

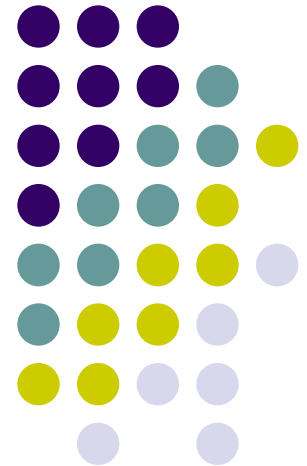
# Improvised presentation on Upcoming changes to ISO 9001



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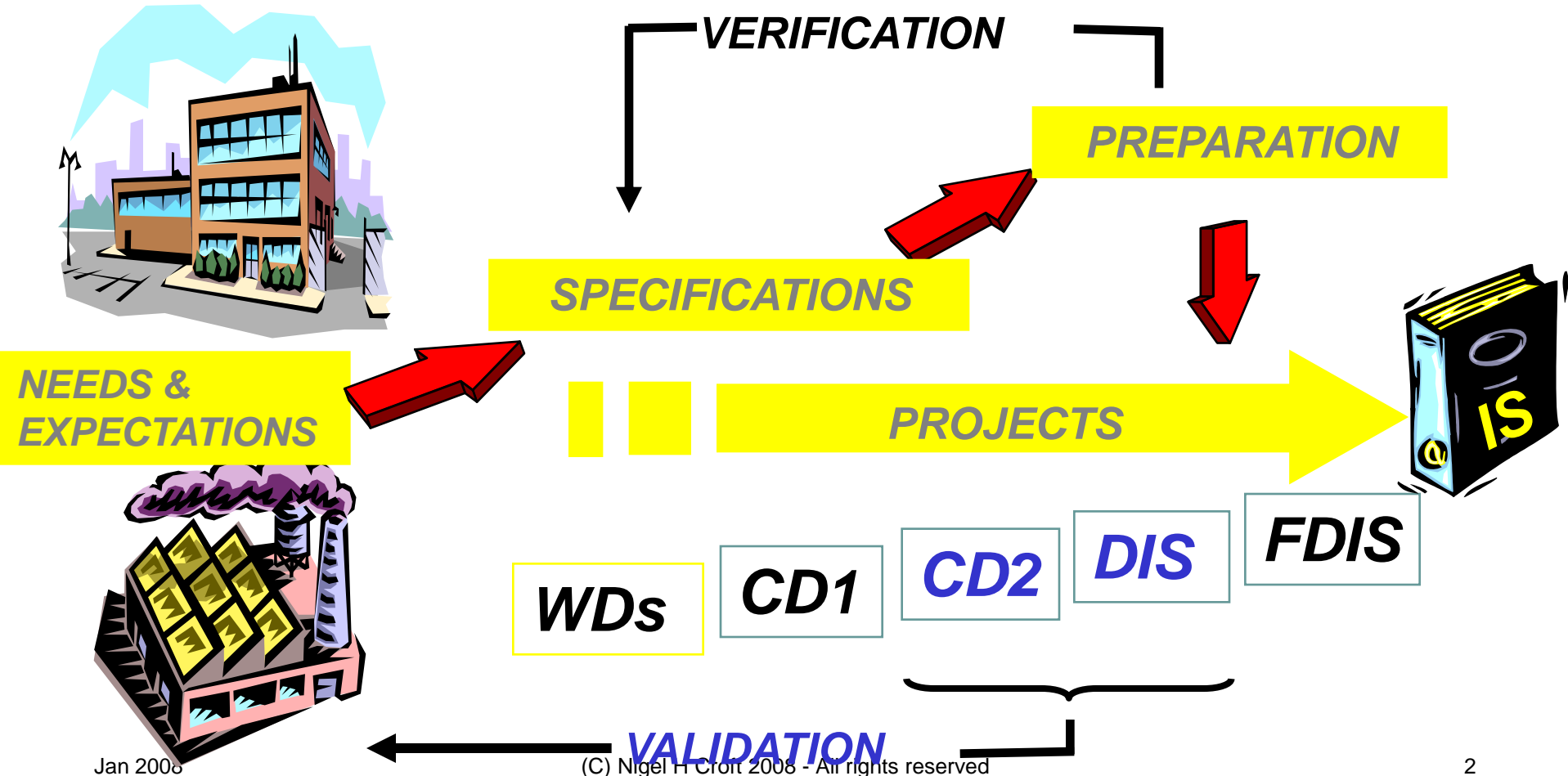
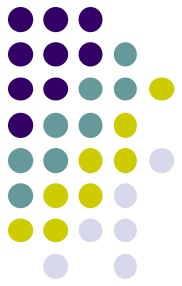
**Nigel H Croft**

**Chairman, ISO/TC176/SC2 – Quality Systems**



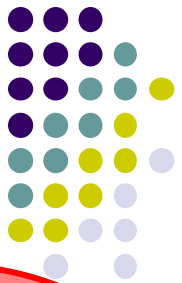


# The standards development process





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Sistemas da Qualidade  
(ISO 9001, ISO 9004  
& outras)

ISO/TC 176

CALG

CSAG 

WG Governos locais

TG Trad. Espanhol

WG Eleições

TG Trad. Árabe

WG Educação

TG Automotivo

Tecnologias de  
Suporte  
(ISO 100xx)

Fundamentos &  
Vocabulário  
(ISO 9000)

 SC 1

 SC 2

SC 3



Brasil também tem boa representação nos GTs



# TC176 Rio 1997

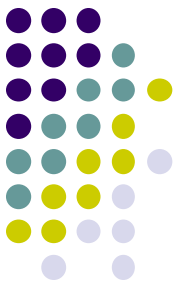
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# Londres 1998 - Nasce a “Abordagem de processo”

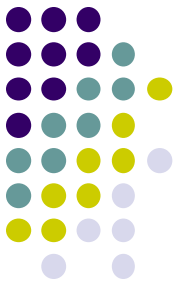


Martinus Bakhuisen





# ISO Directives Annex SL “High level structure” .....

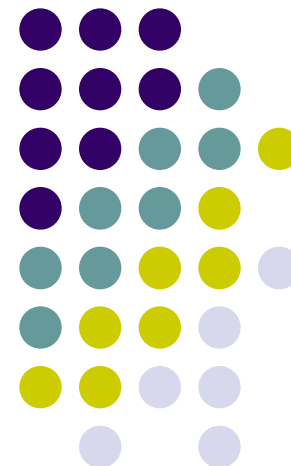


1. Scope
2. Normative references
3. Terms and definitions
4. ***Context of the organization***
5. ***Leadership***
6. Planning
7. Support
8. Operation
9. ***Performance evaluation***
10. ***Improvement***



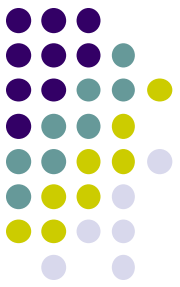
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# Some examples.....





## 4.1 “Understanding the organization and its context”



“The organization shall determine **external and internal issues** that are relevant to its purpose and that affect its ability to achieve the **intended outcome(s)** of its “XXX” management system.”

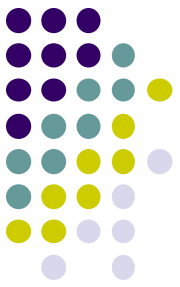
**NOTE: “XXX” = “quality”, “environmental”, “information security” etc**

- **ISO 9001:2015 will use the term “goods and services” instead of “product”**





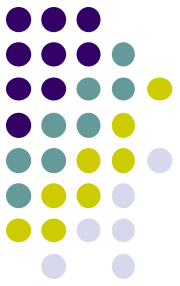
## 4.2 “Understanding the needs and expectations of interested parties”



- “The organization shall determine
  - the interested parties that are relevant to the XXX management system, and
  - the related requirements of these interested parties”
- ISO 9001 is likely to add text requiring the organization to include
  - direct customers
  - end users
  - suppliers, distributors, retailers or others involved in the supply chain
  - Regulators



## 4.4 XXX management system



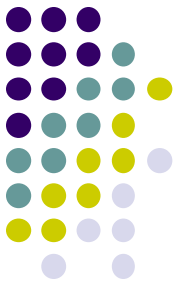
The organization shall establish, implement, maintain and continually improve an XXX management system, ***including the processes needed and their interactions,*** in accordance with the requirements of this International Standard.

***(This is key to maintaining the “process approach”, which will now be embedded in ALL ISO management system standards)***

***(Current clause 4.1 of ISO 9001:2008 likely to be incorporated into this clause)***



## 5.1 Leadership - General

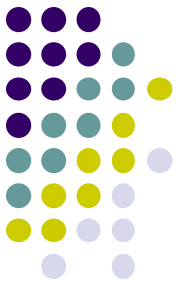


“Persons in top management ***and other relevant management roles throughout the organization*** shall ***demonstrate leadership*** with respect to the XXX management system.

NOTE This can be shown, for example, by ***motivating and empowering persons to contribute to the effectiveness of the XXX management system.***”



## 5.2 Management commitment

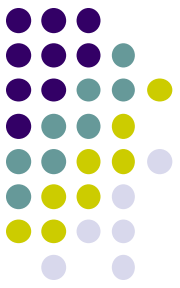


“Top management shall demonstrate its commitment by

- ensuring the XXX management system is compatible with the **strategic direction** of the organization
- **integrating** the XXX management system requirements into the organization’s business processes;
- **providing the resources** to establish, implement, maintain and continually improve the XXX management system
- communicating the importance of effective XXX management and conforming to the XXX management system requirements;
- ensuring that the XXX management system **achieves its intended outcomes**
- directing and supporting continual improvement”



# 6.1 Actions to address risks and opportunities



“The organization shall consider the issues referred to in 4.1 and the requirements referred to in 4.2 and **determine the risks and opportunities** that need to be addressed to

- assure the management system can achieve its intended outcome(s)
- prevent undesired effects
- realize opportunities for improvement.

The organization shall:

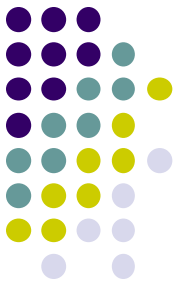
a) evaluate the need to **plan actions to address these risks and opportunities**, and

b) where applicable

- integrate and implement these actions into its XXX management system processes (see 8.1)
- ensure information will be available to evaluate if the actions have been effective (see 9.1).”



## 6.2 XXX objectives and planning to achieve them



“The organization shall establish XXX objectives at relevant functions and levels.

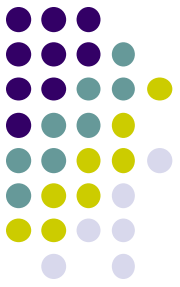
The XXX objectives shall

- be consistent with the XXX policy
- be ***measurable (if practicable)***
- take into account applicable requirements
- be ***monitored***
- be communicated, and
- be updated as appropriate.

The organization shall retain documented information on the XXX objectives.”

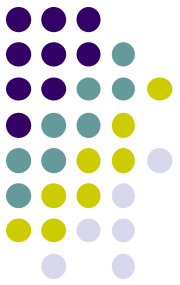


## 6.2 XXX objectives and planning to achieve them (contd...)



“When planning how to achieve its XXX objectives, the organization shall determine

- **what** will be done
- **what resources** will be required
- **who** will be responsible
- **when** it will be completed
- **how** the results will be evaluated.”



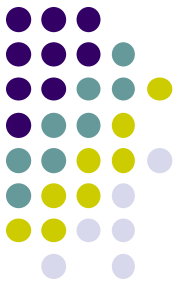
## 7.1 Resources

- The organization shall determine and provide the resources needed for the establishment, implementation, maintenance and continual improvement of the quality management system.
- Additional text for ISO 9001 likely to include:
  - Infrastructure
  - Process environment
  - Monitoring & Measurement
  - Knowledge





## 7.3 Awareness



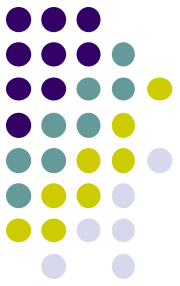
***“Persons doing work under the organization’s control***

shall be aware of:

- the XXX policy
- ***their contribution to the effectiveness*** of the XXX management system, including the benefits of improved XXX performance
- ***the implications of not conforming*** with the XXX management system requirements.”



## 7.4 Communication

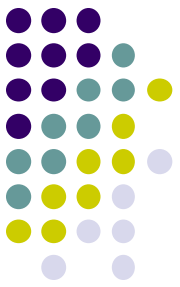


“The organization shall determine the need for internal and external communications relevant to the XXX management system including

- ***what*** to communicate
- ***when*** to communicate
- ***to whom*** it will communicate”



# 8.1 Operational planning and control



“The organization shall ***plan, implement and control those processes needed to address the risks and opportunities determined in 6.1 and to meet requirements***, by:

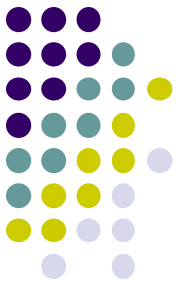
- establishing criteria for those processes
- implementing the control of these processes in accordance with the criteria
- keeping documented information to demonstrate that the processes have been carried out as planned

The organization shall control planned changes and review the consequences of unintended changes, ***taking action to mitigate any adverse effects***, as necessary

The organization shall ensure that outsourced processes are controlled.”



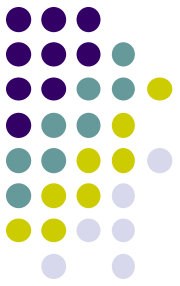
# Probable ISO 9001 “adders” for Clause 8



- This is where most of the current ISO 9001:2008 Clause 7 will be included.
  - Customer related processes
  - Operational planning
  - “Control of external providers” (Purchasing and outsourcing addressed together)
  - “Creation or change of product” (Incorporates “design & development” from ISO 9001:2008)
  - Product realization
  - Monitoring and measurement of product
  - Nonconforming goods and services



## 9.1 Monitoring, measurement, analysis and evaluation



“The organization shall determine:

- what needs to be measured and monitored;
- the **methods** for monitoring, measurement, analysis and evaluation, as applicable, **to ensure valid results**.
- **when** the monitoring and measuring shall be performed;
- **when** the analysis and evaluation of monitoring and measurement results shall be performed.

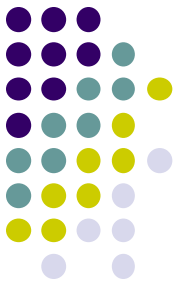
The organization shall evaluate the XXX performance and the effectiveness of the XXX management system.

Additionally, the organization shall:

- **take action when necessary to address adverse trends or results before a nonconformity occurs.**
- retain relevant documented information as evidence of the results.”



# Probable ISO 9001 “adders” for Clause 9

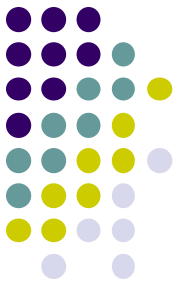


- Customer satisfaction
- Analysis and evaluation of data
- Greater emphasis on product conformity



# 10 Improvement

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## 10.1 Nonconformity and corrective action

“When a nonconformity occurs, the organization shall:

a) react to the nonconformity, and as applicable

- take action to **control and correct it**, and
- **deal with the consequences**;

b) evaluate the need for action to eliminate the causes of the nonconformity, **in order that it does not recur or occur elsewhere**, by

- reviewing the nonconformity
- **determining the causes** of the nonconformity, and
- determining if similar nonconformities exist, or could potentially occur;

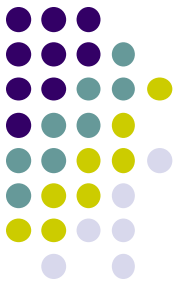
c) implement any action needed;

d) review the effectiveness of any corrective action taken; and

e) make changes to the XXX management system, if necessary.”



# Positioning of ISO 9001 and ISO 9004



- **ISO 9001**

- Focus on providing confidence in the organization's PRODUCTS (Organizational improvement is a secondary objective)
- Most probable “entry point” for many organizations
  - Needs to stimulate interest to “look BEYOND certification”

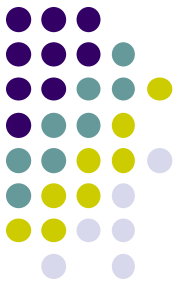
- **ISO 9004**

- Focus on providing confidence in the ORGANIZATION
- Should provide links to other management systems and methodologies

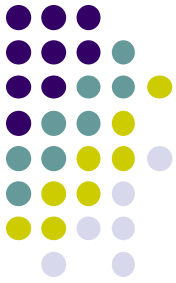




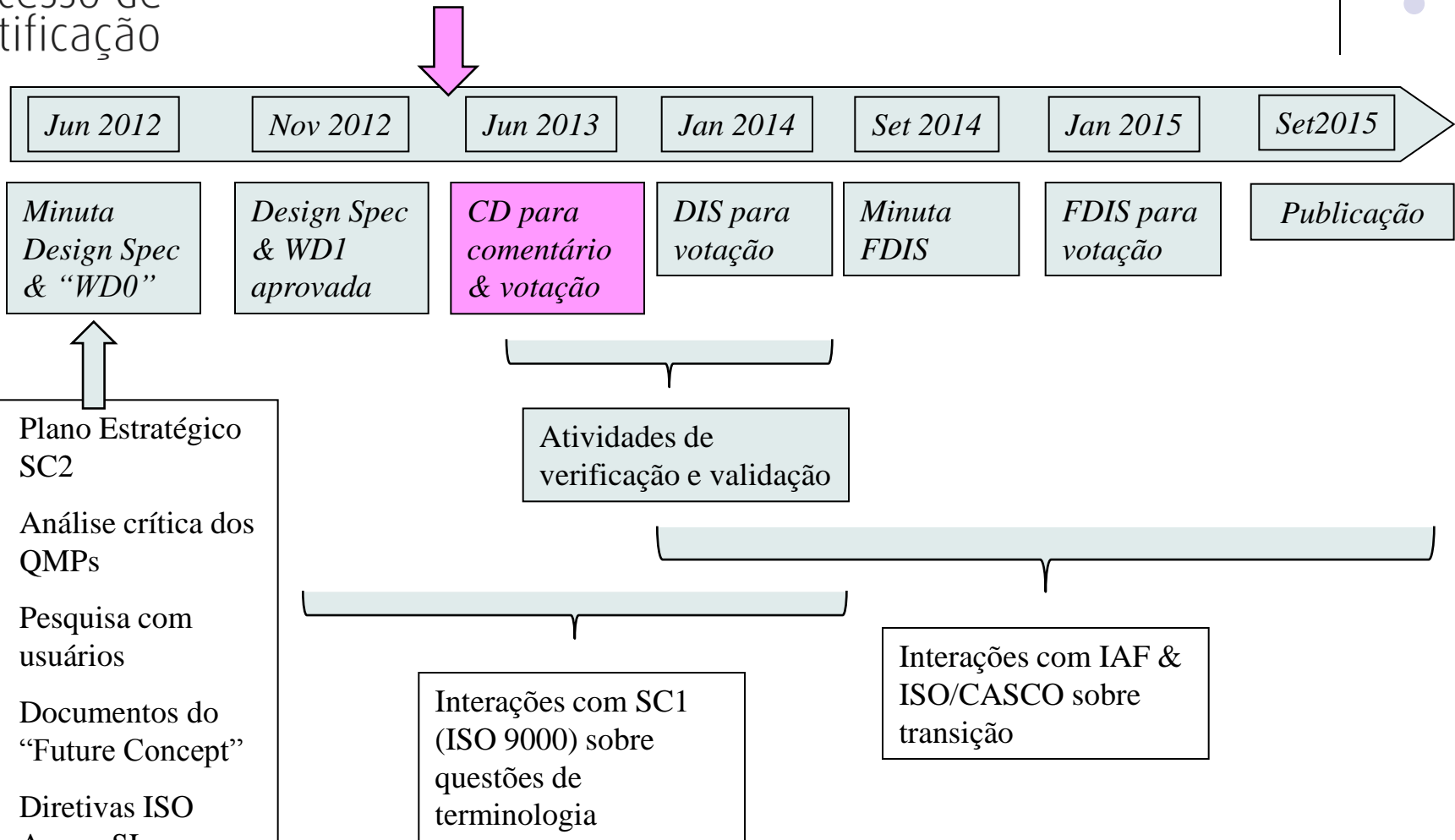
# Revision of ISO 9004?



- Due for ISO “systematic review” in 2014
- “Ad-hoc” group currently being formed within ISO/TC176/SC2 to review ISO 9004, and report back to the next ISO/TC176 Plenary (November 2013)
- Possibilities:
  - Leave it unchanged
  - Make small improvements to the main part of the standard, and bigger changes to Annex A



# Provável Cronograma de Alto Nível para a ISO 9001:2015



- Plano Estratégico SC2
- Análise crítica dos QMPs
- Pesquisa com usuários
- Documentos do "Future Concept"
- Diretivas ISO Anexo SL

May 2013

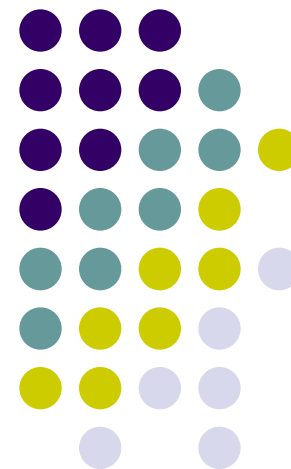
(c) Nigel H Croft



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# OBRIGADO!

Perguntas?



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