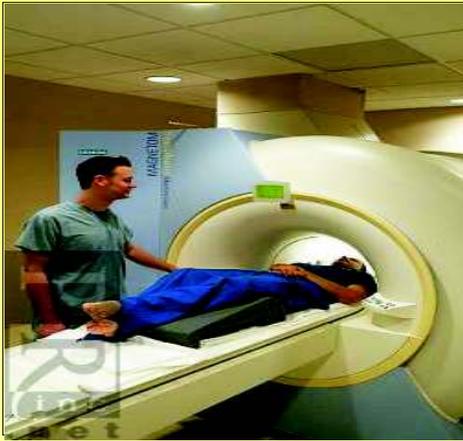


Quality Māntrā

APRIL, 2009



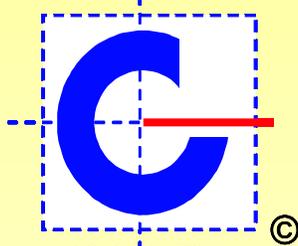
A Newsletter of International Certification Services



SPECIAL ISSUE
ON
HEALTH CARE
SERVICES



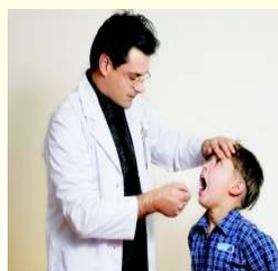
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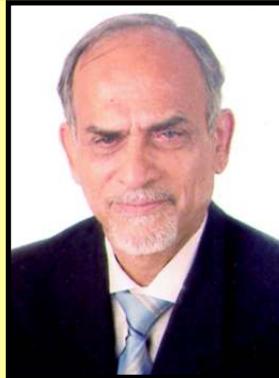
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QMS 009
EMS 003



QUALITY IN HEALTH CARE SERVICES FOR BETTER NATIONAL WELL-BEING



**Message From:-
Sundar Kataria
CMD**

“HEALTH IS WEALTH” is a well known proverb and true even today. National Well-being will very much depend upon the happy and healthy human being. The Republic of Bhutan is a small country in the world, but known as one of the best country for HAPPINESS. They consider not GDP but the GDH.

India is a large country and a large portion of our population lives in the rural areas. India is well known for the excellent medical facility but it is limited to the urban masses only. Rural area has been deprived of the good medical facilities. Very large number of rural population do not have basic medical facilities to combat illnesses ranging from viral fever, TB, Cancer etc; Living to unhealthy life, maternity homes in rural areas, not available unlike in urban area thereby leading to high child mortality rate. Today India has been attracting medical facility due to excellent well qualified and experienced Doctors and world class medical facility. Number of NRI's are Visiting India to take the advantage of above medical treatment at a very reasonable cost otherwise they would have to spend lot of money through their nose to get similar medical treatment in abroad.

Unfortunately; I feel sorry for rural masses who can not afford and reach to the modern medical treatment. Some of the interior and rural area do not have good maternity home and basic medical facility for the children. We have failed to attract the medical personnel for rural areas and to develop minimum basic medical facilities like dispensaries / hospitals and Maternity home. Thus the medical quacks take the advantage and provide poor and harmful medical treatment to the sufferers.

We need to look into the matter at National front by hang good and effective governance in the medical sector.6 . The hospital should adopt to modern Quality Management System by adopting to ISO 9001, International Quality Management System and shall also give respect to the Environmental and Safety by adopting to other Management System like ISO 14001, and OHSAS 18001, Occupation Health And Safety Management System.

Pathological testing facilities and R&D Centers should have management system in accordance with ISO 17025, Accreditation system for the Laboratories. Other management system like ISO 27001, Information security management system most vital and important to keep the confidentiality and information security etc. Quality of Medicines are covered by the FDA. Whereas the medical devices are to be assured of quality by adopting to the harmonized standards and product certification like CE Marking.

Our Organisation, International Certification Services extend their services for the certification of the various Management Systems and CE Marking including Quality Assurance.



By:- Arvind Gajjar
Station Manager
ICS, Ahmedabad

Road map to Certification For Health Care Organization

In order to fulfill changing demands and services requirements, balancing efficiency and effectiveness becomes a prime objective to establish leadership in any field. In health care sector where delivery of efficient and effective services is of critical importance, certification plays major role. Service for single health care organization is a circle of multiple contacts and failure of any one may lead to patient dissatisfaction. ISO 9001 : 2008 has five clauses, each of which is interpreted in regard to the activity performed by the organization. They are QMS requirements, Management Responsibility, Resource Management, Product realization, Measurement Analysis & Improvement.

Vision, Courage, Determination and Conviction are the essential to the quality improvements of healthcare services. Now as they were at the point of time. Acceptable quality services are not only includes the quality of direct medical services i.e. diagnosis, Medicines, Surgery, OPD, consultation etc. but other aspects i.e. administration, purchasing etc. are equally important. Other services like food, lodging, safety, security, attitude of employee etc., & Time also becomes major aspects, time to fix appointment, services time with regard to medicines, providing treatment, surgery etc. For hospital/Health care organization regulatory aspects applicable to equipments and demonstrated compliance to be defined & monitored. Radiation protection (x- rays & radioactive sources), Lasers, Ultra violet Radiation, safe use of such devices to be ensured & procedures for protection to eyes & skin of operators & patients should be followed. For disposal of bio medical waste disposal authorization form Pollution control authority is necessary.

> Quality Management System Requirements.

QMS documents shall include; Quality policy & quality objective, Quality Manual defining scope and how requirements are applicable. Documented Procedures as specified in std. Procedures needed by the unit to ensure effective planning, functioning & control of activities. Quality record required by the Standard Management Responsibility The quality planning shall be based on

- 1) Patient requirements
 - 2) Performance criteria of health care services.
 - 3) Quality objectives
 - 4) One of the members of the organization shall be nominated as MR who shall ensure the QMS meets the requirements.
- Resource Management Necessary competence & training needs to be identified for staff related to safety, security, handling of chemicals & drugs, bio medical equipments, Utility services, Infection control, waste management & other support services. The infrastructure & work environment needs special consideration with respect to Ergonomics, Hygiene, and pollution & environment parameters.

> Product Realization;

Planning: responsibility & authority for delivering quality services to the patients to be identified. Requirements in terms of Infrastructure, equipments, Compliance to legal requirements. Customer related processes Procedures to be established, to cover all the activities of interface between Patients & health care unit.

> Design & Development:

Requirements of design & development in healthcare organization refer to new processes of treatment/patient care services. Competent medical professionals & administration are needed for planning & providing such services. Analysis of patient history & needs. Process control and evaluation parameters Comments of patients. Associates/external experts. Reviewing of all clinical guidelines, manuals, and patient's review prior to administering actual need to be validated. Design validation in healthcare unit is also an ongoing process.

Purchase:

The purchase of products, drugs, foodstuff, medical aid etc. and services like disposal of bio medical waste, infection control, housekeeping, maintenance etc. conforms to specified requirements as applied need for to be complied in all purchase.

> Production & services provision:

It includes compliances with specified requirements to satisfy patients, Also required to established tracking of patients treatment, & care should be taken for patient supplied items. The environmental condition required for preservation and shelf life of items should be defined. results comply with planned arrangements and to determine the effectiveness of QMS Corrective actions shall be taken to ensure that services are as per the specified requirements.

The satisfaction level of services rendered to patients should be evaluated .eg. Patient satisfaction index, Infection control data, Clinical lab .data, After effect of treatment/drugs. The monitoring/observation of the Patients, during the delivery

> Control on monitoring & measuring equipment:

It shall also cover all critical equipments i.e. diagnosis & radiology equipment, pathological analyzers. Test equipments, bed side monitors, ECG machines, Incubators etc .All such devices needs to be calibrated having traceability to national std. Where traceability do not exist, the method for verification, using first principal or having reference samples, should be established for measurement, analysis & improvement. The management of healthcare unit shall plan & implement the monitoring, analysis & improvement processes needed to demonstrate that the services are as per the specified requirement and to continually improve the effectiveness of QMS. Unit shall establish & maintain documented procedures for planning & carrying out internal audits to verify whether quality activities & related Delivery of services/treatment should be made as per the plan drawn for individual patient should be communicated to patient or patients associate. Management of Healthcare unit shall plan & review the QMS at defined intervals. Efficiency & effectiveness of QMS and improvements there of by way of corrective and preventive actions. The CA/PA on the basis of patients/associate complaints or feedback shall be recorded and analyzed. Some of the examples of corrective actions.

- 1) Revision/modification of treatment plan for patient ailment.
- 2) Training t o Doctors/Paramedical staff to enhance their competence.
- 3) Change in documented procedures
- 4) Up gradation of facility & work environment

Preventive action on other hand are to be taken based on the extrapolation of data available on patient complaint, on conformity observed and other performance indices. After getting certification the next step for health care organization is Continual Improvement.



**By:- Micheal Paul
Medical Specialist**

About The Writer:

Michael Paul working as Administrative Head in a Multispeciality Hospital Lifecare Institute of Medical Sciences and Research, Ahmedabad and is a QMS Auditor and Trainer for Motivational, Personal Growth Development and Counselor for students in School and College.

Health Industry is experiencing dynamic changes; demand for Quality healthcare is attributed to the highest peak. It really needs efforts to take a quantum leap in designing the future of healthcare by continually improvising on quality by focusing on the internal qualitative tools of any healthcare organization. Looking to the present development and growth in the healthcare the future looks towards in experiencing dynamic changes, wherein demand for Quality Healthcare will be attributed at the highest peak. To have this clear vision healthcare sector have to access the requirements of implementing Quality Standards if it needs to take a quantum leap in continuously designing the quality by focusing on internal qualitative tools in the healthcare organization.

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It has been observed that healthcare consumers are now much more aware of their rights and responsibilities, hence performance and performing is an important issues for any organization. Introduction of new technology, rapid innovations and development in medical sciences, innovative techniques and therapies, today Health Industry will give a new diversification to the society. Looking back to the past 10 years, hospitals were not so recognized as an asset because of its unorganized system and quality of services.

The healthcare system was driven on focusing the trends each hospital had developed and the process was implemented to the patient, the area of thinking and perception was related to admission, treatment and discharge, thinking beyond these was not in sight, but recent growth in this sector has stabilized itself by being challenged to meet the demands raised by the healthcare consumers. Now the prime responsibility being focused by hospital to achieve quality care is related to Patient safety and Care which becomes priority area to focus on. Hence the need arises to measure the internal performance for a planned outcome, and these outcomes are clearly valued by the patients and appear to be more aligned with the goal of any hospital.

To ensure quality outputs, hospitals will need to perform on the process measures/indictors it is true that process measures can be based on scientific evidence which can be relatively easily measured and compared within the controls of physicians. Health Industry is being challenged by fast growing economy, rising incomes, rising of affluent population, changing definition of health with the changes in the lifestyle and increasing awareness in changing the perception of patients as consumers, making hospital to be more cautious to be challenged with. Patients are more informed now then before; demands of patient are increasing along with their expectation levels. Patients are showing their readiness to inspend money in the hospital they wish to go to get the best quality care and services.

With rising income and better options to Health Insurance Schemes, consumers are precisely more aware in ensuring to meet the expenditures which enable them to empower in taking sole decision to choose the Hospitals of their choice. Considering this fact it opens an area for each hospital to meet the challenges which is knocking the doors. Continuing trends towards evolution of healthcare developments, hospitals need to sharpen their innovative ideas, services, offerings, in a Qualitative way which

meets the demands of the patient and attracts the patients to approach them, or generate an idea of bringing healthcare closer to the consumers. To bring healthcare consumer closer what really matters is Internal Quality Management System Many organizations have found that practical implementation on internal quality improvements in hospital have a major impact on healthcare services, which can be achieved by focusing on continues Quality improvement, the process should be on going focusing on Services related to patient care and safety, satisfaction level, financial outcomes, trainings and education, considering time factor. Quality improvement on daily base and parameters and quality check points derived by standardization will open various choices for healthcare consumers in selecting the hospital, which includes Good Diagnostic Facilities, Good Doctors and Specialist, Good Nursing Care, Good housekeeping facility enhancing the accountability of services by the providers, Good education provide to the patient. The elements for improvement of quality can be identified on below parameters:

1. Care & Safety of patient
2. Effectiveness
3. Patient centered
4. Timely care
5. Efficiency

The synergy of Quality Improvement movement is rapidly giving rise to all designated hospitals whether private or government. Gradually healthcare system will have to take proactive steps to ensure care of patient and safety, not only because patient is aware of their medical problems and rights and privileges but also to ensure a quality marking within the hospital. To generate the impetus and support for perfection hospitals should start the generating simple and measurable goals, goals to be formulated to improvise overall operation along with the time frame of achieving it. Primary responsibility of Management of any hospital is to involve the staff to identify their responsibilities and their roles they require to perform with the hospital. Predicting on success without any goals to measure is mere a talk of no conclusion. Continuous improvement is identifying results on a specific improvement process you wish to demonstrate and then analyzing the specific quality measures and check parameters to achieve it. By using quality measures and process like (PDCA) Plan-Do-Check- Act, it helps an organization to ensure ongoing process of learning and improvement. QMS ISO 9001 Certification is the answer to Quality for any organization. Putting eight principles of ISO in process as a measurement tools quality automatically will be generated and assessed. Since the process is purely based on DCA plan-do-check-act methodology, it is easy to measure each parameters of Quality. To put it in another way Healthcare is what happens when provider capacity meets the demand for care to produce the outcomes or results, to realize he grater possibility of brighter and patient concern process methodology Quality Management Systems will be a better option to adopt.

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Need for ISO 13485: 2003 Certification for Medical device manufacturing units.

By:- Samir Mehta Principal Consultant, KD Consultancy, Ahmedabad

The Medical devices manufacturing units in INDIA are on rampant growth. Globalization of technology, economic operational expenditures, awareness about English language, low labor cost, highest percentage of youth with sound education & incentives from government provide the right environment for even brighter future for Medical device Manufacturing units to explore the export market.

Indian Medical device Manufacturer can take lion share in international market provided they opt for the change. This change is nothing more than international recognition to the organization & product. This recognition or recommendation can be achieved by international certification like ISO

ISO 9001:2008 is the International certificate for Quality Management System which can be applied to any organization. This certification may be the first step to system standardization in the organization.

ISO 13485:2003 is the recent version of international certificate for Medical device Quality Management System which can be applied to Medical device manufacturing units. Before that ISO 13485:1996 was applicable. The requirements in ISO 13485:2003 are specific to Medical device manufacturing units. This is the company certification emphasize on quality & safety of product, process & management system. Comprises of requirements of eight quality management system clauses.

ISO 13485: 2003 certification may be considered as the second step to international recommendation to the medical device manufacturer & first step for product certification like CE marking of medical device.

If any Medical device Manufacturer wants to export their product, ISO 9001 certification is preferred but for the European market, they are supposed to have CE certificate to their product.

ISO 13485: 2003 certification provides a certified organization opportunity to compete with certified organization & put ahead of non certified organization.

Even for loan license manufacturing & job work manufacturing ISO 13485:2003 certificate provides a certified organization better opportunity.

Wish you better progress, prosperity, profitability & productivity through Company & product certification.

ICS Welcome the below members in the ICS family

1. Pramod Kush	Vice President (Certification)	Mumbai
2. Satish Kumar	Inspector	Delhi
3. Shankar Vishnu Natu	Auditor (OHSAS)	Mumbai
4. Ratnakar Pokharkar	Inspector	TPA
5. Jai Prakash Pathak	Inspector	Mumbai
6. Santosh Manche	Inspector	TPI
7. Ram Prasad Deep	Inspector	Delhi
8. Sisir Kumar Panda	Inspector	Mumbai
9. Aniruddh Yadav	Inspector	TPI
10. Subhash Chand	Inspector	Delhi
11. Sandeep Deokar	Inspector	Delhi
12. Abhijit Patil	Technical Executive - FSMS	Mumbai
13. Siddhi Palande	Jr. Office Executive	FSMS
14. Shahzad Hasan	Inspector	Mumbai
15. Jithesh P. K.	Inspector	TPI
16. Wilson Dsouza	Inspector	Mumbai
17. Gufran Ahmad	Inspector	TPI
18. Chand Kumar	Inspector	Delhi
19. Chandra Kumar Dwivedi	Inspector	Delhi
20. Chandra Moli Sharma	Inspector	Delhi
21. S. Krishnamoorthy	Office Executive	Chennai
22. Anuj Kumar Tyagi	Inspector	Delhi
23. Abhishek Kumar	Inspector	Delhi
24. Shashi Kumar Singh	Auditor	Ludhiana
25. Rahul Kumar Negi	Inspector	Ludhiana
26. Ullhas Pal	Jr. Inspector	Mumbai
27. Rajendra Vaidya	Inspector	ECD
28. M. D. Seetharaman	Jr. Office Executive	Mumbai
		TPI
		Chennai

ICS Wishes the family member a very Happy B'Day

Name of the employee	Date of Birth	Branch
1) Pravin Kumar Yadav	1 Apr	Mumbai
2) Shyam Vispute	3 Apr	Nasik
3) P. K. Sharma	5 Apr	Ludhiana
4) S. Madan Kumar	5 Apr	Karur
5) Vikas Ahire	7 Apr	Nasik
6) Sandeep Sukla	7 Apr	Mumbai
7) Javed Esmail Badshah	11 Apr	Mumbai
8) R. Saravanan	12 Apr	Bangalore
9) Amar Pednekar	13 Apr	Mumbai
10) Kusuma Rudraiah	14 Apr	Bangalore
11) Ajay Kumar Maurya	17 Apr	Delhi
12) Hiren Parekh	18 Apr	Ahmedabad
13) Ashim k sinha	20 Apr	Mumbai
14) Nagaraju Etikala	20 Apr	Hyderabad
15) Omprakash Dandasena	20 Apr	Mumbai
16) Sunil Datar	22 Apr	Belguam
17) Rakesh Pathak	25 Apr	Delhi
18) Tribhuvan Nath Singh	26 Apr	Delhi
19) Deepak Pandey	30 Apr	Indore
20) Rajiv Sharma	30 Apr	Ukraine

Quality Māntrā

APRIL, 2009



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CORPORATE JOKES

A man wanted to buy his son a parrot as a birthday present day he went to the pet shop and saw three identical parrots in a cage. The Man, "how much for the parrot on the right? owner said it was Rs. 2500. "Knows how to use all of the functions of Microsoft Office 2000, responds the clerk.

"He can do all of your spreadsheets and type all of your letters."

An then asked what the second parrot cost.

The clerk replied, Rs. 5000, but he not only knows Office 2000, but is an expert computer programmer. The man inquired about the cost of the last parrot.

The clerk replied, "Rs. 10,000."

Curious as to how a bird can cost Rs. 10,000, the man asked what this bird's specialty was.

The clerk replies, "Well to be honest I haven't seen him doing anything. But other two call him

The newly appointed health minister of a northern state, whose knowledge of English was some what elementary, was on his first official visit to the largest hospital in the capital. The director of the medical services took the minister around the operating theatres and general wards till they came to the women patients ward.

This sir, is the labour ward, explained the director.

The minister stopped in his tracks and remarks firmly, I will not visit this ward. Don't you know we have a labour minister in the government? I must not trespass into his domain.

An inspector of schools went to a government aided school and put the following question to students of the sixth std. Class: You have read the *Ramayann*. Tell me who broke Shivas *Dhanush*

Only one boy raised his hand: Sir I don't know who broke it but it was not me.

The inspector turned to the teacher and reprimanded him for not having done his job the teacher replied; Sir, the boy is very naughty, I am sure it was he who broke it, but will admit it.

The inspector went to the headmaster and narrated the whole story. After hearing him the headmaster said: Why make a fuss about such a petty. Whatever is broken forever. While paying us the grant you may deduct the price of a new *Dhanush* and pay the balance.

FORECAST

Capricorn: Love is in the air for you. This is a surprise for you, Cap. You actually haven't given romance or love much thought. But life's bag of tricks is full of unexpected treats - some of them in the form of love and romance. Just when you thought things couldn't get much worse, you forgot to think about the healing power of love. A chance meeting, a reunion, or a match-up will introduce you to the dizzying delight of love. There is so much more in this life than money. Cap, you're just about to find that out for yourself.

FORECAST

Aries: Your bold face needs to keep that bravado in mind during April as situations, bad and good, roll out like a carpet at a movie premier. Part of April is like your own personal horror flick; hop, chop, cut, cut, slice and dice - at least where it concerns work and your personal spending. But once that segment ends and you have swept away all that is unnecessary,

Taurus: you've been bearing the brunt of other people's problems and worries lately. You are not yourself - that's why you wear a hang-dog look instead of that of the brute-strong look of the Bull. This month, you must remember you are still The Bull. And even while the bears tear up the stock market, you must patiently wait for the better time to re-appear. It will come, There's still mass confusion this month, especially where it regards stocks and certain other investments. But keep in mind, there is money sitting on the sidelines, waiting for the right moment, to come back in the market and invest. The mattress is not any sort of long-term plan. So take heart, Taurus. Practice patience.

Gemini: Sign of Twins. Your moods and emotions have bounced back and forth between hope and despair in the recent past. you look forward. It's pick and choose time for you this month, Gemini, as you come down to earth. Do I stay or do I go? Since you are the Sign of Duality you can always take the other side of any argument. But this is no time to argue with yourself over matters of import. Go strictly with your One on One intuition.

Cancer/Moon Child: The lyric is about recognizing what and who is going on around you. And it's meant for you this month, Moon Child. Are you seeing the same archetypes enter your life, over and over again? What lessons do you learn from them? Some of these archetypes are shadowy figures (like those in the song), but the very good news, this month, is that you are now recognizing the dough faces quickly and showing them to the door. The wool-pulling days are over now, Moon Child. Look strangers straight in the eye. If they blink, pass them by without a second thought.

Leo: Leos like to get right to the point; no fancy dancing, no 10-letter words. They want to hear it like it is, tell it like it is, and press on. So you've been doing a lot of facing-up lately. you've lost weight and more than a few nights sleep. April brings you some respite as you re-group, re-formulate and re-charge. You are still in a leadership role, or will soon be. When it comes to implementing some one's plan nobody does it better. So keep leading the Truth Leader charge. You will make a lasting difference and be rewarded for it.

Virgo: You've been grumbling and groaning about some business plans gone awry (or about to). And your whole face and demeanor shows it. Failure is not a word in your vocabulary, especially since you work so hard and are so darned practical. But sometimes hard work and practicality are just not enough to foot the bill. This is hard for you to see, because you've put so much work into your work. And hard for you to accept, because it's never happened to you before - at least not quite like this. You need to lift your spirit, by focusing your practical mind on how you can put the pieces back together again. "Just do it."

Libra: You've changed direction, and not a moment too soon. As an air sign, you can tell which way the wind is blowing; you don't need to be a weatherman; you just know. It may seem odd, but this is an oddly auspicious time for you. Libra is one of the most comforting and soothing of all the Signs, and so many of us still need soothing and comforting. This is a great time for you to re-invent; to put your creativity and benevolence to work together to create a concept that is both timely and desirable. Recognize what's needed and rise to meet the demand this month.

Scorpio: you are so lithe and light on your feet. All the better to move around the dance floor, size up your competition and put yourself in the best position. Times are tough for you. Nobody knows how to play dead better than Scorpio - or how to quickly move from break-dance to twist to foxtrot to jitterbug and back again. I see a Great April for you, Scorpio. Just one word to the wise: Watch whose feet you step on as you step it up.

Sagittarius: You are one of the most- uplifting of all the Signs. Witty, jokey, pun-filled. . . Go searching for humor, if you must. There's plenty around - on and off YouTube. April may not seem particularly funny to you (taxes, and all), but if there's a silver lining to any dark clouds, you'll find it. Spread the cheer and the silver lining all around and it will come back to you, many-fold.

Aquarius: Actually, you're doing a lot more than making faces this month, Aquarius; . The need to solve some of the problems facing this Planet have driven you to research, write and work, harder than ever, coming up with new ideas for these new, leaner times. Many great solutions to the toughest problems will come from Aquarius. So while you may be squinting and frowning more than usual, that's only because you are so very hard in thought. Expect to come up with some creative, workable solutions to help

Pisces: Facing Time. Pisces, you are one of the Signs who can work around the clock, . Time changes seem to have little meaning or disturbance for you. . . And unless you have a firm deadline, you rarely have a routine. Because you are so adverse to keeping time by wall clock or wrist watch, sometimes you miss some of the important clues or hints that exist, for the rest of us, in the here and now. Like reading your snail mail; paying your bills; responding to personal emails and so on. April has some important "times" for you - . April will remind you of the value of spending time on people and projects that exist outside your focus. This could be a rude awakening, or one - just "in time"

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MOTIVATION LINE

“The greatest regret in our lives are the risks, We did not take. If you think something will make you happy, go for it. Remember that you pass this way only once.”

“Be positive, Success is never ending Failure is never final.”

During our lives we are faced with so many elements as well, we experience so many setbacks, and fight such a hand to hand battle with failure, head down in the rain, just trying to stay upright and have a little

ACHIEVEMENTS

Certificate presentation

To

Employee State Insurance
Corporation (ESIC)

by Mr. B. K. Singh,

Station Manager

Belgaum.



This Edition Compiled and Presented by ICS Ahmedabad,

Arvind Gajjar (Station Manager), N. R. Lekha, Srikant Satapathy, Vinod Sharma, S. K. Nair,
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