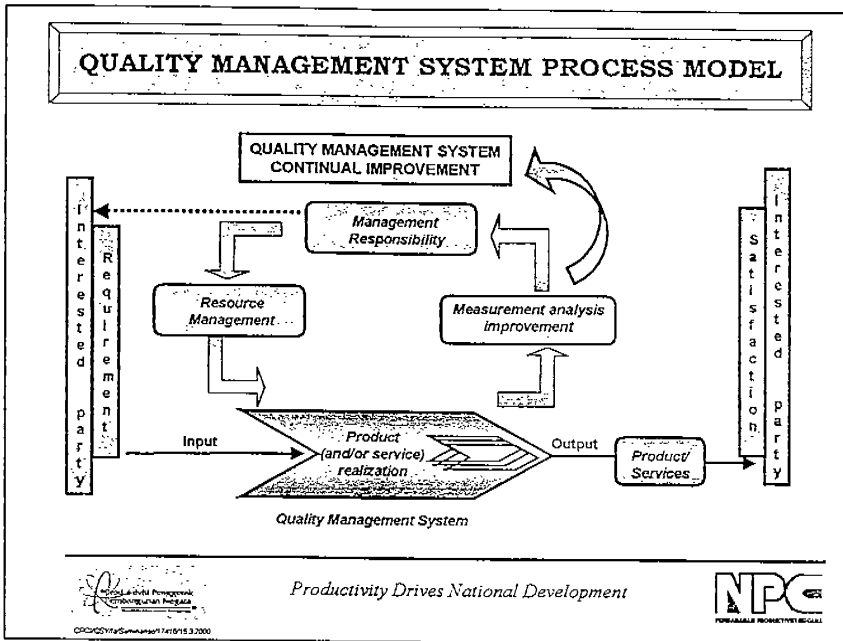
If design is required to demonstrate your capability to meet customer requirements, then this must be included in the scope of the ISO 9001:2000 certification

If design is not required, this can be excluded under the “permissible exclusions” provision ; however; reasons for exclusion should be indicated.



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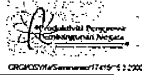




- ### TRANSITION TO YEAR 2000 STANDARDS
- New structure of Standards should not oblige organizations to revise their systems documentation to match
 - System documentation is unique to each organization
- Productivity Drives National Development*
-

**CAN ORGANIZATION CONTINUE TO BE
CERTIFIED TO ISO 9001 : 1994 OR
ISO 9002 : 1994?**

- There will be a transition period (proposed 3 years) after the standard is published during which the old standard will continue to remain valid.
- Effectively, this means certification to the old standards will be valid until the end of the transition period
- At the end of the transition period, any certificate not upgraded to ISO 9001 : 2000 will be withdrawn



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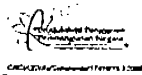
INTERPRETATIONS OF THE NEW STANDARD

ISO TC 176 has set up a mechanism for providing interpretations; a group has been formed to examine and validate interpretations

Request should go through NSBs (National Standards Bodies)

Will only be implemented after the publication of the new standard

Some countries not in favour of this because of the expected volume of work

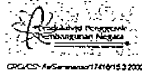


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PART 3

Guidance For The Transition



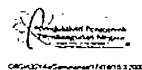
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ORGANISASI PENELITIAN DAN PENGEMBANGAN

TRANSITION PLANNING

- ISO/TC 176 has established a Task Group to prepare a guidance document concerning transitional issues by different user groups.
- To identify and provide guidance concerning transitional issues by different user groups.
- Database on frequently asked questions (FAQs) available on ISO/TC 176/SC2 open Web site (<http://www.bsi.org.uk/iso-tc176-sc2>)



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ORGANISASI PENELITIAN DAN PENGEMBANGAN

TRANSITION GUIDANCE

The following users groups have been identified:

- Current Users - Standard
- Current Users - Supplemental
- Transitional/Intermediate Users
- New Users

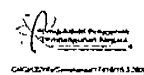


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Current Users

User category that has completed implementation of ISO 9001:1994, ISO 9002; 1994 or ISO 9003, whether certified or not.

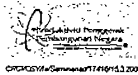


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Current User- Supplemented

User group that has adopted ISO 9001:1994, ISO 9002:1994 or ISO 9003:1994 and included additional requirements to form a set of criteria that can either be certified or accredited under the guidelines of a particular sector scheme e.g QS-9000.

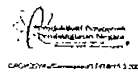


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Transitional/Intermediate Users

- User group that in the process of implementing ISO 9001:1994, ISO 9002:1994 or ISO 9003:1994 and have not yet reached full implementation of the standards requirements.
- This group may be in the process of implementing a system based on the CD or DIS version.
- This group may be seeking certification in the near future.

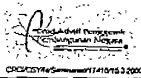


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General issues on transition

- Certification Bodies world-wide implemented own transition arrangement after the 1994 revision.
- Effort being made by all concerned parties to ensure uniform transition arrangements are applied all over the world.
- Uniform transition is very important given the number of ISO 9000 certificates that have already been issued (~270,000 as at Dec 1998)

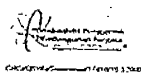


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Latest development on transition

- Certification Bodies will be guided by transition plans adopted by the International Accreditation Federation (IAF).
- ISO/TC 176 is working with IAF and CASCO on the adoption on proposals prepared by TC 176.
- Latest IAF proposal recommends three year transition period beginning from date of publication of the standard.
- All certificates will have to be upgraded to be ISO 9000:2000 by the end of the transition period.
- Both versions of the standard will continue to be valid during the transition period.



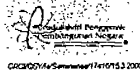
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Transition guidance for current users (certified companies)

To facilitate a smooth transition, key areas to be addressed are:

- Internal Quality Auditor training focused on the relation between the versions and the new requirements.
- Management awareness focused on structure of new version and the management role.
- General staff awareness program
- Understanding of process management.
- Clear understanding of the term "permissible exclusion" if you intend to exclude some requirements.



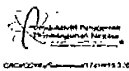
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Clause 5.1 – Management Commitment

Top management shall demonstrate commitment by :

- Communicating importance of customer and legal/regulatory requirements.
- Establishing quality policy and objectives.
- Performing management reviews.
- Ensuring availability of resources.



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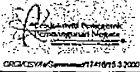


Clause 5.2 – Customer Focus

Organization shall ensure customer needs and expectations are determined and converted into requirements. Related legal/regulatory requirements should also be considered.

✓ Documented Procedure: No requirement
ISO 9001: 1994 : No corresponding requirements

< 2/10/13 >



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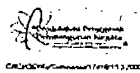


Clause 5.3 – Quality Policy

Quality policy shall:

- Be appropriate to the purpose of the organization
- Includes commitment to meeting requirements and continual improvement.
- Provides framework for establishing and reviewing quality Objectives.
- Be communicated and understood at relevant levels in the organization.
- Is reviewed for continuing suitability

✗ Documented procedure: No requirement
ISO 9001:1994: Clause 4.1.1



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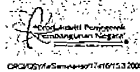


Clause 5.3 – Quality Objectives (enhanced)

Quality objectives:

- Shall be established at relevant functions and levels
- Shall be measurable and consistent with QP.
- Shall include objectives needed to meet requirements of product

Documented procedure: No requirement
ISO 9001:1994: Clause 4.1.1

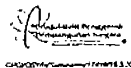


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Clause 5.4 – Quality Planning

- Processes and resources needed to achieve quality objectives shall be identified and planned.
- Results of planning shall be documented



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Clause 5.5 – Quality Planning

Quality Planning shall include:

- 1) Required processes of the QMS
- 2) Operational processes and resources
- 3) Verification & validation activities, acceptance criteria and records to be maintained.
- 4) Continual improvement

Change shall be conducted in a controlled manner and system integrity shall be maintained during this process

Documented Procedure: No requirement
ISO 9001:1994: Clause 4.2.3



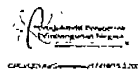
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Clause 5.5 – Administration

Functions and interrelations within the organization, including responsibility and authorities, shall be defined and communicated.

Documented Procedure: No requirement
ISO 9001:1994: Clause 4.1.2.1
(specifies defined and documented)



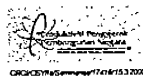
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Clause 5.5.3 – Management Representative

Responsibility enhanced to include reporting on needs for improvement and promoting awareness of customer requirements throughout the organization.

Documented Procedure: No requirement
ISO 9001:1994: Clause 4.1.2.3



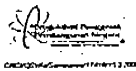
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Clause 5.5.4 – Internal Communication

New requirement to ensure adequate communication between various levels/functions regarding processes of QMS and their effectiveness.

Documented Procedure: No requirement
ISO 9001:1994: No corresponding requirement



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Clause 5.5.5 – Quality Manual

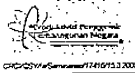
Quality Manual shall include:

Scope of quality management system (including reason for permissible exclusions)

Description of processes of the QMS & their interaction.

Documented procedures or reference thereto

ISO 9001:1994: Clause 4.2.1



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Clause 5.5.6 – Control of Documents

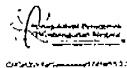
Quality records considered as documents but different requirements specified for quality records.

Control of documents "required by the quality management system"

Control shall over:

- approved prior to issue
- reviewed, updated as necessary and reproved
- relevant versions of applicable documents at all points of use
- legible, readily identifiable and retrievable
- documents of external origin given identification and distribution.
- obsolete documents to prevent unintended use and suitably identified if retained.

Documented procedure: Yes
ISO 9001:1994: Clause 4.2.1



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②

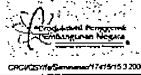
Clause 5.5.7 – Control of Quality Records

Control shall cover “records required by the quality management system”

Records maintained to provide evidence of conformance and effective operation of the quality management system.

Requirements include: identification, storage, retrieval, protection, retention time and disposition.

Documented Procedure: Yes
ISO 9001:1994: Clause 4.16



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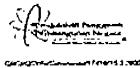
Clause 5.6 – Management Review

Top management shall review QMS at planned intervals.

Purpose of review: To ensure its continuing suitability, adequacy and effectiveness.

Review inputs shall cover current performance and improvement opportunities related to:

- result of audits
- customer feedback
- process performance and product and/or service conformance
- status of corrective and preventive actions
- follow-up actions from earlier management reviews.
- changes affecting QMS



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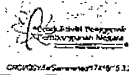


Review output shall include actions related to:

- Improvement of QMS
- Process, product and/or service audits
- Resource needs

Records of reviews shall be maintained

Documented procedure: No requirement
ISO 9001:1994: Clause 4.1.3

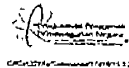


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Clause 6.1 – Provision of Resources

Provision of resources: Resources needed to establish, maintain and improve QMS and to achieve customer satisfaction shall be determined and provided in a timely manner.



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Clause 6.2 – Human Resource

Personnel assigned responsibilities shall be competent on the basis of applicable education, training, skills and experience.

Training, awareness and competence shall include:

- Determine competency needs for personnel
- Provide training
- Evaluate effectiveness of training
- Awareness relating to importance of activities and contribution to achievement of quality objectives.
- Records of education training, qualification & experience

Documented procedure: No requirement
ISO 9001:1994: Clause 4.1.8, 4.1.2.2



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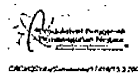
Clause 6.3 – Facilities

Define, provide & maintain facilities needed to achieve conformity of product of service.

This shall cover:

- Workspace and associated facilities
- Equipment, hardware and software
- Supporting services

Documented Procedure: No requirement
ISO 9001:1994: No corresponding clause



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Clause 6.4 – Work environment

- Define and manage the human and physical factors of the work environment
- Specific reference to health & safety conditions, work methods, work ethics & ambient working conditions have been removed
- Supporting services

Documented Procedure: No requirement
ISO 9001:1994: No corresponding requirement



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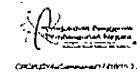
Clause 7.1 – Planning of Realization Process

Planning of sequence of processes needed to identify customer needs and expectations, converting them into requirements and realizing of the product and/or service shall be documented.

Process/service realization processes shall:

- Operate under controlled conditions
- Produce output which meet defined requirements.

Documented Procedure: No requirement
ISO 9001:1994: Clause 4.2



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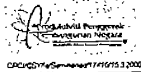


Clause 7.2 – Customer-related processes

Customer related processes involve:

- Identification of customer requirements (7.2.1)
- Review of product/services requirement (7.2.2)
- Customer communication (7.2.3)

Documented Procedure: No requirement
ISO 9001:1994: Clause 4.3 (expanded)



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Clause 7.2.1 – Identification of customer requirements

Identification of customer requirements shall include:

- Customer requirement for availability, delivery and support
- Requirements necessary for intended/specified use
- Regulatory and legal requirements



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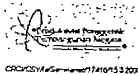


Clause 7.2.2 – Review of product/ Service requirements

Before commitment to supply, organization shall ensure:

- Product/service requirements are defined
- Where no documented statement of requirement, confirm requirement before acceptance
- Conflicting/ambiguous requirements resolved
- Ability to meet requirements

Revision to requirements shall result in amendment to relevant documentation and communicated to personnel in organization.



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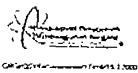


Clause 7.2.3 – Customer Communication

Communication to customer relating to following shall be defined and implemented:

- product / service Information
- enquiry / order handling
- customer feedback, including complaints

ISO 9001:1994: (No equivalent requirement)



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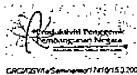


Clause 7.3 – Design and Development

Covers:

- Design and development planning
- Design development inputs
- Design and development outputs
- Design and development review
- Design and development verification
- Design and development validation
- Control of changes

Documented procedure: No requirement
ISO 9001:1994: Clause 4.4 (expanded)



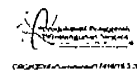
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Clause 7.3.1 – Design and Development Planning

- Stages of the design/development process
- Required review, verification and validation activities
- Responsibilities & Authorities for design/development planning

ISO 9001:1994: Clause 4.4.3
(No significant change)



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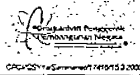
Clause 7.3.2 – Design and Development Inputs

Product/service requirement shall be defined and documented, including:

- Functional and performance requirements
- Applicable regulatory/legal requirements
- Information derived from previous similar designs
- Other requirements essential for design/development.

Requirement shall be reviewed for adequacy. Incomplete, ambiguous or conflicting requirements shall be resolved.

ISO 9001:1994: Clause 4.4.4
(Enhanced with minor change)



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Clause 7.3.3 – Design and Development Output

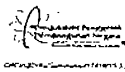
Outputs of design/development process shall be documented.

Design output shall:

- Meet design input requirements
- Provide information for production/service operations.
- Contain or reference product/service acceptance criteria.
- Define characteristics of product/service essential for safe and proper use.

Design/development documents approved prior to release

ISO 9001:1994: Clause 4.4.5
(Minor enhancement)



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Clause 7.3.4 – Design and Development Review

Review shall be conducted at suitable stages to:

- Evaluate capability to fulfill requirements
- Identify problems and propose follow-up action

Result of review and follow-up actions shall be documented.

ISO 9001:1994: Clause 4.4.6
(No significant change except purpose of review explained)



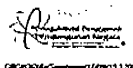
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Clause 7.3.5 – Design and Development Verification

- Verification shall be performed to ensure output meets input requirements.
- Results of verification and subsequent follow-up action shall be recorded (documented?)

ISO 9001:1994: Clause 4.4.7
(Almost identical except typical methods for design verification not given)



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Clause 7.3.6 – Design and Development Validation

- Design validation shall be carried out to confirm resultant product/service capable of meeting requirements of intended use.
- Partial validation may be done if full validation not practical prior to delivery of product or implementation of service.
- Results of validation and follow-up action shall be recorded

ISO 9001:1994: Clause 4.4.8
(No. significant change)



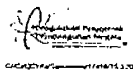
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Clause 7.3.7 – Control of Changes

- Design/development changes shall be identified, documented and controlled.
- Evaluation of effects of changes on components parts and delivered products/services required.
- Changes shall be verified, validated and approved before implementation.

ISO 9001:1994: Clause 4.4.9
(Requirement has been enhanced)



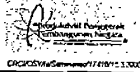
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Clause 7.4 – Purchasing

- 7.4.1 Purchasing Control
- 7.4.2 Purchasing information
- 7.4.3 Verification of purchased product/service

Documented Procedure: No requirement
ISO 9001: 1994 Clause: 4.6
(main requirements not significantly changed)



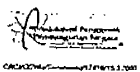
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Clause 7.4.1 – Purchasing Control

- Purchasing processes shall be controlled to ensure purchased product conforms to organization requirements.
- Types and extent of control dependent on effect on delivered product.
- Evaluation and selection of suppliers shall be carried out.
- Criteria for selection and periodic evaluation shall be defined.

ISO 9001:1994: Clause 4.4.9
(Requirement has been enhanced)



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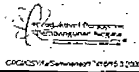


Clause 7.4.2 – Purchasing Information

Purchasing documents shall contain information describing product/service ordered, including:

- Requirements for approval or qualification of product/service
- Quality management systems requirements.
- Adequacy of specified requirement in documents shall be ensured prior to release.

ISO 9001:1994: Clause 4.6.3
(Requirement not significantly different)



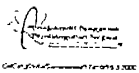
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Clause 7.4.3 – Verification of Purchased Product/service

- Activities necessary for verification of purchased product/service shall be determined and implemented.
- Supplier shall be informed through purchasing information of intended verification by organization or customer at supplier's premises.

ISO 9001:1994: Clause 4.6.4.1, 4.6.4.2 and 4.10.2



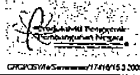
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Clause 7.5 – Production and Service Operations

Production and service operation covers:

- Operation control (7.5.1)
- Identification and tractability (7.5.2)
- Customer property (7.7.3)
- Preservation of product and/or service (7.5.4)



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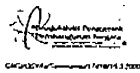


Clause 7.5.1 – Operation Control

Production/service operation controlled through:

- Availability of information that specifies characteristics of product/service.
- Availability of work instruction, where necessary.
- Use and maintenance of suitable equipment.
- Availability and use of suitable measuring and monitoring devices.
- Implementation of suitable monitoring activities.
- Suitable methods for release, delivery and applicable post-delivery.

ISO 9001:1994: Clause 4.9
(Requirement generally quite similar with part of the
Process Control Requirement)



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Clause 7.5.2 – Identification and Traceability

- Where appropriate, product/service shall be identified at all stages of production/service operations.
- Status of product/services with respect to measurement and monitoring requirement.
- Control and record unique identification of product/service if traceability required.

ISO 9001:1994: Clause 4.8 and 4.12
(Generally similar except inspection and test status
Requirements are less prescriptive)



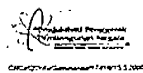
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Clause 7.5.3 – Customer Property

- Care shall be exercised with customer property when under organization's control or being used by it.
- Customer property shall be identified, verified, protected and maintained.
- Record and report to customer if lost, damaged or unsuitable for use.
- May include intellectual property.

ISO 9001:1994: Clause 4.7 (Requirements almost identical)



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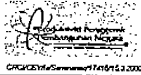
Clause 7.5.4 – Preservation of Product/services

Conformity to customer requirement shall be preserved during internal processing and final delivery to intended destination.

Where applicable, it shall include: identification, handling, packaging, storage and protection.

Applicable to parts or component of product or elements of service.

ISO 9001:1994: Clause 4.15
(Requirements almost identical but less prescriptive)



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Clause 7.5.5 – Validation of Processes

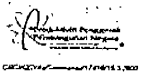
Production/service processes where output is not verified by subsequent measurement or monitoring shall be identified.

Such process shall be validated

Validation arrangement shall include, as applicable:

- qualification of processes prior, to use
- qualification of equipment and/or personnel.
- use of specific procedures
- Revalidation, when applicable

ISO 9001:1994: Clause 4.15
(Requirements almost identical but less prescriptive)



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Clause 7.6 – Control of Measuring and Monitoring Devices

- Measurements to be made and measuring and monitoring device required shall be defined.
- Measuring and monitoring devices shall be used in a manner that ensure measurements are consistent with measurement requirements.
- Software shall be validated before use.
- Calibration at specified intervals or before use, with traceability to national/international standards.
- Safeguard against adjustments
- Provide methods of handling, maintenance, preservation and storage to protect from damage/deterioration.
- Assess validity of previous results when equipment is found to be out of calibration and take appropriate action.

ISO 9001:1994: ~~Clause 4.11~~ (Almost similar but less prescriptive)



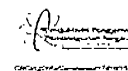
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Clause 8 - Measurement, analysis and improvement

Measurement, analysis and improvement covers:

- Planning (8.1)
- Measurement and monitoring (8.2)
- Control of non-conformity (8.3)
- Analysis of data (8.4)
- Improvement (8.5)



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Clause 8.1 - Planning

- Define, plan and implement measuring and monitoring activities.
- Includes determination of need for and use of applicable methodologies and statistical techniques

ISO 9001: 1994 Clause: 4.10.1, 4.2.3 and 4.20



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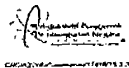


Clause 8.2 - Measuring, and Monitoring

Measurement and monitoring covers:

- Customer satisfaction (8.2.1)
- Internal audit (8.2.2)
- Processes (8.2.3)
- Product/service (8.2.4)

ISO 9001: 1994 Clause: 4.10.1, 4.2.3 and 4.20



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Clause 8.2.1- Customer Satisfaction

- Monitor information on customer satisfaction/dissatisfaction
- Define methods for obtaining and utilizing such information

ISO 9001: 1994 Clause: 4.10.1, 4.2.3 and 4.20



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Clause 8.2.2 - Internal Quality Audits

Periodic internal audits to determine if QMS

- Conforms to requirements of this international standard
- Has been effectively implemented and maintained

Audits planned based on (i) status and importance of activities and (ii) results of previous audits.

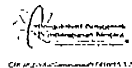
Audits performed by personnel other than those who performed work being audited.

Procedure covering responsibilities and requirements, recording results and reporting, audit scope, frequency and methodologies shall be defined.

Documented procedure: Yes

ISO 9001: 1994 Clause: 4.17

(almost identical except procedure needs to be more detailed)



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Clause 8.2.3 Measurement and Monitoring of Processes

Suitable methods shall be applied for measurement and monitoring of product/service realization processes.

ISO 9001: 1994 Clause: 4.9



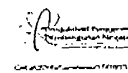
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Clause 8.2.4 Measurement and Monitoring of Product/service

Product/service characteristics shall be measured and monitored measurement and monitoring shall be carried out at various stages. Evidence of conformance with acceptance criteria shall be recorded. Authority responsible for release of product/service shall be indicated in records.

ISO 9001: 1994 Clause: 4.9 (d) and 4.10



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Clause 8.3 Control of nonconformity

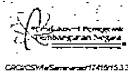
Not-conforming product/service shall be identified and controlled to prevent unintended use;

Non-conforming product shall be dispositioned and reverified

Appropriate action to be taken if non-conforming product/service is detected after delivering or use has started.

Proposed use of non-conforming product/service shall be reported to customers for concession.

ISO 9001: 1994 Clause: 4.13
(requirement has been slightly enhanced)



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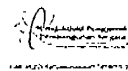
Clause 8.4 Analysis of Data

- Collect and analyze appropriate data
- Data analysis to be used for determining suitability and effectiveness of QMS and for identifying areas for improvement.
- Data to be analyzed may include those from measuring and monitoring activities.

Data analysis to provide information on:

- Customer satisfaction/dissatisfaction;
- Conformance to customer requirements;
- Characteristics of processes/products services;
- suppliers

ISO 9001: 1994 Clause: No corresponding requirement



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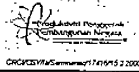


Clause 8.5 Improvement

Improvement covers:

- Planning for continual improvement
- Corrective Action
- Preventive Action

ISO 9001: 1994 Clause: 4.14
(Contains additional requirements)



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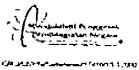
Clause 8.5.1 Planning for Continual Improvement

Processes necessary for continual improvement of QMS shall be planned and managed.

Continual improvement shall be facilitated through use of:

- 1) Quality Policy
- 2) Quality Objectives
- 3) Audit Result
- 4) Analysis of data
- 5) Correction/Preventive Action
- 6) Management Review

ISO 9001: 1994 (No. equivalent requirement)



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Clause 8.5.2 Corrective Action

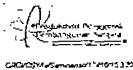
- To eliminate cause of non-conformance to prevent recurrence
- Shall be appropriate to the magnitude and impact of problems.

Procedure to cover:

- Identification of non-conformities (including customer complaints)
- Determination of causes of non-conformities
- Evaluation of need for actions to prevent recurrence
- Determine and implement corrective action needed
- Review of corrective action taken

➤ Documented procedure: Yes
ISO 9001: 1994 Clause 4.14.2

(Almost identical – emphasis on action to prevent recurrence)



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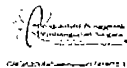
Clause 8.5.3 Preventive Action

- To eliminate cause of potential non-conformities to prevent occurrence.
- Shall be appropriate to the magnitude and impact of problems encountered.

Procedure to cover:

- Identification of potential non-conformities
- Determination of potential causes
- Determination of preventive action needed
- Implementation of preventive actions
- Review of preventive action taken

➤ Documented procedure: Yes
ISO 9001: 1994 Clause 4.14.3 (Requirement is almost identical with clear emphasis on prevention of potential non-conformities)



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